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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 905

[Doc. No. AMS–SC–23–0041]

Oranges, Grapefruit, Tangerines, and Pummelos Grown in Florida; Increased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule implements a recommendation from the Citrus Administrative Committee (Committee) to increase the assessment rate established for the 2023–2024 and subsequent fiscal periods from \$0.015 to \$0.02 per $\frac{1}{5}$ -bushel carton or equivalent for Florida citrus handled under the marketing order. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Effective August 21, 2024.

FOR FURTHER INFORMATION CONTACT:

Jennie M. Varela, Marketing Specialist, or Christian D. Nissen, Branch Chief, Southeast Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA; Telephone: (863) 324–3375, or Email: Jennie.Varela@usda.gov or Christian.Nissen@usda.gov.

Small businesses may request information on complying with this regulation by contacting Richard Lower, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–8085, or Email: Richard.Lower@usda.gov.

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This rule is issued under Marketing Order No. 905 as amended (7 CFR part 905), regulating the handling of oranges, grapefruit, tangerines, and

pummelos grown in Florida. Part 905 (referred to as “the Order”) is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the “Act.” The Committee locally administers the Order and is comprised of growers and handlers of fresh citrus operating within the area of production, and one public member.

The Agricultural Marketing Service (AMS) is issuing this rule in conformance with Executive Orders 12866, 13563, and 14094. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 reaffirms, supplements, and updates Executive Order 12866 and further directs agencies to solicit and consider input from a wide range of affected and interested parties through a variety of means. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

This rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments, which requires agencies to consider whether their rulemaking actions would have Tribal implications. AMS has determined that this rule is unlikely to have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

This rule has been reviewed under Executive Order 12988—Civil Justice Reform. Under the Order now in effect, Florida citrus handlers are subject to assessments. Funds to administer the Order are derived from such assessments. It is intended that the assessment rate will be applicable to all assessable fruit for the 2023–2024 fiscal period, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 8c(15)(A) of the Act (7 U.S.C. 608c(15)(A)), any handler subject to an order may file with the U.S. Department of Agriculture (USDA) a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA’s ruling on the petition, provided an action is filed no later than 20 days after the date of the entry of the ruling.

This rule increases the assessment rate for Florida citrus handled under the Order from \$0.015 per $\frac{1}{5}$ -bushel carton or equivalent, the rate that was initially established for the 2018–2019 and subsequent fiscal periods, to \$0.02 per $\frac{1}{5}$ -bushel carton or equivalent for the 2023–2024 and subsequent fiscal periods.

Sections 905.40 and 905.41 authorize the Committee, with the approval of AMS, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members are familiar with the Committee’s needs and with the costs of goods and services in their local area and are able to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting, and all directly affected persons have an opportunity to participate and provide input.

For the 2018–2019 and subsequent fiscal periods, the Committee recommended, and AMS approved, an assessment rate of \$0.015 per $\frac{1}{5}$ -bushel carton or equivalent of citrus. That rate continues in effect from fiscal period to fiscal period until modified, suspended, or terminated by AMS upon recommendation and information submitted by the Committee or other information available to AMS. This rule increases the assessment rate from \$0.015 to \$0.02 per $\frac{1}{5}$ -bushel carton or

equivalent of citrus for the 2023–2024 and subsequent fiscal periods.

The Committee met on August 8, 2023, and recommended 2023–2024 fiscal period expenditures of \$124,624 and an assessment rate of \$0.02 per $\frac{4}{5}$ -bushel carton or equivalent of citrus handled for the 2023–2024 and subsequent fiscal periods. In comparison, last period's budgeted expenditures were \$122,680. The increased assessment rate of \$0.02 is \$0.005 higher than the rate currently in effect. The Committee recommended increasing the assessment rate to better align assessment revenue with budgeted expenses. The Committee projects handler receipts of approximately 6,700,000 $\frac{4}{5}$ -bushel cartons or equivalent of citrus for the 2023–2024 fiscal period, which is higher than the 4,764,544 cartons handled in the 2022–2023 fiscal period.

The total expenditures recommended by the Committee for the 2023–2024 fiscal period are approximately \$124,624. The major budgeted expenditures include \$99,624 for management; \$10,000 for auditing; and \$5,000 for data from the Division of Fruits and Vegetables. By comparison, budgeted expenditures for these activities in the 2022–2023 fiscal period were \$97,680; \$10,000; and \$5,000, respectively.

At the current assessment rate of \$0.015, the expected 6,700,000 $\frac{4}{5}$ -bushel cartons or equivalent of assessable Florida citrus would generate \$100,500 in assessment revenue (6,700,000 cartons multiplied by \$0.015 assessment rate), short of the Committee's anticipated expenditures of \$124,624 for the 2023–2024 fiscal period. By increasing the assessment rate by \$0.005 to \$0.02, assessment income will generate \$134,000 (6,700,000 cartons multiplied by \$0.02 assessment rate) for the 2023–2024 fiscal period. This amount should be appropriate to ensure that the Committee has sufficient revenue to fully fund its recommended 2023–2024 fiscal period budgeted expenditures.

The Committee derived the recommended assessment rate by considering anticipated expenses, an estimated 6,700,000 $\frac{4}{5}$ -bushel cartons or equivalent of assessable Florida citrus, and the amount of funds available in reserve. Income derived from handler assessments (\$134,000) will be adequate to cover budgeted expenses (\$124,624). Funds available in the reserve (currently about \$165,000) are expected to be kept within the maximum permitted by the Order (approximately two fiscal periods' expenses as authorized in § 905.42).

The assessment rate will continue in effect indefinitely unless modified, suspended, or terminated by AMS upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate will be in effect for an indefinite period, the Committee will continue to meet prior to or during each fiscal period to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or AMS. Committee meetings are open to the public and interested persons may express their views at these meetings. AMS will evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The Committee's 2023–2024 budget, and those for subsequent fiscal periods, will be reviewed and, as appropriate, approved by AMS.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are 14 handlers of Florida citrus who are subject to regulation under the Order and approximately 500 citrus producers in the regulated area. At the time this analysis was prepared, the Small Business Administration (SBA) defined small agricultural growers as those having annual receipts of no more than \$4,000,000 for orange producers (NAICS code 111310, Orange Groves) or \$4,250,000 for other citrus producers (NAICS code 111320, Citrus (except Orange) Groves), and small agricultural service firms, including handlers, are defined as those whose annual receipts are less than \$34,000,000 (NAICS code 115114, Postharvest Crop Activities) (13 CFR 121.201).

According to data from the National Agricultural Statistics Service (NASS), the weighted average packing house

door equivalent price for fresh Florida oranges for the 2022–2023 season was approximately \$10.54 per carton with total shipments of around 3,224,000 cartons. Based on this information, the majority of orange handlers have average annual receipts of significantly less than \$34,000,000 (\$10.54 multiplied by 3,224,000 cartons equals \$33,980,960, divided by 14 handlers equals \$2,427,211 per handler). The weighted average packing house door price for other Florida citrus for the 2022–2023 season was \$19.12 per carton with total shipments of 2,804,000 cartons. Based on this information, the majority of other citrus handlers have average annual receipts of significantly less than \$34,000,000 (\$19.12 multiplied by 2,804,000 cartons equals \$53,612,480, divided by 14 handlers equals \$3,829,463 per handler).

In addition, based on the NASS data, the weighted average orange grower price for the 2022–2023 season was estimated at \$9.45 per carton of fresh oranges. Based on grower price, shipment data, and the total number of Florida orange growers, the average annual grower revenue is well below \$4,000,000 (\$9.45 multiplied by 3,224,000 cartons equals \$30,466,800, divided by 500 growers equals \$60,934 per grower). The weighted average other citrus grower price for the 2022–2023 season was estimated at \$16.28 per carton of fresh citrus. Based on grower price, shipment data, and the total number of Florida citrus growers, the average annual grower revenue is well below \$4,250,000 (\$16.28 multiplied by 2,804,000 cartons equals \$45,649,120, divided by 500 growers equals \$91,298 per grower). Thus, the majority of Florida citrus handlers and growers may be classified as small entities.

This rule increases the assessment rate for the 2023–2024 and subsequent fiscal periods from \$0.015 to \$0.02 per $\frac{4}{5}$ -bushel carton or equivalent of citrus. The Committee recommended 2023–2024 expenditures of \$124,624 and an assessment rate of \$0.02 per $\frac{4}{5}$ -bushel carton. The increased assessment rate of \$0.02 is \$0.005 more than the previous rate. The quantity of assessable Florida citrus for the 2023–2024 season is estimated at 6,700,000 $\frac{4}{5}$ -bushel cartons or equivalent. Thus, the \$0.02 rate should provide \$134,000 in assessment income (6,700,000 cartons multiplied by \$0.02 assessment rate). Income derived from handler assessments should be adequate to cover budgeted expenses.

The major expenditures recommended by the Committee for the 2023–2024 fiscal period include \$99,624 for management; \$10,000 for auditing; and \$5,000 for data from the Division of

Fruits and Vegetables. Budgeted expenses for these same items in the 2022–2023 fiscal period were \$97,680; \$10,000; and \$5,000, respectively.

The Committee recommended increasing the assessment rate to cover anticipated expenses for the 2023–2024 fiscal period. Shipments for the 2023–2024 season are projected to be 6,700,000 $\frac{4}{5}$ -bushel cartons or equivalent, about 2 million more than estimated for the previous period. At the current assessment rate of \$0.015, assessment income would equal \$100,500 (6,700,000 cartons multiplied by \$0.015 assessment rate), an amount below the Committee's anticipated expenditures of \$124,624 for the 2023–2024 fiscal period. By increasing the assessment rate by \$0.005, assessment income will be approximately \$134,000 (6,700,000 cartons multiplied by \$0.02 assessment rate). This amount should provide sufficient funds to meet anticipated expenses for the 2023–2024 fiscal period.

Prior to arriving at this budget and assessment rate, the Committee considered maintaining the current assessment rate of \$0.015. However, the Committee would need to further draw down reserves to meet its expenses. The Committee had to use some of its reserves in the 2022–2023 fiscal period after a hurricane damaged the crop, and Committee members did not want to utilize additional funds from reserves to meet 2023–2024 expenses. Consequently, the alternative of maintaining the current assessment rate was rejected.

A review of historical information and preliminary information pertaining to the upcoming fiscal period indicates the average grower price for the 2023–2024 season should be approximately \$11.00 per $\frac{4}{5}$ -bushel carton or equivalent of citrus. Therefore, the estimated assessment revenue for the 2023–2024 crop year as a percentage of total grower revenue should be about 0.18 percent (\$0.02 divided by \$11.00 multiplied by 100).

This action increases the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to producers. However, these costs are expected to be offset by the benefits derived by the operations of the Order.

The Committee's meetings are widely publicized throughout the Florida citrus industry and all interested persons are invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the August 8, 2023, meeting was a public meeting and all entities,

both large and small, were able to express views on this issue. Finally, interested persons were invited to submit comments on the proposed rulemaking, including the regulatory impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0189 Fruit Crops. No changes in those requirements will be necessary as a result of this rule. Should any changes become necessary, they would be submitted to OMB for approval.

This rule will not impose any additional reporting or recordkeeping requirements on either small or large Florida citrus handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

AMS has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

A proposed rulemaking concerning this action was published in the **Federal Register** on February 1, 2024 (89 FR 6440). Copies of the proposed rulemaking were also mailed or sent via email to all Florida citrus handlers. The proposal was also made available through the internet by AMS and the Office of the Federal Register. A 30-day comment period ending March 4, 2024, was provided for interested persons to respond to the proposal.

AMS received a total of nine comments during the comment period. Five comments supported the revised assessment rate, two comments opposed the rate, one did not take a position on the proposal, and one did not address the merits of the rule.

Several comments in support of the increased rate included statements that the rate change could be beneficial in accounting for the effects of citrus greening and hurricane damage. Another commenter stated the industry's current situation calls for the decision to use additional funds. One commenter noted that the proposal seemed reasonable as the budgeted expenses are higher than the Committee's revenue.

The two comments opposed to the rule both focused on the potential increase to the price of citrus. One expressed concern that this change would have a negative impact on the larger economies for citrus and citrus products, namely juice, candy, and raw fruit. This commenter also mentioned potential negative impacts on Native American producers.

In previous seasons, the Committee has used reserves to cover some of the shortfalls in administering the program. In their discussion of the budget for the 2023–2024 season, the Committee determined it was in their best interest to make a minor increase to the rate rather than draw down on financial reserves further. The Committee also made this decision as they determined the benefits of the Order outweigh the small increase in the assessment rate.

In addition, this action only applies to the handling of fresh Florida citrus. According to NASS, the fresh segment makes up only about 16 percent of Florida's citrus production. The price of fresh citrus is usually higher than that of fruit being sent to processing. This action, therefore, only applies to a smaller, higher value segment of the industry and should not impact the price of juice or any other processed citrus product.

Regarding the overall concern about the increase in the price of citrus, the Committee made its recommendation with the awareness that the additional cost to handlers may be passed on to growers and consumers. However, this rule only increases the assessment rate by \$0.005 per a $\frac{4}{5}$ -bushel carton, accounting for an estimated \$33,500 increase in assessments for the entire fresh industry. Further, as noted in the final regulatory flexibility analysis, the total assessment rate is equivalent to about 0.18 of a percent of the grower price, and if compared to the anticipated price received by handlers, the percentage would be even smaller. Given these numbers, this change is not expected to result in a significant increase in cost for growers, handlers, or consumers.

One of the commenters in opposition to the rule also suggested there may be an impact on the Seminole Tribe of Florida as they have historically owned citrus groves. The comment stated increasing regulations and adding costs like assessments are potentially limiting factors to Native participation in the industry. AMS spoke with the Committee directly, which had recently contacted the Tribe as a part of its routine outreach. The Tribe confirmed they are completely out of the citrus business and that they did not have

concerns with this rulemaking or its potential to limit participation in the industry. AMS therefore determined the assessment rate change will not have an impact on Tribes in the production area. Accordingly, AMS made no changes to the rule based on the comments received.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <https://www.ams.usda.gov/rules-regulations/moa/small-businesses>. Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendations submitted by the Committee and other available information, AMS has determined that this rule is consistent with and will effectuate the purposes of the Act.

List of Subjects in 7 CFR Part 905

Grapefruit, Marketing agreements, Oranges, Pummelos, Reporting and recordkeeping requirements, Tangerines.

For the reasons set forth in the preamble, the Agricultural Marketing Service amends 7 CFR part 905 as follows:

PART 905—ORANGES, GRAPEFRUIT, TANGERINES, AND PUMMELOS GROWN IN FLORIDA

- 1. The authority citation for 7 CFR part 905 continues to read as follows:

Authority: 7 U.S.C. 601–674.

- 2. Section 905.235 is revised to read as follows:

§ 905.235 Assessment rate.

On and after August 1, 2023, an assessment rate of \$0.02 per ⅔-bushel carton or equivalent is established for Florida citrus covered under the Order.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2024–15975 Filed 7–19–24; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–2242; Project Identifier MCAI–2023–00704–T; Amendment 39–22763; AD 2024–11–02]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Bombardier, Inc., Model BD–100–1A10 airplanes. This AD was prompted by a determination that new or more restrictive maintenance tasks are necessary. This AD requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive maintenance tasks. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 26, 2024.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of August 26, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2023–2242; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Bombardier material, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email ac.yul@aero.bombardier.com; website [bombardier.com](https://www.bombardier.com).

- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2023–2242.

FOR FURTHER INFORMATION CONTACT:

Gabriel Kim, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email 9-avs-nyaco-cos@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Bombardier, Inc., Model BD–100–1A10 airplanes. The NPRM published in the **Federal Register** on December 19, 2023 (88 FR 87725). The NPRM was prompted by AD CF–2023–34, dated May 25, 2023, issued by Transport Canada, which is the aviation authority for Canada (referred to after this as the MCAI). The MCAI states that new or more restrictive maintenance tasks have been developed.

In the NPRM, the FAA proposed to require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive maintenance tasks. The FAA is issuing this AD to address failure or degradation of the horizontal stabilizer trim actuator (HSTA) and motor brake assembly. A failed or degraded HSTA or motor brake assembly could result in loss of control of the airplane.

You may examine the MCAI in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2023–2242.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from a commenter. The following presents the comments received on the NPRM and the FAA’s response to each comment.

Request for Revised Compliance Language

The commenter requested a revision to paragraph (g) of the proposed AD to reflect the language from MCAI that more explicitly allows for the use of superseding Temporary Revisions or later revisions. The commenter stated that the proposed phrase, “incorporate the information specified in,” is too open to interpretation.

The FAA partially agrees with the request to revise the proposed language. The phrase “incorporate the information specified” refers to the information stated in the tasks referenced in figures 1 and 2 to paragraph (g) of this AD. As long as the information in the referenced task remains the same, an operator can show compliance with that task without having to obtain an alternative method of compliance

(AMOC) approval. The FAA has revised paragraph (g) of this AD to include “incorporate the information in the tasks specified . . .” to clarify that it’s only the information within the task that is mandated to be incorporated into the maintenance or inspection program and that as long as that task information doesn’t change from the time limit/maintenance check (TLMC) document revision specified in figures 1 and 2 to paragraph (g) of this AD an AMOC is not required.

Request for Reference to Later Revision of Service Information

The commenter requested that the FAA revise figures 1 and 2 to paragraph (g) of the proposed AD to reference a general revision of a TLMC instead of a temporary revision. The commenter stated that without the language from the MCAI that states permission to use “or later revision,” the proposed AD would not allow the use of the general revision of the TLMC that contains the task information. The commenter added that an operator would then be required to maintain a copy of the temporary revision and general revisions of the TLMC that are noted in figures 1 and 2 to paragraph (g) of the proposed AD.

The FAA provides the following clarification. As previously mentioned, the AD requires that the maintenance or inspection program be revised to incorporate the task information specified in the applicable time TLMC or temporary revision (TR) document. Therefore, as long the information is the same in the general revision of a TLMC as the task information specified in the TR document, an AMOC is not required. The FAA has revised paragraph (g) of this AD for clarification.

Conclusion

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

Related Service Information Under 1 CFR Part 51

The FAA reviewed the following Bombardier service information, which describes new or more restrictive airworthiness limitation maintenance tasks that specify inspection and overhaul of the HSTA and add flight cycle and flight-hour limitations. Note: The asterisk (or “one star”) or double asterisk (“two star”) with the last three digits of the task numbers indicates that the task is an airworthiness limitation task.

- Sections 5–10–20, “Time Limits—Supplementary Limitations,” and 5–10–40, “Certification Maintenance Requirements,” of part 2, “Airworthiness Limitations,” of the Bombardier Challenger 350 Time Limits/Maintenance Check, Publication No. CH 350 TLMC, Revision 13, dated June 14, 2022, which include Task 27–40–00–104*, “Restoration (Overhaul) of the Horizontal-Stabilizer Trim-Actuator (HSTA), Part No. C47100–004 and subs,” and Task 27–41–05–104*, “Restoration (Overhaul) of the Horizontal-Stabilizer Trim-Actuator (HSTA), Part No. C47100–004/-005.”

- Sections 5–10–20, “Time Limits—Supplementary Limitations,” and 5–10–40, “Certification Maintenance Requirements,” of part 2, “Airworthiness Limitations,” of the Bombardier Challenger 300 Time Limits/Maintenance Check, Publication No. CH 300 TLMC, Revision 23, dated June 14, 2022, which include Task 27–40–00–104*, “Restoration (Overhaul) of the Horizontal-Stabilizer Trim-Actuator (HSTA), Part No. C47100–004 and subs,” and Task 27–41–05–104*, “Restoration (Overhaul) of the Horizontal-Stabilizer Trim-Actuator (HSTA), Part No. C47100–004/-005.”

- Temporary Revision 5–2–31, dated January 31, 2023, which includes Task 27–40–00–108**, “Restoration (Inspection) of the Horizontal-Stabilizer Trim-Actuator (HSTA), Part No. C47100–003 and subs.”

- Temporary Revision 5–2–102, dated January 31, 2023, which includes Task 27–40–00–108**, “Restoration (Inspection) of the Horizontal-Stabilizer Trim-Actuator (HSTA), Part No. C47100–003 and subs.”

These documents are distinct since they apply to different airplane models. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

Costs of Compliance

The FAA estimates that this AD affects 737 airplanes of U.S. registry.

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

The FAA has determined that revising the maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, the agency estimates the average total cost per operator to be \$7,650 (90 work-hours × \$85 per work-hour).

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Will not affect intrastate aviation in Alaska, and
- (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2024–11–02 Bombardier, Inc.: Amendment 39–22763; Docket No. FAA–2023–2242; Project Identifier MCAI–2023–00704–T.

(a) Effective Date

This airworthiness directive (AD) is effective August 26, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., Model BD–100–1A10 airplanes, certificated in any category, having serial numbers (S/Ns) 20003 through 20500 inclusive, and 20501 through 20959 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks; 27, Stabilizer.

(e) Reason

This AD was prompted by a determination that new or more restrictive maintenance tasks are necessary. The FAA is issuing this AD to address failure or degradation of the horizontal stabilizer trim actuator (HSTA) and motor brake assembly. The unsafe condition, if not addressed, could result in loss of control of the airplane.

(f) Compliance

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

(g) Maintenance or Inspection Program Revision

Within 60 days after the effective date of this AD, revise the existing maintenance or inspection program, as applicable, to incorporate the information in the tasks specified in figure 1 or 2 to paragraph (g) of this AD, as applicable. The initial compliance time for doing the tasks is at the time specified in the applicable temporary revision (TR) or time limit/maintenance check (TLMC) document specified in figures 1 and 2 to paragraph (g) of this AD, or within 60 days after the effective date of this AD, whichever occurs later. When the information in the applicable TR has been incorporated into the general revision of that Bombardier TLMC, the maintenance or inspection program may be revised using the information in the general revision.

Figure 1 to Paragraph (g)—Tasks for Model BD–100–1A10 Airplanes Having S/Ns 20003 Through 20500

Task number	Task title	TLMC section	TLMC or TR document
27-40-00-108**	Restoration (Inspection) of the Horizontal-Stabilizer Trim-Actuator (HSTA), Part No. C47100-003 and subs	5-10-40, Certification Maintenance Requirements	Bombardier Temporary Revision 5-2-102, dated January 31, 2023
27-40-00-104*	Restoration (Overhaul) of the Horizontal-Stabilizer Trim-Actuator (HSTA), Part No. C47100-004 and subs	5-10-40, Certification Maintenance Requirements	Part 2, “Airworthiness Limitations,” of the Bombardier Challenger 300 Time Limits/Maintenance Check, Publication No. CH 300 TLMC, Revision 23, dated June 14, 2022
27-41-05-104*	Restoration (Overhaul) of the Horizontal Stabilizer Trim actuator (HSTA), Part No. C47100-004/-005	5-10-20, Time Limits – Supplementary Limitations	Part 2, “Airworthiness Limitations,” of the Bombardier Challenger 300 Time Limits/Maintenance Check, Publication No. CH 300 TLMC, Revision 23, dated June 14, 2022

Note 1 to Figure 1 to paragraph (g): The section number in the footer on certain pages of the TLMC sections is incomplete (*i.e.*, “05–10–2” instead of “05–10–20” and “05–10–4” instead of “05–10–40”).

Note 2 to Figure 1 to paragraph (g): The asterisk (or “one star”) or double asterisk (“two star”) with the last three digits of the task numbers listed in figures 1 and 2 to

paragraph (g) of this AD indicates that the task is an airworthiness limitation task.

Figure 2 to Paragraph (g)—Tasks for Model BD–100–1A10 Airplanes Having S/Ns 20501 Through 20959

Task number	Task title	TLMC section	TLMC or TR document
27-40-00-108**	Restoration (Inspection) of the Horizontal-Stabilizer Trim-Actuator (HSTA), Part No. C47100-003 and subs	5-10-40, Certification Maintenance Requirements	Bombardier Temporary Revision 5-2-31, dated January 31, 2023
27-40-00-104*	Restoration (Overhaul) of the Horizontal-Stabilizer Trim-Actuator (HSTA), Part No. C47100-004 and subs	5-10-40, Certification Maintenance Requirements	Part 2, “Airworthiness Limitations,” of the Bombardier Challenger 350 Time Limits/Maintenance Check, Publication No. CH 350 TLMC, Revision 13, dated June 14, 2022
27-41-05-104*	Restoration (Overhaul) of the Horizontal Stabilizer Trim actuator (HSTA), Part No. C47100-004/-005	5-10-20, Time Limits – Supplementary Limitations	Part 2, “Airworthiness Limitations,” of the Bombardier Challenger 350 Time Limits/Maintenance Check, Publication No. CH 350 TLMC, Revision 13, dated June 14, 2022

(h) No Alternative Actions, or Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.*, inspections) or intervals may be used unless the actions and intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (i)(1) of this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation

Branch, mail it to ATTN: Program Manager, Continuing Operational Safety, at the address identified in paragraph (j) of this AD or email to: 9-avs-nyaco-cos@faa.gov. If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(j) Additional Information

For more information about this AD, contact Gabriel Kim, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite

410, Westbury, NY 11590; telephone 516–228–7300; email 9-avs-nyaco-cos@faa.gov.

(k) Material Incorporated by Reference

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

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

(i) Section 5–10–20, “Time Limits—Supplementary Limitations,” of Part 2, “Airworthiness Limitations,” of the Bombardier Challenger 300 Time Limits/Maintenance Check, Publication No. CH 300 TLMC, Revision 23, dated June 14, 2022.

Note 3 to paragraph (k)(2)(i): The section number in the footer on pages 1 and 2 of Section 5–10–20, “Time Limits—Supplementary Limitations,” of Part 2, “Airworthiness Limitations,” of the Bombardier Challenger 300 Time Limits/

Maintenance Check, Publication No. CH 300 TLMC, Revision 23, dated June 14, 2022, is incorrectly identified as “05–10–2” instead of “05–10–20.”

(ii) Section 5–10–20, “Time Limits—Supplementary Limitations,” of Part 2, “Airworthiness Limitations,” of the Bombardier Challenger 350 Time Limits/Maintenance Check, Publication No. CH 350 TLMC, Revision 13, dated June 14, 2022.

Note 4 to paragraph (k)(2)(ii): The section number in the footer on pages 1 and 2 of Section 5–10–20, “Time Limits—Supplementary Limitations,” of Part 2, “Airworthiness Limitations,” of the Bombardier Challenger 350 Time Limits/Maintenance Check, Publication No. CH 350 TLMC, Revision 13, dated June 14, 2022, is incorrectly identified as “05–10–2” instead of “05–10–20.”

(iii) Section 5–10–40, “Certification Maintenance Requirements,” of Part 2, “Airworthiness Limitations,” of the Bombardier Challenger 300 Time Limits/Maintenance Check, Publication No. CH 300 TLMC, Revision 23, dated June 14, 2022.

Note 5 to paragraph (k)(2)(iii): The section number in the footer on the cover page of Section 5–10–40, “Certification Maintenance Requirements,” of Part 2, “Airworthiness Limitations,” of the Bombardier Challenger 300 Time Limits/Maintenance Check, Publication No. CH 300 TLMC, Revision 23, dated June 14, 2022, is incorrectly identified as “05–10–4” instead of “05–10–40.”

(iv) Section 5–10–40, “Certification Maintenance Requirements,” of Part 2, “Airworthiness Limitations,” of the Bombardier Challenger 350 Time Limits/Maintenance Check, Publication No. CH 350 TLMC, Revision 13, dated June 14, 2022.

Note 6 to paragraph (k)(2)(iv): The section number in the footer on the cover page of Section 5–10–40, “Certification Maintenance Requirements,” of Part 2, “Airworthiness Limitations,” of the Bombardier Challenger 350 Time Limits/Maintenance Check, Publication No. CH 350 TLMC, Revision 13, dated June 14, 2022, is incorrectly identified as “05–10–4” instead of “05–10–40.”

(v) Bombardier Temporary Revision 5–2–31, dated January 31, 2023.

(vi) Bombardier Temporary Revision 5–2–102, dated January 31, 2023.

(3) For Bombardier material, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email ac.yul@aero.bombardier.com; website bombardier.com.

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

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

Issued on July 16, 2024.

James D. Foltz,

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

[FR Doc. 2024–15972 Filed 7–19–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1891; Project Identifier AD–2023–00612–R; Amendment 39–22774; AD 2024–12–10]

RIN 2120–AA64

Airworthiness Directives; Centerpointe Aerospace Inc. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Centerpointe Aerospace Inc. (Centerpointe) Model S–58BT, S–58DT, S–58ET, S–58FT, S–58HT, and S–58JT helicopters. This AD was prompted by an indication of a crack on the angle gearbox mount (AGBM). This AD requires repetitively performing a fluorescent penetrant inspection (FPI) of the AGBM at specified time intervals and, depending on the results, removing the AGBM from service. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 26, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 26, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2023–1891; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Centerpointe Aerospace service information identified in this AD, contact Centerpointe Aerospace Inc., 279 Blackland Road, Fate, TX 75189; phone: (972) 636–9601; email: Operations@avnresources.com; website: californiahelicopter.com.

- You may view this service information at the FAA, Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at regulations.gov under Docket No. FAA–2023–1891.

FOR FURTHER INFORMATION CONTACT: Jacob Fitch, Aviation Safety Engineer, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; phone: (817) 222–4130; email: jacob.fitch@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Centerpointe Model S–58BT, S–58DT,

S–58ET, S–58FT, S–58HT, and S–58JT helicopters. The NPRM published in the **Federal Register** on October 3, 2023 (88 FR 68002). The NPRM was prompted by fatigue cracking that was found on a Model S–58BT helicopter during a preflight inspection. The fatigue cracking was found in the angle supports and cross-members forming the edges of the AGBM. Due to their similarity to the Model S–58BT helicopter, the FAA determined that Centerpointe Model S–58DT, S–58ET, S–58FT, S–58HT, and S–58JT helicopters are also affected by the same unsafe condition. In the NPRM, the FAA proposed to require repetitive FPIs of the AGBM for a crack. The FAA is issuing this AD to address the unsafe condition on these products.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from one commenter, Midwest Helicopter Airways, Inc. (Midwest). Midwest disagrees with the FAA’s determination of the unsafe condition in the proposed AD and opines that a supplemental enhanced visual inspection in addition to inspections performed on the AGBM during routine maintenance is sufficient. The following presents the comments received on the NPRM and the FAA’s response to each comment.

Request To Change the Unsafe Condition

Midwest stated its opinion that the root cause for the failure of the AGBM structural member was not a result of fatigue cracking, but was due to improper installation, routing, or securing of an electrical wire. Midwest submitted photos sent from a

representative of Centerpointe Aerospace to current S-58T operators that show abrasions in several locations on the failed angle support structure. According to Midwest, these abrasion marks look to be the result of a wire shown in the photos not properly routed or secured, that began to wear into the structural member. Several abrasions can be seen in the photo just above the crack with a larger abrasion being directly at the crack of the structure. Midwest stated that the chafing marks shown in the photos indicate improper installation, routing, or securing of an electrical wire and other damage from unsecured wiring and advises that wire installation requirements regarding chafing on the airframe are specified in the Acceptable Methods, Techniques, and Practices Aircraft Inspection and Repair, FAA Advisory Circular 43.13-1B Chg. I, Chapter 11, Section 8, Paragraph 11.96(q), which states: "Ensure that wires and cables are routed in such a manner that chafing will not occur against the airframe or other components."

The FAA disagrees with the comments regarding the cause of the unsafe condition as evidence shows that fatigue and not chafing is the root cause of the crack found on the AGBM. Additionally, there are other likely crack initiation points in the structure of the cracked AGBM leg that can be seen in other photos. The FAA did not change this AD as a result of this comment.

Comment Regarding Compliance With the Service Information

Midwest's second comment pertains to compliance with the proposed AD to perform the procedures specified in Centerpointe Aerospace Service Bulletin No. 58B75, dated April 26, 2023 (SB58B75). Midwest states that the proposed AD would require specific procedures to be performed which are outlined in SB58B75; that compliance with the SB would require replacement of the AGBM assembly, if the affected part is cracked; and that replacing the AGBM would remove privileges the maintenance organization and technicians have under their certifications and repair abilities. Midwest further states that SB58B75 does not provide guidance with regards to blending of material, removal of corrosion, or limitations for repair of the AGBM. Additionally, Midwest states that SB58B75 requires a qualified engineer to provide guidance, without explanation of what qualifications must be obtained to determine airworthiness. Midwest then states that SB58B75 does not address preparation of the structure

for the inspection to be completed and that this would potentially cause delays in service and additional costs to operators. Instead of compliance with SB58B75, Midwest suggests thoroughly cleaning and conducting a visual inspection for damage to the mounting structure including gouges, dents, deformity, chafing, loose fasteners, and corrosion. If gouging or chafing, caused by plumbing or wiring, are evident, Midwest suggests taking action to remove or reposition the cause of the discrepancy and evaluate the discrepancy of the mount for limitations of wear. In addition, Midwest suggests an enhanced visual inspection using a 10-power magnification device and a bright light to identify potential cracks; primarily inspecting the areas around the fastener holes and attaching hardware. Subsequently, if this visual or enhanced inspection results in a suspected crack, Midwest suggests verifying using an FPI, as specified in SB58B75. Additionally, Midwest states based on the historical data of the S-58T helicopters, that the AGBM is a durable structure, and this unsafe condition is unlikely to exist or develop on any S-58T or similar model helicopter.

The FAA would like to clarify that this AD refers to SB58B75 for the locations of the eight inspection areas only. The AD requires performing an FPI of the areas shown in figures in SB58B75 by a Level II or Level III inspector certified in the FAA-acceptable standards for nondestructive inspection personnel; it is understood that the accomplishment of the FPI must be done with acceptable procedures. An alternative method of compliance (AMOC) under the provisions of paragraph (h) of this AD may be requested. The FAA did not change this AD as a result of this comment.

Conclusion

The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

The FAA reviewed SB58B75, which specifies procedures for repetitively performing an FPI and reporting the results to the manufacturer. This service information is reasonably available because the interested parties have access to it through their normal course

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

Differences Between This AD and the Service Information

Where the service information specifies that the initial FPI be performed within 120 days after receipt of the service information, this AD requires the initial FPI to be performed within 250 hours time-in-service. The service information specifies reporting the results of the FPI to the manufacturer, whereas this AD does not.

Where the service information requires compliance with the Procedures in the Accomplishment Instructions specified in the service bulletin, this AD requires accomplishing the Required Actions specified in paragraph (g) of this AD using standard procedures and Figures 1A and 1B of the Accomplishment Instructions of the service bulletin.

Costs of Compliance

The FAA estimates that this AD affects 14 helicopters of U.S. registry. Labor rates are estimated at \$85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Performing an FPI of the AGBM takes about 5 work-hours and parts cost \$150 for an estimated cost of \$575 per helicopter, and \$8,050 for the U.S. fleet, per inspection cycle.

If necessary, replacing an AGBM takes about 41 work-hours and parts cost are approximately \$30,000, for an estimated cost of \$33,485 per helicopter.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Will not affect intrastate aviation in Alaska, and
- (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2024–12–10 Centerpointe Aerospace Inc.:
Amendment 39–22774; Docket No. FAA–2023–1891; Project Identifier AD–2023–00612–R.

(a) Effective Date

This airworthiness directive (AD) is effective August 26, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Centerpointe Aerospace Inc. Model S–58BT, S–58DT, S–58ET, S–58FT, S–58HT, and S–58JT helicopters, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC)
Code: 6300, Main Rotor Drive System.

(e) Unsafe Condition

This AD was prompted by the discovery of a fatigue crack on the angle gearbox mount (AGBM). The FAA is issuing this AD to detect fatigue cracking of the AGBM. The

unsafe condition, if not addressed, could lead to loss of the angle gearbox, resulting in loss of main rotor drive and subsequent loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) Within 250 hours time-in-service (TIS) after the effective date of this AD, and thereafter at intervals not to exceed 250 hours TIS, perform a fluorescent penetrant inspection (FPI) to inspect for any crack on the AGBM in the eight areas depicted in the Accomplishment Instructions, Figures 1A and 1B, of Centerpointe Aerospace Service Bulletin No. 58B75, dated April 26, 2023. This FPI must be accomplished by a Level II or Level III inspector certified in the FAA-acceptable standards for nondestructive inspection personnel.

(2) If there is any crack, before further flight, remove the AGBM from service.

(h) Alternative Methods of Compliance (AMOCs)

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

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

(i) Additional Information

For more information about this AD, contact Jacob Fitch, Aviation Safety Engineer, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; phone: (817) 222–4130; email: jacob.fitch@faa.gov.

(j) Material Incorporated by Reference

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

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

(i) Centerpointe Aerospace Service Bulletin No. 58B75, dated April 26, 2023.

(ii) [Reserved]

(3) For Centerpointe Aerospace service information identified in this AD, contact Centerpointe Aerospace Inc., 279 Blackland Road, Fate, TX 75189; phone: (972) 636–9601; email: Operations@avnresources.com; website: californiahelicopter.com.

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

information on the availability of this material at the FAA, call (817) 222–5110.

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

Issued on July 16, 2024.

James D. Foltz,

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

[FR Doc. 2024–16012 Filed 7–19–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–0775; Airspace
Docket No. 24–ASW–6]

RIN 2120–AA66

Establishment of Class E Airspace; Lubbock, TX

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace at Lubbock, TX. The FAA is taking this action to support new public instrument procedures.

DATES: Effective date 0901 UTC, October 31, 2024. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at www.regulations.gov using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

FAA Order JO 7400.11H, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Raul Garza Jr., Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5874.

SUPPLEMENTARY INFORMATION:**Authority for This Rulemaking**

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes Class E airspace extending upward from 700 feet above the surface at Lubbock Exec Airpark, Lubbock, TX, to support instrument flight rule operations at this airport.

History

The FAA published an NPRM for Docket No. FAA 2024–0775 in the **Federal Register** (89 FR 34171; April 30, 2024), proposing to establish the Class E airspace at Lubbock, TX. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Differences From the NPRM

An FAA database review noted that the incorrect coordinates were used in the NPRM. This final rule replaces the incorrect coordinates with the correct coordinates, Lat 33°29'01" N, long 101°48'46" W. This action does not change the airspace dimensions or operating requirements.

Incorporation by Reference

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023 and effective September 15, 2023. FAA Order JO 7400.11H is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11H lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by establishing Class E airspace upward from 700 feet above the surface within a 6.7-mile radius of Lubbock Exec Airpark, Lubbock, TX.

This action supports new public instrument procedures.

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

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

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

- 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

- 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11H,

Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

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

* * * * *

ASW TX E5 Lubbock, TX [Establish]

Lubbock Exec Airpark, TX

(Lat 33°29'01" N, long 101°48'46" W)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of the Lubbock Exec Airpark.

* * * * *

Issued in Fort Worth, Texas, on July 16, 2024.

Steven Phillips,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2024–15995 Filed 7–19–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE**Bureau of Industry and Security****15 CFR Part 700**

[Docket No240628–0180]

RIN 0694–AJ15

Clarifications and Updates to Defense Priorities and Allocations System Regulation

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) is finalizing amendments to its Defense Priorities and Allocations System (DPAS) regulation as originally proposed on February 7, 2024 with minor technical amendments. This final rule clarifies existing standards and procedures by which BIS may provide Special Priorities Assistance (SPA); revises Schedule I to provide transparency and differentiation between other departments' priorities jurisdiction and the Department of Commerce's jurisdiction; and provides technical edits to reflect certain non-substantive updates since the DPAS regulation was last amended in 2014, including updated contact information, legal citations, and definitions. The two technical amendments are made to accurately reflect updated information sourced from other Federal agencies. **DATES:** This final rule is effective August 21, 2024.

FOR FURTHER INFORMATION CONTACT:

Katie Reid at (202) 482–3634, *DPAS@bis.doc.gov*.

SUPPLEMENTARY INFORMATION:**Background**

On February 7, 2024 in 89 FR 8363, the Bureau of Industry and Security (BIS) proposed to update the priorities and allocations provisions set forth in the Defense Priorities and Allocations System (DPAS) regulation (15 CFR part 700) and implemented by the Department of Commerce (DOC), BIS, consistent with its authorities under Title I of the Defense Production Act of 1950, as amended (50 U.S.C. 4501 *et seq.*) (DPA), as delegated by Executive Order 13603 (March 16, 2012).

The DPAS has two principal components, priorities and allocations. Under the priorities component, certain contracts between the government and private parties or between private parties for the production or delivery of industrial resources are required to be given priority over other contracts to facilitate expedited delivery in promotion of the U.S. national defense. Under the allocations component, materials, services, and facilities may be allocated to promote the national defense. For both components, the term “national defense” means programs for military and energy production or construction, homeland security, stockpiling, space, emergency preparedness, critical infrastructure protection and restoration, and any directly related activity. The term also includes military and critical infrastructure assistance to any foreign nation.

Section-by-Section Analysis of the Clarifications and Updates That This Final Rule Makes to the Existing DPAS Regulation

The following discussion explains the changes that this final rule makes to the existing DPAS regulation.

Subpart A—Purpose

Section 700.1—Purpose of this part. This section adds the legal citation for the DPA and updates the legal citation for the Robert T. Stafford Disaster Relief Emergency Assistance Act. This rule also makes minor changes to the language to be consistent with the DPA and Executive Order (E.O.) 13603.

Subpart B—Overview

Section 700.2—Introduction. This section changes the reference to “industrial items” to “industrial resources” in paragraph (b) in order to use the term “industrial resources” defined in § 700.8. It also revises paragraph (c) to highlight that the DOC is also listed as an agency in Schedule I and the reason why. BIS believes that

the additional information provides a more complete description of Schedule I.

Section 700.3—Priority ratings and rated orders. This section adds in paragraph (a) references to the rating symbol to conform with the current definition of priority rating in section 700.8 as well as a description of a rating symbol. BIS makes these changes so that paragraph (a) will give a more complete description of a priority rating. It also revises paragraph (d) of this section by changing “items” to “industrial resources” in order to use the term “industrial resources” defined in section 700.8.

Subpart C—Definitions

Section 700.8—Definitions. This section updates the legal citation for the DPA found in the definition of “Defense Production Act.” It updates the legal citation for the Stafford Act found in the definitions of “national defense” and “Stafford Act,” and it updates the legal citation for the Selective Service Act found in the definition of “Selective Service Act.” This section updates both the definition of “approved program” and “priorities authority,” which is consistent with the language of the DPA and E.O. 13603. It also updates the definition of “priority rating” to clarify that the DOC may assign the priority rating, which is consistent with 15 CFR part 700. It removes the definition of “item” and updates the definition of “industrial resources” to clarify and be consistent with the use of both terms in 15 CFR part 700. This section includes the definitions of “facilities,” “materials,” and “services” to provide clarity and consistency with the DPA. It also provides a definition for “determination department” and “resources department” to provide clarity and consistency with sections 201 and 202 of E.O. 13603 and other priorities and allocations regulations. It also makes non-substantive changes by adding a comma after “administrative subpoenas” in the definition of official action and a comma after “chemicals” in the definition of “maintenance and repair and/or operating supplies (MRO).”

Subpart D—Industrial Priorities

Section 700.10—Authority. This section revises the last sentence of paragraph (c)(1), to clarify what the provisions of 15 CFR part 700 are inapplicable to by removing “those other items which include.” This change is consistent with the use of “item” in 15 CFR part 700.

Section 700.11—Priority ratings. This section makes a non-substantive change

in paragraph (a)(1) by moving the period inside the quotation. It also capitalizes the word “schedule” in paragraph (b) as this word references Schedule I, a specific part of 15 CFR part 700, which is capitalized throughout 15 CFR part 700. It also clarifies the explanation of what “A7” signifies consistent with Schedule I. This section updates paragraph (c) by replacing reference to the “C2” program identification symbol with “A7” in order to refer to the program identification symbol later referenced as an example of a priority rating in this paragraph.

Section 700.12—Elements of a rated order. This section replaces the example that refers to a “DX-A4” priority rating, which is not currently in use, with a reference to a “DX-A2” priority rating, which is more commonly used, in paragraph (a)(1). It also revises paragraph (a)(4) by changing the word “regulations” to “regulation,” which is consistent with the use of the word when referencing 15 CFR part 700.

Section 700.13—Acceptance and rejection of rated orders. This section replaces the brackets with parentheses in paragraph (c)(5) consistent with other sections of 15 CFR part 700. It adds “(1)” in between “one” and “working day” in paragraph (d)(3), which is consistent with other parts of this section.

Section 700.14—Preferential scheduling. This section revises the “Examples” by changing “June 2” to “June 3” so that the fact pattern makes sense.

Section 700.15—Extension of priority ratings. This section revises paragraphs (a), (b), and (c) by changing “items” to “industrial resources,” which clarifies the type of resource covered by the extension of priority ratings provision. It also revises paragraph (a) by adding a pinpoint citation to section 700.17, adding clarity as to which section of 15 CFR part 700 is referenced. This section inserts language in paragraphs (a) and (b) that clarifies that all four required elements of a rated order outlined in section 700.12 must be included on each successive order placed to fulfill a rated order. It also inserts language in the “Example” that clarifies that a “DO-A3” is a priority rating on a rated order.

Section 700.16—Changes or cancellations of priority ratings and rated orders. This section makes one non-substantive change to paragraph (b) by removing the comma after “DO”.

Section 700.17—Use of rated orders. This section clarifies in paragraph (a)(4) that a “DO-A3” and “DO-H7” are a priority rating on a rated order. This section updates paragraph (b)(1) by adding the spelling of “90” and

parentheses around “90,” which is consistent with other sections of 15 CFR part 700. This section revises paragraph (d)(1)(ii) by changing the word “regulations” to “regulation,” which is consistent with the use of the word when referencing 15 CFR part 700. This section changes the value of \$75,000 listed in paragraph (f) to \$125,000. This change is made to conform with the changes to the Simplified Acquisition Threshold (SAT) value made under the National Defense Authorization Act for Fiscal Year 2018 (Public Law 115–91), which raised the SAT from \$150,000 to \$250,000. As a result of the SAT increase, U.S. firms are not required to place a priority rating on an order less than \$125,000 (one-half of the revised SAT of \$250,000), as this amount is greater than \$75,000. BIS posted a notice to its website notifying the public of the change in the SAT after it was raised by statute but is making the change in the regulation itself with this update.

Section 700.18—Limitations on placing rated orders. This section changes the cross reference of section 700.41 found in paragraph (a)(2)(iii) and paragraph (a)(2)(iv)(B) to section 700.51, which is the correct cross reference. It also makes a non-substantive change by adding a comma after “expansion” in paragraph (a)(2)(iv)(A).

Subpart E—Industrial Priorities for Energy Programs

Section 700.21—Application for priority rating authority. This section updates the contact information for the Department of Energy.

Subpart F—Allocations Actions

Section 700.31—General Procedures. This section makes one non-substantive change in paragraph (f). “Allocations” is made singular to instead state “allocation,” which is consistent with the definition of “allocation order” in section 700.8.

Section 700.33—Types of allocation orders. This section makes one non-substantive change in the heading of this section and the first paragraph. “Allocations” is made singular to instead state “allocation,” which is consistent with the definition of “allocation order” in section 700.8.

Section 700.34—Elements of an allocation order. This section makes four non-substantive changes. In paragraph (a)(1), a comma is added after “DO rated orders.” In paragraph (b)(1), the word “regulations” is changed to “regulation,” which is consistent with the use of the word when referencing 15 CFR part 700. In paragraph (c), “that gives” is changed to “issued by.” In

paragraph (c)(1), the word “regulations” is changed to “regulation,” which is consistent with the use of the word when referencing 15 CFR part 700.

Subpart H—Special Priorities Assistance

Section 700.50—General Provisions. This section re-organizes paragraph (a) to include two paragraphs to clarify when special priorities assistance should be sought from the DOC or the Delegate Agency. This section changes the word “can” to “may” in the first sentence of paragraph (b), which is consistent with the use of the word “may” in other sections of 15 CFR part 700. It also changes paragraph (c) to clarify that special priorities assistance can be sought from the DOC, which is consistent with other sections of 15 CFR part 700. This section also includes a website reference to FORM BIS–999 in paragraph (c).

Section 700.51—Requests for priority rating authority. This section adds a new paragraph as paragraph (b) that clarifies what a person should do if they do not have priority rating authority under this part and would like to request priority rating authority. This change is consistent with current practice and requirements under E.O. 13603. As a result of this additional paragraph, this section changes paragraph (b) to paragraph (c) and paragraph (c) to paragraph (d). This section clarifies how to request priority rating authority for production and construction equipment from Delegate Agencies and the DOC in paragraph (c)(1), which is consistent with the delegations issued to the Delegate Agencies. This section includes the phrase “or those authorized by the DOC to priority rate the prime contract” in paragraph (d)(1) and removes reference to the “Delegate Agency” in paragraph (d)(2) to take into account that sponsorship may be obtained from sources other than just the Delegate Agencies. This section clarifies in paragraph (d)(4) that “Commerce” is referencing the “Department of Commerce.”

Section 700.52—Examples of assistance. This section emphasizes in paragraph (a) that special priorities assistance is in support of an approved program and inserts cross references on how to request a determination from the appropriate Determination Department that a request is necessary or appropriate to promote the national defense, consistent with the DPA and E.O. 13603. This section also adds paragraph (3) to paragraph (a) to list another situation in which special priorities assistance is usually provided.

Section 700.53—Criteria for assistance. This section adds “Determination Department” to the list of agencies that require timely requests, consistent with E.O. 13603.

Section 700.54—Instances where assistance will not be provided. This section adds “Determination Departments” in the list of agencies that have input on special priorities assistance requests, consistent with E.O. 13603.

Section 700.55—Homeland security, emergency preparedness, and critical infrastructure protection and restoration assistance programs within the United States. This section changes the title of this section to “Requests for determination that program within the United States is necessary or appropriate to promote the national defense”. The information originally in this section is made into a new paragraph (a). This section clarifies what types of requests should be submitted to the Federal Emergency Management Agency (FEMA), consistent with E.O. 13603. This section updates the contact information for FEMA’s Office of Policy and Program Analysis in paragraph (a). This section creates paragraph (b) to provide information on requesting a determination from the Department of Defense (DOD), consistent with E.O. 13603. Paragraph (c) is created to provide information on requesting a determination from the Department of Energy (DOE), consistent with E.O. 13603.

Section 700.56—Military assistance programs with Canada. This section updates the contact information, including the name of the agency, for the Government of Canada. It clarifies in paragraph (g) that requests for assistance in obtaining items in Canada must submit a request to the Office of Strategic Industries and Economic Security. This change clarifies that while these requests may go through the Delegate Agency, it is not required.

Section 700.57—Military assistance programs with other nations and international organizations. This section revises information regarding the list of countries that are signatory to a bilateral security of supply arrangement with the DOD in paragraphs (a) and (c). The revision adds Denmark, Estonia, Israel, Japan, Latvia, Lithuania, Norway, Republic of Korea, and Singapore to the list of countries that are signatory to a bilateral security of supply arrangement with the DOD. It also provides the DOD website for up-to-date information on the security of supply arrangements, including the current list of foreign

nations that are signatories to the bilateral security of supply arrangements with the DOD. This change is needed as the list of foreign nations that are signatories to bilateral security of supply arrangements with the DOD was updated to include Denmark, Estonia, Israel, Japan, Latvia, Lithuania, Norway, Republic of Korea, and Singapore, and it is expected that this list will continually be updated. This section also updates the DOD contact information in paragraph (b) and paragraph (c). This section moves the last sentence of paragraph (2) to a new paragraph (3) so that the information provided in this sentence is not lost as it is different from the information provided in paragraph (2).

Section 700.58—Critical infrastructure assistance programs to foreign nations and international organizations. This section makes a non-substantive change in paragraph (a) by adding a comma after “for example.” It updates paragraph (b) by re-organizing the information into two paragraphs. This section clarifies in the new paragraph (b)(1) that requests for assistance should be submitted on Form BIS-999, which is consistent with other types of special priorities assistance requests. This section clarifies in the new paragraph (b)(2) what the request to FEMA is for, which is consistent with E.O. 13603. It also updates the contact information for FEMA’s Office of Policy and Program Analysis.

Subpart I—Official Actions

Section 700.61—Rating authorizations. This section clarifies in paragraph (a)(1) that a rating authorization permits a person to place a priority rating on an order for an item which, for example, can include an item not normally ratable under this regulation. This clarification is consistent with the clarifications made in section 700.51 and section 700.52.

Section 700.63—Letters of Understanding. This section changes “which” to “that” in paragraph (a) as well as revises information in the parentheses to add “e.g.,” and remove “and” which clarifies this is an example list of parties. It also adds “Determination Department” to the example list of parties.

Subpart J—Compliance

Section 700.70—General provisions. This section removes specific penalties information for violating the DPA, and instead directly references the penalties’ sections within the DPA.

Section 700.71—Audits and investigations. This section makes one non-substantive change to paragraph (a).

A comma after “other writings” is added.

Section 700.74—Violations, penalties, and remedies. This section removes specific penalties information for violating the DPA in paragraph (a), and instead directly references the penalties sections of the DPA. It also changes the word “Sections” in paragraph (a) to “sections” as this word references sections of the DPA, which begins with a lower case “s” throughout 15 CFR part 700. This section changes “also, for example” to “e.g.,” in paragraph (c), which is consistent with how 15 CFR part 700 refers to examples.

Subpart K—Adjustments, Exceptions, and Appeals

Section 700.80—Adjustments or exceptions. This section makes one non-substantive change to paragraph (c). The number “25” is moved behind the word “twenty-five” and put in parentheses, and the parentheses are removed around the word “twenty-five”. This change is consistent with other sections of 15 CFR part 700.

Section 700.81—Appeals. This section makes one non-substantive change to paragraph (b). In both sentences, the number “45” is placed in parentheses and the word “forty-five” is added. This change is consistent with other sections of 15 CFR part 700.

Subpart L—Miscellaneous Provisions

Section 700.93—Communications. This section makes one non-substantive change by moving “and” to after “explanatory information.”. It adds the address of the Office of Strategic Industries and Economic Security. It also adds “special” in front of “priorities assistance” in the last paragraph, consistent with this part.

Schedule I to Part 700—Approved Programs and Delegate Agencies

This section revises the first paragraph to clarify that Schedule I is a list of approved programs, which is a defined term in section 700.8. A sentence is added that also clarifies that use of the authority under 15 CFR part 700 requires written authorization by the DOC, consistent with other sections of 15 CFR part 700. It also moves footnote 2 to the end of the first paragraph and adds a cross reference to section 700.50 for additional information.

This section updates the description of the “A2” program identification symbol from “Missile” to “Missile and Space” in Schedule I, which is consistent with DOD’s program determination that the approved program that uses the “A2” program

identification symbol includes both Missile and Space programs.

This section removes the “C1” program identification symbol for food resources in Schedule I as “food resources (combat rations)” now falls under the jurisdiction of the Department of Agriculture’s (USDA) Agriculture Priorities and Allocation System (APAS) regulation (7 CFR part 789). Although items that fell under this program identification symbol were always food resources, the authority for which has always been delegated to USDA under E.O. 13603 and its predecessors, USDA did not have a published regulation to enact that delegated authority. Therefore, under an agreement between USDA and the DOC, DOD was permitted to place ratings using the “C1” symbol for combat rations using the DPAS. However, in 2015, USDA published the APAS regulation and DOD now uses that authority to place priority ratings on combat rations, and no longer uses the previous agreement to rate them under the DPAS.

This section updates the description of the “J1” program identification symbol to “Co-Production Programs” in Schedule I to reflect DOD’s update to the approved program. DOD made a program determination under E.O. 13603 to expand the approved program that uses the “J1” program identification symbol from “F-16 Co-Production Program” to “Co-Production Programs.” This change expands DOD’s use of this program identification symbol to other programs outside of the F-16 program.

This section also makes a non-substantive change to the description of the “H1” program identification symbol to change “section” to the symbol.

This section updates the description of the “N8” program identification symbol in Schedule I from “Miscellaneous” to “Continuity of Government” to clarify DHS’s program determination is for Continuity of Government-related programs.

This section also adds an “Other Programs” section to Schedule I, which includes the program identification symbols for national defense programs administered by other departments but that might, in some instances, need industrial resources that are under the jurisdiction of the DPAS. BIS makes these revisions to Schedule I to help provide transparency and ease between other departments’ priorities authority and the DOC’s priorities authority when a Delegate Agency needs industrial resources to implement any approved program related to other resources (*i.e.*, food resources, energy resources, health resources, civil transportation, or water resources) subject to other departments’

priorities authority and authorized for priorities support by the appropriate department.

Four U.S. government agencies are administering priorities and allocations regulations similar to the DPAS for resources under their jurisdictions as outlined in E.O. 13603. Those departments and the resources under their jurisdiction are: USDA, food resources; DOE, energy resources; the Department of Health and Human Services (HHS), health resources; and the Department of Transportation (DOT), civil transportation. Persons placing priority ratings on contracts and orders pursuant to those systems may need industrial resources that are subject to DPAS in support of those contracts or orders. For example, spare tires or engine parts (industrial resources under DPAS jurisdiction) might be needed to support a contract to provide civil transportation resources.

In administering the DPAS, BIS has noted that the Departments of Defense, Energy, Homeland Security, and Health and Human Services and the General Services Administration are the U.S. Government agencies that most frequently procure industrial resources needed to implement approved national defense programs. Accordingly, BIS has delegated to those five agencies certain DPAS authority to place priority ratings on contracts and orders for industrial resources in support of approved national defense programs (Delegate Agencies). BIS expects that those five agencies are also likely to be the agencies that most frequently procure any industrial resources that may be needed to implement any future approved programs related to food resources, energy resources, health resources, civil transportation, and water resources.

Considering these facts and to assist in developing “a consistent and unified Federal priorities and allocations system” as called for by Section 101(d)(2) of the DPA, BIS, as part of those delegations, has authorized these Delegate Agencies to place priority ratings on contracts and orders for industrial resources needed to implement any program related to food resources, energy resources, health resources, civil transportation, or water resources determined as necessary or appropriate to promote the national defense and authorized for priorities support by the appropriate resource agency (*i.e.*, Departments of Agriculture, Energy, Health and Human Services, and Transportation). Therefore, Delegate Agencies are authorized to use the same program identification symbol on such

contracts and orders for industrial resources as authorized by the appropriate resource agency to support the approved program. However, any priority rated contract or order for industrial resources placed to implement an approved program related to food resources, energy resources, health resources, civil transportation, or water resources remains subject to the DPAS. The addition of the second paragraph before the Schedule I and the “Other Programs” section within Schedule I reflects this delegated authority.

BIS invited written comments on the February 7, 2024 (89 FR 8363), proposed rule, stating that any such comments must be received by March 8, 2024. BIS received no comments, and thus adopts the rule as originally proposed with two minor technical amendments made to the proposed rule. They have been made to accurately reflect updated information sourced from other Federal agencies. The first technical amendment is to section 700.57, reflected earlier in the Preamble. Specifically, paragraphs (a) and (c) of section 700.57 are amended to accurately reflect the most current list of countries that are signatory to a bilateral security of supply arrangement with the DOD. DOD updated this list of countries on its website (<https://www.businessdefense.gov/security-of-supply.html>) after the proposed rule was published. The revision adds Denmark, Estonia, Israel, Japan, Latvia, Lithuania, Norway, Republic of Korea, and Singapore to the list of countries that are signatory to a bilateral security of supply arrangement with the DOD. The second minor technical amendment, also reflected earlier in the Preamble, is to information provided under the “Health Resources/Health Resources Priorities and Allocations System (HRPAS)” subsection of the “Other Programs” section of Schedule I, which refers to information in HHS’s HRPAS regulation (45 CFR part 101). BIS amends this section of Schedule I for consistency with updates to the HRPAS regulation reflected in the HRPAS final rule published on February 9, 2024 (89 FR 9020). The revisions to this section of Schedule I remove the M5 through M9 program identification symbols; revise the descriptions of the M1 through M4 program identification symbols; and update the **Federal Register** citation to the HRPAS from the HRPAS proposed rule to the HRPAS final rule published on February 9, 2024.

Defense Production Act of 1950, as Amended

On September 8, 1950, the President signed the Defense Production Act of 1950 (DPA), as amended into law. Title VII of the DPA includes a sunset clause for the majority of the DPA authorities which require periodic reauthorization. On August 13, 2018, the President signed the John S. McCain National Defense Authorization Act for Fiscal Year 2019 into law, which reauthorized the DPA, 50 U.S.C. 4501 *et seq.*, through September 30, 2025. The DPA provides the legal basis for BIS’s principal authorities and serves as the authority under which BIS issues this final rule.

Expected Impact of the Rule

BIS believes this final rule merely provides clarifications and transparency to Federal, State, local, Tribal, and territorial government agencies, foreign governments, and the public to ensure ease of understanding and implementation of established procedures and will not have a significant economic impact on government agencies or the public. No comments were received and BIS is finalizing this section with no changes.

These changes improve the ease, clarity, and transparency of the existing standards and procedures used to authorize and require priority performance of certain contracts or orders that promote the national defense over other contracts and orders. The changes to ensure consistency with the Defense Production Act of 1950 (DPA) and E.O. 13603; provide clarity on procedures for the placement, acceptance, and performance of the Defense Priorities and Allocations System (DPAS) priority rated orders; and provide transparency to the process for parties to request SPA.

The standards and process under which a rated order is authorized, placed, or performed on are not changed with this final rule. There are no modifications to the procedures for the placement, acceptance, and performance of rated orders or for the allocation of materials, services, and facilities. Firms are not required to reduce the total volume of orders or require the recipient of a rated order to reduce prices or provide rated orders with more favorable terms than comparable unrated orders. Nor do the changes amend the requirements or procedures for requesting Special Priorities Assistance (SPA).

Rulemaking Requirements

1. This final rule is not a significant regulatory action for purposes of Executive Order (E.O.) 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. With the proposed rule published in February 2024, BIS also requested comments on changes to an existing information collection, *Request for Special Priorities Assistance* (OMB Control Number 0694–0057). No public comments were received and BIS has submitted for OMB approval a revised information collection which reflect the changes discussed in the proposed rule.

3. These changes do not contain policies with federalism implications as that term is defined in E.O. 13132.

4. The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.*, generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to the notice and comment rulemaking requirements under the Administrative Procedure Act (5 U.S.C. 553) or any other statute. Under section 605(b) of the RFA, however, if the head of an agency certifies that a rule will not have a significant impact on a substantial number of small entities, the statute does not require the agency to prepare a regulatory flexibility analysis. Pursuant to section 605(b), the Chief Counsel for Regulation, Department of Commerce, certified to the Chief Counsel for Regulation, Small Business Administration that this final rule will not have a significant impact on a substantial number of small entities for the reasons explained below. No other law requires such an analysis and no comments were received on the certification. Consequently, no regulatory flexibility analysis is required, and none has been prepared.

List of Subjects in 15 CFR Part 700

Administrative practice and procedure, Business and industry, Government contracts, National defense, Reporting and recordkeeping requirements, Strategic and critical materials.

Accordingly, 15 CFR part 700 of the DPAS regulation, is amended as follows:

PART 700—DEFENSE PRIORITIES AND ALLOCATIONS SYSTEM

■ 1. The authority citation for 15 CFR part 700 continues to read as follows:

Authority: 50 U.S.C. 4501 *et seq.*; 42 U.S.C. 5195, *et seq.*; 50 U.S.C. 3816; 10 U.S.C. 2538; 50 U.S.C. 82; E.O. 12656, 53 FR 226, 3 CFR, 1988 Comp., p. 585; E.O. 12742, 56 FR 1079, 3 CFR, 1991 Comp., p. 309; E.O. 13603, 77 FR 16651, 3 CFR, 2012 Comp., p. 225.

■ 2. Section 700.1 is amended by revising the second and third sentences to read as follows:

§ 700.1 Purpose of this part.

* * * The DPAS implements the priorities and allocations authority of the Defense Production Act (50 U.S.C. 4501 *et seq.*), delegated to the Department of Commerce under Executive Order 13603, including use of that authority to support emergency preparedness activities pursuant to Title VI of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*), and the priorities authority of the Selective Service Act and related statutes, all with respect to industrial resources. The DPAS establishes procedures for the placement, acceptance, and performance of priority rated contracts and orders (other than contracts of employment) and for the allocation of materials, services, and facilities for approved programs. * * *

■ 3. Revise section 700.2 to read as follows:

§ 700.2 Introduction.

(a) Certain national defense and energy programs (including military, emergency preparedness, homeland security, and critical infrastructure protection and restoration activities) may be eligible for priorities and allocations support as determined by a Determination Department.

(b) The Department of Commerce administers the DPAS and may exercise priorities and allocations authority to ensure the timely delivery of industrial resources to meet approved program requirements.

(c) The Department of Commerce has delegated authority to place priority ratings on contracts or orders necessary or appropriate to promote the national defense to certain government agencies that issue such contracts or orders. Such delegations include authority to authorize recipients of rated orders to place ratings on contracts or orders to contractors, subcontractors, and suppliers. Schedule I to this part includes a list of agencies to which the Department of Commerce has delegated authority. The Department of Commerce

is also listed as an agency for programs where its authorization is necessary to place rated orders.

■ 4. Section 700.3 is amended by revising paragraphs (a) and (d) to read as follows:

§ 700.3 Priority ratings and rated orders.

(a) Rated orders are identified by a priority rating, which consists of a rating symbol (DO or DX), and a program identification symbol. Rated orders take precedence over all unrated orders as necessary to meet required delivery dates. Rating symbols indicate the level of priority. Among rated orders, DX rated orders take precedence over DO rated orders. Program identification symbols indicate which approved program is attributed to the rated order.

* * * * *

(d) Persons who receive rated orders must in turn place rated orders with their suppliers for the industrial resources they need to fill the orders. This provision ensures that suppliers will give priority treatment to rated orders from contractor to subcontractor to suppliers throughout the procurement chain.

* * * * *

■ 5. Section 700.8 is amended by:

- a. Revising the definitions of “Approved program” and “Defense Production Act”;
- b. Adding in alphabetical order the definitions of “Determination Department” and “Facilities”;
- c. Revising the definition of “Industrial resources”;
- d. Removing the definition of “Item”;
- e. Adding in alphabetical order a definition for “Materials”;
- f. Revising the definitions of “National defense”, “Official action”, “Priorities authority”, and “Priority rating”;
- g. Adding in alphabetical order a definition for “Resource Department”;
- h. Revising the definition of “Selective Service Act”;
- i. Adding in alphabetical order a definition for “Services”; and
- j. Revising the definition of “Stafford Act”;

The revisions and additions read as follows:

§ 700.8 Definitions.

* * * * *

Approved program. A program determined in writing as necessary or appropriate for priorities and allocations support to promote the national defense by the Secretary of Defense, the Secretary of Energy, or the Secretary of Homeland Security, under the authority

of the Defense Production Act and Executive Order 13603, or the Selective Service Act and Executive Order 12742.

* * * * *

Defense Production Act. The Defense Production Act of 1950, as amended (50 U.S.C. 4501 *et seq.*).

* * * * *

Determination Department. Any of the three Federal departments whose head is delegated authority by the President under section 202 of Executive Order 13603 to determine in writing that a program is necessary or appropriate to promote the national defense (referred to as “approved program”):

(1) The Secretary of Defense with respect to military production and construction, military assistance to foreign nations, military use of civil transportation, stockpiles managed by the Department of Defense, space, and directly related activities;

(2) The Secretary of Energy with respect to energy production and construction, distribution and use, and directly related activities; and

(3) The Secretary of Homeland Security with respect to all other national defense programs, including civil defense and continuity of Government.

* * * * *

Facilities. The term includes all types of buildings, structures, or other improvements to real property (but excluding farms, churches or other houses of worship, and private dwelling houses), and services relating to the use of any such building, structure, or other improvement.

* * * * *

Industrial resources. All materials, services, and facilities, including construction materials, the authority for which has not been delegated to other agencies under Executive Order 13603. This term may also be referred to as “item” in this part.

* * * * *

Materials. Includes:

(1) Any raw materials (including minerals, metals, and advanced processed materials), commodities, articles, components (including critical components), products, and items of supply; and

(2) Any technical information or services ancillary to the use of any such materials, commodities, articles, components, products, or items.

National defense. Programs for military and energy production or construction, military or critical infrastructure assistance to any foreign nation, homeland security, stockpiling, space, and any directly related activity.

Such term includes emergency preparedness activities conducted pursuant to Title VI of The Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*) and critical infrastructure protection and restoration.

Official action. An action taken by the Department of Commerce under the authority of the Defense Production Act, the Selective Service Act and related statutes, and this part. Such actions include the issuance of rating authorizations, directives, letters of understanding, demands for information, inspection authorizations, administrative subpoenas, and allocation orders.

* * * * *

Priorities authority. The authority of the Department of Commerce, pursuant to section 101 of the Defense Production Act, to require priority performance of contracts and orders (other than contracts of employment) for industrial resources for use in approved programs.

Priority rating. An identifying code, consisting of the rating symbol and the program identification symbol, assigned by the Department of Commerce, a Delegate Agency, or authorized person and placed on all rated orders.

* * * * *

Resource Department. Any of the six Federal departments whose head is delegated authority by the President under section 201 of Executive Order 13603 to require acceptance and priority performance of contracts or orders (other than contracts of employment) to promote the national defense over performance of any other contracts or orders, and to allocate materials, services, and facilities as deemed necessary or appropriate to promote the national defense (referred to as “approved program”):

(1) The Secretary of Agriculture with respect to food resources, food resource facilities, livestock resources, veterinary resources, plant health resources, and the domestic distribution of farm equipment and commercial fertilizer;

(2) The Secretary of Energy with respect to all forms of energy;

(3) The Secretary of Health and Human Services with respect to health resources;

(4) The Secretary of Transportation with respect to all forms of civil transportation;

(5) The Secretary of Defense with respect to water resources; and

(6) The Secretary of Commerce with respect to all other materials, services, and facilities, including construction materials (referred to as “industrial resources”).

* * * * *

Selective Service Act. Section 18 of the Selective Service Act of 1948 (50 U.S.C. 3816).

Services. Includes any effort that is needed for or incidental to:

(1) The development, production, processing, distribution, delivery, or use of an industrial resource or a critical technology item;

(2) The construction of facilities; or

(3) Other national defense programs and activities.

* * * * *

Stafford Act. Title VI (Emergency Preparedness) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended (42 U.S.C. 5121 *et seq.*).

* * * * *

■ 6. Section 700.10 is amended by revising the last sentence in paragraph (c)(1) introductory text to read as follows:

§ 700.10 Authority.

* * * * *

(c) * * *

(1) * * * Unless otherwise agreed to by the concerned agencies, the provisions of this part are not applicable to:

* * * * *

■ 7. Section 700.11 is amended by revising paragraph (a)(1), the second and third sentences of paragraph (b), and the first sentence of paragraph (c) to read as follows:

§ 700.11 Priority ratings.

(a) * * *

(1) There are two levels of priority established by this regulation, identified by the rating symbols “DO” and “DX.”

* * * * *

(b) * * * The list of approved programs and their identification symbols is found in schedule I to this part. For example, A1 identifies defense aircraft programs and A7 signifies defense electronic and communications equipment programs. * * *

(c) *Priority ratings.* A priority rating consists of the rating symbol—DO and DX—and the program identification symbol, such as A1, A7, or N1. * * *

■ 8. Section 700.12 is amended by revising paragraphs (a)(1) and (a)(4) to read as follows:

§ 700.12 Elements of a rated order.

(a) * * *

(1) The appropriate priority rating and program identification symbol (*e.g.*, DO–A1, DX–A2, DO–N1).

* * * * *

(4) A statement that reads in substance: “This is a rated order certified for national defense use and

you are required to follow all the provisions of the Defense Priorities and Allocations System regulation (15 CFR part 700).”

* * * * *

■ 9. Section 700.13 is amended by revising paragraphs (c)(5) and (d)(3) to read as follows:

§ 700.13 Acceptance and rejection of rated orders.

* * * * *

(c) * * *

(5) If acceptance of a rated order or performance against a rated order would violate any other regulation, official action, or order of the Department of Commerce issued under the authority of the Defense Production Act or the Selective Service Act and related statutes (see § 700.75).

(d) * * *

(3) If a person has accepted a rated order and subsequently finds that shipment or performance will be delayed, the person must notify the customer immediately, give the reasons for the delay, and advise of a new shipment or performance date. If notification is given verbally, written (hard copy) or electronic confirmation must be provided within one (1) working day of the verbal notice.

■ 10. Section 700.14 is amended by revising the second sentence in “Examples” to paragraph (b) to read as follows:

§ 700.14 Preferential Scheduling.

* * * * *

(b) * * *

Examples:

* * * If a DX rated order is received calling for delivery on July 15 and a person has a DO rated order requiring delivery on June 3 and operations can be scheduled to meet both deliveries, there is no need to alter production schedules to give any additional preference to the DX rated order. * * *

* * * * *

■ 11. Revise Section 700.15 to read as follows:

§ 700.15 Extension of priority ratings.

(a) A person must use rated orders with suppliers to obtain industrial resources needed to fill a rated order. All elements of a rated order outlined in section 700.12 must be included on the rated order. The person must use the priority rating indicated on the customer’s rated order, except as otherwise provided in this part (see § 700.17) or as directed by the Department of Commerce.

Example:

If a person is in receipt of a rated order with a priority rating of DO–A3

for a navigation system and needs to purchase semiconductors for its manufacture, that person must use a DO–A3 priority rating to obtain the needed semiconductors.

(b) The required elements of a rated order outlined in § 700.12 must be included on each successive order placed to obtain industrial resources needed to fill a customer’s rated order. Therefore, the inclusion of the rating will continue from contractor to subcontractor to supplier throughout the entire supply chain.

(c) A person must use rated orders with suppliers to obtain industrial resources needed to fill an emergency preparedness rated order. That person must require acceptance or rejection, and transmission of that acceptance or rejection by the supplier within the time limit stated in the rated order that is being filled.

■ 12. Section 700.16 is amended by revising paragraph (b) to read as follows:

§ 700.16 Changes or cancellations of priority ratings and rated orders.

* * * * *

(b) If an unrated order is amended so as to make it a rated order, or a DO rating is changed to a DX rating, the supplier must give the appropriate preferential treatment to the order as of the date the change is received by the supplier.

* * * * *

■ 13. Section 700.17 is amended by revising paragraphs (a)(4), (b)(1), (d)(1)(ii), and (f) to read as follows:

§ 700.17 Use of rated orders.

(a) * * *

(4) MRO needed to produce the finished items to fill rated orders. However, for MRO, the priority rating used must contain the program identification symbol H7 along with the rating symbol contained on the customer’s rated order. For example, a person in receipt of a rated order with a priority rating of DO–A3 rated order, who needs MRO, would place a rated order with a priority rating of DO–H7 rated order with the person’s supplier.

(b) * * *

(1) The order must be placed within ninety (90) days of the date of use of the inventory.

* * * * *

(d) * * *

(1) * * *

(ii) The elements of a rated order, as required by § 700.12, are included on the order with the statement required in § 700.12(a)(4) modified to read in substance: “This purchase order contains rated order quantities certified

for national defense use, and you are required to follow all the provisions of the Defense Priorities and Allocations System regulation (15 CFR part 700) as it pertains to the rated quantities.”

* * * * *

(f) A person is not required to place a priority rating on an order for less than \$125,000, or one half of the Simplified Acquisition Threshold (as established in the Federal Acquisition Regulation (FAR)) (see FAR section 2.101), whichever amount is greater, provided that delivery can be obtained in a timely fashion without the use of the priority rating.

■ 14. Section 700.18 is amended by revising paragraphs (a)(2)(iii), (a)(2)(iv)(A), and (a)(2)(iv)(B) to read as follows:

§ 700.18 Limitations on placing rated orders.

(a) * * *

(2) * * *

(iii) Items in advance of the receipt of a rated order, except as specifically authorized by the Department of Commerce (see § 700.51(c) for information on obtaining authorization for a priority rating in advance of a rated order); or

(iv) * * *

(A) Items for plant improvement, expansion, or construction, unless they will be physically incorporated into a construction project covered by a rated order; or

(B) Production or construction equipment or items to be used for the manufacture of production equipment (for information on requesting priority rating authority, see § 700.51).

* * * * *

■ 15. Section 700.21 is amended by revising the last sentence of paragraph (a) to read as follows:

§ 700.21 Application for priority rating authority.

(a) * * * Further information may be obtained from the Department of Energy, Office of Cybersecurity, Energy Security, and Emergency Response, 1000 Independence Avenue SW, Washington, DC 20585; Telephone: (202) 586–8100; Email: *askcr@hq.doe.gov*.

* * * * *

■ 16. Section 700.31 is amended by revising paragraph (f) to read as follows:

§ 700.31 General procedures.

* * * * *

(f) A detailed description of the provisions that will be included in the allocation orders, including the type(s) of allocation orders, the percentages or

quantity of capacity or output to be allocated for each purpose, the relationship with previously or subsequently received priority rated and unrated contracts and orders, and the duration of the allocation action (*e.g.*, anticipated start and end dates);

* * * * *

■ 17. Section 700.33 is amended by revising the section heading and introductory text to read as follows:

§ 700.33 Types of allocation orders.

There are three types of allocation orders available for communicating allocation actions.

* * * * *

■ 18. Section 700.34 is amended by revising paragraphs (a)(1), (b)(1), (c) introductory text, and (c)(1) to read as follows:

§ 700.34 Elements of an allocation order.

* * * * *

(a) * * *

(1) A detailed description of the required allocation action(s), including its relationship to previously or subsequently received DX rated orders, DO rated orders, and unrated orders.

* * * * *

(b) * * *

(1) A statement that reads in substance: “This is an allocation order certified for national defense use. [Insert the name of the person receiving the order] is required to comply with this order, in accordance with the provisions of the Defense Priorities and Allocations System regulation (15 CFR part 700).”

* * * * *

(c) *Elements to be included in an allocation order issued by constructive notice through publication in the Federal Register.* (1) A statement that reads in substance: “This is an allocation order certified for national defense use. [Insert the name(s) of the person(s) to whom the order applies or a description of the class of persons to whom the order applies] is (are) required to comply with this order, in accordance with the provisions of the Defense Priorities and Allocations System regulation (15 CFR part 700).”

* * * * *

■ 19. Revise section 700.50 to read as follows:

§ 700.50 General provisions.

(a) Once a priority rating has been authorized pursuant to this part, further action by the Department of Commerce generally is not needed. However, it is anticipated that from time-to-time problems will occur. In this event, a person should immediately contact the appropriate contract administration

officer or the Department of Commerce for guidance or assistance. Special priorities assistance is a service provided to alleviate problems that do arise.

(1) If additional formal aid is needed for a rated order placed by a Delegate Agency, special priorities assistance should be sought from the Delegate Agency through the contract administration officer. If the Delegate Agency is unable to resolve the problem or to authorize the use of a priority rating and believes additional assistance is warranted, the Delegate Agency may forward the request to the Department of Commerce for action.

(2) If additional formal aid is needed for a rated order placed by other authorized persons, special priorities assistance should be sought from the Department of Commerce.

(b) Special priorities assistance may be provided for any reason consistent with this part, such as assisting in obtaining timely deliveries of items needed to satisfy rated orders or authorizing the use of priority ratings on orders to obtain items not otherwise ratable under this part. If the Department of Commerce is unable to resolve the problem or to authorize the use of a priority rating and believes additional assistance is warranted, the Department of Commerce may forward the request to another agency, identified in § 700.10(c), as appropriate, for action.

(c) A request for special priorities assistance must be submitted on Form BIS–999 (OMB control number 0694–0057) to the local contract administration representative or to the Department of Commerce. Form BIS–999 may be obtained from the Delegate Agency representative or from the Department of Commerce. A sample Form BIS–999 is attached at appendix I. A fillable Form BIS–999 may be obtained on the following website: <https://www.bis.doc.gov/>.

■ 20. Revise 700.51 to read as follows:

§ 700.51 Requests for priority rating authority.

(a) If a rated order is likely to be delayed because a person is unable to obtain items not normally rated under this part, the person may request the authority to use a priority rating in ordering the needed items. Examples of items for which priority ratings may be authorized include:

(1) Production or construction equipment;

(2) Computers when not used as production items; and

(3) Expansion, rebuilding or replacing plant facilities.

(b) If a person does not have priority rating authority under this part from a Delegate Agency or the Department of Commerce and is unable to ensure the timely delivery of industrial resources, the person may request the authority to use a priority rating in ordering the needed items.

(1) A request for priority rating authority under this part must be submitted on Form BIS–999 to the Department of Commerce (see § 700.50(c) for information on Form BIS–999).

(2) A request for priority rating authority under this part may be used only to support approved programs (see § 700.55, § 700.57, and § 700.58 for information on requesting a determination by the appropriate Determination Department that the request supports a program that is necessary or appropriate to promote the national defense).

(c) *Rating authority for production or construction equipment.* (1) A request for priority rating authority for production or construction equipment must be submitted to the appropriate Delegate Agency or the Department of Commerce. Requests in support of Department of Defense approved programs should be submitted to the Department of Defense on Department of Defense Form DD 691. All other requests should be submitted on Form BIS–999. If the Delegate Agency is unable to resolve the problem or authorize the use of a priority rating, the Delegate Agency may forward the request to the Department of Commerce for action.

(2) When the use of a priority rating is authorized for the procurement of production or construction equipment, a rated order may be used either to purchase or to lease such equipment. However, in the latter case, the equipment may be leased only from a person engaged in the business of leasing such equipment or from a person willing to lease rather than sell.

(d) *Rating authority in advance of a rated prime contract.* (1) In certain cases and upon specific request, the Department of Commerce, in order to promote the national defense, may authorize a person to place a priority rating on an order to a supplier in advance of the issuance of a rated prime contract. In these instances, the person requesting advance rating authority must obtain sponsorship of the request from the appropriate Delegate Agency or those authorized by the Department of Commerce to priority rate the prime contract. The person shall also assume any business risk associated with the placing of rated orders if these orders

have to be cancelled in the event the rated prime contract is not issued.

(2) The person must state the following in the request: "It is understood that the authorization of a priority rating in advance of our receiving a rated prime contract and our use of that priority rating with our suppliers in no way commits the Department of Commerce or any other government agency to enter into a contract or order or to expend funds. Further, we understand that the Federal Government shall not be liable for any cancellation charges, termination costs, or other damages that may accrue if a rated prime contract is not eventually placed and, as a result, we must subsequently cancel orders placed with the use of the priority rating authorized as a result of this request."

(3) In reviewing requests for rating authority in advance of a rated prime contract, the Department of Commerce will consider, among other things, the following criteria:

- (i) The probability that the prime contract will be awarded;
 - (ii) The impact of the resulting rated orders on suppliers and on other authorized programs;
 - (iii) Whether the contractor is the sole source;
 - (iv) Whether the item being produced has a long lead time; and
 - (v) The time period for which the rating is being requested.
- (4) The Department of Commerce may require periodic reports on the use of the rating authority granted under paragraph (c) of this section.
- (5) If a rated prime contract is not issued, the person shall promptly notify all suppliers who have received rated orders pursuant to the advanced rating authority that the priority rating on those orders is cancelled.

■ 21. Section 700.52 is amended by revising paragraph (a) to read as follows:

§ 700.52 Examples of assistance.

(a) While special priorities assistance may be provided for any reason in support of this regulation and an approved program (see § 700.55, § 700.57, § 700.58, and Schedule I of this part), it is usually provided in situations where:

- (1) A person is experiencing difficulty in obtaining delivery against a rated order by the required delivery date;
- (2) A person cannot locate a supplier for an item needed to fill a rated order; or
- (3) A person is experiencing difficulty in obtaining delivery for an unrated order by the required delivery date.

* * * * *

■ 22. Amend section 700.53 by revising the introductory text to read as follows:

§ 700.53 Criteria for assistance.

Requests for special priorities assistance should be timely, *i.e.*, the request has been submitted promptly and enough time exists for the Determination Department, Delegate Agency, or the Department of Commerce to effect a meaningful resolution to the problem, and must establish that:

* * * * *

■ 23. Amend section 700.54 by revising the first sentence of the introductory text to read as follows:

§ 700.54 Instances where assistance will not be provided.

Special priorities assistance is provided at the discretion of the Determination Departments, Delegate Agencies, and the Department of Commerce when it is determined that such assistance is warranted to meet the objectives of this regulation. * * *

* * * * *

■ 24. Revise section 700.55 to read as follows:

§ 700.55 Requests for determination that program within the United States is necessary or appropriate to promote the national defense.

(a) *Homeland security, emergency response, and critical infrastructure protection and restoration assistance programs within the United States.* Any person requesting priority rating authority or requiring assistance in obtaining rated items under this part supporting homeland security, emergency preparedness, and critical infrastructure protection and restoration related activities should submit a request for a determination in writing that the request supports a program that is necessary or appropriate to promote the national defense (referred to as "approved program") to the Office of Policy and Program Analysis, Federal Emergency Management Agency, Department of Homeland Security, 500 C Street SW, Washington, DC 20472; Telephone: (202) 212-2900; Fax: (202) 646-4601; Email: FEMA-DPA@fema.dhs.gov, website: <https://www.fema.gov/disaster/defense-production-act>.

(b) *Military production and construction, military use of civil transportation, stockpiles managed by the Department of Defense, space, and directly related activities within the United States.* Any person requesting priority rating authority or requiring assistance under this part in obtaining rated items supporting military production and construction, military

use of civil transportation, stockpiles managed by the Department of Defense, space, and directly related activities should submit a request for a determination in writing that the request supports a program that is necessary or appropriate to promote the national defense (referred to as "approved program") to the Department of Defense DPA Title I Lead in the Office of the Assistant Secretary of Defense for Industrial Base Policy, 3330 Defense Pentagon, Room 3B854, Washington, DC 20301; Telephone: (703) 697-0051; Fax: (703) 695-4885; Email: osd.pentagon.ousd-a-s.mbx.indpol-dpa-title-i@mail.mil; website: <https://www.businessdefense.gov/>.

(c) *Energy production and construction, distribution and use, and directly related activities within the United States.* Any person requesting priority rating authority or requiring assistance under this part in obtaining rated items supporting energy production and construction, distribution and use, and directly related activities should submit a request for a determination in writing that the request supports a program that is necessary or appropriate to promote the national defense (referred to as "approved program") to the Department of Energy, Office of Cybersecurity, Energy Security, and Emergency Response, 1000 Independence Avenue SW, Washington, DC 20585; Telephone: (202) 586-8100; Email: askcr@hq.doe.gov.

■ 25. Section 700.56 is amended by revising paragraphs (c), (d), (e), (f), and (g) to read as follows:

§ 700.56 Military assistance programs with Canada.

* * * * *

(c) The Department of Commerce coordinates with Public Works and Government Services Canada on all matters of mutual concern relating to the administration of this part.

(d) Any person in the United States ordering defense items in Canada in support of an approved program should inform the Canadian supplier that the items being ordered are to be used to fill a rated order. The Canadian supplier should be informed that if production materials are needed from the United States by the Canadian supplier or the Canadian supplier's vendor to fill the order, the Canadian supplier or vendor should contact Public Works and Government Services Canada for authority to place rated orders in the United States: Public Works and Government Services Canada, Acquisitions Branch, Business

Management Directorate, Phase 3, Place du Portage, 0B2-103, 11 Laurier Street, Gatineau, Quebec, K1A 0S5, Canada; Telephone: (819) 420-7200; Fax: (819) 997-9776, or electronically at TPSGC.PAPrioritesdedefense-APDefencePriorities.PWGSC@tpsgc-pwgsc.gc.ca.

(e) Any person in Canada producing defense items for the Canadian government may also obtain priority rating authority for items to be purchased in the United States by applying to Public Works and Government Services Canada, Acquisitions Branch, Business Management Directorate, in accordance with its procedures.

(f) Persons in Canada needing special priorities assistance in obtaining defense items in the United States may apply to Public Works and Government Services Canada, Acquisitions Branch, Business Management Directorate, for such assistance. Public Works and Government Services Canada will forward appropriate requests to the Department of Commerce.

(g) Any person in the United States requiring assistance in obtaining items in Canada must submit a request to the Office of Strategic Industries and Economic Security, U.S. Department of Commerce on Form BIS-999. The Department of Commerce will forward appropriate requests to Public Works and Government Services Canada.

■ 26. Section 700.57 is amended by revising paragraphs (a), (b)(1), and (c) to read as follows:

§ 700.57 Military assistance programs with other nations and international organizations.

(a) *Scope.* To promote military assistance to foreign nations and international organizations (for example, the North Atlantic Treaty Organization or the United Nations), this section provides for authorizing priority ratings to persons in foreign nations or international organizations to obtain items in the United States in support of approved programs. Although priority ratings have no legal authority outside of the United States, this section also provides information on how persons in the United States may obtain informal assistance in foreign nations that are signatories to bilateral security of supply arrangements with the Department of Defense. These foreign nations include Australia, Estonia, Denmark, Finland, Israel, Italy, Japan, Latvia, Lithuania, The Netherlands, Norway, Republic of Korea, Singapore, Spain, Sweden, and the United Kingdom. The most current security of supply arrangement

information, including an up-to-date list of countries, may be found on the following website: <https://www.businessdefense.gov/security-of-supply.html>.

(b) * * *

(1) Any person in a foreign nation other than Canada, or any person in an international organization, requiring assistance in obtaining items in the United States or priority rating authority for items to be purchased in the United States, should submit a request for such assistance or priority rating authority to the Department of Defense DPA Title I Lead in the Office of the Assistant Secretary of Defense for Industrial Base Policy, 3330 Defense Pentagon, Room 3B854, Washington, DC 20301; Telephone: (703) 697-0051; Fax: (703) 695-4885; Email: osd.pentagon.ousd-a-s.mbx.indpol-dpa-title-i@mail.mil, website: <https://www.businessdefense.gov/>.

(i) If the end product is being acquired by a U.S. Government agency, the request should be submitted to the Department of Defense DPA Title I Lead through the U.S. contract administration representative.

(ii) If the end product is being acquired by a foreign nation or international organization, the request must be sponsored prior to its submission to the Department of Defense DPA Title I Lead by the government of the foreign nation or the international organization that will use the end product.

* * * * *

(c) *Requesting assistance in foreign nations that are signatories to bilateral security of supply arrangements.* (1) The Department of Defense has entered into bilateral security of supply arrangements with several foreign nations that allow the Department of Defense to request the priority delivery for Department of Defense contracts, subcontracts, and orders from companies in these countries. These countries include Australia, Denmark, Estonia, Finland, Israel, Italy, Japan, Latvia, Lithuania, The Netherlands, Norway, Republic of Korea, Singapore, Spain, Sweden, and the United Kingdom. The most current security of supply arrangement information, including an up-to-date list of countries, may be found on the following website: <https://www.businessdefense.gov/security-of-supply.html>.

(2) Any person in the United States requiring assistance in obtaining the priority delivery of a contract, subcontract, or order in foreign nations that are signatories to bilateral security of supply arrangements with the

Department of Defense should contact the Department of Defense DPA Title I Lead in the Office of the Assistant Secretary of Defense for Industrial Base Policy for assistance.

(3) Persons in foreign nations that are signatories to bilateral security of supply arrangements with the Department of Defense should request assistance in accordance with paragraph (b)(1) of this section.

■ 27. Revise section 700.58 to read as follows:

§ 700.58 Critical infrastructure assistance programs to foreign nations and international organizations.

(a) *Scope.* To promote critical infrastructure assistance to foreign nations, this section provides for authorizing priority ratings to persons in foreign nations or international organizations (for example, the North Atlantic Treaty Organization or the United Nations) to obtain items in the United States in support of approved programs.

(b) *Foreign nations or international organizations.* (1) Any person in a foreign nation or representing an international organization requiring assistance in obtaining items under this part to be purchased in the United States for support of critical infrastructure protection and restoration should submit a request for priority rating authority on Form BIS-999 to the Department of Commerce (see § 700.50(c) for information on Form BIS-999).

(2) Any person in a foreign nation or representing an international organization requesting priority rating authority or requiring assistance in obtaining rated items under this part in support of critical infrastructure protection and restoration related activities should submit a request for a determination in writing that the request supports a program that is necessary or appropriate to promote the national defense to the Office of Policy and Program Analysis, Federal Emergency Management Agency, Department of Homeland Security, 500 C Street SW, Washington, DC 20472; Telephone: (202) 212-2900; Fax: (202) 646-4601; Email: FEMA-DPA@fema.dhs.gov, website: <https://www.fema.gov/disaster/defense-production-act>.

■ 28. Section 700.61 is amended by revising paragraph (a)(1) to read as follows:

§ 700.61 Rating authorization.

(a) * * *

(1) Permits a person to place a priority rating on an order for an item, such as

an item not normally ratable under this regulation; or

* * * *

■ 29. Section 700.63 is amended by revising paragraph (a) to read as follows:

§ 700.63 Letters of understanding.

(a) A letter of understanding is an official action that may be issued in resolving special priorities assistance cases to reflect an agreement reached by all parties (e.g., the Department of Commerce, the Determination Department, the Delegate Agency, the supplier, the customer).

* * * *

■ 30. Section 700.70 is amended by revising paragraph (b) to read as follows:

§ 700.70 General provisions.

* * * *

(b) Willful violation of any of the provisions of Title I or section 705 of the Defense Production Act, this part, or an official action of the Department of Commerce, is a criminal act, punishable as provided in sections 103 and 705 of the Defense Production Act.

■ 31. Section 700.71 is amended by revising the first sentence of paragraph (a) to read as follows:

§ 700.71 Audits and investigations.

(a) Audits and investigations are official actions involving the examination of books, records, documents, other writings, and information to ensure that the provisions of the Defense Production Act, the Selective Service Act and related statutes, and this part have been properly followed. * * *

* * * *

■ 32. Section 700.74 is amended by revising paragraph (a) and paragraph (c) introductory text to read as follows:

§ 700.74 Violations, penalties, and remedies.

(a) Willful violation of the provisions of Title I or sections 705 or 707 of the Defense Production Act, the priorities provisions of the Selective Service Act and related statutes or this part is a crime and upon conviction, a person may be punished by fine or imprisonment, or both as provided in

sections 103 and 705 of the Defense Production Act and in section 468(f) of the Selective Service Act.

* * * *

(c) In order to secure the effective enforcement of the Defense Production Act, this part, and official actions, the following are prohibited (see section 704 of the Defense Production Act; see e.g., sections 2 and 371 of Title 18 United States Code):

* * * *

■ 33. Section 700.80 is amended by revising the last sentence in paragraph (c) to read as follows:

§ 700.80 Adjustments or exceptions.

* * * *

(c) * * * The Office of Strategic Industries and Economic Security shall respond to requests for adjustment of or exceptions to compliance with the provisions of this part or an official action within twenty-five (25) days, not including Saturdays, Sundays or Government holidays, of the date of receipt.

* * * *

■ 34. Section 700.81 is amended by revising paragraph (b) to read as follows:

§ 700.81 Appeals.

* * * *

(b) Appeals of denied requests for exceptions from or adjustments to compliance with the provisions of this part or an official action must be received by the Assistant Secretary for Export Administration no later than forty-five (45) days after receipt of a written notice of denial from the Office of Strategic Industries and Economic Security. After this forty-five (45) day period, an appeal may be accepted at the discretion of the Assistant Secretary for Export Administration.

* * * *

■ 35. Revise section 700.93 to read as follows:

§ 700.93 Communications.

General communications concerning this part, including how to obtain copies of this part, explanatory information, and requests for guidance or clarification, may be addressed to the Office of Strategic Industries and

Economic Security, Room 3876, Department of Commerce, 1401 Constitution Ave. NW, Washington, DC 20230, Ref: DPAS; Telephone (202) 482-3634, email DPAS@bis.doc.gov. Request for special priorities assistance under § 700.50, adjustments or exceptions under § 700.80, or appeals under § 700.81, must be submitted in the manner specified in those sections.

■ 36. Revise Schedule I to Part 700 to read as follows:

Schedule I to Part 700—Approved Programs and Delegate Agencies

Schedule I provides a list of approved programs. They have equal preferential status. Use of this part in support of an approved program requires written authorization by the Department of Commerce. The Department of Commerce has authorized the delegate agencies listed in the third column to use this part in support of those programs assigned to them, as indicated below. The Department of Commerce is also listed as an agency in the third column for programs where its authorization in writing is necessary to place rated orders (see § 700.51 for information on how to request priority rating authority).

The Department of Commerce has authorized Delegate Agencies to place priority ratings on contracts and orders for industrial resources needed to implement any approved program that has been authorized for priorities support by the appropriate Resource Department. The program identification symbol used on priority rated contracts and orders authorized by the appropriate Resource Department to support the approved program must also be used on rated orders for industrial resources needed to implement the approved program. However, any rated order for industrial resources placed to implement an approved program that has been authorized for priorities support by a Resource Department remains subject to the provisions of this part. The program identification symbols for these approved programs are found under the "Other Programs" section of Schedule I.

Program identification symbol	Approved program	Agency(ies)
Defense Programs		
A1	Aircraft	Department of Defense.
A2	Missiles and Space	Department of Defense.
A3	Ships	Department of Defense.
A4	Tank—Automotive	Department of Defense.
A5	Weapons	Department of Defense.
A6	Ammunition	Department of Defense.

Program identification symbol	Approved program	Agency(ies)
A7	Electronic and communications equipment	Department of Defense.
B1	Military building supplies	Department of Defense.
B8	Production equipment (for defense contractor's account)	Department of Defense.
B9	Production equipment (Government owned)	Department of Defense.
C2	Department of Defense construction	Department of Defense.
C3	Maintenance, repair, and operating supplies (MRO) for Department of Defense facilities.	Department of Defense.
C9	Miscellaneous	Department of Defense.
Military Assistance to Canada		
D1	Canadian military programs	Department of Commerce.
D2	Canadian production and construction	Department of Commerce.
D3	Canadian atomic energy program	Department of Commerce.
Military Assistance to Other Foreign Nations		
G1	Certain munitions items purchased by foreign governments through domestic commercial channels for export.	Department of Commerce.
G2	Certain direct defense needs of foreign governments other than Canada	Department of Commerce.
G3	Foreign nations (other than Canada) production and construction	Department of Commerce.
Critical Infrastructure Assistance to Foreign Nations		
G4	Foreign critical infrastructure programs	Department of Commerce.
Co-Production		
J1	Co-Production Program	Departments of Commerce and Defense.
Atomic Energy Programs		
E1	Construction	Department of Energy.
E2	Operations—including maintenance, repair, and operating supplies (MRO).	Department of Energy.
E3	Privately owned facilities	Department of Energy.
Domestic Energy Programs		
F1	Exploration, production, refining, and transportation	Department of Energy.
F2	Conservation	Department of Energy.
F3	Construction, repair, and maintenance	Department of Energy.
Other Defense, Energy, and Related Programs		
H1	Certain combined orders (see § 700.17(c))	Department of Commerce.
H5	Private domestic production	Department of Commerce.
H6	Private domestic construction	Department of Commerce.
H7	Maintenance, repair, and operating supplies (MRO)	Department of Commerce.
H8	Designated Programs	Department of Commerce.
K1	Federal supply items	General Services Administration.
Homeland Security Programs		
N1	Federal emergency preparedness, mitigation, response, and recovery	Department of Homeland Security.
N2	State, local, Tribal, and territorial government emergency preparedness, mitigation, response, and recovery.	Department of Homeland Security.
N3	Intelligence and warning systems	Department of Homeland Security.
N4	Border and transportation security	Department of Homeland Security.
N5	Domestic counter-terrorism, including law enforcement	Department of Homeland Security.
N6	Chemical, biological, radiological, and nuclear countermeasures	Department of Homeland Security.
N7	Critical infrastructure protection and restoration	Department of Homeland Security.
N8	Continuity of Government	Department of Homeland Security.
Other Programs		
<i>Health Resources/Health Resources Priorities and Allocations System (HRPAS)</i>		
M1	Emergency Support Function 8 Public Health and Medical Services.	
M2	Strategic National Stockpile.	
M3	Biodefense and Related Medical Countermeasures.	
M4 [89 FR 9020; February 9, 2024].	ASPR Critical Infrastructure Protection Program.	

Program identification symbol	Approved program	Agency(ies)
<i>Food Resources/Agriculture Priorities and Allocations System (APAS)</i>		
P1	Food and food resources (civilian).	
P2	Agriculture and food critical infrastructure protection and restoration.	
P3	Food resources (combat rations).	
P4 [80 FR 63890; Dec. 21, 2015].	Certain combined orders.	
<i>Transportation Resources/Transportation Priorities and Allocations System (TPAS)</i>		
T1	Federal emergency preparedness, mitigation, response, and recovery.	

Eric Longnecker,
Deputy Assistant Secretary for Technology Security.
[FR Doc. 2024–15370 Filed 7–19–24; 8:45 am]
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DEPARTMENT OF HOMELAND SECURITY
U.S. Customs and Border Protection
DEPARTMENT OF THE TREASURY
19 CFR Part 12
[CBP Dec. 24–12]
RIN 1515–AE66

Imposition of Import Restrictions on Archaeological and Ethnological Material of Tunisia
AGENCY: U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.
ACTION: Final rule.

SUMMARY: This document amends the U.S. Customs and Border Protection (CBP) regulations to reflect the imposition of import restrictions on certain archaeological and ethnological material from the Republic of Tunisia (Tunisia). These restrictions are imposed pursuant to an agreement between the United States and Tunisia, entered into under the authority of the Convention on Cultural Property Implementation Act. This document amends the CBP regulations by adding Tunisia to the list of countries which have bilateral agreements with the United States imposing cultural property import restrictions and contains the Designated List, describing the archaeological and ethnological materials to which the restrictions apply.
DATES: Effective on July 22, 2024.
FOR FURTHER INFORMATION CONTACT: For legal aspects, W. Richmond Beevers, Chief, Cargo Security, Carriers and Restricted Merchandise Branch,

Regulations and Rulings, Office of Trade, (202) 325–0084, *ot-trrculturalproperty@cbp.dhs.gov*. For operational aspects, Julie L. Stoeber, Chief, 1USG Branch, Trade Policy and Programs, Office of Trade, (202) 945–7064, *1USGBranch@cbp.dhs.gov*.
SUPPLEMENTARY INFORMATION:

Background
The Convention on Cultural Property Implementation Act (Pub. L. 97–446, 19 U.S.C. 2601 *et seq.*) (CPIA), which implements the 1970 United Nations Educational, Scientific and Cultural Organization (UNESCO) Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property (823 U.N.T.S. 231 (1972)) (Convention), allows for the conclusion of an agreement between the United States and another party to the Convention to impose import restrictions on certain archaeological and ethnological material. Pursuant to the CPIA, the United States entered into a bilateral agreement with the Republic of Tunisia (Tunisia) to impose import restrictions on certain archaeological and ethnological material of Tunisia. This rule announces that the United States is now imposing import restrictions on certain archaeological and ethnological material of Tunisia through February 6, 2029. This period may be extended for additional periods, each extension not to exceed five years, if it is determined that the factors justifying the initial agreement still pertain and no cause for suspension of the agreement exists (19 U.S.C. 2602(e); § 12.104g(a) of title 19 of the Code of Federal Regulations (19 CFR 12.104g(a))).

Determinations
Under 19 U.S.C. 2602(a)(1), the United States must make certain determinations before entering into an agreement to impose import restrictions under 19 U.S.C. 2602(a)(2). On September 23, 2020, the Assistant Secretary for Educational and Cultural Affairs, United States Department of

State, after consultation with and recommendation by the Cultural Property Advisory Committee, made the determinations required under the statute with respect to certain archaeological and ethnological material originating in Tunisia that is described in the Designated List set forth below in this document.
These determinations include the following: (1) that the cultural patrimony of Tunisia is in jeopardy from the pillage of archaeological material representing Tunisia’s cultural heritage dating from approximately 200,000 B.C. to A.D. 1750, and ethnological material representing Tunisia’s cultural heritage from the Ottoman and early Husseinite periods, ranging in date from approximately A.D. 1574 to 1881 (19 U.S.C. 2602(a)(1)(A)); (2) that the Tunisian government has taken measures consistent with the Convention to protect its cultural patrimony (19 U.S.C. 2602(a)(1)(B)); (3) that import restrictions imposed by the United States would be of substantial benefit in deterring a serious situation of pillage and remedies less drastic are not available (19 U.S.C. 2602(a)(1)(C)); and (4) that the application of import restrictions as set forth in this final rule is consistent with the general interests of the international community in the interchange of cultural property among nations for scientific, cultural, and educational purposes (19 U.S.C. 2602(a)(1)(D)). The Assistant Secretary also found that the material described in the determinations meets the statutory definition of “archaeological or ethnological material of the State Party” (19 U.S.C. 2601(2)).
The Agreement
On March 16, 2023, the Governments of the United States and Tunisia signed a bilateral agreement, “Memorandum of Understanding between the Government of the United States of America and the Government of the Republic of Tunisia Concerning the Imposition of Import Restrictions on Archaeological and Ethnological Material of Tunisia” (the

Agreement), pursuant to the provisions of 19 U.S.C. 2602(a)(2). The Agreement entered into force on February 6, 2024, following the exchange of diplomatic notes, and enables the promulgation of import restrictions on certain categories of archaeological material ranging in date from approximately 200,000 B.C. to A.D. 1750, as well as certain categories of ethnological material from the Ottoman and early Husseinite periods, ranging in date from approximately A.D. 1574 to 1881. A list of the categories of archaeological and ethnological material subject to the import restrictions is set forth later in this document.

Restrictions and Amendment to the Regulations

In accordance with the Agreement, importation of material designated below is subject to the restrictions of 19 U.S.C. 2606 and 19 CFR 12.104g(a) and will be restricted from entry into the United States unless the conditions set forth in 19 U.S.C. 2606 and 19 CFR 12.104c are met. CBP is amending 19 CFR 12.104g(a) to indicate that these import restrictions have been imposed.

Import restrictions listed at 19 CFR 12.104g(a) are effective for no more than five years beginning on the date on which an agreement enters into force with respect to the United States. This period may be extended for additional periods of not more than five years if it is determined that the factors which justified the agreement still pertain and no cause for suspension of the agreement exists. Therefore, the import restrictions will expire on February 6, 2029, unless extended.

Designated List of Archaeological and Ethnological Material of Tunisia

The Agreement between the United States and Tunisia includes, but is not limited to, the categories of objects described in the Designated List set forth below. Importation of material on this list is restricted unless the material is accompanied by documentation certifying that the material left Tunisia legally and not in violation of the export laws of Tunisia.

The Designated List includes archaeological and ethnological material from Tunisia. The archaeological material in the Designated List includes, but is not limited to, objects made of stone, ceramic, metal, bone, ivory, shell and other organic materials, glass, faience, semi-precious stone, painting, plaster, wood, and textiles ranging in date from approximately 200,000 B.C. to A.D. 1750. The ethnological material in the Designated List includes, but is not limited to, architectural elements, manuscripts, and ceremonial, ritual, and

funerary objects of the Islamic culture from the Ottoman and early Husseinite periods, ranging in date from approximately A.D. 1574 to 1881. This would exclude Jewish ceremonial or ritual objects. The Designated List is representative only. Any dates and dimensions are approximate.

Categories of Archaeological and Ethnological Material

I. Archaeological Material

- A. Stone
- B. Ceramic
- C. Metal
- D. Bone, Ivory, Shell, and Other Organic Materials
- E. Glass, Faience, and Semi-Precious Stone
- F. Painting and Plaster
- G. Textiles, Basketry, and Rope
- H. Wood

II. Ethnological Material

- A. Stone
- B. Metal
- C. Ceramic and Clay
- D. Wood
- E. Bone, Ivory, and Shell
- F. Glass and Semi-Precious Stone
- G. Leather, Parchment, and Paper
- H. Textiles

Approximate chronology of well-known periods and sites:

Paleolithic period (c. 200,000–6000

B.C.): Bir Oum Ali, Chotts, El Akarit, El Mekta, Gafsa, Khanguet el Mouhaad, Redayef, Sidi Zin

Neolithic period (c. 6000–1100 B.C.):

Ain Khanfous, Dhraa Lassoued, Dougga, Djebibina, Ghomrassen, Jebel Ousselat

Phoenician/Punic period (c. 1100–300

B.C.): Arg el Ghazouani, Carthage, Hadrumetum, Kerkouane, Utica

Numidian period (c. 300–29 B.C.):

Dougga, Chemtou (Simittus), Ellès (Ulules), Hammam Zouakra (Thigibba), Henchir Bourgou, Makthar (Mactaris)

Roman period (c. 29 B.C.–A.D. 500):

Bulla Regia, Carthage, Chemtou, Dougga, El Jem, Kerkouane, Ksar Ghilane (Tisavar), Makthar, Neapolis, Sufetula, Uthina, Utica

Vandal period (c. A.D. 439–533):

Carthage

Byzantine period (c. A.D. 500–647):

Bulla Regia, Chemtou (Simittus), Kélibia

Islamic period (A.D. 647–1574): Djerba,

Gabés, Hammamet, Kairouan, Gabés, Mahdia, Monastir, Raqqada, Sabra al-Mansuriya, Sfax, Sousse, Tozeur, Tunis

Ottoman/Husseinite period (A.D. 1574–

1881): al-Kef, Bizerte, Ghar al-Melh, Jédeida, Kairouan, Medjez al-Bab, Qal'at al-Andalus, Soliman, Testour, Tébourba, Tunis (noting that import

restrictions for this period apply to categories of archaeological material dating up to the middle of the Ottoman/Husseinite period in Tunisia, A.D. 1750).

I. Archaeological Material

Archaeological material includes categories of objects from the Stone Age (Paleolithic and Neolithic), Lybic, Phoenician, Punic, Roman, Vandal, Byzantine, Islamic, Ottoman, and early Husseinite periods and cultures, ranging in date from approximately 200,000 B.C. to A.D. 1750.

A. Stone

1. Architectural Elements—This category includes doors, door frames, window fittings, columns, capitals, bases, lintels, jambs, roofs, archways, friezes, pilasters, engaged columns, altars, prayer niches (*mihrabs*), screens, fountains, inlays, and blocks from walls, floors, and ceilings of buildings. Architectural elements may be plain, molded, or carved and are often decorated with motifs and inscriptions. Marble, limestone, sandstone, and gypsum are most commonly used, in addition to porphyry and granite.

2. Mosaics—Floor mosaics are made from stone cut into small bits (tesserae) or glass and laid into a plaster matrix. Wall and ceiling mosaics are made with a similar technique but may include tesserae of both stone and glass. Subjects can include landscapes; scenes of deities, humans, or animals; religious imagery; and activities, such as hunting or fishing. There may also be vegetative, floral, or geometric motifs and imitations of stone.

3. Architectural and Non-Architectural Relief Sculptures—Types include carved slabs with figural, vegetative, floral, geometric, or other decorative motifs, carved relief vases, steles, palettes, and plaques. All types can sometimes be inscribed in various languages, plastered, or painted. Sculptures may be used for architectural decoration, including in religious, funerary (e.g., grave markers), votive, or commemorative monuments. Marble, limestone, and sandstone are most commonly used.

4. Monuments—Types include votive statues, funerary or votive stelae, and bases and base revetments made of marble, limestone, and other kinds of stone. These may be painted, plastered, carved with relief sculpture, decorated with moldings, and/or carry dedicatory or funerary inscriptions in various languages.

5. Statuary—Types include large-scale representations of deities, humans, animals, or hybrid figures made of

marble, limestone, or sandstone. The most common types of statuary are large-scale and free-standing statuary from approximately 1 m to 2.5 m (approximately 3 ft to 8 ft) in height and life-sized portrait busts (head and shoulders of an individual). Statuary figures may be painted.

6. Figurines—Figurines are small-scale representations of deities, humans, or animals made of limestone, calcite, marble, or sandstone.

7. Sepulchers—Types of burial containers include sarcophagi, caskets, reliquaries, and chest urns made of marble, limestone, or other kinds of stone. Sepulchers may be plain or have figural (including those typical of Punic/Phoenician deities such as Tanit and Astarte), geometric, or floral motifs painted on them. They may be carved in relief and/or have decorative moldings.

8. Vessels and Containers—These include bowls, cups, jars, jugs, lamps, flasks, and smaller funerary urns. Funerary urns can be egg-shaped vases with button-topped covers and may have sculpted portraits, painted geometric motifs, inscriptions, scroll-like handles, and/or be ribbed. Vessels and containers can be made of marble, limestone, calcite, or other stone.

9. Furniture—Types include thrones, tables, and beds, from funerary or domestic contexts. Furniture may be made from marble or other stone.

10. Tools and Weapons—Chipped stone types include blades, borers, scrapers, sickles, burins, notches, retouched flakes, cores, arrowheads, cleavers, knives, chisels, and microliths (small stone tools). Ground stone types include grinders (e.g., mortars, pestles, millstones, whetstones, querns), choppers, spherical-shaped hand axes, hammers, mace heads, and weights. The most commonly used stones are flint, chert, obsidian, and other hard stones.

11. Jewelry—Types include seals, beads, finger rings, and other personal adornment made of marble, limestone, or various semi-precious stones, including rock crystal, amethyst, jasper, agate, steatite, and carnelian.

12. Seals and Stamps—These are small devices with at least one side engraved (in intaglio and relief) with a design for stamping or sealing. Stamps and seals can be in the shape of squares, disks, cones, cylinders, or animals.

13. Rock Art—Rock art can be painted and/or incised drawings on natural rock surfaces. Common motifs include humans, animals, geometric, and/or floral elements.

B. Ceramic

1. Architectural Elements—These are baked clay (terracotta) elements used to

decorate buildings. Examples include acroteria, antefixes, painted and relief plaques, revetments, carved and molded bricks, knobs, plain or glazed roof tiles, and glazed tile wall ornaments and panels.

2. Figurines—These include clay (terracotta) statues and statuettes in the shape of deities, humans, and animals ranging in height from approximately 5 cm to 20 cm (2 in to 8 in). Ceramic figurines may be undecorated or decorated with paint, appliques, or inscribed lines.

3. Vessels and Containers—Types, forms, and decoration vary among archaeological styles and over time. Shapes include jars, jugs, bowls, pitchers, plates, basins, cups, flasks, storage and shipping amphorae, cooking pots (such as Roman *mortaria*), and large water jugs (*zirs*). Specific Punic, Phoenician, and Roman types include *hydriae*, *oinochoi*, *kylikes*, *albastra*, *aryballoi*, *pyxides*, *unguentaria*, *kantharoi*, *kylixes*, *askoi*, and *lekythoi*. Roman *terra sigillata* and other red gloss wares are common. Examples may be painted or unpainted, handmade or wheel-made, and may be decorated with burnishes, glazes, stamps, or carvings (such as incised *sgraffitto*). Ceramic vessels can depict imagery of humans, deities, animals, floral decorations, or inscriptions in multiple languages.

4. Lamps—Lamps can be handmade or molded, glazed or unglazed, and appear in “saucer,” “slipper,” or other forms; they typically will have rounded bodies with a hole on the top and in the nozzle, handles or lugs, and may be decorated with motifs, such as beading, human faces, and rosettes or other floral elements. Inscriptions may also be found on the body. Later period examples such as glazed mosque lamps may have straight or round, bulbous bodies with a flared top and several branches.

5. Objects of Daily Use—These include game pieces carved from ceramic sherds, loom weights, toys, *guttus*, incense burners, tobacco pipes, andirons, and ceramic sherds painted with text in Latin or Greek, called *ostraka*.

C. Metal

1. Statuary—These are large- and small-scale, including deities, human, and animal figures in bronze, iron, silver, or gold. Common types are large-scale, free-standing statuary ranging in height from approximately 1 m to 2.5 m (approximately 3 ft to 8 ft) and life-size busts (head and shoulders of an individual).

2. Reliefs—These include plaques, appliques, steles, and masks, often in

bronze. Reliefs may include inscriptions in various languages.

3. Inscribed or Decorated Sheet Metal—These are engraved inscriptions and thin metal sheets with engraved or impressed designs often used as attachments to furniture or figures. They are primarily made of copper alloy, bronze, or lead.

4. Vessels and Containers—Forms include bowls, cups, plates, jars, jugs, strainers, cauldrons, and boxes, as well as vessels in the shape of an animal or part of an animal. This category also includes scroll and manuscript containers, reliquaries, and incense burners. These vessels and containers are made of bronze, silver, or gold, and may portray deities, humans, or animals, as well as floral motifs in relief. They may include an inscription.

5. Jewelry—Jewelry includes necklaces, chokers, pectorals, finger rings, beads, pendants, bells, belts, buckles, earrings, diadems, straight pins and fibulae, bracelets, anklets, girdles, wreaths and crowns, cosmetic accessories and tools, metal strigils (scrapers), crosses, and lamp holders. Jewelry may be made of iron, bronze, silver, or gold. Metal can be inlaid with items, such as colored stones and glass.

6. Seals and Sealings—Seals are small devices with at least one side engraved with a design for stamping or sealing. Types include finger rings, amulets, and seals with a shank. Seals can be made of lead, tin, copper, bronze, silver, and/or gold. Sealings are lead strips, stamped in Arabic, that are used for closing bags of coins.

7. Tools—Types include hooks, weights, axes, scrapers, hammerheads, trowels, locks, keys, nails, hinges, tweezers, ingots, mirrors, thimbles, and fibulae (for pinning clothing); tools may be made of copper, bronze, or iron.

8. Weapons and Armor—This includes body armor, such as helmets, cuirasses, bracers, shin guards, and shields, and horse armor, often decorated with elaborate designs that are engraved, embossed, or perforated. This also includes both launching weapons (e.g., spears, javelins, arrowheads) and hand-to-hand combat weapons (e.g., swords, daggers, etc.) in copper, bronze, and iron.

9. Lamps—Lamps can be open saucer-type or closed, rounded bodies with a hole on the top and in the nozzle, handles, or lugs. They can include decorative designs, such as beading, human faces, animals or animal parts, and rosettes or other floral elements. This category includes handheld lamps, candelabras, braziers, sconces, chandeliers, and lamp stands.

10. Coins—This category includes coins of Numidian, Carthaginian (sometimes called Punic), Roman provincial, Vandal, Byzantine, Islamic, Norman, and Ottoman types that circulated primarily in Tunisia, ranging in date from the fifth century B.C. to A.D. 1750. Numidian, Roman provincial, and Vandal coins were made primarily in bronze, though some Numidian and Vandal types occur also in silver. Carthaginian types occur in electrum, a natural pale yellow alloy of gold and silver. Local Byzantine and later coin types were made in copper, bronze, silver, and gold. Coins may be square or round, have writing, and show imagery of animals, buildings, symbols, or royal figures.

D. Bone, Ivory, Shell, and Other Organic Materials

1. Small Statuary and Figurines—These include representations of deities, humans, or animals in bone or ivory. These range from approximately 10 cm to 1 m (4 in to 40 in).

2. Reliefs, Plaques, Steles, and Inlays—These are carved and sculpted and may have figurative, floral, and/or geometric motifs. Examples may also have inscriptions in various languages.

3. Jewelry—Types include amulets, pendants, combs, pins, spoons, bracelets, buckles, beads, and pectorals. Jewelry can be made of bone, ivory, and spondylus shell.

4. Seals and Stamps—These are small devices with at least one side engraved with a design for stamping or sealing. Seals and stamps can be in the shape of squares, disks, cones, cylinders, or animals.

5. Vessels and Luxury Objects—Ivory, bone, and shell were used either alone or as inlays in luxury objects, including furniture, chests and boxes, writing and painting equipment, musical instruments, games, cosmetic containers, and combs. Examples can include decorated vessels made of ostrich eggshell.

6. Tools—Tools include bone points and awls, burnishers, needles, spatulae, and fish hooks.

7. Manuscripts—Manuscripts can be written or painted on paper or specially prepared animal skins (e.g., cattle, sheep, goat, camel skins) known as parchment. They may be single leaves, bound as a book or codex, or rolled into a scroll.

8. Human Remains—This includes skeletal remains from the human body, preserved in burials or other contexts.

E. Glass, Faience, and Semi-Precious Stone

1. Architectural Elements—These include glass inlay and tesserae pieces from floor and wall mosaics, mirrors, and windowpanes.

2. Vessels and Containers—These can take various shapes, such as jars, bottles, bowls, beakers, goblets, candle holders, perfume jars (*unguentaria*), urns, chalices, and flasks. Vessels and containers may have cut, incised, raised, enameled, molded, or painted decoration. Examples may be engraved and/or light blue, blue-green, green, or colorless, while those from later periods may include animal, floral, and/or geometric motifs.

3. Jewelry—Jewelry includes bracelets and rings (often twisted with colored glass); pendants; and beads in various shapes (e.g., circular, globular), some with relief decoration, including multi-colored “eye” beads.

4. Lamps—Lamps may have a straight or round, bulbous body. Some examples are in the form of a goblet with a flared top and engraved or molded decorations, while others are in a conical shape with blobbed decoration that were inset into metal candelabra. Lamps may have a single or several branches.

F. Painting and Plaster

1. Wall Painting—Wall painting can include figurative (i.e., deities, humans, animals), floral, and/or geometric motifs, as well as funerary scenes. These are painted on stone, mud plaster, and lime plaster (wet—*buon fresco*—and dry—*secco fresco*), sometimes to imitate marble.

2. Stucco—Stucco is a fine plaster used for coating wall surfaces, or molding and carving into architectural decorations, such as reliefs, plaques, steles, and inlays.

G. Textiles, Basketry, and Rope

1. Textiles—These include linen, hemp, and silk cloth used for burial wrapping, shrouds, garments, banners, and sails. These also include linen and wool used for garments and hangings.

2. Basketry—Plant fibers were used to make baskets and containers in a variety of shapes and sizes, as well as sandals and mats.

3. Rope—Rope and string were used for a great variety of purposes, including binding, lifting water for irrigation, fishing nets, measuring, lamp wicks, and stringing beads for jewelry and garments.

H. Wood

Includes tablets with painted text, generally in Latin but also in Greek.

Examples were made from cedar, pine, and other softwoods.

II. Ethnological Material

Ethnological material includes architectural elements, manuscripts, and ceremonial, ritual, and funerary objects of the Islamic culture from the Ottoman and early Husseinite periods, ranging in date from approximately A.D. 1574 to 1881. This would exclude Jewish ceremonial or ritual objects.

A. Stone

1. Architectural Elements—This category includes doors, door frames, window fittings, columns, capitals, plinths, bases, lintels, jambs, roofs, archways, friezes, pilasters, engaged columns, altars, prayer niches (*mihrabs*), screens, fountains, inlays, and blocks from walls, floors, and ceilings of buildings. Architectural elements may be plain, molded, or carved and are often decorated with motifs and inscriptions. Marble, limestone, and sandstone are most commonly used.

2. Architectural and Non-Architectural Relief Sculpture—This category includes slabs, plaques, steles, capitals, and plinths carved with religious, figural, floral, or geometric motifs or inscriptions in Arabic for ceremonial, ritual, and funerary use. Examples occur primarily in marble, limestone, and sandstone.

3. Memorial Stones and Tombstones—This category includes tombstones, grave markers, and cenotaphs. Examples occur primarily in marble and are engraved with Arabic script.

4. Vessels and Containers—This category includes ceremonial, ritual, and funerary stone lamps and containers.

B. Metal

1. Architectural Elements—This category includes doors, door fixtures, such as knockers, bolts, and hinges, chandeliers, screens, taps, spigots, fountains, and sheets. Copper, brass, lead, and alloys are most commonly used.

2. Architectural and Non-Architectural Relief Sculpture—This category includes appliques, plaques, and steles, primarily made of bronze and brass, for ceremonial, ritual, and funerary use. Examples often include religious, figural, floral, or geometric motifs. They may also have inscriptions in Arabic.

3. Lamps—This category includes handheld lamps, candelabras, braziers, sconces, chandeliers, and lamp stands for ceremonial, ritual, and funerary use.

4. Vessels and Containers—This category includes containers used for religious services, such as Koran (*Qur'an*) cases, amulet boxes, and incense burners. Brass, copper, silver, and gold are most commonly used. Containers may be plain, engraved, hammered, or otherwise decorated.

5. Musical Instruments—This category includes instruments used in Islamic/Sufi religious ceremonies or rituals, such as cymbals and trumpets.

C. Ceramic and Clay

1. Architectural Elements—This category includes carved and molded brick, and engraved and/or painted and glazed tile wall ornaments and panels, sometimes with Arabic script.

2. Lamps—This category includes glazed mosque lamps that may have straight or round, bulbous bodies with a flared top and several branches.

D. Wood

1. Architectural Elements—This category includes doors, door frames and fixtures, windows, window frames, panels, beams, balconies, stages, screens, prayer niches (*mihirabs*), minbars, and ceilings. Examples may be decorated with religious, geometric, or floral motifs or inscriptions, and may be either carved or painted.

2. Architectural and Non-Architectural Relief Sculpture—This category includes panels, roofs, beams, balconies, stages, panels, ceilings, and doors for ceremonial, ritual, and funerary use. Examples are carved, inlaid, or painted with decorations of religious, floral, or geometric motifs, or Arabic inscriptions.

3. Furniture—This category includes furniture, such as minbars, professorial chairs, divans, stools, and tables from Islamic ceremonial, ritual, or funerary contexts. Examples can be carved, inlaid, or painted and are made from various types of wood.

4. Vessels and Containers—This category includes containers used for religious purposes such as Koran (*Qur'an*) cases. Examples may be carved, inlaid, or painted with decorations in religious, floral, or geometric motifs, or Arabic script.

5. Writing Implements—This category includes printing blocks, writing tablets, and Islamic study tablets inscribed in Arabic and used for teaching the Koran (*Qur'an*).

6. Musical Instruments—This category includes instruments used in Islamic/Sufi religious ceremonies or rituals, such as frame drums (*banadir*).

7. Beads—This category includes Islamic prayer beads (*mas'baha*).

Examples may be plain or decorated with carved designs.

E. Bone, Ivory, and Shell

1. Architectural Elements—This category includes inlays for architectural elements.

2. Ceremonial Paraphernalia—This category includes boxes, reliquaries (and their contents), plaques, pendants, candelabra, and stamp and seal rings.

F. Glass and Semi-Precious Stone

1. Architectural Elements—This category includes window panes, mosaic elements, inlays, and stained glass.

2. Vessels and Containers—This category includes glass and enamel mosque lamps and vessels used for Islamic religious services.

3. Beads—This category includes Islamic prayer beads (*mas'baha*) in glass or semi-precious stones.

G. Leather, Parchment, and Paper

1. Books and Manuscripts—Manuscripts can be written or painted on paper or specially prepared animal skins (e.g., cattle, sheep, goat, camel skins) known as parchment. They occur as single leaves, bound with leather or wood as a book or codex, or rolled into a scroll. Types include the Koran (*Qur'an*) and other Islamic books and manuscripts, often written in black or brown ink, and sometimes embellished with painted colorful floral or geometric motifs.

2. Vessels and Containers—This category includes containers used for Islamic religious services, such as leather Koran (*Qur'an*) cases or pouches.

3. Musical Instruments—This category includes instruments used in Islamic/Sufi religious ceremonies or rituals, such as leather drums (*banadir*).

H. Textiles

This category includes hangings, shrine covers, and prayer rugs used in Islamic/Sufi religious ceremonies or rituals. Examples can be made from linen, silk, and/or wool.

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Inapplicability of Notice and Delayed Effective Date

This amendment involves a foreign affairs function of the United States and is, therefore, being made without notice or public procedure (5 U.S.C. 553(a)(1)). For the same reason, a delayed effective date is not required under 5 U.S.C. 553(d)(3).

Executive Orders 12866 and 13563

Executive Orders 12866 (Regulatory Planning and Review), as amended by Executive Order 14094 (Modernizing Regulatory Review), and 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. CBP has determined that this document is not a regulation or rule subject to the provisions of Executive Orders 12866 and 13563 because it pertains to a foreign affairs function of the United States, as described above, and therefore is specifically exempted by section 3(d)(2) of Executive Order 12866 and, by extension, Executive Order 13563.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, requires an agency to prepare and make available to the public a regulatory flexibility analysis that describes the effect of a proposed rule on small entities (*i.e.*, small businesses, small organizations, and small governmental jurisdictions) when the agency is required to publish a general notice of proposed rulemaking for a rule. Since a general notice of proposed rulemaking is not necessary for this rule, CBP is not required to prepare a regulatory flexibility analysis for this rule.

Signing Authority

This regulation is being issued in accordance with 19 CFR 0.1(a)(1) pertaining to the Secretary of the Treasury's authority (or that of the Secretary's delegate) to approve regulations related to customs revenue functions.

Troy A. Miller, the Senior Official Performing the Duties of the Commissioner, having reviewed and approved this document, has delegated the authority to electronically sign this document to the Director (or Acting Director, if applicable) of the Regulations and Disclosure Law Division for CBP, for purposes of publication in the **Federal Register**.

List of Subjects in 19 CFR Part 12

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise, Reporting and recordkeeping requirements.

For the reasons set forth above, part 12 of title 19 of the Code of Federal Regulations (19 CFR part 12), is amended as set forth below:

PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 and the specific authority citation for § 12.104g continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624.

* * * * *

Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

* * * * *

■ 2. In § 12.104g, the table in paragraph (a) is amended by adding Tunisia to the list in appropriate alphabetical order as follows:

§ 12.104g Specific items or categories designated by agreements or emergency actions.

(a) * * *

State party	Cultural property	Decision No.
Tunisia	Archaeological material of Tunisia ranging in date from approximately 200,000 B.C. to A.D. 1750, and ethnological material of Tunisia ranging in date from approximately A.D. 1574 to 1881.	CBP Dec. 24–12.

* * * * *

Robert F. Altneu,

Director, Regulations & Disclosure Law Division, Regulations & Rulings, Office of Trade, U.S. Customs and Border Protection.

Aviva R. Aron-Dine,

Acting Assistant Secretary of the Treasury for Tax Policy.

[FR Doc. 2024–16037 Filed 7–19–24; 8:45 am]

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DEPARTMENT OF EDUCATION**34 CFR Chapter III**

[Docket ID ED–2024–OSERS–0001]

Technical Assistance on State Data Collection—National Technical Assistance Center To Improve State Capacity To Collect, Report, Analyze, and Use Accurate Early Childhood IDEA Data

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Final priorities and requirements.

SUMMARY: The Department of Education (Department) announces priorities and requirements for the National Technical Assistance Center To Improve State Capacity To Collect, Report, Analyze, and Use Accurate Early Childhood IDEA Data (Center) under the Technical Assistance on State Data Collection

program. The Department may use these priorities and these requirements in fiscal year (FY) 2024 and later years. We will use the priorities to award a cooperative agreement for a Center to provide technical assistance (TA) to improve the capacity of States to meet the early childhood data collection and reporting requirements under Part B and Part C of the Individuals with Disabilities Education Act (IDEA).

DATES: The priority and requirements are effective August 21, 2024.

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SUPPLEMENTARY INFORMATION:

Purpose of Program: The purpose of the Technical Assistance on State Data Collection program is to improve the capacity of States to meet IDEA data collection and reporting requirements. Funding for the program is authorized under section 611(c)(1) of IDEA, which gives the Secretary authority to reserve not more than one-half of one percent of the amounts appropriated under Part B for each fiscal year to provide TA activities, where needed, to improve the capacity of States to meet the data collection and reporting requirements

under Parts B and C of IDEA. The maximum amount the Secretary may reserve under this set-aside for any fiscal year is \$25,000,000, cumulatively adjusted by the rate of inflation. Section 616(i) of IDEA requires the Secretary to review the data collection and analysis capacity of States to ensure that data and information determined necessary for implementation of section 616 and 642 of IDEA are collected, analyzed, and accurately reported to the Secretary. It also requires the Secretary to provide TA, where needed, to improve the capacity of States to meet the data collection requirements, which include the data collection and reporting requirements in sections 616 and 618 of IDEA. In addition, the Further Consolidated Appropriations Act, 2024, Public Law 118–47, gives the Secretary authority to use funds reserved under section 611(c) of IDEA to “administer and carry out other services and activities to improve data collection, coordination, quality, and use under parts B and C of the IDEA.” Further Consolidated Appropriations Act, 2024, Public Law 118–47, Div. D, Title III, 138 Stat. 460, 685 (2024).

Assistance Listing Number: 84.373Z.

Program Authority: 20 U.S.C. 1411(c), 1416(i), 1418(c), 1418(d), 1442; Further Consolidated Appropriations Act, 2024, Public Law 118–47, Div. D, Title III, 138 Stat. 460, 685 (2024).

Applicable Program Regulations: 34 CFR 300.702.

We published a notice of proposed priority and requirements (NPP) for this program in the **Federal Register** on February 22, 2024 (89 FR 13294). That document contained background information and our reasons for proposing the priority and requirements.

There are differences between the NPP and this notice of final priority and requirements (NFP) as discussed in the *Analysis of Comments and Changes* section of this document. The most significant change, as discussed below, is the elimination of the requirement for an electronic open-source tool to assist States in linking and integrating their Part C early intervention and Part B preschool special education data with other data/data systems associated with other Federal programs that support infants, toddlers, and young children and their families.¹ We are also adding expected outcome (i) for the Center.

Public Comment: In response to our invitation in the NPP, eight parties submitted comments addressing the proposed priority and requirements. We received one additional comment unrelated to the priority.

Generally, we do not address technical and other minor changes, or suggested changes the law does not authorize us to make under the applicable statutory authority. In addition, we do not address general comments that raised concerns not directly related to the proposed priority and requirements.

Analysis of Comments and Changes: An analysis of the comments and of any changes in the priority and requirements since publication of the NPP follows. We received comments on a number of specific topics, including the topics for TA. Each topic is addressed below.

General Comments

Comments: All commenters specifically expressed support for the proposed Center, as it would improve State capacity for IDEA early childhood data collection, analysis, and reporting.

Discussion: The Department appreciates the comments and agrees with the commenters that the Center funded under this program will provide necessary and valuable TA to States to improve the capacity of States to meet their IDEA early childhood data collection, analysis, and reporting requirements.

Changes: None.

Comment: The majority of commenters focused their comments on the Department's directed question regarding the phased-in funding strategy, which entails smaller initial awards followed by larger ones in subsequent years. Many expressed reservations about this approach, particularly in light of the expanded scope and obligations introduced by Proposed Priority 2: Technical Assistance To Improve State Capacity To Collect, Report, Analyze, and Use Accurate Child Find Data For Infants and Toddlers. They highlighted concerns about the added requirement to create an open-source electronic tool aimed at assisting States in integrating their Part C early intervention and Part B preschool special education data with other Federal program data systems supporting infants, toddlers, and young children and their families. The commenters also noted that the strategy would restrict the Center's ability to offer comprehensive support to States. One commenter suggested postponing intensive TA on data utilization for Child Find processes until full funding could be secured, emphasizing the need for additional financial resources to develop the open-source electronic tool.

Discussion: The Department agrees with the feedback provided by commenters regarding the necessity to align the scope and requirements of these priorities with the available funding for this project. We recognize the ongoing needs of States concerning the collection, reporting, analysis, and use of IDEA Part C and Part B preschool special education data. Consequently, any expansion of the scope and requirements for these priorities should align to the most pressing needs identified by States. To address the concerns raised by commenters, the Department is refining the scope and requirements of these priorities accordingly. Furthermore, we expect applicants to propose suitable timelines for implementing general, targeted, and intensive TA, taking into account the annual funding levels provided for this project.

Changes: The Department is adjusting the scope of these priorities and requirements to align with the funding available for this Center by eliminating the requirement for an open-source tool and narrowing the scope of TA associated with data integration to primarily focus on the sharing, linking, or integrating of IDEA Part C early intervention and IDEA Part B preschool special education data.

Integrating Early Childhood Data Systems

Comments: Two commenters expressed approval for incorporating an open-source electronic tool to aid States in linking and integrating their Part C early intervention and Part B preschool special education data with other data/data systems associated with other Federal programs that support infants, toddlers, and young children and their families. However, several commenters voiced concerns regarding the inclusion of this requirement in Priority 1. They pointed out that creating such a tool would demand significant project resources and a substantial commitment of State staff, which may currently be unfeasible. Moreover, one commenter provided evidence suggesting that this tool is not a top priority for State staff compared to other aspects of these priorities.

Discussion: The Department appreciates the feedback provided on the open-source electronic tool to assist States in linking and integrating their Part C early intervention and Part B preschool special education data with other data/data systems associated with other Federal programs that support infants, toddlers, and young children and their families. We agree with the commenters that the development of the open-source electronic tool should be omitted from the requirements of these priorities to align the scope of this center with the most pressing needs identified by States.

Changes: We removed the requirement for an open-source electronic tool from Priority 1.

Comments: Several commenters suggested modifications to the scope and expected outcomes of the TA concerning the enhancement, streamlining, and integration of statewide, child-level early childhood data systems. One commenter stated that many States have a considerable amount of work to do before they are able to integrate and/or link data outside of the IDEA Part C early intervention and Part B preschool special education programs. Another commenter noted that, while TA is an important component to the data integration work, States must also have State leadership support, support of other programs and agencies, as well as necessary staff, financial resources, and data capacity to plan for and accomplish the complexities involved in this type of data integration. This commenter noted that States expressed that the expected outcome related to data system integration was of lower priority to Part C early intervention programs. They

¹ This NFP describes infants, toddlers and/or children with disabilities as "children with disabilities" or "young children with disabilities" to include children referred to both Parts C and B of the IDEA, birth through age five.

noted that given the current challenges and priorities of Part C lead agencies, data integration for many States remains aspirational at this point. For these reasons, commenters suggested to focus this TA on—(1) data sharing and linking between the IDEA Part C early intervention program and IDEA Part B preschool special education programs; and (2) States' readiness to engage in TA related to linking or integrating Part C and Part B preschool special education data with other statewide, child-level early learning data systems (e.g., early childhood integrated data systems (ECIDS)).

Discussion: The Department acknowledges that States vary in their levels of interest, capability, and commitment to share, link, or integrate their Part C and Part B preschool special education data with data from other early learning data systems. Additionally, we recognize that engaging in TA regarding data sharing, linking, and integrating requires a significant commitment of State staff and resources. Moreover, we appreciate the feedback indicating that data sharing, linking, and integrating with other early learning data systems is a lower priority for Part C and Part B preschool special education programs at this time. We also appreciate the recommendation to assess the readiness of States to engage in TA on this topic. Consequently, we are refining the scope of Priority 1 in light of these considerations.

Changes: The Department has removed expected outcome (e) concerning State capacity to utilize available integrated or linked Part C early intervention and Part B preschool special education data and/or early childhood integrated data systems to analyze high-quality data on the participation and outcomes of infants, toddlers, and children with disabilities served under IDEA who may also participate in other programs.

Additionally, we have made the following revisions:

- Expected outcome (c) in Priority 1 now emphasizes increasing the number of States with plans to share, link, or integrate data, specifically considering the linking of Part C early intervention and Part B preschool special education data.
- Expected outcome (e) in Priority 1 now concentrates on enhancing States' readiness to engage in data sharing, linking, or integration activities among Part C and Part B preschool special education data/systems and other statewide longitudinal and early learning data/systems. This includes data/systems associated with child care,

Early Head Start, Head Start, publicly funded preschool, and home visiting programs.

- Expected outcome (f) in Priority 1 now centers on data management policies and procedures, encompassing data sharing, linking, and integration, as well as data system integration activities. These policies and procedures aim to facilitate the collection, reporting, analysis, and use of high-quality IDEA Part C early intervention and Part B preschool special education data.

Areas of State Need

Comments: Several commenters recommended the inclusion of additional areas of State need associated with the IDEA section 616 data (as modified by IDEA section 642), including early childhood and family outcomes data, data to be reported on the new general supervision indicator, and data for the State Systemic Improvement Plan (SSIP). Additionally, commenters provided support for providing TA around Part C child find data and analyses, including defining, collecting, and using data to improve the processes for identifying young children eligible for IDEA services and to monitor equitable access to early intervention services.

Discussion: The Department agrees with the need for this Center to increase State capacity to collect, report, analyze and use Part C child find data, early childhood and family outcomes data, general supervision data, and program improvement data. These areas align with the following indicators that State Part C Programs report under the IDEA section 616 data: Indicator 3 (Early Childhood Outcomes), Indicator 4 (Family Outcomes), Indicators 5 and 6 (Child Find), Indicator 11 (SSIP), and Indicator 12 (General Supervision). This Center will provide TA in these areas as they relate to the collection, reporting, analysis, and use of the IDEA section 616 data under expected outcome (a) of Priority 1.

Changes: The Department inserted a footnote to clarify the data reported under IDEA section 616 in expected outcome (a) of Priority 1.

Comments: Two commenters expressed the need for this Center to provide TA to support State capacity to participate in the Differentiated Monitoring and Support (DMS) process.

Discussion: The Department acknowledges the necessity of enhancing State capacity to collect, report, analyze and use data for evidence-based monitoring protocols within the DMS process. DMS is a cyclical monitoring process that focuses

on States' general supervision systems. General supervision encompasses each State's responsibility to ensure that the State and its subgrantees and contractors meet the requirements of IDEA. These requirements include improving educational results and functional outcomes for all children with disabilities, and early intervention results and functional outcomes for all infants and toddlers with disabilities. Additionally, public agencies must meet the program requirements under Parts B and C of IDEA, with a particular emphasis on those requirements that are most closely related to improving early intervention results for infants and toddlers with disabilities and educational results for children with disabilities. The Office of Special Education Programs (OSEP) identifies data, including the State Performance Plan (SPP)/Annual Performance Report (APR), as one of the four components of general supervision that is examined in the DMS process. Consequently, we have incorporated an expected outcome related to strengthening State capacity to collect, report, analyze, and use data, demonstrating State-level implementation of IDEA policies and procedures.

Changes: The Department inserted expected outcome (i) in Priority 1 to build State capacity to collect, report, analyze, and use Part C early intervention and Part B preschool special education data to improve State IDEA data analyses regarding results and functional outcomes for all infants, toddlers, and children with disabilities to demonstrate and improve how public agencies meet the program requirements under Parts B and C of IDEA, with a particular emphasis on those requirements that are most closely related to improving early intervention results for infants and toddlers with disabilities and educational results for children with disabilities as monitored by the Department via its DMS process.

Comments: Two commenters suggested a specific focus on building State capacity in the area of data leadership.

Discussion: The Department agrees that there is a need to build State capacity in data leadership. Data leaders are expected to create a culture of data use in their programs, facilitate and promote building the capacity of staff and stakeholders to use data, and enhance the data infrastructure needed to improve the management of Part C and Part B preschool special education data through the entire life cycle.

Changes: The Department revised expected outcome (g) in Priority 1 to

include building State capacity to address data leadership training needs.

Components for TA

Comments: One commenter suggested a need for the Center to offer cross-State connections and learning opportunities and another commenter suggested adding a requirement for the Center to host a data conference.

Discussion: The Department agrees there is a need for the Center to offer cross-State training opportunities. We think that expected outcome (g) in Priority 1, which requires the Center to facilitate both in-person and virtual cross-State training for data leaders and personnel in State and local programs and agencies, effectively addresses this need. Applicants should propose the type(s) of cross-State training opportunities they believe are most effective and efficient to build State capacity to collect, report, analyze, and use the Part C and Part B preschool special education data.

Changes: None.

Comments: One commenter suggested that there should be an intentional focus on equitable data collection, analysis, and use within these priorities.

Discussion: The Department agrees that there is a need to build State capacity to collect, report, analyze, and use Part C and Part B preschool special education data to support equitable identification, access, services, outcomes, and impact of early intervention and preschool special education and related services on infants, toddlers, and young children receiving services under IDEA. Additionally, we think the expected outcome (h) in Priority 1 and the expected outcomes (b), (c), and (d) in Priority 2 address this need.

Changes: None.

Final Priorities

This document contains two final priorities.

Priority 1: National Technical Assistance Center To Improve State Capacity To Collect, Report, Analyze, and Use Accurate Early Childhood IDEA Data

Priority:

The purpose of this priority is to fund a cooperative agreement to establish and operate a National Technical Assistance Center to Improve State Capacity to Collect, Report, Analyze, and Use Accurate Early Childhood IDEA Data (Center).

The Center will provide TA to (1) improve State capacity to collect, report, analyze, and use high-quality IDEA Part C early intervention data (including

IDEA section 618 Part C data and IDEA section 616 Part C data) and IDEA Part B preschool special education data on children with disabilities; and (2) enhance and streamline Part C and Part B preschool special education data systems by sharing, linking, and integrating statewide, child-level early childhood data (including Part C and Part B preschool special education data) to improve the analyses of IDEA data to address critical policy questions that will facilitate program improvement, improve compliance accountability, and improve outcomes or results for children served under Part C and Part B preschool special education programs. These Part C early intervention and Part B preschool special education data systems must allow the States to (1) effectively and efficiently respond to all IDEA-related data submission requirements (e.g., Part C section 616 and 618 data and Part B preschool special education data); (2) improve the analyses of IDEA data to respond to critical policy questions that will facilitate program improvement and compliance accountability; and (3) comply with applicable privacy requirements, including the privacy and confidentiality requirements under Parts B and C of IDEA and applicable provisions of the Family Educational Rights and Privacy Act (20 U.S.C. 1232g) and its regulations at 34 CFR part 99.² The Center must achieve, at a minimum, the following expected outcomes:

(a) Increased capacity of States to collect, report, analyze, and use high-quality IDEA Part C early intervention data (including IDEA section 616 Part C data³ and section 618 Part C data⁴);

(b) Increased capacity of States to collect, report, analyze, and use high-quality IDEA Part B preschool special education data;

² The Center must review the need for additional resources (with input from the Department) and disseminate existing resources developed by the Department, such as: (1) *Understanding the Confidentiality Requirements Applicable to IDEA Early Childhood Programs* (October 2016); (2) *IDEA/FERPA Crosswalk* (Surprenant & Miller, August 24, 2022) (https://studentprivacy.ed.gov/sites/default/files/resource_document/file/IDEA-FERPA%20Crosswalk_08242022.pdf); (3) Webinars such as *Navigating IDEA and FERPA To Protect Privacy in Today's Early Childhood World* (September 22, 2023); and (4) Data sharing agreement template (at <https://dasycenter.org/us-dept-ed-shares-idea-data-sharing-mou-template/>).

³ The IDEA section 616 Part C data includes Indicators 1 through 12 as discussed in the Part C State Performance Plan (SPP) and Annual Performance Report (APR) Indicator Measurement Table.

⁴ The IDEA section 618 Part C data includes Part C Child Count and Settings data collection, Part C Exiting data collection, and the Part C Dispute Resolution data collection.

(c) Increased number of States with plans to share, link, or integrate Part C early intervention and Part B preschool special education data (that comply with all applicable privacy laws) and use such shared, linked, or integrated Part C early intervention and Part B preschool special education data to improve program compliance and accountability;

(d) Increased number of States that use their Part C early intervention and Part B preschool special education data system to identify and answer critical State-determined policy questions to drive program improvement, improve results for children with disabilities, and improve compliance accountability;

(e) Increased number of States who consider engaging in data sharing, linking, or integration activities related to Part C and Part B preschool special education data/data systems to other statewide longitudinal and early learning data/data systems (e.g., Early Head Start, Head Start, child care, publicly funded preschool, and home visiting programs) and identify how to enable such sharing, linkages, or integration so that it would comply with all applicable privacy laws;

(f) Increased capacity of States to implement and document Part C early intervention and Part B preschool special education data management policies and procedures, including data sharing, linking, and integration activities, used to collect, report, analyze, and use high-quality IDEA Part C early intervention and Part B preschool special education data;

(g) Increased capacity of States to address data leadership and personnel training needs to collect, report, analyze, and use the Part C early intervention and Part B preschool special education data collection through development of effective tools and resources, as well as providing opportunities for in-person and virtual cross-State training for data leaders and personnel in State and local programs and agencies to collect, report, analyze, and use Part C early intervention and Part B preschool special education;

(h) Increased capacity of States to collect, report, analyze, and use Part C and Part B preschool special education data to support equitable identification, access, services, outcomes, and impact of early intervention and preschool special education and related services on infants, toddlers, and young children receiving services under IDEA; and

(i) Increased capacity of States to collect, report, analyze, and use Part C early intervention and Part B preschool special education data to improve State IDEA data analyses regarding results

and functional outcomes for all infants, toddlers, and young children with disabilities to demonstrate and improve how public agencies meet the program requirements under Parts B and C of IDEA, with a particular emphasis on those requirements that are most closely related to improving early intervention results for infants and toddlers with disabilities and educational results for children with disabilities as monitored by OSEP via its Differentiated Monitoring and Support process.

Priority 2: Technical Assistance To Improve State Capacity To Collect, Report, Analyze, and Use Accurate Child Find Data for Infants and Toddlers

Priority:

The purpose of this priority is to fund TA to increase the capacity of States to collect, report, analyze, and use available data to improve the Part C child find data they report through their Part C SPP/APR.

The Center must achieve, at a minimum, the following expected outcomes:

(a) Increased capacity of States to collect, report, analyze, and use available data to improve the root cause analysis of their Part C child find data (including IDEA section 616 Part C data for indicators C5 and C6 and section 618 Part C data);

(b) Increased number of States that have the capacity to identify, for children served under IDEA Part C, other data they may collect (such as number of infants and toddlers referred, screened, evaluated, eligible, and enrolled in early intervention services under Part C) by various characteristics of the child, including race, ethnicity, home language, gender, socio-economic status, and geographic location;

(c) Increased number of States that have the capacity to conduct a root cause analysis of available child find data to better identify disparities among demographic groups and potential barriers to enrollment in early intervention services under Part C of IDEA; and

(d) Increased number of States that have the capacity to use their IDEA and non-IDEA Part C child find data to improve their IDEA child find processes at the State and local program levels.

Types of Priorities:

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

This document does not preclude us from proposing additional priorities or requirements, subject to meeting applicable rulemaking requirements.

Note: This document does *not* solicit applications. In any year in which we choose to use this priority and these requirements, we invite applications through a notice in the **Federal Register**.

Final Requirements

The Assistant Secretary establishes the following requirements for this program. In addition to the program requirements contained in both priorities, to be considered for funding applicants must meet the application and administrative requirements. We may apply these requirements in any year in which this program is in effect.

Requirements:

Applicants must—

(a) Demonstrate, in the narrative section of the application under “Significance,” how the proposed project will—

(1) Address State challenges associated with early childhood data management and data sharing, linking, and integration, including implementing early childhood data system integration and improvements; enhancing and streamlining Part C early intervention and Part B preschool special education data systems to respond to critical policy questions; using ECIDS for program improvement and compliance accountability for Part C early intervention and Part B preschool special education programs; reporting high-quality IDEA Part C data (including IDEA section 616 Part C data and section 618 Part C data) and IDEA Part B preschool special education data to the Department and the public; and analyzing Part C child find data to improve equitable access to Part C early

intervention services. To meet this requirement the applicant must—

(i) Present applicable national, State, or local data demonstrating the challenges of States to implement effective early childhood data management policies and procedures and data sharing, linking, and integration activities, including integrating early childhood data systems across IDEA programs, other early learning programs, and other educational programs for school-aged students; link Part C and Part B preschool special education program data; use their Part C and Part B preschool special education data systems to respond to critical State-determined policy questions for program improvement and compliance accountability; and collect, report, analyze, and use Part C child find data to improve equitable access to Part C early intervention services;

(ii) Demonstrate knowledge of current educational and technical issues and policy initiatives relating to early childhood data management and data sharing, linking, and integration; data use; data privacy; Part C IDEA sections 616 and 618 data; Part C child find data; Part B preschool special education data; and Part C and Part B preschool special education data systems; and

(iii) Present information about the current level of implementation of sharing, linking, and integrating Part C and Part B preschool special education data; sharing, linking, or integrating Part C and/or Part B preschool special education data systems with other early learning data systems; using Part C and Part B preschool special education data systems to respond to critical State-determined policy questions; and collecting, reporting, analyzing, and using high-quality IDEA Part C data (including IDEA section 616 Part C data and section 618 Part C data) and IDEA Part B preschool special education data; and

(2) Improve early childhood data management policies and procedures and data sharing, linking, and integration practices to: collect, report, and analyze high-quality Part C and Part B preschool special education data (including Part C child find data); share, link, or integrate Part C and Part B preschool special education data; share, link, or integrate these data with data on children participating in other early learning programs and data on school-aged children; and use robust early childhood data systems to improve the analyses of IDEA data to the extent these analyses answer critical State-determined policy questions. Include

the likely magnitude or importance of the improvements.

(b) Demonstrate, in the narrative section of the application under “Quality of project services,” how the proposed project will—

(1) Ensure equal access and treatment for members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. To meet this requirement, the applicant must describe how it will—

(i) Identify the needs of the intended recipients for TA and information; and

(ii) Ensure that products and services meet the needs of the intended recipients of the grant;

(2) Achieve its goals, objectives, and intended outcomes. To meet this requirement, the applicant must provide—

(i) Measurable intended project outcomes; and

(ii) In appendix A, the logic model (as defined in 34 CFR 77.1) by which the proposed project will achieve its intended outcomes that depicts, at a minimum, the goals, activities, outputs, and intended outcomes of the proposed project;

(3) Use a conceptual framework (and provide a copy in appendix A) to develop project plans and activities, describing any underlying concepts, assumptions, expectations, beliefs, or theories, as well as the presumed relationships or linkages among these variables, and any empirical support for this framework;

Note: The following websites provide more information on logic models and conceptual frameworks: https://osepideasthatwork.org/sites/default/files/2021-12/ConceptualFramework_Updated.pdf and www.osepideasthatwork.org/resources-grantees/program-areas/ta-ta/tad-project-logic-model-and-conceptual-framework.

(4) Be based on current research and make use of evidence-based⁵ practices (EBPs). To meet this requirement, the applicant must describe—

(i) The current research on early childhood data management and data sharing, linking, and integration, and related EBPs; and

(ii) How the proposed project will incorporate current research and EBPs in the development and delivery of its products and services;

(5) Develop products and provide services that are of high quality and sufficient intensity and duration to achieve the intended outcomes of the proposed project. To address this requirement, the applicant must describe—

(i) How it proposes to identify and develop the knowledge base on early childhood data management and data system integration;

(ii) Its proposed approach to universal, general TA,⁶ which must identify the intended recipients, including the type and number of recipients, that will receive the products and services under this approach;

(iii) The proposed approach to targeted, specialized TA,⁷ which must identify—

(A) The intended recipients, including the type and number of recipients, that will receive the products and services;

(B) The proposed approach to measure the readiness of potential TA recipients to work with the project, assessing, at a minimum, their current infrastructure, available resources, and ability to build capacity at the State and local level; and

(C) The process by which the proposed project will collaborate with OSEP-funded centers and other federally funded TA centers to develop and implement a coordinated TA plan when the work of the center or centers overlaps with the proposed project; and

(iv) Its proposed approach to intensive, sustained TA,⁸ which must identify—

⁶ “Universal, general TA” means TA and information provided to independent users through their own initiative, resulting in minimal interaction with TA center staff and including one-time, invited or offered conference presentations by TA center staff. This category of TA also includes information or products, such as newsletters, guidebooks, or research syntheses, downloaded from the TA center’s website by independent users. Brief communications by TA center staff with recipients, either by telephone or email, are also considered universal, general TA.

⁷ “Targeted, specialized TA” means TA services based on needs common to multiple recipients and not extensively individualized. A relationship is established between the TA recipient and one or more TA center staff. This category of TA includes one-time, labor-intensive events, such as facilitating strategic planning or hosting regional or national conferences. It can also include episodic, less labor-intensive events that extend over a period of time, such as facilitating a series of conference calls on single or multiple topics that are designed around the needs of the recipients. Facilitating communities of practice can also be considered targeted, specialized TA.

⁸ “Intensive, sustained TA” means TA services often provided on-site and requiring a stable, ongoing relationship between the TA center staff and the TA recipient. “TA services” are defined as negotiated series of activities designed to reach a valued outcome. This category of TA should result in changes to policy, program, practice, or

(A) The intended recipients, including the type and number of recipients, that will receive the products and services under this approach;

(B) Its proposed approach to addressing States’ challenges associated with limited resources to engage in early childhood data sharing, linking, and integration and enhancement activities that streamline the established Part C and Part B preschool special education data systems to respond to critical policy questions and to report high-quality IDEA data to the Department and the public, which must, at a minimum, include providing on-site consultants to the State lead agency (LA) or State educational agency (SEA) to—

(1) Model and document data management and data sharing, linking, and integration policies, procedures, processes, and activities within the State;

(2) Develop and adapt tools and provide technical solutions to meet State-specific data needs; and

(3) Develop a sustainability plan for the State to continue the data management and data sharing, linking, and integration work in the future;

(C) Its proposed approach to measure the readiness of State LA and SEA personnel to work with the project, including their commitment to the initiative, alignment of the initiative to their needs, current infrastructure, available resources, and ability to build capacity at the State and local levels;

(D) Its proposed approach to prioritizing TA recipients with a primary focus on meeting the needs of States with known ongoing data quality issues, as measured by OSEP’s review of the quality of the IDEA sections 616 and 618 data;

(E) Its proposed plan for assisting State LAs and SEAs to build or enhance training systems that include professional development based on adult learning principles and coaching;

(F) Its proposed plan for working with appropriate levels of the education system (e.g., State LAs, SEAs, regional TA providers, districts, local programs, families) to ensure that there is communication between each level and that there are systems in place to support the collection, reporting, analysis, and use of high-quality IDEA Part C data (including IDEA section 616 Part C data, section 618 Part C data, and Part C child find data) and IDEA Part B preschool special education data as well as early childhood data management and data system integration; and

operations that support increased recipient capacity or improved outcomes at one or more systems levels.

⁵ For purposes of these requirements, “evidence-based” means, at a minimum, demonstrating a rationale (as defined in 34 CFR 77.1) based on high-quality research findings or positive evaluation that such activity, strategy, or intervention is likely to improve student outcomes or other relevant outcomes.

(G) Its proposed plan for collaborating and coordinating with the National Technical Assistance Center to Improve State Capacity to Collect, Report, Analyze, and Use Accurate IDEA Part B Data, the Early Childhood Technical Assistance Center, other Department-funded TA investments, other federally funded TA investments, and Institute of Education Sciences/National Center for Education Statistics research and development investments, where appropriate, in order to align complementary work and jointly develop and implement products and services to meet the purposes of this priority and to develop and implement a coordinated TA plan when they are involved in a State; and

(6) Develop products and implement services that maximize efficiency. To address this requirement, the applicant must describe—

(i) How the proposed project will use technology to achieve the intended project outcomes;

(ii) With whom the proposed project will collaborate and the intended outcomes of this collaboration; and

(iii) How the proposed project will use non-project resources to achieve the intended project outcomes.

(c) In the narrative section of the application under “Quality of the project evaluation,” include an evaluation plan for the project developed in consultation with and implemented by a third-party evaluator.⁹ The evaluation plan must—

(1) Articulate formative and summative evaluation questions, including important process and outcome evaluation questions. These questions should be related to the project’s proposed logic model required in paragraph (b)(2)(ii) of these application and administrative requirements;

(2) Describe how progress in and fidelity of implementation, as well as project outcomes will be measured to answer the evaluation questions.

Specify the measures and associated instruments or sources for data appropriate to the evaluation questions. Include information regarding reliability and validity of measures where appropriate;

(3) Describe strategies for analyzing data and how data collected as part of this plan will be used to inform and

improve service delivery over the course of the project and to refine the proposed logic model and evaluation plan, including subsequent data collection;

(4) Provide a timeline for conducting the evaluation, and include staff assignments for completing the plan. The timeline must indicate that the data will be available annually for the annual performance report (APR) and at the end of Year 2; and

(5) Dedicate sufficient funds in each budget year to cover the costs of developing or refining the evaluation plan in consultation with a “third-party” evaluator, as well as the costs associated with the implementation of the evaluation plan by the third-party evaluator.

(d) Demonstrate, in the narrative section of the application under “Adequacy of resources,” how—

(1) The proposed project will encourage applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability, as appropriate;

(2) The proposed key project personnel, consultants, and subcontractors have the qualifications and experience to carry out the proposed activities and achieve the project’s intended outcomes;

(3) The applicant and any key partners have adequate resources to carry out the proposed activities;

(4) The proposed costs are reasonable in relation to the anticipated results and benefits and funds will be spent in a way that increases their efficiency and cost-effectiveness, including by reducing waste or achieving better outcomes.

(e) Demonstrate, in the narrative section of the application under “Quality of the management plan,” how—

(1) The proposed management plan will ensure that the project’s intended outcomes will be achieved on time and within budget. To address this requirement, the applicant must describe—

(i) Clearly defined responsibilities for key project personnel, consultants, and subcontractors, as applicable; and

(ii) Timelines and milestones for accomplishing the project tasks;

(2) Key project personnel and any consultants and subcontractors will be allocated to the project and how these allocations are appropriate and adequate to achieve the project’s intended outcomes;

(3) The proposed management plan will ensure that the products and

services provided are of high quality, relevant, and useful to recipients; and

(4) The proposed project will benefit from a diversity of perspectives, including those of families, educators, TA providers, researchers, and policy makers, among others, in its development and operation.

(f) Address the following application requirements. The applicant must—

(1) Include, in appendix A, personnel-loading charts and timelines, as applicable, to illustrate the management plan described in the narrative;

(2) Include, in the budget, attendance at the following:

(i) A one and one-half day kick-off meeting in Washington, DC, after receipt of the award, and an annual planning meeting in Washington, DC, with the OSEP project officer and other relevant staff during each subsequent year of the project period.

(ii) A three-day project directors’ conference in Washington, DC, during each year of the project period, provided that, if the conference is conducted virtually, the project must reallocate unused travel funds no later than the end of the third quarter of each budget period.

(iii) Three annual two-day trips to attend Department briefings, Department-sponsored conferences, and other meetings, as requested by OSEP;

(3) Provide an assurance that the project will—

(i) Reallocate unused travel funds no later than the end of the third quarter if the kick-off or planning meetings are conducted virtually; and

(ii) Within 30 days of receipt of the award, participate in a post-award teleconference between the OSEP project officer and the grantee’s project director or other authorized representative;

(4) Include, in the budget, a line item for an annual set-aside of 5 percent of the grant amount to support emerging needs that are consistent with the proposed project’s intended outcomes, as those needs are identified in consultation with, and approved by, the OSEP project officer. With approval from the OSEP project officer, the project must reallocate any remaining funds from this annual set-aside no later than the end of the third quarter of each budget period;

(5) Budget at least 50 percent of the grant award for providing targeted and intensive TA to States;

(6) Provide an assurance that it will maintain a high-quality website, with an easy-to-navigate design, that meets government or industry-recognized standards for accessibility; and

⁹ A “third-party” evaluator is an independent and impartial program evaluator who is contracted by the grantee to conduct an objective evaluation of the project. This evaluator must not have participated in the development or implementation of any project activities, except for the evaluation activities, or have any financial interest in the outcome of the evaluation.

(7) Include, in appendix A, an assurance to assist OSEP with the transfer of pertinent resources and products and to maintain the continuity of services to States during the transition to these new award period and at the end of this award period, as appropriate.

Executive Orders 12866, 13563, and 14094

Regulatory Impact Analysis

Under Executive Order 12866, the Office of Management and Budget (OMB) must determine whether this regulatory action is “significant” and, therefore, subject to the requirements of the Executive order and subject to review by OMB. Section 3(f) of Executive Order 12866, as amended by Executive Order 14094, defines a “significant regulatory action” as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of \$200 million or more (adjusted every three years by the Administrator of Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise legal or policy issues for which centralized review would meaningfully further the President’s priorities, or the principles set forth in the Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

This final regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866 (as amended by Executive Order 14094). Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a “major rule,” as defined by 5 U.S.C. 804(2).

We have also reviewed this final regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency “to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.” The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include “identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.”

We are issuing the final priorities and requirements only on a reasoned determination that their benefits justify the costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action does not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

In accordance with these Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department’s programs and activities.

Discussion of Potential Costs and Benefits

The Department believes that this regulatory action does not impose significant costs on eligible entities, whose participation in this program is voluntary. While this action does impose some requirements on participating grantees that are cost-bearing, the Department expects that applicants for this program will include in their proposed budgets a request for funds to support compliance with such cost-bearing requirements. Therefore, costs associated with meeting these requirements are, in the Department’s estimation, minimal.

The Department believes that these benefits to the Federal Government outweigh the costs associated with this action.

Paperwork Reduction Act of 1995

The final priorities, including requirements, contain information collection requirements that are approved by OMB under OMB control number 1820–0028; the final priorities, including requirements, do not affect the currently approved data collection.

Regulatory Flexibility Act

Certification: The Secretary certifies that this final regulatory action will not have a significant economic impact on a substantial number of small entities.

The small entities that this final regulatory action will affect are LEAs, including charter schools that operate as LEAs under State law; institutions of higher education; other public agencies; private nonprofit organizations; freely associated States and outlying areas; Indian Tribes or Tribal organizations; and for-profit organizations. We believe that the costs imposed on an applicant by these final priorities and requirements will be limited to paperwork burden related to preparing an application and that the benefits will outweigh any costs incurred by applicants.

Participation in the Technical Assistance on State Data Collection program is voluntary. For this reason, the final priorities and requirements impose no burden on small entities unless they applied for funding under the program. We expect that in determining whether to apply for Technical Assistance on State Data Collection program funds, an eligible entity will evaluate the requirements of preparing an application and any associated costs and weigh them against the benefits likely to be achieved by receiving a Technical Assistance on State Data Collection program grant. An eligible entity will apply only if it

determines that the likely benefits exceed the costs of preparing an application.

We believe that the final priorities and requirements will not impose any additional burden on a small entity applying for a grant than the entity would face in the absence of the proposed action. That is, the length of the applications those entities would submit in the absence of this final regulatory action and the time needed to prepare an application would likely be the same.

This final regulatory action would not have a significant economic impact on a small entity once it receives a grant because it will be able to meet the costs of compliance using the funds provided under this program.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at www.govinfo.gov. At this site you can view this document, as well as all other Department documents published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access Department documents published in the **Federal Register** by using the article search feature at www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit

your search to documents published by the Department.

Danté Allen,

Commissioner, Rehabilitation Services Administration, Office of Special Education and Rehabilitative Services.

[FR Doc. 2024–16115 Filed 7–18–24; 11:15 am]

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LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 201 and 202

[Docket No. 2023–8]

Group Registration of Updates to a News Website

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Final rule.

SUMMARY: The U.S. Copyright Office is creating a new group registration for frequently updated news websites. This option will enable online news publishers to register a group of updates to a news website as a collective work with a deposit composed of identifying material representing sufficient portions of the work, rather than the complete contents of the website. The final rule is nearly identical to the provisions set forth in the January 2024 notice of proposed rulemaking, with one modification in response to public comments and one to reflect a technical change in the process for submitting these claims.

DATES: Effective July 22, 2024.

FOR FURTHER INFORMATION CONTACT: Rhea Efthimiadis, Assistant to the General Counsel, by email at meft@copyright.gov or by telephone at 202–707–8350.

SUPPLEMENTARY INFORMATION:

I. Background

The Copyright Act authorizes the Register of Copyrights to specify by regulation the administrative classes of works for the purpose of registration and the deposit required for each class.¹ In addition, Congress gave the Register the discretion to allow registration of groups of related works with one application and one filing fee.² This procedure is known as “group registration.”³ Pursuant to this authority, the Register has issued several regulations permitting group registrations for certain types of works,

including newspapers, newsletters and serials, unpublished works, unpublished and published photographs, contributions to periodicals, secure test items, works on an album of music, short online literary works, and database updates.⁴

This rulemaking expands the available group registration options because of several factors specifically impacting news websites. Along with receiving requests from online publishers, the Office observed the increase in news content offered online and the dynamic nature of such material.⁵ It also reviewed stakeholder comments in prior proceedings that discussed the challenges associated with registering online news content, including those submitted in response to its 2022 *Copyright Protections for Press Publishers* report.⁶ Finally, the Office acknowledged the deposit challenges associated with websites, particularly news websites, in its 2011 publication titled *Priorities and Special Projects of the United States Copyright Office (October 2011–October 2013)*.⁷

On January 3, 2024, the Office published a Notice of Proposed Rulemaking (“NPRM”) to establish a new group registration option for frequently updated news websites.⁸ The proposed rule would allow an applicant to register a news website as a collective work (including any individual component works it fully owns, such as literary works, photographs, and/or graphics)⁹ with a deposit composed of identifying material, rather than the complete contents of the website. The proposed rule would also allow registration of the news website and any updates published within one calendar month, if the deposit evidences a sufficiently creative selection, coordination, or arrangement within each collective work to constitute a copyrightable compilation.¹⁰ Each

⁴ *Id.* at 202.3(b)(5), 202.4(c)–(k), (o).

⁵ See 89 FR 311, 311–12 (Jan. 3, 2024).

⁶ U.S. Copyright Office, Copyright Protection for Press Publishers (June 2022), <https://copyright.gov/policy/publishersprotections/202206-Publishers-Protections-Study.pdf>.

⁷ See 89 FR 311, 312.

⁸ *Id.* at 311. The final rule defines a “news website” as “a website that is designed to be a primary source of written information on current events, either local, national, or international in scope, that contains a broad range of news on all subjects and activities and is not limited to any specific subject matter.” 37 CFR 202.4(m)(1)(i).

⁹ Because the Office will not examine each component work within the collective work, the copyright claimant bears the burden of proving that it owns the individual component works claimed in the submission.

¹⁰ A “collective work” is a type of compilation.

See 17 U.S.C. 101. A “compilation” is “a work

Continued

¹ 17 U.S.C. 408(c)(1).

² *Id.*

³ See generally 37 CFR 202.3(b)(5), 202.4.

collective work must have been created as a work made for hire, with the same person or entity named as both the author and copyright claimant. The proposed rule stated that applicants would be required to submit their claims through the online copyright registration system, using the application currently in use for a group of newspaper issues.¹¹

The Office received twenty comments in response to the NPRM.¹² All but one¹³ supported the Office's proposal to create the new group registration option, though the majority requested various modifications. Two commenters, however, expressly conditioned their support on substantive changes to the rule, which would substantially change its scope.¹⁴ In general, commenters were interested in expanding eligibility for this option to a greater number of works and changing the deposit requirement. Proposals included revising the definition of "news website," removing the work made for hire and author/claimant requirements, increasing the time limitation for updates to the news website, clarifying the "home page" deposit requirement, and asking the Office to confirm the scope of remedies for copyright infringement of a collective work.¹⁵ Finally, one commenter encouraged the Office to "identify opportunities for

improvement" and to remain "adaptive to technological changes."¹⁶

Having reviewed and carefully considered each of the comments, the Office now issues a final rule that is nearly identical to the proposed rule, with one modification reflecting concerns raised by some commenters regarding the "home page" deposit requirement and one modification concerning the application form for this option. These modifications are discussed in more detail below. With respect to requests that we received to expand the scope of the rule, the Office will closely monitor how the new group option performs, including the number and complexity of the claims submitted, the amount of time needed to examine these claims, and the modest filing fee for this option. The Office remains open to revisiting these issues in the future based on this rule's performance.

II. Final Rule

A. Eligibility Requirements

1. Works That May Be Included in the Group

In the NPRM, the Office proposed to limit this group registration option to updates to a "news website," defined as "a website that is designed to be a primary source of written information on current events, either local, national, or international in scope, that contains a broad range of news on all subjects and activities and is not limited to any specific subject matter." As described in the NPRM, the proposed rule stems from the rapid development and predominance of news websites over print newspapers,¹⁷ and requests from news publishers for a feasible way to register "newspaper websites" that are "updated frequently."¹⁸ Thus, the proposed rule is an extension of the existing group newspaper option that has been available for decades.¹⁹ Consistent with the *Compendium of U.S. Copyright Office Practices*, the

proposed rule defines a "website" as "a web page or set of interconnected web pages that are accessed using a uniform resource locator ("URL") organized under a particular domain name." A number of commenters encouraged the Office to expand the type of works eligible under the rule and recommended revisions to both definitions.

i. Constitutional Challenge

Before turning to the requests to expand the rule, the Office addresses the argument made by a small number of commenters that the proposed group registration option would violate the First Amendment by limiting the option to a particular type of work. In a joint comment, NWU, NPPA, and NASW stated that restricting the option to "news" websites constitutes "[c]ontent-based discrimination," which they considered "[c]onstitutionally suspect and subject to strict scrutiny" that the rule "cannot meet."²⁰ In support of this argument, they cited *Arkansas Writers Project v. Ragland*, 481 U.S. 221 (1987), which reviewed a state sales tax scheme that taxed general interest magazines, but exempted newspapers and religious, professional trade, and sports journals. Because Arkansas "advanced no compelling justification for selective, content-based taxation of certain magazines," the Supreme Court held the tax scheme invalid under the First Amendment.²¹ Analogizing the tax scheme in *Arkansas Writers Project* to the proposed registration option, NWU, NPPA, and NASW argued that the exclusion of any web content that does not meet the "news website" definition is unconstitutional.²²

Aligned with NWU, NPPA, and NASW, another commenter, Gordon Firemark, contended that, by limiting the group option to updates to news websites, the proposed rule "excludes other types of content from [its] benefits" and denies content creators "relief from the burdens of the current system."²³ He argued that recent Supreme Court precedent concerning trademark registration requires a content-neutral approach.²⁴

The Office disagrees with these arguments. It is correct that the Supreme Court has held that content-based laws—laws restricting or compelling

formed by the collection and assembling of preexisting materials or of data that are selected, coordinated, or arranged in such a way that the resulting work as a whole constitutes an original work of authorship." *Id.*

¹¹ As noted in the NPRM, "in appropriate circumstances, the Office may waive the online filing requirement, subject to the conditions the Associate Register of Copyrights and Director of the Office of Registration Policy and Practice may impose." 89 FR 311, 316 n.55.

¹² The Office also received a letter from several organizations reflecting their collective support for finalizing the rulemaking in a timely manner and in-line edits to the Office's proposed regulatory language. Letter from Ass'n of Am. Publishers et al. to Suzanne Wilson, Gen. Counsel and Assoc. Register of Copyrights (Apr. 4, 2024), <https://www.copyright.gov/rulemaking/newswebsite/Association-of-American-Publishers-et-al%E2%80%93Letter-to-Copyright-Office.pdf>.

¹³ See Am. Ass'n of Independent Music, Ass'n of Am. Publishers, Inc. and Recording Industry Ass'n of Am., Inc. ("A2IM, AAP, & RIAA") Comment at 2 ("Commenters express no position on the primary focus of the NPRM—whether the Office should create a new group registration option for frequently updated news websites—or on the details of how such an option should be implemented.").

¹⁴ See generally Nat'l Writers Union, Nat'l Press Photographers Ass'n, Nat'l Ass'n of Sci. Writers ("NWU, NPPA, & NASW") Comment; Gordon Firemark 2 Comment.

¹⁵ A handful of commenters also proposed that the Office should adopt the NPRM immediately, as an interim rule. See, e.g., Copyright All. Comment at 11; Nat'l Pub. Radio ("NPR") Comment at 3–5; News Media All. ("NMA") Comment at 2.

¹⁶ Am. Bar Ass'n Section of Intell. Prop. L. ("ABA–IPL") Comment at 4.

¹⁷ 89 FR at 311–12 (noting that "[m]ore than eight in ten Americans get news from digital devices, and, as of 2021, more than half prefer digital platforms to access news").

¹⁸ *Id.* (citing Newspaper Association of America Comments at 12–18, Submitted in Response to July 15, 2009 Notice of Proposed Rulemaking, Mandatory Deposit of Published Electronic Works Available Only Online, U.S. Copyright Office Dkt. No. 2009–3 (Aug. 31, 2009) (emphasis omitted), <https://www.copyright.gov/rulemaking/online-only/comments/naa.pdf>).

¹⁹ 37 CFR 202.4(e). The Office's definition of newspapers is based on the Library of Congress's collection policy definition. Library of Congress, Collections Policy Statements: Newspapers—United States 1 (Sept. 2023), <https://www.loc.gov/acq/devpol/neu.pdf>.

²⁰ NWU, NPPA, & NASW Comment at 12–13; Gordon Firemark 2 Comment (asserting that "the proposed regulation is not Content Neutral, as required under the First Amendment").

²¹ *Arkansas Writers Project*, 481 U.S. at 234.

²² NWU, NPPA, & NASW Comment at 12–13.

²³ Gordon Firemark 2 Comment.

²⁴ *Id.* (citing *Iancu v. Brunetti*, 139 S. Ct. 2294 (2019), and *Matal v. Tam*, 582 U.S. 218 (2017)).

speech based on its communicative content—are presumptively unconstitutional,²⁵ and subject to strict scrutiny, under which the government must show that the law is the “least restrictive means” of advancing a “compelling” governmental interest.²⁶ A regulation can be content-based “on its face,” if its text applies to speech based on the subject matter, topic, or viewpoint of that speech. It can also be content-based if it has a discriminatory purpose that “cannot be justified without reference to the content of the regulated speech” or was “adopted by the government because of disagreement with the message” conveyed.²⁷ However, a regulation that places “a differential burden on speakers is insufficient by itself to raise First Amendment concerns.”²⁸ The tax scheme in *Arkansas Writers Project* was found to violate these principles by being directed at particular subjects, thus targeting a small group within the press.²⁹ That is not the case here.

The Office’s proposed group registration option is not analogous to the unconstitutional tax statute in *Arkansas Writers Project* for multiple reasons. First, the option does not restrict or compel speech based on its communicative content. Nor does it favor or disfavor particular topics or subjects, or exclude a small group of the press.³⁰ Instead the option is available for updates to news websites that contain a broad range of topics regardless of the content of the speech involved.

Second, the registration option is viewpoint neutral and operates not as a restriction on speech, but as a condition for qualifying for one of many options available to register copyrights, including online websites and other publications. The Standard Application is available to any type of author for any type of work within the statutory categories.³¹ Group registration options are discretionary accommodations offered by the Office in a number of areas. Currently, the Office administers ten group options covering unpublished

works, short online literary works, works on an album of music, serials, newspapers, newsletters, contributions to periodicals, published and unpublished photographs, automated databases, and secure test items.³² For online publications, group serials and group newsletters are other registration options for publications that fall outside of the “newspaper” or “news website” definitions.

The Supreme Court’s recent ruling in a case involving trademark regulations supports the Office’s view. There the Court reviewed a rule of the U.S. Patent and Trademark Office (“USPTO”) barring the registration of trademarks that use the names of particular living individuals without their written consent.³³ The Court held that this bar, though content-based, is viewpoint neutral and does not violate the First Amendment.³⁴ The Court noted that while its precedents “distinguish between content-based and content-neutral regulations of speech,”³⁵ they further distinguish “a particularly ‘egregious form of content discrimination’—viewpoint discrimination,” which targets not merely a subject matter, “but particular views taken by speakers on a subject.”³⁶ The Court identified “[s]everal features of trademark [law]” that “counsel against a *per se* rule of applying heightened scrutiny to viewpoint-neutral, but content-based trademark regulations.” Most notably, it found that “trademark rights have always coexisted with the First Amendment, despite the fact that trademark protection necessarily requires content-based distinctions.”³⁷ Accordingly, the Court held that USPTO’s “content-based, but viewpoint-neutral, trademark restriction [] is compatible with the First Amendment.”³⁸

Similarly, copyright registration, and the broad administrative classification authority Congress granted to the Register, necessarily requires content-based distinctions. Indeed, since its passage in 1976, the Copyright Act has authorized the Register “to specify by regulation the administrative classes into which works are to be placed for purposes of deposit and registration” and to permit “for particular classes, the deposit of identifying material instead

of copies or phonorecords, the deposit of only one copy or phonorecord where two would normally be required, or a single registration for a group of related works.”³⁹ Like the USPTO’s name bar, these administrative distinctions are not based on the particular views taken by authors and have always coexisted with the First Amendment. The addition of an administrative classification for this new group registration option, which adopts near-identical criteria for determining “news” content to that of the existing group option for newspapers, is “a matter of policy and discretion”⁴⁰ fully compatible with the First Amendment.

Further, unlike the viewpoint-based trademark provisions held unconstitutional for barring registration of scandalous or disparaging marks,⁴¹ the Office’s viewpoint-neutral administrative classification does not bar registration for non-news content or websites. Quite the opposite: to increase participation in the registration system, the Office has created several group options for the registration of works that are published online.⁴² The Standard Application also remains available to any type of author for any type of work within the statutory categories. This rule does not prevent anyone’s ability to register non-news works.

ii. News Website Limitation

Multiple commenters urged the Office to expand the rule’s definition of “news website” by removing the condition that the website must contain news on all subjects and activities.⁴³ In encouraging

³⁹ 17 U.S.C. 408(c)(1) (emphasis added).

⁴⁰ *Leathers*, 499 U.S. at 452 (quoting *Regan v. Taxation with Representation*, 461 U.S. 540, 549 (1983)).

⁴¹ See Gordon Firemark 2 Comment (citing *Iancu v. Brunetti*, 139 S. Ct. 2294 (2019), and *Matal v. Tam*, 582 U.S. 218 (2017)).

⁴² See, e.g., 85 FR 37341, 37345 (June 22, 2020) (final rule for group registration of short online literary works); 83 FR 61546, 61546–48 (Nov. 30, 2018) (final rule for group registration of newsletters and serials); 82 FR 29410, 29410–11 (June 29, 2017) (final rule for group registration of contributions to periodicals).

⁴³ See ABA–IPL Comment at 2; Am. Intell. Prop. L. Ass’n (“AIPLA”) Comment at 1 (“We encourage the Office to reconsider [the definition of ‘news website’] and clarify the final clause—‘not limited to any specific subject matter’—which could be construed as excluding news websites with an industry-specific focus (e.g., wired.com), and thus unnecessarily limiting access to this group registration option.”); Copyright All. Comment at 4 (“We urge deletion of the phrase ‘. . . on all subjects and activities and is not limited to any specific subject matter’ in the proposed rule”); Harvard Bus. Publ’g (“HBP”) Comment; Nat’l Ass’n of Broad. (“NAB”) Comment at 3; NWU, NPPA, & NASW Comment at 12–13; NMA Comment at 8; The Authors Guild Comment at 2; see also Letter from Ass’n of Am. Publishers et al.

Continued

²⁵ *Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2015).

²⁶ *Sable Commc’ns of Cal. v. FCC*, 492 U.S. 115, 126 (1989).

²⁷ *Reed*, 576 U.S. at 164 (internal quotes omitted).

²⁸ *Leathers v. Medlock*, 499 U.S. 439, 452–53 (1991) (citing *Mabee v. White Plains Publ’g Co.*, 327 U.S. 178 (1946), and *Oklahoma Press Publ’g Co. v. Walling*, 327 U.S. 186 (1946)).

²⁹ *Arkansas Writers Project*, 481 U.S. at 229 (finding the tax scheme impermissibly targets a small group of the press because “the magazine exemption means that only a few Arkansas magazines pay any sales tax”).

³⁰ *Arkansas Writers Project*, 481 U.S. at 229–30.

³¹ 37 CFR 202.3(b)(2)(i)(A).

³² See generally *id.* at 202.4.

³³ *Vidal v. Elster*, No. 22–704, slip op. at 1 (2024).

³⁴ *Id.*

³⁵ *Id.* at 4 (2024) (quoting *National Institute of Family and Life Advocates v. Becerra*, 585 U.S. 755, 766 (2018)).

³⁶ *Id.* (2024) (quoting *Rosenberger v. Rector and Visitors of Univ. of Va.*, 515 U.S. 819, 829 (1995)).

³⁷ *Id.* at 6.

³⁸ *Id.* at 12.

the Office “not to exclude . . . specialized websites,” the ABA–IPL noted that the “proposed rule may provide especially meaningful benefit to smaller news websites—including those that focus on certain ‘specific subject matter.’”⁴⁴ HBP argued that “websites, like HBR.org, that focus on a particular area of news . . . still face the same registration problems afflicting all news websites.”⁴⁵ The Authors Guild also expressed concern that the rule would exclude more specialized news publications, such as those that focus on political news. It argued that “these publications clearly qualify as news websites under any ordinary understanding of that term.”⁴⁶ Relatedly, commenters claimed that content restrictions “put[] examiners in an untenable position of deciding what is or is not ‘news.’”⁴⁷ Finally, four commenters asked the Office to abandon the “news website” definition and extend the group option “to any periodically-produced content distributed through the internet.”⁴⁸

After considering this request and in the interest of implementing this final rule as quickly as possible, the Office declines to revise the definition at this time. As an extension of the newspaper group option, the “news website” definition is modeled on the Office’s longstanding regulation defining a “newspaper” as a publication that is “mainly designed to be a primary source of written information on current events, either local, national, or international in scope,” that “contains a broad range of news on all subjects and activities and is not limited to any specific subject matter.”⁴⁹ This definition is very broad and it is intended to “make any newspaper eligible for a group registration.”⁵⁰ It is also intended to distinguish a “newspaper” from a “newsletter,” which is defined elsewhere in the regulations as a publication that contains “news or information that is chiefly of interest to a special group, such as trade and professional

associations, colleges, schools, or churches.”⁵¹

Under this definition, newspapers are aimed at any member of the general public who may be interested in newsworthy information or events that are reported on a given day.⁵² By applying a similar definition to websites, the final rule recognizes that “news websites” are also intended to have universal appeal.

This definition would encompass news websites that cover current events and provide information on diverse topics, including some political websites like those identified in the Authors Guild’s comment.⁵³ Although these sites focus primarily on issues involving politics and events with political implications, they do not limit their coverage to a particular subject matter nor are they directed at narrow or discrete groups of readers.⁵⁴

The Office also disagrees with commenters that the “news website” eligibility requirement places a burden on examiners. Indeed, the definitions for “news website” and “newspaper” are similar, in part, to enable consistent application of both rules. Examiners are accustomed to assessing eligibility based on this definition.

However, if the definition proves too rigid or unworkable, the Office is willing to revisit this issue based on its experience in administering this rule. Importantly, however, this new group option is not intended to extend to the websites of all serials or newsletters, which in print or ePrint form have the benefit of separate group registration options.⁵⁵

iii. Website Limitation

The Office received requests to expand the rule beyond websites. Commenters recommended that the proposed rule be amended to include mobile applications (“apps”) in the definition of “website.”⁵⁶ They argued that “[m]any news publishers encourage

users to access content on an app rather than a website.”⁵⁷

The Office declines to amend the definition. It considers an app to be “a computer program that is used directly or indirectly in a computer or handheld electronic device.”⁵⁸ The Office has a procedure for registering the underlying code that operates the app.⁵⁹ To the extent that news publishers seek to register the works published on the app, a registration for a newspaper or a news website would protect those works if they contain the same content.

AIPLA encouraged the Office to revise the definition of “website” to clarify that a website is not limited to content accessed using a single domain name.⁶⁰ It explained that “web pages are composed of various elements, like text, images, and videos” that “might be hosted on a different server than the one hosting the main web page for reasons such as efficiency, speed, and cost.”⁶¹ The Office appreciates this distinction but declines to revise the definition. To qualify for this option, each collective work in the group must be published under one particular domain name. For registration purposes, the Office does not assess eligibility based on where component digital works may be stored. The Office believes the “particular web page” requirement is necessary to prevent applicants from using the option to register collective works published under different domain names on the same application, which would make it difficult to identify the website that is covered by the registration. Therefore, the final rule retains the definition proposed in the NPRM.

2. Scope of Collective Work

The proposed rule provides that claims registered under this option will be limited to the collective work authorship based on the selection, coordination, and/or arrangement of the individual component works, and that all parts of the collective work will constitute one work for purposes of 17 U.S.C. 504(c)(1).⁶² Additionally, the

to Suzanne Wilson, Gen. Counsel and Assoc. Register of Copyrights (Apr. 4, 2024).

⁴⁴ ABA–IPL Comment at 2.

⁴⁵ HBP Comment.

⁴⁶ The Authors Guild Comment at 1–2.

⁴⁷ John Murphy Comment; The Authors Guild Comment at 2 (arguing that “making eligibility determinations based on the substantive content of the materials submitted for registration . . . goes well beyond the Office’s ordinary examination process”).

⁴⁸ Gordon Firemark 1 Comment; *see* NWU, NPPA, & NASW at 12–13; Brenda Ulrich Comment; John Murphy Comment.

⁴⁹ 37 CFR 202.4(e)(1).

⁵⁰ 82 FR 51369, 51371 (Nov. 6, 2017).

⁵¹ 37 CFR 202.4(f)(1)(i).

⁵² *Id.* at 202.4(e)(1) (“Newspapers are intended either for the general public or for a particular ethnic, cultural, or national group”).

⁵³ The Authors Guild Comment at 1–2.

⁵⁴ *Cf.* 37 CFR 202.4(f)(1)(i) (designed for newsletters that “contain news or information that is chiefly of interest to a special group”).

⁵⁵ Group registration of serials provides a registration option for serial issues within a three-month period that meet the eligibility requirements for that option. *Id.* at 202.4(d)(1). Group registration of newsletters provides an option for registering a group of newsletters published within a one-month period. *Id.* at 202.4(f)(1).

⁵⁶ Copyright All. Comment at 6; NAB Comment at 4; NMA Comment at 10.

⁵⁷ The Authors Guild Comment at 2; Copyright All. Comment at 6; NAB Comment at 4.

⁵⁸ U.S. Copyright Office, *Compendium of U.S. Copyright Office Practices* sec. 722 (3d ed. 2021) (“*Compendium (Third)*”).

⁵⁹ *Id.*

⁶⁰ AIPLA Comment at 1–2.

⁶¹ *Id.*

⁶² In the NPRM, the Office also noted that when a website is registered as a compilation, the statute provides that the copyright owner may seek only one award of statutory damages for infringement of the compilation as a whole—rather than a separate award for each individual work that appears on the website—even if the defendant infringed all of the works covered by the registration. 17 U.S.C.

Office made clear that the registration will also cover the individual contributions contained within the collective work if they are fully owned by the copyright claimant and were first published in that work.

NPR asked the Office to confirm that “the scope of the collective work will explicitly include all copyrightable contributions made by the claimant, not just textual works.”⁶³ As noted above, a “news website” is defined as “a website that is designed to be a primary source of *written* information.”⁶⁴ If the collective work contains individual contributions that are fully owned by the copyright claimant and were first published in the work, then the registration will cover those contributions, so long as they are copyrightable subject matter. However, a component work “that is perceptible to the user only by downloading or separately purchasing that particular work is not considered part of the website for registration purposes and must be registered separately.”⁶⁵ Additionally, any “externally linked content [i.e., content residing on another website] is not considered part of the website’s content for registration purposes.”⁶⁶

HBP recommended that the Office permit applicants to disclaim content that is licensed and not owned by the applicant. As with group newspapers, the Office does not see the need for a limitation of claim for news websites, because the proposed rule expressly states that “[e]ach update to the website must be [an original] collective work.” A registration issued by the Office pursuant to this rule will only cover the new contributions owned by the

copyright claimant. Consistent with any collective work registration, any articles, photos, or other contributions included in the collective work that were previously published, previously registered, owned by another party, or in the public domain are automatically excluded from the claim. As a practical matter, therefore, a disclaimer to expressly exclude material in the application is unnecessary.

Port. Prerogative Club asked the Office to “[c]larify whether updates to numerical information, such as prices, volumes, retweets, or other metrics, qualify as registrable under the rule, and whether the Office has changed its policy on the registrability of short phrases and headlines.” The Office states that its longstanding regulation denying protection for words and short phrases has not changed.⁶⁷ Regarding “prices, volumes, retweets, or other metrics,” it is unclear whether the commenter is referring to individual works of authorship, or whether these items appear in a compilation. Individual numbers and short phrases are not copyrightable. However, a copyrightable compilation of these items may be registrable.

3. One-Month Limitation

The proposed rule permits an applicant to include updates published on the same website within the same calendar month. Three commenters urged the Office to remove the limitation, arguing that it is too “onerous.”⁶⁸ NPR recommended that the Office allow for the option to cover “three months, or six months, or a calendar year” to “reduce registration costs.”⁶⁹ Noting that “attorneys’ fees and statutory damages can be awarded as long as copyright is registered within three months of first publication,” NWU, NPPA, and NASW requested that the rule be amended to allow registration of updates published “during any specified three-month period.”⁷⁰

At this time, given administrative capabilities, the Office cannot expand the option to cover more than one month of updates. As the NPRM explained, to deliver the option promptly, and to minimize development time, the Office is adapting the existing group application for newspapers, which is used to register up to one month of newspaper issues and contains

technical validations that prevent applicants from entering publication dates that are more than one month apart. Changing the limit would require additional modifications to the application and delay implementation of the final rule. Further, the Office seeks an appropriate balance between the interests of copyright owners and the administrative burden to the Office. Based on the modest fee set for this option, some limit on the number of works included in each claim is necessary. The Office will reassess whether the limit can be increased after it has gained sufficient experience administering the rule.

4. Authorship, Ownership, and Work Made for Hire Requirements

Under the proposed rule, to be eligible for the option, each collective work in the group must have been created as a work made for hire, with the same person or entity named as the author and copyright claimant. Multiple commenters questioned this requirement.⁷¹ The Authors Guild argued that the work made for hire requirement “arbitrarily and unfairly confines the benefit of the rule to corporate entities even where other creators are producing substantially the same type of content.”⁷² While they recognized that this requirement reflects practical and technical limitations, NMA and AIPLA noted that “there does not seem to be a fundamental reason for such a limitation in principle, and in many business cases, the work may be fully owned by the publisher, or obtained via assignment or operation of law.”⁷³

The Office acknowledges that the work made for hire requirement may not reflect every business case of ownership. However, this requirement streamlines the registration procedures, which, as noted above, will adapt the existing group application option for newspapers. Under that option, the same person or entity must be named as the author and copyright claimant, and each issue must be a work made for hire. The Office retains the same requirements for the news websites option to minimize the need for additional development time that would otherwise be required.

⁷¹ The Authors Guild Comment at 3; NWU, NPPA, & NASW Comment at 11; NMA Comment at 11; AIPLA Comment at 2; Letter from Ass’n of Am. Publishers et al. to Suzanne Wilson, Gen. Counsel and Assoc. Register of Copyrights (Apr. 4, 2024).

⁷² The Authors Guild Comment at 3; NWU, NPPA, & NASW Comment at 11.

⁷³ NMA Comment at 11; AIPLA Comment at 2 (“[W]e see no clear policy reason to disfavor registration of copyrights acquired through other means (e.g., by assignment).”).

504(c)(1) (“For the purposes of this subsection, all the parts of a compilation or derivative work constitute one work.”). Some commenters urged the Office to acknowledge and adopt the “‘independent economic value’ test to determine when copyrighted material constitutes a separate ‘work’ for the purpose of determining eligibility for statutory damages.” A2IM, AAP, & RIAA Comment at 2–3; Copyright All. Comment at 8; NAB Comment at 6–8. Acknowledging that the NPRM correctly states “that the group registration option will extend to individual works that make up the collective work if they are fully owned by the applicant,” NMA asked the Office to confirm that its statement “do[es] not reflect a substantive opinion on eligibility for statutory damages.” NMA Comment at 11–12. The Office stands by its restatement of section 504(c)(1) and declines to address the matter further in this rulemaking. See H.R. Rep. No. 94–1476, at 162 (1976), *reprinted in* 1976 U.S.C.A.N. 5659, 5770 (“Subsection (c)(1) makes clear, however, that, although they are regarded as independent works for other purposes, ‘all the parts of a compilation or derivative work constitute one work’ for this purpose.”).

⁶³ NPR Comment at 7.

⁶⁴ 37 CFR 202.4(m)(1)(i) (emphasis added).

⁶⁵ *Compendium (Third)* sec. 1002.2.

⁶⁶ *Id.*

⁶⁷ See 37 CFR 202.1(a).

⁶⁸ John Murphy Comment; see NPR Comment at 5 (“[T]he office should further relax the frequency”); NWU, NPPA, & NASW Comment at 16–17.

⁶⁹ NPR Comment at 5.

⁷⁰ NWU, NPPA, & NASW Comment at 16.

Additionally, under general Copyright Office practice, if the author and claimant are not the same person, the applicant is statutorily required to provide a transfer statement explaining how the claimant acquired all of the rights initially belonging to the author.⁷⁴ If an applicant names a third party as the copyright claimant, but fails to provide a transfer statement, then the Office must correspond to determine whether the claimant actually owns all of the exclusive rights in the works, which delays the registration decision. The corresponding additional time and costs that the Office would incur are inconsistent with the reduced fee for examination of multiple collective works.

Moreover, imposing a work made for hire limitation is consistent with the goal of this rulemaking, which is to address obstacles to registering online news content produced by news publishers, who often also publish newspapers. Based on its experience with the existing group newspaper registrations, the Office expects that this requirement will produce an optimal public record, while reducing the administrative burden that these claims impose. The final rule accordingly retains the work made for hire requirement. Applicants who do not qualify for the option may still register their works individually using the Standard Application.

5. Subjects of Inquiry

i. Permitted Additional Title Information

The Office invited public comments on whether it should give applicants the opportunity to provide additional information, such as individual article or photograph titles, as part of this group registration option. Commenters expressed support for the implementation of an opportunity to include granular information concerning individual component works at the applicant's discretion.⁷⁵ The Authors Guild noted that "in the event an individual article is the subject of a later infringement action, the applicant may need to rely on its own recordkeeping to establish that the article was on the website during the period covered by the registration."⁷⁶ It concluded, "[t]he listing of individual titles or other information on the application may provide additional

evidence relevant to that showing."⁷⁷ The Office agrees and will provide instructions on its website explaining how applicants may submit additional information regarding component works on an optional basis.⁷⁸

ii. Permitted Archived URLs

The Office also invited public comments on the availability and effectiveness of technological solutions for saving or archiving websites that could assist or supplement news websites' recordkeeping efforts while also informing the public of the contents of the website and/or any updates registered. The Office suggested that applicants may provide in the "Note to Office" field additional information regarding the contents of the work, such as archived URLs that capture the complete content of each collective work submitted for registration. The Copyright Alliance expressed support for this suggestion, provided that doing so is voluntary.⁷⁹ Therefore the Office encourages applicants to submit archived URLs in the "Note to Office" field on a voluntary basis.

B. Filing Fee

The NPRM provided that the filing fee for this option will be \$95, the same fee that currently applies to a claim in a group of newspapers. It noted that the Office believes it is reasonable to charge the same fee as for the group newspaper option, given the similarities in expected workflow associated with examining these claims. The NMA expressed support for this modest fee, describing it as "reasonable and unarbitrary."⁸⁰ The final rule establishes this fee.

C. Deposit Requirements

The NPRM proposed that for each collective work submitted under this group registration option, applicants must "submit a deposit that is sufficient to identify some of the updates that were made to the website."⁸¹ The Office specified that "applicants will need to submit separate PDF files that each contain a complete copy of the home page for the site. Each PDF must show how the home page appeared at a specific point during each day of the calendar month when new updates were published on the site."⁸² Additionally, the NPRM required that each deposit

demonstrate "that the home page contains a sufficient degree of selection, coordination, and/or arrangement to be registered as a collective work."⁸³ Several commenters requested that the Office consider different deposit requirements, though commenters varied on the specific changes they requested or discussed deposits generally. The Office addresses each suggested change below.

1. "Home Page" Requirement

i. Timing of Deposit Capture

After considering NMA's request to resolve a purported ambiguity in the proposed rule regarding the time of day for daily deposits of home pages, the Office is clarifying the time period for capturing deposits.⁸⁴ The language within section (m)(6)(i) requiring "[e]ach PDF [to] show how the home page appeared at a specific point during each day of the calendar month" does not require applicants to capture PDFs of home pages at the same exact time every day.⁸⁵ Instead, PDFs of home pages must show how the home page appeared at some point during each day, in addition to satisfying other applicable deposit requirements.

ii. "Complete Copy"

Three commenters specifically requested that the Office expand the identifying material it will accept to encompass more than "a complete copy of the home page for the site."⁸⁶ The NAB stated that "the Office should amend the deposit requirements proposed in § 202.4(m)(6)(i) to allow for the submission of a copy of identifying material in lieu of a complete copy of the home page."⁸⁷ It explained that "many news websites utilize an 'infinite scroll' feature that automatically and continuously loads more content as users scroll down the web page" making

⁸³ *Id.*

⁸⁴ NMA Comment at 11.

⁸⁵ 37 CFR 202.4(m)(6)(i) (emphasis added); see also 89 FR at 316 ("Each PDF must show how the home page appeared at a specific point during each day of the calendar month when new updates were published on the site.").

⁸⁶ Copyright Alliance Comment at 10–11; NAB Comment at 4–5; NMA Comment at 11. See also Letter from Ass'n of Am. Publishers et al. to Suzanne Wilson, Gen. Counsel and Assoc. Register of Copyrights at App. 2 (Apr. 4, 2024) (proposing regulatory language altering the deposit requirement when "a complete copy is technically unfeasible or unreadable due to the size or continuous nature of the home page"); Nexstar Media Group Inc. Comment (stating that Nexstar "would like to see even more modification of the requirements for article submission, so that each local television station or other news site would not be required to have dedicated staff purely for depositing copyrighted materials, which may be updated several times per day").

⁸⁷ NAB Comment at 5.

⁷⁴ *Compendium (Third)* sec. 620.4.

⁷⁵ ABA–IPL Comment at 3; AIPLA Comment at 2; Copyright All. Comment at 6–7; NAB Comment at 5; NMA Comment at 7; The Authors Guild Comment at 4.

⁷⁶ The Authors Guild Comment at 4.

⁷⁷ *Id.*

⁷⁸ Note, however, the Office will not certify the accuracy of such additional information based on the identifying material deposited.

⁷⁹ Copyright All. Comment at 7.

⁸⁰ NMA Comment at 7.

⁸¹ 89 FR at 316.

⁸² *Id.*

it “technologically impossible for an applicant to satisfy the deposit requirement of providing a PDF of the home page in its entirety.”⁸⁸ Copyright Alliance echoed this sentiment stating “a user is able to continuously reveal additional content on the web page without having to leave the page to view the content on a separate web page. For such web pages, it is not possible to capture an ‘entire copy’ of the page since the user can endlessly reveal the contents of the page.”⁸⁹ Similarly, NMA noted that, due to the difficulties posed by “extensive or close-to-infinite scroll,” the Office should clarify that an applicant could meet the deposit requirement “as long as [the PDF] captures the masthead, URL identifier, and a defined minimum amount of the homepage (which in most cases will encompass all of it), including representative updates from the previous deposit copy.”⁹⁰

After considering these comments, the Office concludes that the requested modification to the proposed rule is reasonable and supports the overall goal of this group registration option. Accordingly, the final rule includes an alternative to the “complete copy of the home page” requirement where submitting a complete copy is not feasible due to the size or continuous nature of the home page. In such circumstances, applicants may “submit the first 25 pages of the home page that demonstrates updates from the previous deposit copy.” This portion of the rule is designed to decrease the burden on applicants that wish to utilize this group registration option, but are unable to satisfy the “complete copy” deposit requirement. The Office believes that this modification will facilitate registration, while also ensuring that the deposit provided is sufficient to identify the work and the copyrightable authorship covered by the registration. Applicants utilizing this provision are advised that any deposit should only include updates within the time period covered by the application. In the event that an applicant includes updates outside the time period, they would be considered previously published material, and would not be covered by the registration. Additionally, as stated in the NPRM, if a copyright owner is required to prove to a court or an alleged infringer “the specific contents of a website at any particular point in time, it will need to preserve and maintain its own copy of the site and

rely on its own recordkeeping to provide such proof.”⁹¹

2. Site Maps

NWU, NPPA, and NASW disagreed that a home page would constitute sufficient identifying material for registration.⁹² They asserted that “requiring deposit of PDFs of images of the home page is disconnected from the reality that updates aren’t necessarily visible on the ‘home page’ of a website.”⁹³ While “[u]pdates appear on the home pages of some—but far from all—newspaper publishers’ websites,” the home pages of other websites, such as self-published or references websites, are “mostly or entirely static,” with updates occurring on other “inside” pages that are not indexed or referenced on the home page.⁹⁴ Instead, NWU, NPPA, and NASW suggested that the Office accept a “sitemap page or set of sitemap pages,” “as the way to indicate which pages of a site have most recently been added or modified, and when.”⁹⁵ Sitemaps, they alleged, “are structured, standardized, machine-readable, and human-readable” and “all updates in a given period can be identified by a single sitemap or set of sitemaps,” which the Office could “use[] immediately.”⁹⁶

The Office declines to permit applicants to submit a sitemap page or a set of sitemap pages as identifying material for several reasons. First, it is not clear that sitemaps themselves provide information that would allow an examiner to determine whether each collective work within the group application contains sufficient creative selection, coordination, or arrangement.⁹⁷ Second, sitemaps do not satisfy the public notice function that deposits serve, as they do not display

the work requested for registration and are not sufficient to identify the updates made to the websites.⁹⁸ As explained in the NPRM, any deposit requirement must “satisfy the public notice function of capturing, and making available for public inspection, a deposit that should be sufficient to identify” the work covered by the application.⁹⁹ Lastly, accepting sitemap deposits would likely not aid in efficiency as suggested.¹⁰⁰ If an examiner receives a sitemap, they would likely need to correspond with the applicant to determine what exactly the application covers. For these reasons, the Office declines to modify the final rule to include sitemaps.

3. Additional Deposit Suggestions

Commenters also suggested that the Office accept deposits comprised of annotated Portable Document Formats (“PDFs”)¹⁰¹ or PDF deposits of apps.¹⁰² Specifically, one commenter encouraged the Office to consider accepting annotated PDFs of a single web page, where “[a]nnotations could circle content that is not included in registration, such as licensed content as compared to original news organization content” or “content already registered.”¹⁰³ Other commenters, including Copyright Alliance, NMA, and the Authors Guild, proposed that the Office should accept PDFs that “contain a complete copy of the home page of . . . mobile application[s].”¹⁰⁴

⁹⁸ See H.R. Rep. No. 94–1476, at 153 (1976), reprinted in 1976 U.S.C.A.N. 5659, 5769 (“As a general rule the deposit of more than a tear sheet or similar fraction of a collective work is needed to identify the contribution properly and to show the form in which it was published.”).

⁹⁹ 89 FR at 316.

¹⁰⁰ See NWU, NPPA, & NASW Comment at 20 (suggesting that sitemaps “could be used immediately in manual Copyright Office work flow but would also lend themselves to efficiencies through automated parsing”).

¹⁰¹ Erik Gottlieb Comment.

¹⁰² Copyright All. Comment at 6; NMA Comment at 10; The Authors Guild Comment at 2. See also Letter from Ass’n of Am. Publishers et al. to Suzanne Wilson, Gen. Counsel and Assoc. Register of Copyrights at 1 & App. at 2 (Apr. 4, 2024) (proposing the Office “include[e] mobile app content in the scope of the rule”). The Office also received a comment from Port. Prerogative Club, suggesting that the Office “evaluate whether native [version control systems (“VCS”)] files would satisfy [the Office’s] internal requirements for deposit copies.” Port. Prerogative Club Comment at 2. The Office currently does not accept this file format, but will revisit file formats as part of its ongoing work in developing the Enterprise Copyright System.

¹⁰³ Erik Gottlieb Comment.

¹⁰⁴ NMA Comment at App. at 16 (proposing regulatory language). See Copyright All. Comment at 6; NMA Comment at 10; The Authors Guild Comment at 2. See also Letter from Ass’n of Am. Publishers et al. to Suzanne Wilson, Gen. Counsel and Assoc. Register of Copyrights at 1 & App. at 2

⁸⁸ *Id.*

⁸⁹ Copyright All. Comment at 10–11.

⁹⁰ NMA Comment at 11.

⁹¹ 89 FR at 316.

⁹² NWU, NPPA, & NASW Comment at 17–20.

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Id.*; see also *id.* at 20 (proposing “submission of ‘a file or set of files linked from a master file listing in structured form the text files on the site added or modified during the time period covered by the application, including the URL and the date each file was added to the site or most recently modified’”).

⁹⁶ *Id.* at 17, 20. NWU, NPPA, and NASW asserted that “the ‘sitemap.xml’ standard has been widely accepted and adopted by website publishers, web publishing platforms, and developers of content management systems (CMSs).” *Id.* at 17–18.

⁹⁷ See 17 U.S.C. 410(a); *Compendium (Third)* sec. 204.3 (“[D]eposit copy(ies) should be clear and should contain all the authorship that the applicant intends to register.”). This finding is bolstered by the examples cited in NWU, NPPA, and NASW’s comment, which do not provide any information that would allow the examiner to determine any copyrightability of the collective work. See NWU, NPPA, & NASW Comment at 18 nn.19–22; *id.* at 19 nn.23–26.

They discussed the ease with which applicants could submit app PDFs¹⁰⁵ and how PDFs address record-keeping concerns and “concerns over whether the collective works stem from the same source.”¹⁰⁶ Copyright Alliance and NMA also suggested that the absence of a uniform resource locator (“URL”) from app PDFs, a requirement of the proposed rule, is immaterial because apps “generally prominently feature the logo or other visible identifier of the publication in question” and news content on an app is “organized and contained,” similar to a website.¹⁰⁷ NMA further recommended that because the USPTO has “long accepted” app screenshots for trademark specimens, subject to certain requirements, the Office should adopt similar standards.¹⁰⁸

The Office declines to permit parties to submit annotated PDFs of a single web page. As discussed above, each update will be registered as a collective work. For that reason, there is no need to identify component works that are not owned by the claimant or component works that have been previously registered, because as a general rule, a registration for a collective work does not cover this type of preexisting material.

The Office also declines to accept PDF deposits of apps to represent a news website. Initially, it is unclear whether the selection, coordination, and/or arrangement of material encompassed within the PDFs would be identical to the selection, coordination, and/or arrangement of a website’s home page, regardless of whether the same content is present on both.¹⁰⁹ Further, the Office continues to believe that the rule’s deposit regulations offer flexibility, while still satisfying the public notice function of deposits. The regulation will permit applicants to submit a complete copy of the website’s home page, and when that is not feasible due to the size or continuous nature of the home page,

applicants may submit the first 25 pages of the home page demonstrating updates from the previous deposit copy.

4. Other Comments

Commenters made additional suggestions and remarks on the proposed rule’s deposit requirements and the Office’s deposit requirements generally. With respect to the Office’s modernization efforts, ABA–IPL suggested that the Office consider generally expanding the “format of deposit copies accepted” and regularly reviewing and updating registration regulations.¹¹⁰ ABA–IPL stated that the Office should accept deposits in .xml format for regularly updated news content, such as content covered under the proposed rule, “as [.xml] and similar formats are widely used in digital content creation and management.”¹¹¹ The University of Michigan Library (“UM–Library”) expressed concerns with the proposed regulations regarding fixation and preservation.¹¹² They asserted that the proposed deposit requirements are not “sufficiently fixed for copyright purposes” and that if deposit “materials are not collected and preserved—even as facsimiles or through emulation—then as a practical matter there will be a huge gap in the possibilities for research, scholarship, and understanding.”

The Office is sympathetic to commenters’ desires to expand the file formats accepted for deposit purposes generally, including regularly updated news content. As stated above and in the NPRM, the current registration system only accepts certain file types.¹¹³ The Office anticipates revisiting its acceptable file formats in connection with ongoing improvements to its technology systems. Until then, the Office continues to actively engage in research about the suitability of other file formats.¹¹⁴

The Office appreciates the fixation and preservation concerns about the proposed deposit requirements, codified in the final rule. It continues to believe, however, that the deposit requirements are sufficient. As stated above and in the NPRM, the Copyright Act imbues the Register with broad authority to accept

identifying material in lieu of complete copies or phonorecords¹¹⁵ where such copies or phonorecords are “bulky, unwieldy, easily broken, or otherwise impractical to [serve] . . . as records identifying the work[s] registered.”¹¹⁶ This provision, and its legislative history, give the Register flexibility in determining the deposit requirements when identifying material is involved, and the Office has used this authority in the past. Within this rulemaking, the Office believes the proposed deposit requirements are appropriate, and less burdensome than general deposit requirements for websites.¹¹⁷ As the Office discussed in the NPRM, the proposed deposit requirements satisfy the public notice function and still require that deposits sufficiently “identify some of the updates” made to the website.¹¹⁸ Any fixation concerns may be alleviated by the fact that the proposed regulations are merely registration deposit requirements. They do not relieve a registrant from complying with other legal obligations, such as the obligation to maintain and preserve copies of a website, including its content, in the context of an infringement claim.¹¹⁹

E. Application Requirements

The NPRM explained that the Office planned to use one of its existing group registration application forms to process these claims. Specifically, it said applicants would be required to submit their claims through the current electronic registration system using the application designated for a group of newspaper issues. None of the commenters objected to this proposal.

After consulting with the Library of Congress’s Office of the Chief Information Officer, the Office determined that it would be feasible to create a separate application for news website claims that will be cloned from the corresponding application that is used for group newspaper claims. This should simplify the registration process for both applicants and Office staff by preventing potential confusion between claims involving newspaper issues and claims involving updates to a news website. The cloned application will include the same technical specifications and system validations that appear in the group newspaper

(Apr. 4, 2024) (proposing the Office “includ[e] mobile app content in the scope of the rule”).

¹⁰⁵ Copyright All. Comment at 6; The Authors Guild Comment at 2.

¹⁰⁶ Copyright All. Comment at 6.

¹⁰⁷ *Id.* (noting that “news content on an app is already organized and contained in an interconnected and uniform ecosystem, much like a website”); NMA Comment at 10 (stating that app screenshots serve the same “identifying function as URLs”).

¹⁰⁸ NMA Comment at 10.

¹⁰⁹ See 89 FR at 313 (“[T]he organization and arrangement show in a PDF package may vary depending on whether it depicts the website as it would appear on a desktop computer, a mobile phone or other electronic device.”). *But cf.* ABA–IPL Comment at 4 (“The Section is aware of no substantive difference between what is published at a URL and what is published on an app.”).

¹¹⁰ ABA–IPL Comment at 4–5.

¹¹¹ *Id.* at 4.

¹¹² UM–Library Comment at 1–2.

¹¹³ 89 FR at 313; see also *eCO Acceptable File Types*, U.S. Copyright Office, <https://www.copyright.gov/eco/help-file-types.html> (last visited July 5, 2024) (listing acceptable file formats).

¹¹⁴ For example, the Office is researching the web archive file format (“WARC”) that is utilized by the Library of Congress’ Web Archiving Team. Research has shown that there are many publicly available options for adapting websites in the WARC format, including through internet browser extensions.

¹¹⁵ 17 U.S.C. 408(c)(1); see also 89 FR at 311 (discussing identifying material).

¹¹⁶ H.R. Rep. No. 94–1496, at 154 (1976), *reprinted in* 1976 U.S.C.C.A.N. 5659, 5770.

¹¹⁷ See 89 FR at 313, 316 (discussing how depositing complete copies of websites poses difficulties for applicants and the Office).

¹¹⁸ *Id.* at 316.

¹¹⁹ *Id.*

form. The final rule has been modified to reflect this change. Information and instructions on how to submit these claims will be provided in the application itself and on a dedicated page on the Office's website.

F. Conclusion

Based on requests from affected parties for the expeditious implementation of the rule ¹²⁰ and the absence of arguments supporting a delay, the Office finds that good cause exists to issue these regulations as a final rule with an immediate effective date. Commenters have presented a record supporting "the demonstrable urgency of the conditions [the rule is] designed to correct." ¹²¹ Finally, the registration option authorized by the

final rule will be available to registrants at or near the rule's publication date.

List of Subjects

37 CFR Part 201

Copyright, General provisions.

37 CFR Part 202

Copyright, Copyright claims, preregistration and registration.

Final Regulations

For the reasons set forth in the preamble, the Copyright Office amends 37 CFR parts 201 and 202 as follows:

PART 201—GENERAL PROVISIONS

■ 1. The authority citation for part 201 continues to read as follows:

TABLE 1 TO PARAGRAPH (c)

Registration, recordation, and related services						Fees (\$)
*	*	*	*	*	*	
(12)	Registration of a group of updates to a news website					95
*	*	*	*	*	*	*

* * * * *

PART 202—PREREGISTRATION AND REGISTRATION OF CLAIMS TO COPYRIGHT

■ 3. The authority citation for part 202 continues to read as follows:

Authority: 17 U.S.C. 408(f), 702.

■ 4. Amend § 202.4 by adding paragraph (m) and revising paragraph (r) to read as follows:

§ 202.4 Group registration.

* * * * *

(m) *Group registration of updates to a news website.* Pursuant to the authority granted by 17 U.S.C. 408(c)(1), the Register of Copyrights has determined that a group of updates to a news website may be registered with one application, the required deposit, and the filing fee required by § 201.3 of this chapter, with each update being registered as a collective work, if the following conditions are met:

(1) *Definitions.* For the purposes of this paragraph (m):

(i) *News website* means a website that is designed to be a primary source of written information on current events, either local, national, or international in scope, that contains a broad range of

news on all subjects and activities and is not limited to any specific subject matter.

(ii) *Website* means a web page or set of interconnected web pages that are accessed using a uniform resource locator ("URL") organized under a particular domain name.

(2) *Requirements for collective works.* Each update to the website must be a collective work, and the claim must be limited to the collective work.

(3) *Author and claimant.* Each collective work in the group must be a work made for hire, and the author and claimant for each collective work must be the same person or organization.

(4) *Updates must be from one news website; time period covered.* Each collective work in the group must be published on the same news website under the same URL, and they must be published within the same calendar month. The applicant must identify the earliest and latest date that the collective works were published.

(5) *Application.* The applicant must complete and submit the online application designated for a group of updates to a news website. The application may be submitted by any of the parties listed in § 202.3(c)(1).

Authority: 17 U.S.C. 702.

Section 201.10 also issued under 17 U.S.C. 304.

■ 2. In § 201.3, amend table 1 to paragraph (c) by redesignating paragraphs (c)(12) through (c)(29) as (c)(13) through (c)(30), respectively, and adding a new paragraph (c)(12) to read as follows:

§ 201.3 Fees for registration, recordation, and related services, special services, and services performed by the Licensing Section and the Copyright Claims Board.

* * * * *

(c) * * *

(6) *Deposit.* (i) For each collective work within the group, the applicant must submit identifying material from the news website. For these purposes "identifying material" shall mean separate Portable Document Format (PDF) files that each contain a complete copy of the home page of the website. In case a complete copy is technically unfeasible due to the size or continuous nature of the home page, the applicant may submit the first 25 pages of the home page that demonstrates updates from the previous deposit copy. Each PDF must show how the home page appeared at a specific point during each day of the calendar month when new updates were published on the website.

(ii) The identifying material must demonstrate that the home page contains sufficient selection, coordination, and arrangement authorship to be registered as a collective work. If the home page does not demonstrate sufficient compilation authorship, the deposit should include as many additional pages as necessary to demonstrate that the updates to the news website can be registered as a collective work.

(iii) The identifying material must be submitted through the electronic registration system, and all of the

¹²⁰ See Letter from Ass'n of Am. Publishers et al. to Suzanne Wilson, Gen. Counsel and Assoc.

Register of Copyrights (Apr. 4, 2024); Copyright All. Comment at 11.

¹²¹ H.R. Rep. No. 79–1980, at 260 (1946). See 5 U.S.C. 553(d) (30-day notice not required where agency finds good cause).

identifying material that was published on a particular date must be contained in the same electronic file. The files must be submitted in PDF format, they must be assembled in an orderly form, and each file must be uploaded to the electronic registration system as an individual electronic file (*i.e.*, not .zip files). The file size for each uploaded file must not exceed 500 megabytes, but files may be compressed to comply with this requirement.

(7) *Special relief.* In an exceptional case, the Copyright Office may waive the online filing requirement set forth in paragraph (m)(5) of this section or may grant special relief from the deposit requirement under § 202.20(d) of this chapter, subject to such conditions as the Associate Register of Copyrights and Director of the Office of Registration Policy and Practice may impose on the applicant.

* * * * *

(r) *The scope of a group registration.* When the Office issues a group registration under paragraph (d), (e), or (f) of this section, the registration covers each issue in the group and each issue is registered as a separate work or a separate collective work (as the case may be). When the Office issues a group registration under paragraphs (c), (g), (h), (i), (j), (k), or (o) of this section, the registration covers each work in the group and each work is registered as a separate work. When the Office issues a group registration under paragraph (m) of this section, the registration covers each update in the group, and each update is registered as a separate collective work. For purposes of registration, the group as a whole is not considered a compilation, a collective work, or a derivative work under section 101, 103(b), or 504(c)(1) of title 17 of the United States Code.

Shira Perlmuter,

Register of Copyrights and Director of the U.S. Copyright Office.

Approved by:

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2024–15880 Filed 7–19–24; 8:45 am]

BILLING CODE 1410–30–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2023–0441; FRL–11837–02–R8]

Air Plan Approval; Colorado; 2017 Base Year Inventory and Emission Statement Rule Marginal Nonattainment Requirements, Revisions to Regulation 3

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving elements of state implementation plan (SIP) revisions submitted by the State of Colorado on July 27, 2020, March 22, 2021, and June 26, 2023, to meet certain Clean Air Act (CAA) requirements related to the Denver Metro/North Front Range (DMNFR) area's classification as Marginal nonattainment for the 2015 8-hour ozone national ambient air quality standards (NAAQS). The revisions contain a base year emissions inventory for the nonattainment area and certify that the State's existing Air Pollutant Emission Notice (APEN) program for stationary sources fulfills the CAA's emission statement rule requirement. The revisions also include a new requirement for annual certification of APEN reported emissions for certain stationary sources. Unrelated to Colorado's Marginal ozone nonattainment obligations, the EPA is also approving the State's revisions to Regulation Number 3 concerning an update to the date of incorporation by reference of global warming potentials used in the computation of the carbon dioxide equivalent for comparing emissions from various greenhouse gases (GHGs). The EPA is taking this action pursuant to the CAA.

DATES: This rule is effective on August 21, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2023–0441. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <https://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER**

INFORMATION CONTACT section for additional availability information.

FOR FURTHER INFORMATION CONTACT:

Matthew Lang, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD–IO, 1595 Wynkoop Street, Denver, Colorado 80202–1129, telephone number: (303) 312–6709, email address: lang.matthew@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document “we,” “us,” and “our” means the EPA.

I. Background

The background for this action is discussed in detail in our April 10, 2024 proposal (89 FR 25216). In that document we proposed to approve elements of Colorado's Marginal ozone nonattainment SIP submission, namely its 2017 base year emissions inventory and its certification that its APEN reporting program and the addition of an annual certification requirement meet the CAA's emission statement rule requirements. We found that these two SIP elements were prepared in accordance with the requirements of CAA sections 172(c)(3) and 182(a)(1) (for emissions inventories) and 182(a)(3)(B) (for emission statement rules). We also proposed to approve revisions to Regulation Number 3, including incorporation of updated global warming potentials and the removal of outdated language. The EPA is finalizing its proposed approval of the 2017 base year emissions inventory, emission statement rule certification, and revisions to Regulation Number 3 that were submitted by the State of Colorado.

II. Response to Comments

EPA held a 30-day comment period on the proposed rulemaking for this action, beginning on April 10, 2024, and ending on May 10, 2024. No comments were received.

III. Final Action

For the reasons described in our April 10, 2024 notice of proposed rulemaking at 89 FR 25216, we are taking final action to approve elements of Colorado's July 27, 2020, March 22, 2021, and June 26, 2023 SIP Submittals. Specifically, we are approving Colorado's 2017 base year emissions inventory under CAA sections 172(c)(3) and 182(a)(1). We are approving Colorado's certification of its APEN reporting program (July 27, 2020 SIP Submittal) and the addition of the annual certification requirement in section II.A.3. to Regulation Number 3, Part A (June 26, 2023 SIP Submittal) as meeting the emission statement rule requirements of CAA section

182(a)(3)(B). We are also approving certain revisions to Regulation Number 3, Part A, specifically to the date of incorporation by reference of global warming potentials in sections 1.B.10 and 1.B.44.b.(i) (March 22, 2021 and June 26, 2023 SIP Submittals) and to the computation of the mass of carbon dioxide equivalent in section 1.B.44.b.(i) (June 26, 2023 SIP Submittal).

IV. Incorporation by Reference

In this document, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of Regulation Number 3, Part A as described in sections I. and III. of this preamble and set forth below in the amendments to 40 CFR part 52. The EPA has made, and will continue to make, these materials generally available through <https://www.regulations.gov> and at the EPA Region 8 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by the EPA for inclusion in the SIP, have been incorporated by reference by the EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.¹

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve State choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

- Does not contain any unfunded mandate or significantly or uniquely affect small governments, described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);

- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have Tribal implications and will not impose substantial direct costs on Tribal governments or preempt Tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address "disproportionately high and adverse human health or environmental effects" of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. EPA defines environmental justice (EJ) as "the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies." EPA further defines the term fair treatment to mean that "no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies."

Colorado did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and

applicable implementing regulations neither prohibit nor require such an evaluation. EPA did not perform an EJ analysis and did not consider EJ in this action. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of Executive Order 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 20, 2024. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Greenhouse gases, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: July 16 2024.

KC Becker,

Regional Administrator, Region 8.

For the reasons set forth in the preamble, 40 CFR part 52 is amended as follows:

¹ 62 FR 27968 (May 22, 1997).

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:
Authority: 42 U.S.C. 7401 *et seq.*

Subpart G—Colorado

■ 2. In § 52.320:

- a. In the table in paragraph (c):
 - i. Revise the entries “I. Applicability” and “II. Air Pollution Emission Notice (APEN) Requirements” under the center heading “5 CCR 1001–05, Regulation Number 3, Part A, Concerning General Provisions Applicable to Reporting and Permitting”.
 - b. In the table in paragraph (e):
 - i. Add the entry “Ozone (8-hour, 2015) DMNFR 2017 Base Year

Inventory” after the entry “Reasonably Available Control Technology for the 2008 8-Hour Ozone National Ambient Air Quality Standard (NAAQS) Serious State Implementation Plan (RACT SIP)”.
The revisions and addition read as follows:

§ 52.320 Identification of plan.
* * * * *
(c) * * *

Title	State effective date	EPA effective date	Final rule citation/date	Comments
* * *				
5 CCR 1001–05, Regulation Number 3, Part A, Concerning General Provisions Applicable to Reporting and Permitting				
I. Applicability	2/14/2023	[August 21, 2024]	[insert Federal Register cita- tion], 7/22/2024.	
II. Air Pollution Emission Notice (APEN) Requirements.	2/14/2023	[August 21, 2024]	[insert Federal Register cita- tion], 7/22/2024.	
* * *				
(e) * * *				
Title	State effective date	EPA effective date	Final rule citation/date	Comments
* * *				
Maintenance and Attainment Plan Elements				
* * *				
Denver Metropolitan Area				
* * *				
Ozone (8-hour, 2015) DMNFR 2017 Base Year Inventory.	2/14/2023	[August 21, 2024]	[insert Federal Register cita- tion], 7/22/2024.	
* * *				

[FR Doc. 2024–15953 Filed 7–19–24; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
50 CFR Part 622
[Docket No. 120404257–3325–02; RTID 0648–XE112]
Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Re-Opening of Golden Tilefish for Commercial Harvest With Bottom Longline Gear in the South Atlantic
AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; re-opening.
SUMMARY: NMFS announces the re-opening of the commercial longline component of golden tilefish in South Atlantic Federal waters. The most recent landings data indicate that the commercial annual catch limit (ACL) of golden tilefish caught by bottom longline gear for the 2024 fishing year has not yet been reached. Therefore, NMFS re-opens the commercial longline component to harvest golden tilefish in South Atlantic Federal waters for 8 days. The purpose of this temporary rule is to allow for the commercial longline ACL for golden tilefish to be harvested while minimizing the risk of exceeding the commercial ACL.

DATES: This temporary rule is effective from July 24, 2024, through July 31, 2024. The commercial longline component is closed from August 1, 2024, through the end of 2024.

FOR FURTHER INFORMATION CONTACT:

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

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

The commercial sector for golden tilefish comprises the longline and hook-and-line components. The commercial golden tilefish ACL is allocated 75 percent to the longline component and 25 percent to the hook-and-line component. The total commercial ACL in 2024, which is equivalent to the total commercial quota, is 433,216 pounds (lb) or 196,503 kilograms (kg) in gutted weight. The longline component quota for 2024 is 324,912 lb (147,378 kg) in gutted weight [50 CFR 622.190(a)(2)(iii)(B)].

On June 8, 2024, NMFS closed the commercial longline component for golden tilefish for the rest of the 2024 fishing year when NMFS previously determined that the commercial quota for the golden tilefish longline component in the South Atlantic would be reached, as required under 50 CFR 622.193(a)(1)(ii) (89 FR 48338, June 6, 2024). After the longline component quota is reached or is projected to be reached, golden tilefish may not be commercially fished or possessed by a vessel with a golden tilefish longline endorsement. However, a more recent estimation of golden tilefish landings harvested by longline gear indicates that the commercial longline ACL for golden tilefish has not been met.

Consistent with regulations at 50 CFR 622.8(c), NMFS temporarily re-opens the commercial longline component for golden tilefish as specified in the **DATES** section. The commercial longline component will remain open for 8 days to allow for the commercial longline ACL to be reached. NMFS has determined that this re-opening will allow an additional opportunity to commercially harvest the golden tilefish longline component quota while

minimizing the risk of exceeding the commercial ACL. The commercial longline component will again be closed from August 1, 2024, through the end of 2024.

The sale or purchase of longline-caught golden tilefish taken from South Atlantic Federal waters is prohibited during the commercial longline closure. The operator of a vessel with a valid Federal commercial vessel permit for South Atlantic snapper-grouper and a valid commercial longline endorsement for golden tilefish having golden tilefish on board must have landed and bartered, traded, or sold such golden tilefish before the closure. The prohibition on sale or purchase does not apply to the sale or purchase of longline-caught golden tilefish that were harvested, landed ashore, and sold before August 1, 2024, and were held in cold storage by a dealer or processor.

Also during the commercial longline closure, golden tilefish may still be commercially harvested using hook-and-line gear while the commercial hook-and-line component is open. However, a vessel with a golden tilefish longline endorsement is not eligible to fish for or possess golden tilefish using hook-and-line gear under the hook-and-line commercial trip limit, as specified in 50 CFR 622.191(a)(2)(ii). The operator of a vessel issued a Federal commercial vessel permit for South Atlantic snapper-grouper and a commercial longline endorsement for golden tilefish with golden tilefish on board must have landed and bartered, traded, or sold such golden tilefish before the commercial longline closure.

NMFS closed the recreational harvest of golden tilefish in the South Atlantic on March 1, 2024, because those landings reached its ACL for the 2024 fishing year (89 FR 14415, February 27, 2024). Therefore, there is no allowable harvest of golden tilefish under the recreational bag and possession limits, and all harvest or possession of golden tilefish in or from South Atlantic Federal waters is prohibited by a person on a vessel with a golden tilefish longline endorsement. Additionally, the recreational bag and possession limits and the sale and purchase provisions of the commercial closure apply to a person on a vessel with a golden tilefish longline endorsement in state or Federal waters, as specified in 50 CFR 622.190(c)(1).

The 2025 fishing season for the commercial harvest of South Atlantic golden tilefish with bottom longline gear opens again on January 15, 2025 [50 CFR 622.183(b)(11)].

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 622.8(c), 622.190(a)(2)(iii), and 622.193(a)(1)(ii), issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment is unnecessary. Such procedure is unnecessary, because the regulations associated with the commercial quota for the longline component of golden tilefish and a re-opening to provide an opportunity for the quota to be harvested have already been subject to notice and public comment, and all that remains is to notify the public of the commercial longline component re-opening.

For the reasons just stated, there is also good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

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

Dated: July 17, 2024.

Lindsay Fullenkamp,

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

[FR Doc. 2024–16052 Filed 7–17–24; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 240715–0194]

RIN 0648–BM82

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Greater Amberjack and Red Snapper Management Measures

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

ACTION: Final rule.

SUMMARY: NMFS issues regulations to implement management measures described in a framework action under the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP), as prepared by the Gulf of Mexico Fishery Management Council (Council). This final rule modifies the Gulf of Mexico (Gulf) greater amberjack commercial trip limit and the

recreational fixed closed season. Additionally, this final rule clarifies the Gulf red snapper charter vessel/headboat (for-hire) component quota and annual catch target (ACT) regulations. The purposes of this final rule are to extend the commercial and recreational fishing seasons for Gulf greater amberjack while continuing to prevent overfishing and rebuild the stock; and clarify that a person on a vessel issued a Gulf for-hire permit at any time during the fishing year can only harvest red snapper if the vessel is operating as a for-hire vessel.

DATES: This final rule is effective August 21, 2024, except for amendatory instruction 2 (revising § 622.34(c)), which is effective August 1, 2024.

ADDRESSES: Electronic copies of the framework action, which includes an environmental assessment, a fishery impact statement, an Initial Regulatory Flexibility analysis (IRFA), and a regulatory impact review, may be obtained from the Southeast Regional Office website at <https://www.fisheries.noaa.gov/action/framework-action-modify-greater-amberjack-recreational-fixed-closed-season-and-commercial>.

FOR FURTHER INFORMATION CONTACT: Dan Luers, telephone: 727–824–5305, or email: daniel.luers@noaa.gov.

SUPPLEMENTARY INFORMATION: The Gulf reef fish fishery, which includes greater amberjack, is managed under the FMP. The FMP was prepared by the Council, approved by the Secretary of Commerce, and is implemented by NMFS through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

Background

The Magnuson-Stevens Act requires NMFS and the regional fishery management councils to prevent overfishing and achieve, on a continuing basis, the optimum yield (OY) from federally managed fish stocks. These mandates are intended to ensure fishery resources are managed for the greatest overall benefit to the Nation, particularly with respect to providing food production and recreational opportunities, and to protect marine ecosystems.

On May 15, 2024, NMFS published a proposed rule for the framework action and requested public comment (89 FR 42413).

The greater amberjack stock in the Gulf has been overfished since 2001. To help rebuild the stock, NMFS has implemented several modifications to the rebuilding plan, including changes

to the commercial and recreational catch levels, and changes to management measures intended to constrain harvest and extend the commercial and recreational seasons. NMFS recently implemented Amendment 54 to the FMP, which modified the Gulf greater amberjack rebuilding time period and substantially reduced the sector-specific annual catch limits (ACLs) and ACTs (88 FR 39193, June 15, 2023). Implementation of that final rule and Amendment 54 is expected to result in the stock rebuilding by 2027.

In the Gulf, greater amberjack is not a common target species for the reef fish commercial sector, with the majority of trips landing less than 500 lb (227 kg), gutted weight (520 lb (236 kg), round weight) of the species. As described at 50 CFR 622.41(a)(1), when commercial landings for greater amberjack reach or are projected to reach the commercial ACT, which is codified as the commercial quota, NMFS closes the commercial sector for the remainder of the fishing year. Any overage of the commercial ACL results in both a reduction of the commercial ACT and the commercial ACL in the following fishing year by the amount of the commercial ACL overage.

In 2020, NMFS implemented a framework action that set the current Gulf greater amberjack commercial trip limit to 1,000 lb (454 kg), gutted weight (1,040 lb (472 kg), round weight) (85 FR 20611, April 14, 2020). That framework action and final rule also included a reduction in the trip limit to 250 lb (113 kg), gutted weight (260 lb (118 kg), round weight) when 75 percent of the commercial quota was reached. As described in the current framework action, under the current trip limit, the trip limit reduction was projected to occur in February with a season closure occurring in June.

In the current framework action, the Council is recommending that NMFS further reduce the commercial trip limit due to the substantial catch limit reductions implemented by Amendment 54 to lengthen the commercial fishing season. The framework action would reduce the commercial trip limit for Gulf greater amberjack to seven fish, which is approximately equal to 210 lb (95 kg), gutted weight (218 lb (99 kg), round weight). This reduction in the trip limit is expected to extend the commercial season until September unless an overage of the commercial ACL occurs in the prior fishing year, which then would require a reduction in the commercial ACL and ACT and result in a reduction in the season length. NMFS notes that in the 2023

fishing year, the commercial ACL was exceeded by 35,280 lb (16,003 kg), round weight, resulting in a reduction of the commercial ACL and ACT for the 2024 fishing year (see 88 FR 80995, November 21, 2023). For the 2024 fishing year, NMFS projected that the adjusted commercial ACT would be met on June 30, 2024, and so NMFS prohibited the commercial harvest and possession of Gulf greater amberjack on June 30, 2024 (89 FR 50529, June 14, 2024).

As described in the framework action, this reduction of the trip limit to seven fish is expected to eliminate the remaining direct commercial harvest trips for greater amberjack. The Council recognized that the greater amberjack stock is overfished and has not rebuilt as expected. Thus, the Council determined that a more cautious approach was warranted and chose to recommend reducing the commercial trip limit.

At its October 2023 meeting, the Council discussed the impact of the required reduction to the 2024 commercial catch limits as a result of landings exceeding the ACL in 2023. The Council expressed concern about constraining landings to the reduced catch limits under the current trip limit when the commercial season opened in January 2024, which could have potentially resulted in another commercial overage in 2024 and further reduced the catch limits for 2025. Since the reduced commercial trip limit in this final rule would not be effective until later in 2024, the Council requested that NMFS implement an emergency action to reduce the commercial trip limit to seven fish. NMFS and the Council expected this lower trip limit to benefit the greater amberjack stock by increasing the duration of the commercial open season, which is expected to result in fewer regulatory discards (*i.e.*, discards required after the quota has been reached). On December 18, 2023, a final temporary rule for emergency action for Gulf greater amberjack was published in the **Federal Register** and was effective through June 15, 2024 (88 FR 87365).

The Council decided to specify the commercial trip limit in numbers of fish instead of pounds of fish based in part on recommendations from its Reef Fish Advisory Panel (AP) and the Law Enforcement Technical Committee on their preferred way to specify the trip limit. A trip limit in numbers of fish is more enforceable and reduces the chance of commercial fishermen exceeding the trip limit.

The Council decided that the reduced trip limit, which would extend the

commercial fishing season as long as practicable, was a more desirable solution. The new commercial trip limit is expected to allow for as many fishing days as practicable while reducing the chance of exceeding the reduced lower catch limits implemented under the final rule for Amendment 54, and addresses needs of the rebuilding plan.

In the framework action, the Council also decided to recommend modifying the Gulf greater amberjack recreational fixed closed season in order to extend the recreational fishing season and to protect greater amberjack spawning. As described in the framework action, under the current recreational season structure which opens annually on August 1, projections indicate that the season would only last approximately 3 weeks. For the recreational sector, when recreational landings for greater amberjack reach or are projected to reach the recreational ACT, NMFS closes the sector for the remainder of the fishing year and any overage of the recreational ACL is reduced from the following fishing year's recreational ACT and ACL (50 CFR 622.41(a)(2)). NMFS notes that when the Gulf greater amberjack recreational sector is closed, the species remains a popular catch and release fish.

In 2012, the final rule implementing Amendment 35 established a Gulf greater amberjack recreational fixed closed season of June 1 to July 31 to restrict harvest during times of peak recreational fishing. In 2017, NMFS implemented a framework action under the FMP to set the Gulf greater amberjack recreational fixed closed season to January 1 through June 31 to protect greater amberjack spawning and allow the Council additional time to consider further modify the fixed closed season (82 FR 61485, December 28, 2017). In 2018, NMFS implemented a framework action under the FMP that revised the recreational fishing year from the calendar year (January 1 through December 31) to be from August 1 through July 31, and set the current Gulf greater amberjack recreational fixed closed season to be from November 1 through April 30 and from June 1 through July 31 (83 FR 13426, March 29, 2018). This means that until the recreational ACT is reached or projected to be reached, recreational harvest would be allowed during the months of August through October, and during the month of May. The current fixed closed season prohibits harvest during the peak greater amberjack spawning period in the majority of the Gulf (*i.e.*, March and April) and allows for both a fall and spring recreational season if no in-season closure is required.

For the present action, the Council decided to recommend modifying the recreational fixed closed season in response to the substantial recreational catch limit reductions implemented through the final rule for Amendment 54 in order to lengthen the recreational fishing season and to protect the greater amberjack stock during all documented spawning periods in the Gulf (*i.e.*, March through June). This change to the recreational fixed closed season, from the current closures of January 1 through April 30, from June 1 through July 31, and from November 1 through December 31, each year, to new closures from January 1 through August 31, and from November 1 through December 31, each year, would eliminate the spring recreational season. The revised recreational closure would allow for protection of the stock during the entire spawning period in the Gulf.

As described in the framework action, this fixed closed season modification is projected to allow the recreational fishing season to be open for all of September and most of October (*i.e.*, projected to extend to October 26th) each year. However, if recreational effort were to shift as a result of the fixed closed season change, then it is possible a recreational closure may occur earlier. For the revised recreational fixed closed season, the Council determined that a more cautious approach for management was warranted in order to meet the rebuilding timeline.

Management Measures Contained in This Final Rule

This final rule revises the commercial trip limit and recreational fixed closed season for Gulf greater amberjack.

Commercial Trip Limit

The existing regulations set the commercial trip limit for Gulf greater amberjack at 1,000 lb (454 kg), gutted weight (1,040 lb (472 kg), round weight), with a reduction to 250 lb (113 kg), gutted weight (260 lb (118 kg), round weight) when 75 percent of the commercial quota has been reached. This final rule changes the commercial trip limit to seven fish. Once the commercial quota has been reached, the commercial sector will close and commercial harvest is prohibited (50 CFR 622.41(a)(1)(i)).

As described in the framework action, the trip limit reduction to seven fish (*i.e.*, approximately 210 lb (95 kg), gutted weight (218 lb (99 kg), round weight) is expected to extend the length of the commercial fishing season into September, which would not occur under the status quo commercial trip limit. While the commercial ACT has

been met for the 2024 season and an in-season closure began on June 30 (89 FR 50529, June 14, 2024), if the commercial ACL is not exceeded in 2024, an in-season closure under a seven fish trip limit is expected to occur in September of 2025.

In recommending this trip limit, the Council recognized that the Gulf greater amberjack stock is overfished and has not rebuilt as expected under the current and previous rebuilding plans. NMFS determined, in accordance with the Council's findings, that a more cautious approach for the commercial sector was warranted and chose to substantially reduce the commercial trip limit.

Recreational Fixed Closed Season

The current Gulf greater amberjack recreational fixed closed season is from January 1 through April 30, June 1 through July 31, and November 1 through December 31, each year. This final rule revises the closed season to January 1 through August 31, and November 1 through December 31, each year. This results in the recreational season being scheduled to be open from September 1 through October 31, each year. As described in the Classification of this final rule, NMFS has found good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in the effective date for changes to the Gulf greater amberjack recreational fixed closed season at 50 CFR 622.34(c). Based on the timing of the rulemaking for this final rule, this has been done to avoid the recreational season opening on August 1, 2024, and to instead open on September 1, 2024, consistent with the revisions in this final rule and the framework action. This will allow NMFS to evaluate landings from the May 2023 portion of the recreational season of the previous fishing year and determine if an adjustment would be needed to the recreational ACL and ACT in the next fishing year. NMFS notes that during the closure, the recreational bag and possession limit for greater amberjack in or from the Gulf exclusive economic zone (EEZ) is zero (50 CFR 622.34(c)).

Regulatory Language Contained in This Final Rule But Not Described in the Framework Action

In addition to the Gulf greater amberjack management measures in the framework action, this final rule clarifies language related to the Gulf red snapper Federal charter vessel/headboat (for-hire) component quota (50 CFR 622.39(a)(2)(i)(B)) and the Gulf red snapper Federal for-hire component ACT (50 CFR 622.41(q)(2)(iii)(B)). When Amendment 40 to the FMP was

implemented in 2015 and allocated the recreational ACL (quota) between the Federal for-hire and private angling components, the provisions referenced above specified that the Federal for-hire quota and ACT apply “to vessels that have been issued a valid Federal charter vessel/headboat permit for Gulf reef fish any time during the fishing year.” (80 FR 22422, April 22, 2015). This language was necessary to maintain the selected allocation between the components by allowing only those vessels issued the Federal for-hire permit during the fishing year to harvest red snapper under the for-hire component quota.

Subsequently, NMFS determined that it would be helpful to clarify these provisions to specify the restrictions on harvest and possession of red snapper when the for-hire season is closed by adding the following language: “A person aboard a vessel that has been issued a charter vessel/headboat permit for Gulf reef fish any time during the fishing year may not harvest or possess red snapper in or from the Gulf when the Federal charter vessel/headboat component is closed” (85 FR 6819, February 6, 2020; 88 FR 37475 June 8, 2023). In this final rule, and consistent with Amendment 40, NMFS adds additional clarifying language to specify the restrictions on harvest and possession of red snapper when the for-hire season is open. This language provides that when the Federal for-hire component is open, a person on board a vessel that has been issued a for-hire permit for Gulf reef fish at any time during the fishing year may harvest or possess red snapper in or from the Gulf only when the vessel is operating as a charter vessel or headboat.

Comments and Responses

NMFS received four comment submissions in response to the proposed rule for the framework action. Of the comments contained in these submissions, one expressed general support for the rule. One comment was generally against the proposed rule, but expressed support for the closure of the greater amberjack recreational season during red snapper season. One comment suggested that fishing seasons for greater amberjack and other Gulf reef fish species (e.g., red snapper and groupers) should overlap in order to reduce discards and decrease overall mortality of each of these reef fish species. The commenter also suggested reducing the greater amberjack recreational bag limit, which was beyond the scope of the proposed rule. The final comment did not support concurrent open recreational seasons for

Gulf reef fish species, since the timing of seasons could negatively impact recreational fishermen, especially the for-hire component. Specific comments related to the proposed rule and the framework action are summarized below and followed by NMFS’ respective responses. There have been no changes to the proposed rule as a result of public comment.

Comment 1: Recreational fishing seasons for greater amberjack and other Gulf reef fish species (e.g., red snapper, groupers) should overlap in order to reduce discards and decrease overall mortality of each of these reef fish species. Also, consideration should be given to establishing a combined recreational fishing season for all reef fish of 60 days or less.

Response: In the framework action, the Council recommended that the greater amberjack recreational fishing season open on September 1, instead of the current season where the sector is open in May and then again opens on August 1. Changing the recreational greater amberjack season start date to September 1 and removing the months of May and August from the open season is expected to increase the number of greater amberjack fishing days available to the recreational sector before the recreational ACT would be projected to be met. Also, modifying the fixed closed season as proposed would protect greater amberjack during spawning months and would allow fishing during a time when recreational effort is expected to be less than the previous open months of May and August.

A September 1 recreational season opening date provides overlap with the recreational fishing season opening date for Gulf gag, which is also September 1, as suggested by this comment. This overlap could result in fewer greater amberjack discards when targeting gag. While a concurrent fishing season for all reef fish could reduce discards, a goal of the Council is to maximize recreational fishing opportunities throughout the year while constraining harvest to allowable catch levels. This often requires different management measures such as fishing seasons for different reef fish species due to different stock statuses, spawning periods, and seasonal distributions. A single concurrent recreational fishing season for all reef fish species is not practical to help achieve OY within the fishery and maintain recreational fishing opportunities throughout the Gulf.

Classification

Pursuant to section 304(b)(3) of the Magnuson-Stevens Act, the NMFS

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

This final rule has been determined to be not significant for purposes of Executive Order 12866. The Magnuson-Stevens Act provides the legal basis for this final rule. No duplicative, overlapping, or conflicting Federal rules have been identified.

A final regulatory flexibility analysis (FRFA) was prepared for this rule. The FRFA incorporates the IRFA, a summary of any significant issues raised by public comment in response to the IRFA, any applicable NMFS responses to those comments, and a summary of the analyses completed to support the action. NMFS did not receive any public comments with respect to the IRFA. A copy of the full analysis is available from NMFS (see **ADDRESSES**). A summary of the FRFA follows.

The objectives of this final rule are to maintain commercial and recreational access to the greater amberjack component of the Gulf reef fish fishery, given the substantial ACL decreases under the Gulf greater amberjack rebuilding plan in Amendment 54, and ensure anglers and for-hire vessel operators understand that a person on a vessel that has been issued a Gulf for-hire permit at any time during the fishing year can only harvest red snapper if the vessel is operating as a for-hire vessel. All monetary estimates in the following analysis are in 2021 dollars.

This final rule reduces the commercial trip limit for greater amberjack from 1,000 lb (454 kg), gutted weight (1,040 lb (472 kg), round weight), with a decrease in the trip limit to 250 lb (113 kg), gutted weight, 260 lb (118 kg), round weight, when 75 percent of the commercial quota has been reached, to seven fish. This final rule also establishes the new commercial trip limit based on numbers of fish rather than on weight. As described in the framework action, a trip limit of seven fish is approximately equal to 210 lb (95 kg), gutted weight (218 lb (99 kg), round weight).

This final rule also modifies the recreational fixed closed season for Gulf greater amberjack from the original dates of November 1 through April 30 and June 1 through July 31 to the new dates of August 1 through August 31 and November 1 through July 31.

This final rule also clarifies language in the regulations related to the Gulf red snapper Federal charter vessel/headboat component quota and the Gulf red snapper Federal charter vessel/headboat

component ACT. Specifically, the regulations will be modified to clarify that a person on a vessel issued a Gulf for-hire permit at any time during the fishing year can only harvest red snapper if the vessel is operating as a for-hire vessel. Given these actions, this final rule is expected to regulate commercial fishing businesses and charter vessel/headboat (for-hire) fishing businesses that harvest Gulf greater amberjack. The action to clarify existing regulations related to the Gulf red snapper Federal charter vessel/headboat component quota and the Gulf red snapper Federal charter vessel/headboat component ACT is administrative in nature, and thus would not regulate or directly affect any entities.

A valid commercial Gulf reef fish vessel permit is required in order for commercial fishing vessels to legally harvest greater amberjack in the Gulf. At the end of 2020, 837 vessels possessed valid commercial Gulf reef fish vessel permits. However, not all vessels with a commercial Gulf reef fish permit actually harvest greater amberjack in the Gulf. From 2017 through 2021, the average number of vessels that commercially harvested Gulf greater amberjack was 199. Ownership data regarding vessels that harvest Gulf greater amberjack are incomplete, which prohibits accurately determining affiliations between these particular vessels. Since determining ownership affiliations is not currently feasible, for the purposes of this analysis, NMFS assumes each of these vessels is independently owned by a single business. NMFS expects this assumption to result in an overestimate of the actual number of commercial fishing businesses regulated by this final rule. Thus, it is assumed this final rule would regulate 199 commercial fishing businesses.

Although the changes to the recreational fixed closed season will apply to recreational private anglers, the Regulatory Flexibility Analysis (RFA) does not consider recreational private anglers to be entities. Small entities include small businesses, small organizations, and small governmental jurisdictions (see 5 U.S.C. 601(6) and 601(3)–(5)). Recreational private anglers are not businesses, organizations, or governmental jurisdictions and so they are outside the scope of this analysis (see 5 U.S.C. 603).

A valid Federal charter vessel/headboat (for-hire) permit for Gulf reef fish is required to legally harvest greater amberjack in the Gulf from a for-hire vessel. NMFS does not possess complete ownership data for vessels that hold charter vessel/headboat Gulf reef fish

vessel permits and thus potentially harvest greater amberjack. Therefore, accurately determining affiliations between these vessels and the businesses that own them is not currently feasible. As a result, for purposes of this analysis, NMFS assumes each for-hire vessel is independently owned by a single business, which is expected to result in an overestimate of the actual number of for-hire fishing businesses regulated by this final rule.

NMFS also does not have data indicating how many for-hire vessels actually harvest Gulf greater amberjack in a given year. In 2020, there were 1,289 vessels with valid charter-headboat Gulf reef fish vessel permits. Of these 1,289 vessels, 803 were homeported in Florida. Of these 803 vessels, 62 are primarily used for commercial fishing rather than for-hire fishing purposes and thus are not considered for-hire fishing businesses (*i.e.*, 1,227 vessels are for-hire fishing businesses). In addition, 46 of the permitted vessels are considered headboats. However, headboats take a relatively large, diverse set of anglers to harvest a diverse range of species on a trip and therefore do not typically target a particular species. Therefore, NMFS assumes that no headboat trips would be canceled, and thus no headboats would be directly affected as a result of this final rule.

Charter vessels often target greater amberjack. Of the 803 vessels with valid charter-headboat Gulf reef fish vessel permits that are homeported in Florida, 62 are dually permitted commercial and charter vessel-headboats but are primarily commercial fishing vessels, and 46 are headboats, while the remaining 695 are charter vessels. As described in the framework action, 76 percent of charter vessels with valid charter-headboat permits in the Gulf were active in 2017 (*i.e.*, 24 percent were not fishing). A charter vessel would only be directly affected by this final rule if it is fishing. Given this information, NMFS' best estimate of the number of charter vessels that are likely to target Gulf greater amberjack in a given year is 528. Thus, this final rule is estimated to regulate 528 for-hire fishing businesses.

For RFA purposes, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (North American Industry Classification System (NAICS) Code 114111 (50 CFR 200.2)). A business primarily involved in the commercial fishing industry is classified as a small business if it is independently

owned and operated, is not dominant in its field of operation (including its affiliates), and its combined annual receipts (*i.e.*, revenue) are not in excess of \$11 million for all of its affiliated operations worldwide. From 2017 through 2021, the maximum annual gross revenue earned by a single commercial reef fish vessel during this time was about \$3.19 million, while the average annual gross revenue for a vessel commercially harvesting Gulf greater amberjack was \$194,894. Based on this information, all commercial fishing businesses regulated by this final rule are determined to be small entities for the purpose of this analysis.

For other industries, the Small Business Administration has established size standards for all major industry sectors in the U.S., including for-hire businesses (NAICS code 487210). A business primarily involved in for-hire fishing is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates) and has annual receipts (*i.e.*, revenue) not in excess of \$14.0 million for all its affiliated operations worldwide. The maximum annual gross revenue for a single headboat in the Gulf was about \$1.45 million in 2017. On average, annual gross revenue for headboats in the Gulf is about three times greater than the annual gross revenue for charter vessels, reflecting the fact that businesses that own charter vessels are typically smaller than businesses that own headboats. Based on this information, all for-hire fishing businesses regulated by this final rule are determined to be small businesses for the purpose of this analysis.

NMFS expects this final rule to directly affect 199 of the 837 commercial fishing businesses that possess a valid commercial Gulf reef fish permit (approximately 24 percent of those commercial fishing businesses). Further, NMFS expects this final rule to directly affect 528 of the 1,227 for-hire fishing businesses with valid Federal charter vessel/headboat permits in the Gulf reef fish fishery (approximately 43 percent of those for-hire fishing businesses). For the purpose of this analysis, all affected commercial and for-hire fishing businesses are small entities. Based on this information, NMFS expects the final rule to affect a substantial number of small entities.

For vessels that commercially harvest greater amberjack in the Gulf, currently available data indicate that economic profits are approximately 38 percent of annual average gross revenue. Given that their average annual gross revenue is \$194,894, annual average economic

profit per vessel is estimated to be approximately \$74,060.

This final rule reduces the commercial trip limit for greater amberjack to seven fish. As described in the framework action, a trip limit of seven fish is approximately equal to 210 lb (95 kg), gutted weight; 218 lb (99 kg), round weight. This final rule is expected to lengthen the commercial fishing season for greater amberjack.

Economic effects expected to result from changes in commercial trip limits would typically include changes in ex-vessel revenues and profits of commercial fishing businesses. However, based on the relatively small size of the greater amberjack commercial ACT and harvest projections, commercial fishing businesses are projected to harvest all of the allocated commercial quota regardless of the commercial trip limit. Therefore, changes in ex-vessel revenues and profits for commercial fishing businesses would not be expected to result from the action to change the commercial trip limit from 1,000 lb (454 kg) gutted weight, to seven fish.

Based on the most recent information available, average annual profit is \$27,000 per charter vessel. Net Cash Flow per Angler Trip (CFpA) is the best available estimate of profit per angler trip by charter vessels. CFpA on charter vessels is estimated to be \$149 per angler trip. Expected changes in charter trips targeting greater amberjack were derived from projected closure dates of the action to modify the recreational fixed closed season, and from the average distribution of greater amberjack target trips by wave and mode between 2018 and 2021. Assuming there is no shift in effort, it is estimated that the change in the recreational fixed closed season would result in a decrease to the number of charter trips targeting greater amberjack by 195 trips, and thereby decrease the profits to charter fishing businesses by \$29,108. On average, this would decrease profits by \$55 per vessel. Thus, economic profits are expected to be reduced by 0.2 percent on average per charter fishing business.

Three alternatives, including the status quo, were considered for the action to modify the commercial trip limit for Gulf greater amberjack and establish a new commercial trip limit based on numbers of fish rather than weight. The first alternative, the status quo, would have retained the current commercial trip limit for Gulf greater amberjack of 1,000 lb (454 kg), gutted weight (1,040 lb (472 kg), round weight). Additionally, when 75 percent of the ACT is projected to be reached, the commercial trip limit would have been

reduced to 250 lb (113 kg), gutted weight (260 lb (118 kg) round weight). This alternative would have allowed some targeting of greater amberjack to continue. However, the Council did not recommend, and NMFS did not select, this alternative because it would not modify the trip limit from pounds of fish, which is more difficult to enforce compared to a count of fish. This alternative is also expected to result in the shortest overall season, which is contrary to the objectives of the framework action.

The second alternative would have established a commercial trip limit of eight fish. A trip limit of eight fish is approximately equal to 257 lb (117 kg), gutted weight; 267 lb (121 kg), round weight. The Council did not recommend and NMFS did not select this alternative because it is not expected to extend the commercial season as long as the action in this rule.

The third alternative would have established a commercial trip limit of five fish. A trip limit of five fish is approximately equal to 150 lb (68 kg), gutted weight; 155 lb (70 kg), round weight. Like the action in this rule, this alternative would have modified the trip limit from pounds of fish to numbers of fish. Although this trip limit would have resulted in the longest commercial season, the Council did not recommend and NMFS did not select this alternative because it was deemed to be too restrictive.

Two alternatives, including the status quo, were considered for the action to modify the recreational fixed closed season for Gulf greater amberjack. The first alternative, the status quo, would have retained the current recreational fixed closed season of November 1 through April 30 and June 1 through July 31. As described in the framework action, this alternative was not selected because it results in the shortest projected season (*i.e.*, 21 days), which could promote race to fish (*i.e.*, derby-like) fishing behavior, and does not protect the stock during spawning periods. As described in the framework action, the Council also expressed a desire for a longer season length rather than a split season and a fishing season start date in August. Further, this alternative gives the least flexibility to for-hire operators with respect to rescheduling trips due to inclement weather or other constraints with the short-projected season. For all of the reasons stated above, NMFS agrees with the Council's decision not to recommend the status quo alternative.

The second alternative would have modified the recreational fixed closed season to be August 1 through August

31, October 1 through April 30, and June 1 through July 31. Although this alternative would have been expected to result in a greater amount of charter trips targeting Gulf greater amberjack compared to the status quo, it still allows for harvest during the spawning season. The Council did not recommend and NMFS did not select this alternative because it does not protect the stock during spawning periods as described in the framework action, which ultimately could have negative long-term effects if the stock does not rebuild.

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as "small entity compliance guides." The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, NMFS prepared a fishery bulletin, which also serves as a small entity compliance guide. Copies of this final rule are available from the Southeast Regional Office, and the guide, *i.e.*, fishery bulletin, will be sent to all known industry contacts in the Gulf reef fish fishery and be posted at: https://www.fisheries.noaa.gov/tags/small-entity-compliance-guide?title=&field_species_vocab_target_id=&field_region_vocab_target_id%5B1000001121%5D=1000001121&sort_by=created.

This final rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

NMFS finds good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in the effective date for changes to the Gulf greater amberjack recreational fixed closed season at 50 CFR 622.34(c). Among other measures, this final rule modifies the start of the summer recreational fishing season from August 1 to September 1. The recreational accountability measures require NMFS to prohibit harvest of greater amberjack when recreational landings reach or are projected to reach the recreational ACT (quota) and if recreational landings exceed the recreational ACL, then during the following fishing year, both the recreational quota and the recreational ACL must be reduced by the amount of any recreational ACL overage. NMFS will not have preliminary recreational landings estimates for the May 2024 open fishing season, which was the final month of recreational fishing during the 2023–

2024 recreational fishing year, until mid-August 2024. Therefore, if the changes to the recreational fixed closed season are not made effective by August 1, the recreational fishing season will open before NMFS can determine whether there needs to be an adjustment to the recreational ACT and ACL for the 2024–2025 fishing year. If significant harvest occurs before NMFS can make that determination, an overage of the 2024–2025 recreational ACL could occur, which would have negative impacts on the stock, which is overfished, as well as on those participants in the recreational sector who will have fewer days to fish for Gulf greater amberjack during the following fishing year. Given the time required to receive finalized recreational landings information from May 2024, NMFS is not yet able to make a determination about any recreational ACL overages from the 2023–2024 fishing year. A waiver of the 30-day delay in the effective date for changes to the Gulf greater amberjack recreational fixed closed season will allow the season to open September 1 as specified in the final rule and allow NMFS to determine whether an adjustment to the 2024–2025 catch limits are necessary. In addition, private anglers and Federal for-hire operators have been planning trips in anticipation of the expected September 1 opening and as explained in the framework action, opening on September 1 as opposed to August 1 is expected to allow for a greater number of fishing days, which will benefit private anglers and Federal for-hire operators. A waiver of the 30-day delay in effectiveness for the commercial trip limit specified in 50 CFR 622.43(a) is not necessary because commercial harvest is prohibited until December 31, 2024 as a result of an in-season commercial closure (89 FR 50529, June 14, 2024).

List of Subjects in 50 CFR Part 622

Commercial, Fisheries, Fishing, Greater amberjack, Gulf, Recreational, Red snapper, Reef fish.

Dated: July 15, 2024.

Samuel D. Rauch III,

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

For the reasons set out in the preamble, NMFS amends 50 CFR part 622 as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

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

■ 2. Effective August 1, 2024, in § 622.34, revise paragraph (c) to read as follows:

§ 622.34 Seasonal and area closures designed to protect Gulf reef fish.

* * * * *

(c) *Seasonal closure of the recreational sector for greater amberjack.* The recreational sector for greater amberjack in or from the Gulf EEZ is closed from January 1 through August 31 and from November 1 through December 31 each year. During the closure, the bag and possession limit for greater amberjack in or from the Gulf EEZ is zero.

* * * * *

■ 3. Effective August 21, 2024, in § 622.39, revise paragraph (a)(2)(i)(B) to read as follows:

§ 622.39 Quotas.

* * * * *

(a) * * *

(2) * * *

(i) * * *

(B) *Federal charter vessel/headboat component quota.* The Federal charter vessel/headboat component quota applies to vessels that have been issued a valid Federal charter vessel/headboat permit for Gulf reef fish any time during the fishing year. A person aboard a vessel that has been issued a charter vessel/headboat permit for Gulf reef fish any time during the fishing year may not harvest or possess red snapper in or from the Gulf when the Federal charter vessel/headboat component is closed. When the Federal charter vessel/headboat component is open, a person on board a vessel that has been issued a charter vessel/headboat permit for

Gulf reef fish at any time during the fishing year may harvest or possess red snapper in or from the Gulf only when the vessel is operating as a charter vessel or headboat. The Federal charter vessel/headboat component quota is 3,380,574 lb (1,533,403 kg), round weight.

* * * * *

■ 4. Effective August 21, 2024, in § 622.41, revise paragraph (q)(2)(iii)(B) to read as follows:

§ 622.41 Annual catch limits (ACLs), annual catch targets (ACTs), and accountability measures (AMs).

* * * * *

(q) * * *

(2) * * *

(iii) * * *

(B) *Federal charter vessel/headboat component ACT.* The Federal charter vessel/headboat component ACT applies to vessels that have been issued a valid Federal charter vessel/headboat permit for Gulf reef fish any time during the fishing year. A person aboard a vessel that has been issued a charter vessel/headboat permit for Gulf reef fish any time during the fishing year may not harvest or possess red snapper in or from the Gulf when the Federal charter vessel/headboat component is closed. When the Federal charter vessel/headboat component is open, a person on board a vessel that has been issued a charter vessel/headboat permit for Gulf reef fish at any time during the fishing year may harvest or possess red snapper in or from the Gulf only when the vessel is operating as a charter vessel or headboat. The component ACT is 3,076,322 lb (1,395,396 kg), round weight.

* * * * *

■ 5. Effective August 21, 2024, in § 622.43, revise paragraph (a) to read as follows:

§ 622.43 Commercial trip limits.

* * * * *

(a) *Greater amberjack.* Until the commercial quota specified in § 622.39(a)(1)(v) is reached—7 fish. See § 622.39(b) for the limitations regarding greater amberjack after the quota is reached.

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[FR Doc. 2024–15873 Filed 7–18–24; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 89, No. 140

Monday, July 22, 2024

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

SMALL BUSINESS ADMINISTRATION

13 CFR Part 126

Tribal Consultation for HUBZone Program Updates and Clarifications and Potential Reforms Under Executive Order 14112

AGENCY: U.S. Small Business Administration.

ACTION: Notification of tribal consultation meeting; request for comments.

SUMMARY: The U.S. Small Business Administration (SBA or Agency) announces that it is holding tribal consultation meetings in Albuquerque, New Mexico, Oklahoma City, Oklahoma, and Anchorage, AK, as well as a Listening Session in Honolulu, Hawaii, concerning forthcoming proposed revisions to the Historically Underutilized Business Zone (HUBZone) program regulations. The proposed rule would amend the 8(a) Business Development (BD) and size regulations to clarify certain policies. Additionally, SBA requests comments and input on how best to implement Executive Order (E.O.) 14112, which, among other things, calls on agencies to increase the accessibility, equity, flexibility, and utility of Federal funding and support programs for Tribal Nations. SBA is also seeking comments on prospective policy changes addressing joint venture participation in SBA's programs. Testimony presented at these tribal consultations will become part of the administrative record for SBA's consideration when the Agency deliberates on approaches to changes in the HUBZone and 8(a) BD program regulations.

DATES: The meeting dates are as follows:

1. Monday, August 19, 2024, 9:00 a.m. to 12:30 p.m. (MDT), Albuquerque, New Mexico. Pre-registration for this Tribal Consultation meeting is requested by August 12, 2024.
2. Wednesday, August 21, 2024, 9:00 a.m. to 12:00 p.m. (CDT), Oklahoma City, Oklahoma. Pre-registration for this

Tribal Consultation meeting is requested by August 14, 2024.

3. Tuesday, August 27, 2024, 9:00 a.m. to 12:30 p.m. (AKDT), Anchorage, Alaska. Pre-registration for this Tribal Consultation meeting is requested by August 20, 2024.

4. The Listening Session will be held on Tuesday, September 17, 2024, 8:30 a.m. to 12:00 p.m. (HST), Honolulu, Hawaii. Pre-registration for this Listening Session is requested by September 10, 2024.

ADDRESSES:

Meeting Locations:

1. The Tribal Consultation meeting in Albuquerque, New Mexico will be held at the Indian Pueblo Cultural Center, 2401 12th Street NW, Albuquerque, New Mexico 87104.

2. The Tribal Consultation meeting in Oklahoma City, Oklahoma will be held at the First Americans Museum, 659 First Americans Boulevard, Oklahoma City, OK 73129.

3. The Tribal Consultation meeting in Anchorage, Alaska will be held at the Z.J. Loussac Public Library, 3600 Denali Street, Anchorage, AK 99503.

4. The Listening Session in Honolulu, Hawaii will be held at the SBA Hawaii District Office, 500 Ala Moana Boulevard, Suite 1-306, Honolulu, Hawaii 96813.

Pre-registration: Send pre-registration requests to attend and/or testify to Chequita Carter of SBA's Office of Native American Affairs, U.S. Small Business Administration, 409 3rd Street SW, Washington, DC 20416; Chequita.Carter@sba.gov; or Facsimile to (202) 481-2177.

Comments: You may submit comments by any of the following methods:

- **Email:** to Jackson S. Brossy, Assistant Administrator, Office of Native American Affairs, U.S. Small Business Administration, at tribalconsultation@sba.gov.
- **Mail (for paper, disk, or CD-ROM submissions):** to Jackson S. Brossy, Assistant Administrator, Office of Native American Affairs, U.S. Small Business Administration, 409 3rd Street SW, Washington, DC 20416.

Instructions: All submissions received will become part of the administrative record for any rulemaking resulting from these tribal consultation meetings and listening session. As such, comments received may be posted on

<http://www.regulations.gov>. If you wish to submit confidential business information (CBI) as defined in the User Notice at <http://www.regulations.gov>, please submit the comments to Jackson S. Brossy and highlight the information that you consider to be CBI and explain why you believe this information should be held confidential. SBA will make a final determination as to whether the comments will be published.

FOR FURTHER INFORMATION CONTACT:

Chequita Carter, Program Assistant for SBA's Office of Native American Affairs, at Chequita.Carter@sba.gov or (202) 205-6680 or by facsimile to (202) 481-2177. This phone number can also be reached by individuals who are deaf or hard of hearing, or who have speech disabilities, through the Federal Communications Commission's TTY-Based Telecommunications Relay Service teletype service at 711.

SUPPLEMENTARY INFORMATION:

I. Background

SBA is planning to issue a proposed rule concerning the HUBZone program regulations under RIN 3245-AH68. The proposed rule is intended to clarify and improve several regulatory provisions, including those governing HUBZone contract eligibility. The proposed rule would also make several changes to SBA's size and 8(a) BD program regulations. In particular, the rule would consolidate and redesignate the separate recertification requirements for SBA's size, 8(a) BD, HUBZone, Woman-Owned Small Business, and Service-Disabled Veteran-Owned Small Business programs to a new section to reduce confusion and to ensure consistent application of the size and status recertification requirements. SBA anticipates the proposed rule will be published prior to the tribal consultation meetings and the Listening Session announced in this document.

In addition to the above referenced regulatory proposals, SBA is asking for input on how best to implement E.O. 14112, Reforming Federal Funding and Support for Tribal Nations To Better Embrace Our Trust Responsibilities and Promote the Next Era of Tribal Self-Determination, which was signed by the President on December 6, 2023. This E.O. directs agencies to identify and execute policy reforms designed to promote accessible, equitable, and

flexible administration of Federal funding and support programs for Tribal Nations to better live up to the Federal Government's trust responsibilities and help address the needs of all Tribal Nations. SBA has identified several potential opportunities for improvement, including the current requirements for personal guarantees and a waiver of sovereign immunity for 7(a) loans to tribally-owned business concerns, as well as the match funding requirement applicable to grants awarded by Native-serving entrepreneurship organizations, such as Small Business Development Centers and Community Development Financial Institutions. SBA is seeking comments on these and other potential reforms to reduce burdens and improve the accessibility of SBA's programs for Tribal stakeholders. Additionally, the Agency requests input on a change SBA has already made to address the business and economic development needs of Tribal Nations. Specifically, SBA's Assistant Administrator for Native American Affairs (ONAA)—who previously reported to the Associate Administrator for the Office of Entrepreneurial Development—now reports directly to the SBA Administrator. SBA would like to better understand whether Tribal Nations wish to continue with this current organization and reporting structure.

Lastly, SBA is requesting comments on the perception that mentor-protégé joint ventures are winning an inordinate number of orders issued under small business multiple award contracts and seeks suggestions on how to incentivize a more equitable marketplace for individual small businesses who compete against mentor-protégé joint ventures for multiple award, small business contracts. There is also a perception that small businesses often enter joint ventures to seek multiple award contract awards because procuring agency past performance and experience requirements make it difficult for many small businesses to qualify for the awards individually. SBA is considering whether to propose eliminating the exception to affiliation between an SBA-approved mentor and its protégé for multiple award contracts to address this concern. Such a change would continue to allow joint ventures to seek and be awarded single award small business contracts, but would make joint ventures ineligible for multiple award contracts. If that would occur, SBA would expect the past performance and experience required for award of future multiple award contracts to be adjusted to allow

individual small businesses to more easily qualify for award.

Another potential approach would be to allow an exclusion from affiliation for a joint venture between a protégé firm and its mentor only for contracts or orders that do not exceed five years. As SBA has previously stated, SBA believes that a joint venture should not be an ongoing entity, but something with limited scope and limited duration. Thus, SBA has limited the duration that a joint venture can submit offers for the award of contracts to two years from the date of its first contract award. SBA is questioning whether a joint venture performing a contract or order that exceeds five years is truly a limited duration entity.

Specific to qualified HUBZone protégé firms participating in the Mentor-Protégé Program, SBA is considering steps to clarify the applicability of the HUBZone price evaluation preference to HUBZone joint ventures formed under the Mentor-Protégé Program. Under the HUBZone price evaluation preference, where a procuring agency will award a contract on an unrestricted basis (*i.e.*, full and open competition), the agency must deem the price offered by a certified HUBZone small business concern (including a HUBZone joint venture that complies with the requirements of § 126.616) to be lower than the price offered by an apparent successful large business offeror if the price offered by the certified HUBZone small business concern is not more than 10% higher than the price offered by the large business. SBA is requesting comments and input on whether it is appropriate for a HUBZone mentor-protégé joint venture to benefit from the HUBZone price evaluation preference when the joint venture is already benefitting from its large business mentor's lower cost structures and pricing. SBA is considering whether to propose eliminating the HUBZone price evaluation preference's applicability to all joint ventures formed under the Mentor-Protégé Program or, alternatively, to offer submitting by a HUBZone joint venture where the mentor exceeds the applicable size standard corresponding to the NAICS code assigned to the contract.

II. Tribal Consultation Meetings

The purpose of these tribal consultation meetings is to conform to the requirements of Executive Order 13175, Consultation and Coordination With Indian Tribal Governments (65 FR 67249), and SBA's Tribal Consultation Policy (<https://www.sba.gov/document/support-sba-tribal-consultation-policy>);

to provide interested parties with an opportunity to discuss their views on the issues; and for SBA to obtain the views of SBA's stakeholders on approaches to the HUBZone and 8(a) BD regulations. SBA considers tribal consultation meetings a valuable component of its deliberations and believes that this tribal consultation meeting will allow for constructive dialogue with the Tribal community, Tribal Leaders, Tribal Elders, elected members of Alaska Native Villages or their appointed representatives, and principals of tribally-owned and ANC-owned firms participating in the 8(a) BD program.

The format of these tribal consultation meetings will consist of a panel of SBA representatives who will preside over the session. The oral and written testimony as well as any comments SBA receives will become part of the administrative record for SBA's consideration. Written testimony may be submitted in lieu of oral testimony. SBA will analyze the testimony, both oral and written, along with any written comments received. SBA officials may ask questions of a presenter to clarify or further explain the testimony. The purpose of the tribal consultation is to assist SBA with gathering information to guide SBA's review process and to potentially develop new proposals. SBA requests that the comments pertain to SBA's planned rulemaking concerning the HUBZone and 8(a) BD programs, general issues as they pertain to the HUBZone and 8(a) BD regulations, opportunities for reform under E.O. 14112, or the unique concerns of the Tribal communities. Presenters are encouraged to provide a written copy of their testimony. SBA will accept written material that the presenter wishes to provide that further supplements his or her testimony. Electronic or digitized copies are encouraged.

Each tribal consultation meeting will be held for one day. The meeting in Albuquerque, New Mexico will begin at 9:00 a.m. and end at 12:30 p.m. (MDT); the meeting in Oklahoma City, Oklahoma will begin at 9:00 a.m. and end at 12:30 p.m. (CDT); the meeting in Anchorage, Alaska will begin at 9:00 a.m. and end at 12:30 p.m. (AKDT); and the Listening Session in Honolulu, Hawaii will begin at 8:30 a.m. and end at 12:00 p.m. (HST). All registered speakers will have an opportunity to provide testimony. SBA may adjourn early if all those scheduled have delivered their testimony.

III. Registration

SBA respectfully requests that any elected or appointed representative of

the tribal communities or principal of a tribally-owned, ANC-owned, or NHO-owned 8(a) firm that is interested in attending please pre-register in advance and indicate whether you would like to testify at the hearing. However, pre-registration is not required for attendance. SBA requests that attendees register with SBA no later than: August 12, 2024, for the consultation meeting in Albuquerque; August 14, 2024, for the consultation meeting in Oklahoma City; August 20, 2024, for the consultation meeting in Anchorage; and September 10, 2024, for the Listening Session in Honolulu. To register, please contact Chequita Carter of SBA's Office of Native American Affairs in writing at Chequita.Carter@sba.gov or by facsimile to (202) 481-2177. If you are interested in testifying, please include the following information relating to the person testifying: Name, Organization affiliation, Address, Telephone number, Email address and Fax number. SBA will attempt to accommodate all interested parties that wish to present testimony. Based on the number of registrants it may be necessary to impose time limits to ensure that everyone who wishes to testify has the opportunity to do so. SBA will confirm in writing the registration of presenters and attendees.

IV. Information on Service for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the tribal consultation meeting, contact Chequita Carter at the telephone number or email address indicated under the **FOR FURTHER INFORMATION CONTACT** section of this document.

Authority: 15 U.S.C. 634 and E.O. 13175, 65 FR 67249.

Jackson S. Brossy,
Assistant Administrator, Office of Native American Affairs.

[FR Doc. 2024-16011 Filed 7-18-24; 11:15 am]

BILLING CODE 8026-09-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 183

[Docket No. FAA-2024-0491]

Notice of Availability of Draft FAA Order 8100.15 Regarding Organization Designation Authorization (ODA) Procedures

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of availability; request for comments.

SUMMARY: Draft revision C to FAA Order 8100.15 would incorporate other FAA policy issued to address certain provisions of the Aircraft Certification, Safety, and Accountability Act of 2020 (the Act), among other changes. This draft also introduces the Airmen Certification ODA type, reorganizes the existing content, and applies a systems based approach to oversight.

DATES: Send comments on or before October 21, 2024.

ADDRESSES: Send comments identified by docket number FAA-2024-0491, using any of the following methods:

Federal eRulemaking Portal: Go to <https://www.regulations.gov> and follow the online instructions for sending your comments electronically.

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

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

Fax: Fax comments to Docket Operations at (202) 493-2251.

Privacy: In addition to the final Order revision, the FAA will post all comments it receives, without change, to <https://www.regulations.gov>, including any personal information the commenter provides. DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19476).

FOR FURTHER INFORMATION CONTACT: Mr. Scott Geddie, Policy and Oversight Integration Section, AVS-64, AVS ODA Office, Federal Aviation Administration, by telephone at 405-954-6897 or by email at Scott.Geddie@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

Draft FAA Order 8100.15, Revision C, Organization Designation Authorization (ODA) Procedures, would provide updated policy associated with the requirements set forth in Title 14 Code of Federal Regulations (14 CFR) part 183, subpart D. The proposed changes include introduction of the Airmen Certification ODA type, reorganization of content and the introduction of a systems based approach to oversight. This draft revision also addresses certain provisions of the Act including

the prevention of interference with ODA Unit Members (UMs) at companies that hold ODA, allowing communication between UMs and the FAA, FAA approval of UM selections made by Type Certificate (TC) ODA holders, and assignment of FAA advisors to UMs at TC ODA holders. The FAA seeks comments on a draft revision to the Order. You may examine the Order and an optional comment log template that may be helpful for providing comments in the docket or at: https://www.faa.gov/aircraft/draft_docs/.

Comments Invited

The FAA invites the public to submit comments on the proposed Order revision, as specified in the **ADDRESSES** section of this Notice. Commenters should include docket number FAA-2024-0491 and the subject line, "Comments to Draft Order 8100.15C, Organization Designation Authorization (ODA) Procedures" on all comments submitted to the FAA. The most helpful comments provide a specific recommendation, explain the reason for any recommended change, identify the paragraph(s) and/or subparagraph(s) associated with the recommendation, and include supporting information. The FAA will consider all comments received on or before the closing date before issuing the final Order revision. The FAA will also consider late-filed comments if it is possible to do so without incurring expense or delay.

Issued in Washington, DC.

Kevin A. Dickert,

Director, AVS-60 AVS ODA Office.

[FR Doc. 2024-16015 Filed 7-19-24; 8:45 am]

BILLING CODE 4910-13-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2023-0502; FRL-11773-01-OCSPP]

Pesticide Tolerances; Implementing Registration Review Decisions for Certain Pesticides; Terbacil, et al.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is proposing to implement several tolerance actions under the Federal Food, Drug, and Cosmetic Act (FFDCA) that the Agency determined were necessary or appropriate during the registration review conducted under the

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). During registration review, EPA reviews all aspects of a pesticide case, including existing tolerances, to ensure that the pesticide continues to meet the standard for registration under FIFRA. The tolerance actions and pesticide active ingredients addressed in this rulemaking are identified in Unit I.B. and discussed in detail in Unit III. of this document.

DATES: Comments must be received on or before September 20, 2024.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2023–0502, through the Federal eRulemaking Portal at: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Katherine Atha, Pesticide Re-Evaluation Division (7508M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–1933; email address: atha.katherine@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

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

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

B. What action is the Agency taking?

EPA is proposing several tolerance actions that the Agency previously determined were necessary or appropriate during registration review for the following pesticide active ingredients: terbacil, bromacil, metolachlor and S-metolachlor,

etridiazole, triclopyr, deltamethrin, cyfluthrin and isomer beta-cyfluthrin, cyproconazole, fluroxypyr, pyraflufen-ethyl, etoxazole, acequinocyl, pinoxaden, flonicamid, and d-phenothrin. The proposed tolerance actions for each pesticide active ingredient are described in Unit III and may include but are not limited to the following types of actions:

- Revising tolerance expressions;
- Modifying commodity definitions;
- Updating crop groups;
- Removing expired tolerances;
- Revoking tolerances that are no longer needed; and
- Harmonizing tolerances with Codex Maximum Residue Levels (MRLs).

Although they may not have been identified in the registration review of a particular pesticide, this rule also includes proposals to reflect the Agency's 2019 adoption of the Organization of Economic Cooperation and Development (OECD) Rounding Class Practice. Where applicable, these adjustments are proposed for specific pesticides as reflected in the proposed regulatory text section.

C. What is the Agency's authority for taking this action?

Pursuant to its authority under the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a, EPA is proposing the tolerance actions in this rulemaking that the Agency previously determined were necessary or appropriate during the registration review conducted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*

FFDCA section 408(b) authorizes EPA to establish a tolerance, if the Agency determines that a tolerance is safe; FFDCA section 408(c) authorizes EPA to establish an exemption from the requirement of a tolerance if the Agency determines that the exemption is safe. See 21 U.S.C. 346a(b) and (c). If EPA determines that a tolerance or exemption is not safe, EPA must modify or revoke that tolerance or exemption. The FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” 21 U.S.C.

346a(b)(2)(A)(ii), (c)(2)(A)(ii). This includes exposure through drinking water and in residential settings but does not include occupational exposure. FFDCA section 408(b)(2)(C) requires EPA to give special consideration to the exposure of infants and children to the

pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue[s.]” 21 U.S.C. 346a(b)(2)(C). In addition, FFDCA section 408(b)(2)(D) contains several factors EPA must consider when making determinations about establishing, modifying, or revoking tolerances. 21 U.S.C. 346a(b)(2)(D). FFDCA section 408(c)(2)(B) requires that EPA, when making determinations about exemptions, to take into account, among other things, the considerations set forth in FFDCA section 408(b)(2)(C) and (D). 21 U.S.C. 346a(c)(2)(B).

FFDCA section 408(e), 21 U.S.C. 346a(e), authorizes EPA to establish, modify, or revoke tolerances or exemptions from the requirement of a tolerance on its own initiative. Prior to issuing the final regulation, FFDCA section 408(e)(2) requires EPA to issue a notice of proposed rulemaking for a 60-day public comment period, unless the Administrator for good cause finds that it would be in the public interest to have a shorter period and states the reasons in the rulemaking.

Furthermore, when establishing tolerances or exemptions from the requirement of a tolerance, FFDCA sections 408(b)(3) and (c)(3) require that there be a practical method for detecting and measuring pesticide chemical residue levels in or on food, unless in the case of exemptions, EPA determines that such method is not needed and states the reasons therefore in the rulemaking. 21 U.S.C. 346a(b) and (c).

Under FIFRA section 3(g), 7 U.S.C. 136a(g), EPA is required to periodically review all registered pesticides and determine if those pesticides continue to meet the standard for registration under FIFRA. See also 40 CFR 155.40(a). Consistent with its obligations under FIFRA section 3(g) and FFDCA section 408, EPA has reviewed the available scientific data and other relevant information and determined it is appropriate to take the tolerance actions being proposed in this rulemaking.

D. What can I do if I want the Agency to maintain a tolerance that the Agency proposes to revoke?

This proposed rule provides a 60-day public comment period that allows any person to state an interest in retaining a tolerance proposed for revocation. If EPA receives such a comment within the 60-day period, EPA will not proceed to revoke the tolerance immediately. However, EPA will take steps to ensure the submission of any needed

supporting data and will issue an order in the **Federal Register** under FFDCA section 408(f), if needed. The order would specify data needed and the timeframes for submission of the data and would require that within 90 days some person or persons notify EPA that they will submit the data. If the data are not submitted as required in the order, EPA will take appropriate action under FFDCA.

After considering comments that are received in response to this proposed rule, EPA will issue a final rule. At the time of the final rule, you may file an objection or request a hearing on the action taken in the final rule. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. After the filing deadline specified in the final rule, issues resolved in the final rule cannot be raised again in any subsequent proceedings.

E. What should I consider as I prepare my comments for EPA?

1. Submitting CBI

Do not submit this information to EPA through <https://www.regulations.gov> or email. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the part or all of the information that you claim to be CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for Preparing Your Comments

When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets#tips>.

3. Environmental Justice

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have

atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. Background

A. What is a tolerance?

A “tolerance” represents the maximum level for residues of pesticide chemicals legally allowed in or on food, which includes raw agricultural commodities and processed foods and feed for animals. Under the FFDCA, residues of a pesticide chemical that are not covered by a tolerance or exemption from the requirement of a tolerance are considered unsafe. *See* 21 U.S.C. 346a(a)(1). Foods containing unsafe residues are deemed adulterated and may not be distributed in interstate commerce. *See* 21 U.S.C. 331(a), 342(a)(2)(B). Consequently, for a food-use pesticide (*i.e.*, a pesticide use that is likely to result in residues in or on food) to be sold and distributed, the pesticide must not only have appropriate tolerances or exemptions under the FFDCA, but also must be registered under FIFRA, 7 U.S.C. 136 *et seq.* Food-use pesticides not registered in the United States must have tolerances or exemptions in order for commodities treated with those pesticides to be imported into the United States. For additional information about tolerances, go to <https://www.epa.gov/pesticide-tolerances/about-pesticide-tolerances>.

B. Why does EPA consider international residue limits?

When establishing a tolerance for residues of a pesticide, EPA must determine whether the Codex Alimentarius Commission (Codex) has established a Maximum Residue Limit (MRL) for that pesticide. *See* 21 U.S.C. 346a(b)(4). As part of registration review, EPA determines whether international tolerances or MRLs exist for commodities and chemicals for which U.S. tolerances have been established. Where appropriate, EPA’s intention is to harmonize U.S. tolerances with those international MRLs to facilitate trade. EPA’s effort to harmonize with Codex MRLs is summarized in the tolerance reassessment section of the individual human health risk assessments that support the pesticide registration review.

C. What is pesticide registration review?

EPA periodically reviews existing registered pesticides to ensure they can continue to be used without

unreasonable adverse effects on human health or the environment. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the FIFRA registration standard of no unreasonable adverse effects. As part of the registration review of a pesticide, EPA also evaluates whether existing tolerances are safe, whether any changes to existing tolerances are necessary or appropriate, and whether any new tolerances are necessary to cover residues from registered pesticides. Where appropriate, EPA has included a safety finding under the FFDCA for the proposed tolerance action for the pesticide, which is discussed in detail in the human health risk assessments conducted to support the registration review of each specific pesticide active ingredient or registration review case. In addition, these proposed tolerance changes are summarized in the Proposed Interim Decision (PID), Proposed Final Decision (PFD), Interim Decision (ID) and Final Decision (FD) for each pesticide active ingredient or registration review case. These documents can be found in the public docket that has been opened for each pesticide, which is available online at <https://www.regulations.gov>, using the docket ID number listed in Unit III. for each pesticide active ingredient included in this proposed action. Additional information about pesticide registration review is available at <https://www.epa.gov/pesticide-reevaluation>.

III. Proposed Tolerance Actions

EPA is proposing to take the specific tolerance actions identified in this unit.

A. 40 CFR 180.209; Terbacil, Case 0039 (Docket ID No. EPA-HQ-OPP-2011-0054)

1. Proposed Changes to the Current Tolerances

EPA is proposing to amend the current tolerance by:

- Revising the current tolerance expression to describe more clearly the scope or coverage of the tolerances and the method for measuring compliance. Consistent with EPA policy, the revised tolerance expression will clarify that: (1) As provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of terbacil not specifically mentioned; and (2) Compliance with the specified tolerance levels is to be determined by measuring the specific compounds mentioned in the tolerance expression. The revisions

to the tolerance expression do not substantively change the tolerance or, in any way, modify the permissible level of residues permitted by the tolerances.

- Revising the commodity definitions in paragraph (a) from “Peppermint, tops” to “Peppermint, fresh leaves,” and from “Spearment, tops” to “Spearment, fresh leaves” and modifying the tolerance levels to reflect OECD’s rounding class practices. These revisions of commodity definitions will help facilitate efficient commodity searches and does not substantively change the tolerance or, in any way, modify the permissible level of residues in or on the commodity listed in the regulation.

- Modifying tolerance values in order to reflect OECD’s rounding class practices.

2. Safety Finding

During registration review, EPA assessed the risks from exposure to terbacil, taking into consideration all reliable data on toxicity and exposure, including for infants and children. Based on the supporting risk assessments and registration review documents, which demonstrate that the aggregate exposure is below the Agency’s level of concern, EPA concludes there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to terbacil residues. Thus, EPA has determined that the tolerances for residues of terbacil are safe. Adequate enforcement methodology as described in the supporting documents is available to enforce the tolerance expression. For further detail, see *Terbacil: Human Health Draft Risk Assessment for Registration Review*, which can be found in the docket ID number listed in the heading of this unit.

B. 40 CFR 180.210; Bromacil; Case 0041 (Docket ID No. EPA-HQ-OPP-2012-0445)

1. Proposed Changes to the Current Tolerances

EPA is proposing to amend the current tolerances by:

- Revising the current tolerance expression to describe more clearly the scope or coverage of the tolerances and the method for measuring compliance. Consistent with EPA policy, the revised tolerance expression will clarify that: (1) As provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of bromacil not specifically mentioned; and (2) Compliance with the specified tolerance

levels is to be determined by measuring the specific compounds mentioned in the tolerance expression. The revisions to the tolerance expression do not substantively change the tolerance or, in any way, modify the permissible level of residues permitted by the tolerances. Adequate enforcement methodology as described in the supporting documents is available to enforce the tolerance expression.

- Revising the commodity definition in paragraph (a) from “Fruit, citrus” to “Fruit, citrus, group 10–10.” This revision will help facilitate efficient commodity searches and does not substantively change the tolerance or, in any way, modify the permissible level of residues in or on the commodity listed in the regulation.

2. Safety Finding

During registration review, EPA assessed the risks from exposure to bromacil, taking into consideration all reliable data on toxicity and exposure, including for infants and children. Based on the supporting risk assessments and registration review documents, which demonstrate that the aggregate exposure is below the Agency’s level of concern, EPA concludes there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to bromacil residues. Thus, EPA has determined that the tolerances for residues of bromacil are safe. Adequate enforcement methodology as described in the supporting documents is available to enforce the tolerance expression. For further detail, see *Bromacil and its Lithium Salt—Draft Human Health Risk Assessment for Registration Review*, which can be found in the docket ID number listed in the heading of this unit.

C. 40 CFR 180.368; Metolachlor and S-Metolachlor; Case 0001 (Docket ID No. EPA-HQ-OPP-2014-0772)

1. Proposed Changes to the Current Tolerances

EPA is proposing to amend the current tolerances by:

- Revising the commodity definitions in paragraphs (a)(1) and (2) from “Beet, sugar, tops” to “Beet, sugar, leaves”; from “Cilantro, leaves” to “Cilantro, fresh leaves”; from “Low growing berry subgroup 13–07G, except cranberry” to “Berry, low growing, subgroup 13–07G, except cranberry”; from “Grass, forage” to “Grass, forage, fodder and hay, group 17, forage”; from “Grass, hay” to “Grass, forage, fodder and hay, group 17, hay”; and from “Vegetable, *Brassica*, head and

stem, group 5–16” to “Vegetable, *brassica*, head and stem, group 5–16.” These revisions will help facilitate efficient commodity searches and does not substantively change the tolerance or, in any way, modify the permissible level of residues in or on the commodity listed in the regulation.

- Modifying tolerance values in order to reflect OECD’s rounding class practices.

- Adding the chemical name “S-metolachlor” to the title in 40 CFR 180.368 to more accurately reflect the chemical covered by the tolerances in that section.

2. Safety Finding

During registration review, EPA assessed the risks from exposure to metolachlor and S-metolachlor, taking into consideration all reliable data on toxicity and exposure, including for infants and children. Based on the supporting risk assessments and registration review documents, which demonstrate that the aggregate exposure is below the Agency’s level of concern, EPA concludes there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to metolachlor and S-metolachlor residues. Thus, EPA has determined that the tolerances for residues of metolachlor and S-metolachlor are safe. Adequate enforcement methodology as described in the supporting documents is available to enforce the tolerance expression. For further details, see *Metolachlor and S-Metolachlor: Draft Human Health Risk Assessment for Registration Review*, which can be found in the docket ID number listed in the heading of this unit.

D. 40 CFR 180.370; Etridiazole; Case 0009 (Docket ID No. EPA-HQ-OPP-2014-0414)

1. Proposed Changes to the Current Tolerances

EPA is proposing to amend the current tolerances by:

- Revising the current tolerance expression to describe more clearly the scope or coverage of the tolerances and the method for measuring compliance. Consistent with EPA policy, the revised tolerance expression will clarify that: (1) As provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of etridiazole not specifically mentioned; and (2) Compliance with the specified tolerance levels is to be determined by measuring the specific compounds mentioned in the tolerance expression.

The revisions to the tolerance expression do not substantively change the tolerance or, in any way, modify the permissible level of residues permitted by the tolerances.

- Modifying the tolerance level for etridiazole on tomatoes due to new data submitted by the registrant that shows no measurable residues. The currently available field trial data indicate that residues are below the limit of quantitation (LOQ) of the study method (<0.035 ppm); however, the U.S. tolerance enforcement method for etridiazole has a combined LOQ of 0.1 ppm. Therefore, EPA is proposing to revise the tolerance for tomatoes from 0.15 ppm to 0.1 ppm, because the Agency is not able to set a tolerance level that is below the LOQ.

- Revising the chemical name in the title in 40 CFR 180.370 to “Etridiazole” to more accurately reflect the chemical covered by the tolerances in that section.

2. Safety Finding

During registration review, EPA assessed the risks from exposure to etridiazole, taking into consideration all reliable data on toxicity and exposure, including for infants and children. Based on the supporting risk assessments and registration review documents, which demonstrate that the aggregate exposure is below the Agency’s level of concern, EPA concludes there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to etridiazole residues. Thus, EPA has determined that the tolerances for residues of etridiazole are safe. Adequate enforcement methodology as described in the supporting documents is available to enforce the tolerance expression. For further details, see *Etridiazole. Revised Draft Human Health Risk Assessment (DRA) in Support of Registration Review*, which can be found in the docket ID number listed in the heading of this unit.

E. 40 CFR 180.417; Triclopyr; Case 2710 (Docket ID No. EPA-HQ-OPP-2014-0576)

1. Proposed Changes to the Current Tolerances

EPA is proposing to amend the current tolerances by:

- Revising the commodity definitions from “Fish” to “Fish, freshwater, finfish”; from “Shellfish” to “Fish, shellfish, mollusc” and “Fish, shellfish, crustacean”; from “Grass, forage” to “Grass, forage, fodder and hay, group 17, forage”; and from “Grass, hay” to

“Grass, forage, fodder and hay, group 17, hay” and modifying the tolerance levels to reflect OECD’s rounding class practices. These commodity definition revisions will help facilitate efficient commodity searches and does not substantively change the tolerance or, in any way, modify the permissible level of residues in or on the commodity listed in the regulation.

- Establishing a new paragraph (a)(3) under paragraph (a) for the fish and shellfish commodities in (a)(1) and revising the current tolerance expression to describe more clearly the scope or coverage of the tolerances and the method for measuring compliance. Consistent with EPA policy, the revised tolerance expression will clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of triclopyr not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring the specific compounds mentioned in the tolerance expression. The revisions to the tolerance expression do not substantively change the tolerance or, in any way, modify the permissible level of residues permitted by the tolerances.

- Modifying tolerance values in order to reflect OECD’s rounding class practices.

2. Safety Finding

During registration review, EPA assessed the risks from exposure to triclopyr, taking into consideration all reliable data on toxicity and exposure, including for infants and children. Based on the supporting risk assessments and registration review documents, which demonstrate that the aggregate exposure is below the Agency’s level of concern, EPA concludes there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to triclopyr residues. Thus, EPA has determined that the tolerances for residues of triclopyr are safe. Adequate enforcement methodology as described in the supporting documents is available to enforce the tolerance expression. For further details, see *Triclopyr, Triclopyr Butoxyethyl Ester, and Triclopyr Salts. Human Health Draft Risk Assessment to Support Registration Review*, which can be found in the docket ID number listed in the heading of this unit, and *Triclopyr. Human Health Risk Assessment for Section 3 Use on Sugarcane*, which can be found at docket EPA-HQ-OPP-2022-0890.

F. 40 CFR 180.435; Deltamethrin; Case 7414 (Docket ID No. EPA-HQ-OPP-2009-0637)

1. Proposed Changes to the Current Tolerances

EPA is proposing to amend the current tolerances by:

- Modifying tolerances for “Grain, cereal, group 15, except sweet corn” from 1.0 ppm to 2 ppm, and “Tomato” from 0.2 ppm to 0.3 ppm to harmonize with Codex MRLs.

2. Safety Finding

During registration review, EPA assessed the risks from exposure to deltamethrin, taking into consideration all reliable data on toxicity and exposure, including for infants and children. Based on the supporting risk assessments and registration review documents, which demonstrate that the aggregate exposure is below the Agency’s level of concern, EPA concludes there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to deltamethrin residues. Thus, EPA has determined that the tolerances for residues of deltamethrin are safe.

Adequate enforcement methodology as described in the supporting documents is available to enforce the tolerance expression. For further detail, see *Deltamethrin. Draft Human Health Risk Assessment for Registration Review and Deltamethrin Interim Registration Review Decision*, which can be found in the docket ID number listed in the heading of this unit.

G. 40 CFR 180.436; Cyfluthrin and Isomer Beta-Cyfluthrin; Case 7405 (Docket ID No. EPA-HQ-OPP-2010-0684)

1. Proposed Changes to the Current Tolerances

EPA is proposing to amend the current tolerances by:

- Revising the tolerance expressions for cyfluthrin and isomer beta-cyfluthrin to describe more clearly the scope or coverage of the tolerances and the method for measuring compliance and consolidating the tolerance expression for residues of cyfluthrin resulting from application in food and feed handling establishments into one section. Consistent with EPA policy, the revised tolerance expressions will clarify that: (1) As provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of cyfluthrin and beta-cyfluthrin not specifically mentioned; and (2) Compliance with the specified tolerance levels is to be

determined by measuring the specific compounds mentioned in the tolerance expression. The revisions to the tolerance expression do not substantively change the tolerance or, in any way, modify the permissible level of residues permitted by the tolerances.

- Converting existing crop group tolerances for residues of cyfluthrin and beta-cyfluthrin to the updated crop groups “Brassica, leafy greens, subgroup 4–16B”; “Fruit, citrus, group 10–10”; “Fruit, pome, group 11–10”; “Fruit, stone, group 12–12”; “Leaf petiole vegetable subgroup 22B”; “Leafy greens subgroup 4–16A”; “Nut, tree, group 14–12”; “Vegetable, brassica, head and stem, group 5–16”; “Vegetable, fruiting, group 8–10” at the same levels and is proposing to establish tolerances for the commodities “Celtuce” and “Fennel, florence, fresh leaves and stalk” at 6 ppm and “Kohlrabi” at 2.5 ppm. These conversions would modify existing tolerances for commodities in those crop groups and establish new tolerances for commodities in the updated crop groups. Upon establishment of these new crop groups, EPA proposes to remove tolerances that will be unnecessary once they are superseded by the tolerances established for the new crop group, including the tolerances for “Lettuce, head”; “Lettuce, leaf”; “Mustard greens”; “Pepper”; “Pistachio”; “Tomato”; and “Turnip, greens.” 40 CFR 180.40(j) states that “At appropriate times, EPA will amend tolerances for crop groups that have been superseded by revised crop groups to conform the pre-existing crop group to the revised crop group.” EPA has indicated in updates to its crop group rulemakings that registration review is one of those appropriate times.

- Modifying tolerances in order to reflect OECD’s rounding class practices.

- Modifying the tolerance for “Hog, meat byproducts” from 0.01 ppm to 0.02 ppm and for “Fruit, citrus, group 10–10” from 0.2 ppm to 0.3 ppm to harmonize with Codex MRLs.

2. Safety Finding

During registration review, EPA assessed the risks from exposure to cyfluthrin and beta-cyfluthrin, taking into consideration all reliable data on toxicity and exposure, including for infants and children. Based on the supporting risk assessments and registration review documents, which demonstrate that the aggregate exposure is below the Agency’s level of concern, EPA concludes there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate

exposure to cyfluthrin and beta-cyfluthrin residues. Thus, EPA has determined that the tolerances for residues of cyfluthrin and beta-cyfluthrin are safe. Adequate enforcement methodology as described in the supporting documents is available to enforce the tolerance expression. For further detail, see *Cyfluthrin and Beta-Cyfluthrin. Draft Human Health Risk Assessment for Registration Review*, which can be found in the docket ID number listed in the heading of this unit.

H. 40 CFR 180.485; Cyproconazole; Case 7011 (Docket ID No. EPA-HQ-OPP-2015-0462)

1. Proposed Changes to the Current Tolerances

EPA is proposing to amend the current tolerances by:

- Revising the commodity definitions for “Coffee bean, green (Imported)” to “Coffee, green bean”; “Cattle, meat byproducts (except liver)” to “Cattle, meat byproducts, except liver”; “Goat, meat byproducts (except liver)” to “Goat, meat byproducts, except liver”; “Aspirated grain fractions” to “Grain, aspirated fractions”; “Horse, meat byproducts (except liver)” to “Horse, meat byproducts, except liver”; “Sheep, meat byproducts (except liver)” to “Sheep, meat byproducts, except liver”; and “Wheat, grain, milled byproducts” to “Wheat, milled byproducts” to describe more clearly the scope or coverage of the tolerances and the method for measuring compliance. The revisions to the tolerance commodity definition do not substantively change the tolerance or, in any way, modify the permissible level of residues permitted by the tolerances.

- Modifying tolerances in order to reflect OECD’s rounding class practices.

- Modifying the tolerance for “Wheat, grain” from 0.05 ppm to 0.08 ppm to harmonize with Codex MRLs. The tolerances for livestock commodities are not able to be harmonized with Codex because the U.S. residue definition contains additional metabolites.

2. Safety Finding

During registration review, EPA assessed the risks from exposure to cyproconazole, taking into consideration all reliable data on toxicity and exposure, including for infants and children. Based on the supporting risk assessments and registration review documents, which demonstrate that the aggregate exposure is below the Agency’s level of concern, EPA concludes there is a reasonable certainty that no harm will result to the

general population, or specifically to infants and children, from aggregate exposure to cyproconazole residues. Thus, EPA has determined that the tolerances for residues of cyproconazole are safe. Adequate enforcement methodology as described in the supporting documents is available to enforce the tolerance expression. For further details, see *Cyproconazole: Draft Human Health Risk Assessment for Registration Review*, which can be found in the docket ID number listed in the heading of this unit.

I. 40 CFR 180.535; Fluroxypyr; Case 7248 (Docket ID No. EPA-HQ-OPP-2014-0570)

1. Proposed Changes to the Current Tolerances

EPA is proposing to amend the current tolerances by:

- Revising the current tolerance expression to describe more clearly the scope or coverage of the tolerances and the method for measuring compliance. Consistent with EPA policy, the revised tolerance expression will clarify that: (1) As provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of fluroxypyr not specifically mentioned; and (2) Compliance with the specified tolerance levels is to be determined by measuring the specific compounds mentioned in the tolerance expression. The revisions to the tolerance expression do not substantively change the tolerance or, in any way, modify the permissible level of residues permitted by the tolerances. Adequate enforcement methodology as described in the supporting documents is available to enforce the tolerance expression.

- Revising the commodity definitions for “Grass, forage” to “Grass, forage, fodder and hay, group 17, forage”; and “Grass, hay” to “Grass, forage, fodder and hay, group 17, hay.” These revisions will help facilitate efficient commodity searches and does not substantively change the tolerance or, in any way, modify the permissible level of residues in or on the commodity listed in the regulation.

- Modifying tolerances in order to reflect OECD’s rounding class practices.

- Removing the tolerance for “Barley, hay” at 12.0 ppm since it is already covered by a tolerance listed at 20 ppm for that commodity and adding a tolerance for “Barley, forage” at 12 ppm that was erroneously removed.

2. Safety Finding

During registration review, EPA assessed the risks from exposure to

fluroxypyr, taking into consideration all reliable data on toxicity and exposure, including for infants and children. Based on the supporting risk assessments and registration review documents, which demonstrate that the aggregate exposure is below the Agency's level of concern, EPA concludes there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to fluroxypyr residues. Thus, EPA has determined that the tolerances for residues of fluroxypyr are safe. Adequate enforcement methodology as described in the supporting documents is available to enforce the tolerance expression. For further detail, see *Fluroxypyr: Draft Human Health Risk Assessment for Registration Review*, which can be found in the docket ID number listed in the heading of this unit.

J. 40 CFR 180.585; Pyraflufen-ethyl; Case 7259 (Docket ID No. EPA-HQ-OPP-2014-0415)

1. Proposed Changes to the Current Tolerances

EPA is proposing to amend the current tolerances by:

- Redesignating paragraph (a) as (a)(1) and establishing a new paragraph (a)(2) under paragraph (a) for livestock commodities and revise the current tolerance expression for pyraflufen-ethyl for livestock and plant commodities to describe more clearly the scope or coverage of the tolerances and the method for measuring compliance. Consistent with EPA policy, the revised tolerance expression will clarify that: (1) As provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of pyraflufen-ethyl not specifically mentioned; and (2) Compliance with the specified tolerance levels is to be determined by measuring the specific compounds mentioned in the tolerance expression. The revisions to the tolerance expression do not substantively change the tolerance or, in any way, modify the permissible level of residues permitted by the tolerances.

- Revising the commodity definitions for "Grass, forage, group 17" at 1.0 ppm and "Grass, hay, group 17" at 1.4 ppm by combining to the updated commodity "Grass, forage, fodder and hay, group 17" at 1.5 ppm to describe more clearly the scope or coverage of the tolerances and the method for measuring compliance. Upon establishment of the tolerance for this commodity, EPA also proposes to remove tolerances for "Grass, forage,

group 17" and "Grass, hay, group 17" since they will be unnecessary once they are superseded by the tolerance established for the new commodity.

- Modifying tolerances to reflect current OECD rounding practices.

2. Safety Finding

During registration review, EPA assessed the risks from exposure to pyraflufen-ethyl, taking into consideration all reliable data on toxicity and exposure, including for infants and children. Based on the supporting risk assessments and registration review documents, which demonstrate that the aggregate exposure is below the Agency's level of concern, EPA concludes there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to pyraflufen-ethyl residues. Thus, EPA has determined that the tolerances for residues of pyraflufen-ethyl are safe. Adequate enforcement methodology as described in the supporting documents is available to enforce the tolerance expression. For further details, see *Pyraflufen-ethyl—Human Health Draft Risk Assessment for Registration Review*, which can be found in the docket ID number listed in the heading of this unit.

K. 40 CFR 180.593; Etoxazole; Case 7616 (Docket ID No. EPA-HQ-OPP-2014-0133)

1. Proposed Changes to the Current Tolerances

EPA is proposing to amend the current tolerances by:

- Revising the commodity definitions for "Peppermint, tops" to "Peppermint, fresh leaves," and for "Spearment, tops" to "Spearment, fresh leaves." These revisions will help facilitate efficient commodity searches and does not substantively change the tolerance or, in any way, modify the permissible level of residues in or on the commodity listed in the regulation.

- Modifying tolerances for "Almond, hulls" from 2.0 ppm to 3 ppm, "Peppermint, fresh leaves" from 10 ppm to 15 ppm, and "Spearment, fresh leaves" from 10 ppm to 15 ppm to harmonize with Codex MRLs. The tolerances for individual citrus fruits and tree nuts are already harmonized with Codex MRLs, and the tolerances for pome fruits and hops, dried cones are not able to be harmonized with Codex because the tolerance levels are higher than the Codex MRLs.

- Modifying tolerances to reflect OECD's rounding class practices.

2. Safety Finding

During registration review, EPA assessed the risks from exposure to etoxazole, taking into consideration all reliable data on toxicity and exposure, including for infants and children. Based on the supporting risk assessments and registration review documents, which demonstrate that the aggregate exposure is below the Agency's level of concern, EPA concludes there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to etoxazole residues. Thus, EPA has determined that the tolerances for residues of etoxazole are safe. Adequate enforcement methodology as described in the supporting documents is available to enforce the tolerance expression. For further details, see *Etoxazole: Human Health Draft Risk Assessment for Registration Review and a Proposed Section 3 Use on Sugar Beets*, which can be found in the docket ID number listed in the heading of this unit.

L. 40 CFR 180.599; Acequinocyl; Case 7621 (Docket ID No. EPA-HQ-OPP-2015-0203)

1. Proposed Changes to the Current Tolerances

EPA is proposing to amend the current tolerances by:

- Revising the commodity definition from "Citrus, oil" to "Fruit, citrus, group 10–10, oil." This revision will help facilitate efficient commodity searches and does not substantively change the tolerance or, in any way, modify the permissible level of residues in or on the commodity listed in the regulation.

- Modifying tolerances to reflect OECD's rounding class practices.

2. Safety Finding

During registration review, EPA assessed the risks from exposure to acequinocyl, taking into consideration all reliable data on toxicity and exposure, including for infants and children. Based on the supporting risk assessments and registration review documents, which demonstrate that the aggregate exposure is below the Agency's level of concern, EPA concludes there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to acequinocyl residues. Thus, EPA has determined that the tolerances for residues of acequinocyl are safe. Adequate enforcement methodology as described in the supporting documents

is available to enforce the tolerance expression. For further details, see *Acequinocyl: Draft Human Health Risk Assessment to Support Registration Review*, which can be found in the docket ID number listed in the heading of this unit.

M. 40 CFR 180.611; Pinoxaden; Case 7266 (Docket ID No. EPA-HQ-OPP-2015-603)

1. Proposed Changes to the Current Tolerances

EPA is proposing to amend the current tolerances by:

- Revising the current tolerance expressions in (a)(1) and (a)(2) for agricultural and livestock commodities to describe more clearly the scope or coverage of the tolerances and the method for measuring compliance. Consistent with EPA policy, the revised tolerance expression will clarify that: (1) As provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of pinoxaden not specifically mentioned; and (2) Compliance with the specified tolerance levels is to be determined by measuring the specific compounds mentioned in the tolerance expression. The revisions to the tolerance expression do not substantively change the tolerance or, in any way, modify the permissible level of residues permitted by the tolerances.

- Establishing new tolerances in paragraph (a)(2) for livestock commodities “Goat, fat”; “Goat, meat”; “Goat, meat byproducts”; “Hog, fat”; “Hog, meat”; “Hog, meat byproducts”; “Horse, fat”; “Horse, meat”; “Horse, meat byproducts”; “Sheep, fat”; “Sheep, meat”; and “Sheep, meat byproducts” at 0.04 ppm.

- Modifying tolerances for “Barley, hay” and “Wheat, straw” from 1.5 ppm to 3 ppm, “Barley, straw” from 1.0 ppm to 3 ppm and “Wheat, hay” from 2.0 ppm to 3 ppm to harmonize with Codex MRLs. Because the Codex MRLs for “Barley, grain”; “Wheat, grain”; “Eggs”; “Poultry, fat”; “Poultry, meat”; and “Poultry, meat byproducts” are lower than the established U.S. tolerances for these commodities, the tolerances will not be harmonized.

- Modifying tolerances to reflect OECD’s rounding class practices.

2. Safety Finding

During registration review, EPA assessed the risks from exposure to pinoxaden, taking into consideration all reliable data on toxicity and exposure, including for infants and children. Based on the supporting risk assessments and registration review

documents, which demonstrate that the aggregate exposure is below the Agency’s level of concern, EPA concludes there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to pinoxaden residues. Thus, EPA has determined that the tolerances for residues of pinoxaden are safe.

Adequate enforcement methodology as described in the supporting documents is available to enforce the tolerance expression. For further details, see *Pinoxaden: Human Health Draft Risk Assessment for Registration Review* and *Pinoxaden: Response to United States Department of Agriculture’s (USDA’s) Comments on the Interim Decision for Pinoxaden for Registration Review*, which can be found in the docket ID number listed in the heading of this unit.

N. 40 CFR 180.613; Flonicamid; Case 7436 (Docket ID No. EPA-HQ-OPP-2014-0777)

1. Proposed Changes to the Current Tolerances

EPA is proposing to amend the current tolerances by:

- Revising the commodity definitions for “Florence fennel” to “Fennel, florence, fresh leaves and stalk”, “Peppermint, tops” to “Peppermint, fresh leaves”; and “Spearmint, tops” to “Spearmint, fresh leaves.” These revisions will help facilitate efficient commodity searches and do not substantively change the tolerance or, in any way, modify the permissible level of residues in or on the commodity listed in the regulation.

- Modifying multiple tolerances to reflect OECD’s rounding class practices.

2. Safety Finding

During registration review, EPA assessed the risks from exposure to flonicamid, taking into consideration all reliable data on toxicity and exposure, including for infants and children. Based on the supporting risk assessments and registration review documents, which demonstrate that the aggregate exposure is below the Agency’s level of concern, EPA concludes there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to flonicamid residues. Thus, EPA has determined that the tolerances for residues of flonicamid are safe. Adequate enforcement methodology as described in the supporting documents is available to enforce the tolerance expression. For further details, see

Flonicamid: Human Health Draft Risk Assessment for Registration Review, which can be found in the docket listed in the heading of this unit.

O. 40 CFR 180.647; d-Phenothrin; Case 0426 (Docket ID No. EPA-HQ-OPP-2011-0539)

1. Proposed Changes to the Current Tolerances

EPA is proposing to amend the current tolerances by:

- Revising the current tolerance expression to describe more clearly the scope or coverage of the tolerances and the method for measuring compliance. Consistent with EPA policy, the revised tolerance expression will clarify that: (1) As provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of d-phenothrin not specifically mentioned; and (2) Compliance with the specified tolerance levels is to be determined by measuring the specific compounds mentioned in the tolerance expression. The revisions to the tolerance expression do not substantively change the tolerance or, in any way, modify the permissible level of residues permitted by the tolerances. Adequate enforcement methodology as described in the supporting documents is available to enforce the tolerance expression.

2. Safety Finding

EPA has determined that the proposed change to the tolerance expression would not impact EPA’s previous safety findings for the established tolerances for d-phenothrin, because the change has no substantive effect on the tolerances or supporting risk assessments, but rather is merely intended to clarify the existing tolerance expression. For further details, see *d-Phenothrin Draft Human Health Risk Assessment for Registration Review*, which can be found in the docket listed in the heading of this unit.

IV. Proposed Effective Date

EPA is proposing that these tolerance actions would be effective on the date of publication of the final rule in the **Federal Register**. However, for actions in the final rule that lower or revoke existing tolerances, EPA is proposing an expiration date of six months after the date of publication of the final rule in the **Federal Register**, to allow a reasonable interval for producers in exporting members of the World Trade Organization’s (WTO’s) Sanitary and Phytosanitary (SPS) Measures Agreement to adapt to the requirements.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at <https://www.epa.gov/regulations/and-executive-orders>.

A. Executive Orders 12866: Regulatory Planning and Review and 14094: Modernizing Regulatory Review

This action is exempt under Executive Order 12866 (58 FR 51735) (October 4, 1993), as amended by Executive Order 14094 (88 FR 21879) (April 11, 2023), because it proposes to establish or modify a pesticide tolerance or a tolerance exemption under FFDCA section 408. This exemption also applies to tolerance revocations for which extraordinary circumstances do not exist. As such, this exemption applies to the tolerance revocations in this proposed rule because the Agency knows of no extraordinary circumstances that warrant reconsideration of this exemption for those proposed tolerance revocations.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA 44 U.S.C. 3501 *et seq.*, because it does not contain any information collection activities.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* In making this determination, EPA concludes that the impact of concern for this rulemaking is any significant adverse economic impact on small entities and that the Agency is certifying that this rulemaking will not have a significant economic impact on a substantial number of small entities because the rulemaking has no net burden on small entities subject to the rule. This determination takes into account an EPA analysis for tolerance establishments and modifications that published in the **Federal Register** of May 4, 1981 (46 FR 24950) (FRL-1809-5) and for tolerance revocations on December 17, 1997 (62 FR 66020) (FRL-5753-1).

Additionally, in a 2001 memorandum, EPA determined that eight conditions must all be satisfied in order for an import tolerance or tolerance exemption revocation to adversely affect a significant number of small entity importers, and that there is a negligible joint probability of all eight conditions holding simultaneously with respect to any particular revocation. See Memorandum from Denise Keehner,

Division Director, Biological and Economic Analysis Division, Office of Pesticide Programs, entitled “RFA/SBREFA Certification for Import Tolerance Revocation” and dated May 25, 2001, which is available in the docket.

For the pesticides named in this proposed rule, EPA concludes that there is no reasonable expectation that residues of the pesticides for tolerances listed in this proposed rule for revocation will be found on the commodities discussed in this proposed rule, and the Agency knows of no extraordinary circumstances that exist as to the present proposed rule that would change EPA’s previous analyses.

Any comments about the Agency’s determination for this rulemaking should be submitted to EPA along with comments on the proposed rule and will be addressed in the final rule.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local or Tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255) (August 10, 1999), because it will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249) (November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885) (April 23, 1997) directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health

and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is not subject to Executive Order 13045 because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866 (See Unit V.A.), and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. However, EPA’s *Policy on Children’s Health* applies to this action.

This rule proposes tolerance actions under the FFDCA, which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . .” (FFDCA 408(b)(2)(C)). Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of these proposed tolerance actions. The Agency’s consideration is documented in the pesticide specific registration review decision documents. See the pesticide specific discussions in Unit III. and access the chemical specific registration review documents in each chemical docket at <https://www.regulations.gov>.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer Advancement Act (NTTAA)

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629) (February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs,

policies, and activities on minority populations (people of color and/or indigenous peoples) and low-income populations. As discussed in more detail in the pesticide specific risk assessments conducted as part of the registration review for each pesticide as identified in Unit III., EPA has considered the safety risks for the pesticides subject to this rulemaking and in the context of the tolerance actions set out in this rulemaking. EPA believes that the human health and environmental conditions that exist prior to this action do not result in disproportionate and adverse effects on people of color, low-income populations, and/or indigenous peoples. Furthermore, EPA believes that this action is not likely to result in new disproportionate and adverse effects on people of color, low-income populations and/or indigenous peoples.

List of Subjects in 40 CFR Part 180

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

Dated: June 20, 2024.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, the Environmental Protection Agency proposes to amend 40 CFR chapter I as follows:

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

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

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

■ 2. Amend § 180.209 by:

■ a. Revising the introductory text in paragraph (a);

■ b. In the table in paragraph (a):

■ i. Adding the table heading “Table 1 to Paragraph (a)”;

■ ii. Revising the entries for “Alfalfa, forage” and “Alfalfa, hay”;

■ iii. Adding in alphabetical order the entry for “Peppermint, fresh leaves”;

■ iv. Removing the entry for “Peppermint, tops”;

■ v. Adding in alphabetical order the entry for “Spearmint, fresh leaves”;

■ vi. Removing the entry for “Spearmint, tops”; and

■ vii. Revising the entry for “Watermelon”.

The revisions and additions read as follows:

§ 180.209 Terbacil; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide terbacil, including its metabolites and degradates, in or on the commodities in table 1 to this paragraph (a). Compliance with the tolerance levels specified in table 1 to this paragraph (a) is to be determined by measuring only the sum of terbacil (5-chloro-3-(1,1-dimethylethyl)-6-methyl-2,4(1*H*,3*H*)-pyrimidinedione) and its metabolites 3-*tert*-butyl-5-chloro-6-hydroxymethyluracil, 6-chloro-2,3-dihydro-7-hydroxymethyl 3,3-dimethyl-5*H*-oxazolo(3,2-*a*) pyrimidin-5-one, and 6-chloro-2,3-dihydro-3,3,7-trimethyl-5*H*-oxazolo(3,2-*a*) pyrimidin-5-one, calculated as the stoichiometric equivalent of terbacil, in or on the following commodities:

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Alfalfa, forage	1
Alfalfa, hay	2
* * * * *	
Peppermint, fresh leaves	2
Spearmint, fresh leaves	2
* * * * *	
Watermelon	1

* * * * *

■ 3. Amend § 180.210 by revising and republishing paragraph (a) to read as follows:

§ 180.210 Bromacil; tolerances for residues.

(a) *General.* Tolerances are established for residues of bromacil, including its metabolites and degradates, in or on the commodities in table 1 to this paragraph (a). Compliance

with the tolerance levels specified in table 1 to this paragraph (a) is to be determined by measuring only bromacil, 5-bromo-6-methyl-3-(1-methylpropyl)-2,4(1*H*,3*H*)-pyrimidinedione, in/on the commodity.

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Fruit, citrus, group 10–10	0.1
Pineapple	0.1

* * * * *

■ 4. Amend § 180.368 by:

■ a. Revising the section heading; and

■ b. Revising and republishing the table in paragraph (a)(1) and table 2 to paragraph (a)(2).

The revisions read as follows:

§ 180.368 Metolachlor and S-metolachlor; tolerances for residues.

(a) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Almond, hulls	0.3
Animal feed, nongrass, group 18	1
Cattle, fat	0.02
Cattle, kidney	0.2
Cattle, liver	0.05
Cattle, meat	0.02
Cattle, meat byproducts, except kidney and liver	0.04
Corn, field, forage	6
Corn, field, grain	0.1
Corn, field, stover	6
Corn, pop, grain	0.1
Corn, pop, stover	6
Corn, sweet, forage	6
Corn, sweet, kernel plus cob with husks removed	0.1
Corn, sweet, stover	6
Cotton, gin byproducts	4
Cotton, undelinted seed	0.1
Dillweed	0.5
Egg	0.02
Goat, fat	0.02
Goat, kidney	0.2
Goat, liver	0.05
Goat, meat	0.02
Goat, meat byproducts, except kidney and liver	0.04
Grass, forage, fodder and hay, group 17, forage	10
Grass, forage, fodder and hay, group 17, hay	0.2
Horse, fat	0.02
Horse, kidney	0.2
Horse, liver	0.05
Horse, meat	0.02
Horse, meat byproducts, except kidney and liver	0.04
Milk	0.02
Nut, tree, group 14	0.1
Okra	0.5
Peanut	0.2
Peanut, hay	20
Peanut, meal	0.4
Potato	0.2
Poultry, fat	0.02
Poultry, meat	0.02
Poultry, meat byproducts	0.05
Safflower, seed	0.1
Sheep, fat	0.02
Sheep, kidney	0.2
Sheep, liver	0.05
Sheep, meat	0.02
Sheep, meat byproducts, except kidney and liver	0.04
Sorghum, grain, forage	1
Sorghum, grain, grain	0.3
Sorghum, grain, stover	4
Soybean, forage	5
Soybean, hay	8
Soybean, seed	0.2
Tomato	0.1
Vegetable, foliage of legume, except soybean, subgroup 7A	15
Vegetable, legume, group 6	0.3

(2) * * *

TABLE 2 TO PARAGRAPH (a)(2)

Commodity	Parts per million
Beet, sugar, leaves	15
Beet, sugar, molasses	2
Beet, sugar, roots	0.5
Berry, low growing, subgroup 13–07G, except cranberry	0.4
Brassica, leafy greens, subgroup 4–16B	1.8
Bushberry subgroup 13–07B	0.15

TABLE 2 TO PARAGRAPH (a)(2)—Continued

Commodity	Parts per million
Caneberry subgroup 13–07A	0.1
Carrot, roots	0.4
Cattle, fat	0.02
Cattle, kidney	0.2
Cattle, liver	0.05
Cattle, meat	0.02
Cattle, meat byproducts, except kidney and liver	0.04
Cilantro, fresh leaves	8
Coriander, seed	0.13
Corn, field, forage	40
Corn, field, grain	0.1
Corn, field, stover	40
Corn, pop, grain	0.1
Corn, pop, stover	40
Corn, sweet, forage	6
Corn, sweet, kernel plus cob with husks removed	0.1
Corn, sweet, stover	40
Cotton, gin byproducts	4
Cottonseed subgroup 20C	0.1
Dill, seed	15
Dillweed	5
Dillweed, dried leaves	9
Egg	0.02
Goat, fat	0.02
Goat, kidney	0.2
Goat, liver	0.05
Goat, meat	0.02
Goat, meat byproducts, except kidney and liver	0.04
Grain, aspirated fractions	4
Grass, forage, fodder and hay, group 17, forage	10
Grass, forage, fodder and hay, group 17, hay	0.2
Horse, fat	0.02
Horse, kidney	0.2
Horse, liver	0.05
Horse, meat	0.02
Horse, meat byproducts, except kidney and liver	0.04
Kohlrabi	0.6
Leaf petiole vegetable subgroup 22B	0.1
Lettuce	1.5
Milk	0.02
Onion, bulb, subgroup 3–07A	0.1
Onion, green, subgroup 3–07B	2
Peanut	0.2
Peanut, hay	20
Peanut, meal	0.4
Poultry, fat	0.02
Poultry, meat	0.02
Poultry, meat byproducts	0.05
Rosemary, dried leaves	2
Rosemary, fresh leaves	1.5
Safflower, seed	0.1
Sesame, seed	0.13
Sheep, fat	0.02
Sheep, kidney	0.2
Sheep, liver	0.05
Sheep, meat	0.02
Sheep, meat byproducts, except kidney and liver	0.04
Sorghum, grain, forage	1
Sorghum, grain, grain	0.3
Sorghum, grain, stover	4
Sorghum, sweet, stalk	4
Soybean, forage	5
Soybean, hay	8
Soybean, meal	1.5
Soybean, seed	0.9
Spinach	0.5
Stalk and stem vegetable subgroup 22A, except kohlrabi	0.1
Stevia, dried leaves	15
Sugarcane, cane	0.2
Sugarcane, molasses	1.5
Sunflower, meal	1
Sunflower subgroup 20B	1

TABLE 2 TO PARAGRAPH (a)(2)—Continued

Commodity	Parts per million
Swiss chard	0.15
Tomato, paste	0.3
Vegetable, <i>brassica</i> , head and stem, group 5–16	0.6
Vegetable, cucurbit, group 9	0.5
Vegetable, foliage of legume, except soybean, subgroup 7A	15
Vegetable, fruiting, group 8–10, except tabasco pepper	0.1
Vegetable, leaves of root and tuber group 2, except sugar beet	2
Vegetable, legume, group 6	0.3
Vegetable, root, except sugar beet, subgroup 1B, except carrot	0.3
Vegetable, tuberous and corm, subgroup 1C	0.2

* * * * *

■ 5. Revise and republish § 180.370 to read as follows:

§ 180.370 Etridiazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide

etridiazole, including its metabolites and degradates, in or on the commodities in table 1 to this paragraph (a). Compliance with the tolerance levels is to be determined by measuring only the residues of etridiazole, (5-ethoxy-3-(trichloromethyl)-1,2,4-

thiadiazole), and its metabolite etridiazole acid, (3-carboxy-5-ethoxy-1,2,4-thiadiazole), calculated as the stoichiometric equivalent of etridiazole, in or on the commodity:

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Cotton, gin byproducts	0.1
Cotton, undelinted seed	0.1
Tomato	0.1

(b) [Reserved]

■ 6. Revise and republish § 180.417 to read as follows:

§ 180.417 Triclopyr; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide

triclopyr, including its metabolites and degradates, in or on the commodities in table 1 to this paragraph (a)(1) resulting from the application of the butoxyethyl ester of triclopyr, triethylamine salt of triclopyr, or choline salt of triclopyr. Compliance with the tolerance levels

specified in table 1 to this paragraph (a)(1) is to be determined by measuring only triclopyr, 2-[(3,5,6-trichloro-2-pyridinyl)oxy]acetic acid.

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Egg	0.05
Grass, forage, fodder and hay, group 17, forage	700
Grass, forage, fodder and hay, group 17, hay	200
Milk	0.6
Poultry, fat	0.1
Poultry, meat	0.1
Poultry, meat byproducts, except kidney	0.1
Rice, grain	0.3
Sugarcane, cane	0.04

(2) Tolerances are established for residues of the herbicide triclopyr, including its metabolites and degradates, in or on the commodities in table 2 to this paragraph (a)(2) resulting from the application of the butoxyethyl

ester of triclopyr, triethylamine salt of triclopyr, or choline salt of triclopyr. Compliance with the tolerance levels specified in table 2 to this paragraph (a)(2) is to be determined by measuring the combined residues of triclopyr, 2-

[(3,5,6-trichloro-2-pyridinyl)oxy]acetic acid, and its metabolite 3,5,6-trichloro-2-pyridinol (TCP), calculated as the stoichiometric equivalent of triclopyr.

TABLE 2 TO PARAGRAPH (a)(2)

Commodity	Parts per million
Cattle, fat	0.1
Cattle, meat	0.1
Cattle, meat byproducts	0.5

TABLE 2 TO PARAGRAPH (a)(2)—Continued

Commodity	Parts per million
Goat, fat	0.1
Goat, meat	0.1
Goat, meat byproducts	0.5
Hog, fat	0.1
Hog, meat	0.1
Hog, meat byproducts	0.5
Horse, fat	0.1
Horse, meat	0.1
Horse, meat byproducts	0.5
Sheep, fat	0.1
Sheep, meat	0.1
Sheep, meat byproducts	0.5

(3) Tolerances are established for residues of the herbicide triclopyr, including its metabolites and degradates, in or on the commodities in table 3 to this paragraph (a)(3) resulting from the application of the butoxyethyl

ester of triclopyr, triethylamine salt of triclopyr, or choline salt of triclopyr. Compliance with the tolerance levels specified in table 3 to this paragraph (a)(3) is to be determined by measuring the combined residues of triclopyr (2-

[(3,5,6-trichloro-2-pyridinyl)oxy]acetic acid) and its metabolites 3,5,6-trichloro-2-pyridinol (TCP) and 2-methoxy-3,5,6-trichloropyridine (TMP), calculated as the stoichiometric equivalent of triclopyr.

TABLE 3 TO PARAGRAPH (a)(3)

Commodity	Parts per million
Fish, freshwater, finfish	3
Fish, shellfish, crustacean	3.5
Fish, shellfish, mollusc	3.5

(b) [Reserved]

■ 7. Amend § 180.435, in table 1 to paragraph (a)(1), by revising the entries for “Grain, cereal, Group 15, except

sweet corn”; and “Tomato” to read as follows:

§ 180.435 Deltamethrin; tolerances for residues.

(a) * * *
(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Grain, cereal, group 15, except sweet corn	2
Tomato	0.3

■ 8. Amend § 180.436, in paragraph (a), by:

- a. Revising and republishing paragraph (a)(1);
- b. Revising paragraph (a)(2);
- c. Removing paragraph (a)(3); and
- d. Redesignating paragraph (a)(4) as paragraph (a)(3), and revising newly redesignated paragraph (a)(3).

The revisions read as follows:

§ 180.436 Cyfluthrin and isomer beta-cyfluthrin; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of cyfluthrin, including its metabolites and degradates, in or on the commodities in table 1 to this paragraph (a)(1). Compliance with the tolerance levels

specified in table 1 to this paragraph (a)(1) is to be determined by measuring only cyfluthrin, (cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2dimethyl-cyclopropane-carboxylate, in or on the commodity.

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Alfalfa	5
Alfalfa, forage	5
Alfalfa, hay	13
Almond, hulls	0.5

TABLE 1 TO PARAGRAPH (a)(1)—Continued

Commodity	Parts per million
Barley, bran	0.5
Barley, grain	0.15
Beet, sugar, dried pulp	1
Beet, sugar, roots	0.1
Brassica, leafy greens, subgroup 4–16B	7
Buckwheat, grain	0.15
Carrot, roots	0.2
Cattle, fat	2
Cattle, meat	0.1
Cattle, meat byproducts	0.1
Celtuce	6
Citrus, dried pulp	0.3
Citrus, oil	0.3
Corn, field, grain	0.05
Corn, pop, grain	0.05
Corn, sweet, kernel plus cob with husks removed	0.05
Cotton, hulls	2
Cotton, refined oil	2
Cotton, undelinted seed	1
Egg	0.01
Fennel, florence, fresh leaves and stalk	6
Fruit, citrus, group 10–10	0.3
Fruit, pome, group 11–10	0.5
Fruit, stone, group 12–12	0.3
Goat, fat	2
Goat, meat	0.05
Goat, meat byproducts	0.05
Grain, aspirated fractions	150
Grain, cereal, forage, fodder and hay, group 16, forage, except rice	25
Grain, cereal, forage, fodder and hay, group 16, hay, except rice	6
Grain, cereal, forage, fodder and hay, group 16, stover, except rice	30
Grain, cereal, forage, fodder and hay, group 16, straw, except rice	7
Grape	1
Grape, raisin	3.5
Grass, forage, fodder and hay, group 17, forage	12
Grass, forage, fodder and hay, group 17, hay	50
Hog, fat	0.5
Hog, meat	0.01
Hog, meat byproducts	0.02
Hop, dried cones	20
Hop, vines	4
Horse, fat	2
Horse, meat	0.05
Horse, meat byproducts	0.05
Kohlrabi	2.5
Leaf petiole vegetable subgroup 22B	6
Leafy greens subgroup 4–16A	6
Milk	0.2
Milk, fat	5
Millet, grain	0.15
Nut, tree, group 14–12	0.01
Oat, bran	0.5
Oat, grain	0.15
Pea and bean, dried shelled, except soybean, subgroup 6C	0.15
Pea, dry, seed	0.15
Pea, southern, succulent	0.25
Peanut	0.01
Peanut, hay	6
Poultry, fat	0.01
Poultry, meat	0.01
Poultry, meat byproducts	0.01
Radish, roots	1
Rye, bran	0.5
Rye, grain	0.15
Sheep, fat	2
Sheep, meat	0.05
Sheep, meat byproducts	0.05
Sorghum, grain, grain	3.5
Soybean, forage	8
Soybean, hay	4
Soybean, seed	0.03
Sugarcane, cane	0.05

TABLE 1 TO PARAGRAPH (a)(1)—Continued

Commodity	Parts per million
Sugarcane, molasses	0.2
Sunflower, forage	5
Sunflower, seed	0.02
Teosinte, grain	0.05
Tomato, dry pomace	5
Tomato, paste	0.5
Tomato, wet pomace	5
Triticale, grain	0.15
Vegetable, <i>brassica</i> , head and stem, group 5–16	2.5
Vegetable, cucurbit, group 9	0.1
Vegetable, fruiting, group 8–10	0.5
Vegetable, tuberous and corm, subgroup 1C	0.01
Wheat, bran	0.5
Wheat, grain	0.15
Wheat, shorts	0.5

(2) A tolerance of 0.05 ppm is established for residues of cyfluthrin, including its metabolites and degradates, in or on all food and feed items when cyfluthrin is used in food or feed handling establishments. Compliance with the tolerance level specified is to be determined by measuring only cyfluthrin, (cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2dimethylcyclopropane-carboxylate, in or on the commodity.

(3) Tolerances are established for residues of *beta*-cyfluthrin, including its metabolites and degradates, in or on the commodities in table 2 to this paragraph (a)(3). Compliance with the tolerance levels specified in table 2 is to be determined by measuring only the sum of *beta*-cyfluthrin, cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate [mixture comprising the enantiomeric pair (*R*)- α -cyano-4-fluoro-3-phenoxybenzyl

(1*S*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)- α -cyano-4-fluoro-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate with the enantiomeric pair (*R*)- α -cyano-4-fluoro-3-phenoxybenzyl (1*S*,3*R*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)- α -cyano-4-fluoro-3-phenoxybenzyl (1*R*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate], in or on the commodity.

TABLE 2 TO PARAGRAPH (a)(3)

Commodity	Parts per million
Alfalfa	5
Alfalfa, forage	5
Alfalfa, hay	13
Almond, hulls	0.5
Barley, bran	0.5
Barley, grain	0.15
Beet, sugar, dried pulp	1
Beet, sugar, roots	0.1
Brassica, leafy greens, subgroup 4–16B	7
Buckwheat, grain	0.15
Carrot, roots	0.2
Cattle, fat	2
Cattle, meat	0.1
Cattle, meat byproducts	0.1
Celtuce	6
Citrus, dried pulp	0.3
Citrus, oil	0.3
Corn, field, grain	0.05
Corn, pop, grain	0.05
Corn, sweet, kernel plus cob with husks removed	0.05
Cotton, hulls	2
Cotton, refined oil	2
Cotton, undelinted seed	1
Egg	0.01
Fennel, florence, fresh leaves and stalk	6
Fruit, citrus, group 10–10	0.3
Fruit, pome, group 11–10	0.5
Fruit, stone, group 12–12	0.3
Goat, fat	2
Goat, meat	0.05
Goat, meat byproducts	0.05
Grain, aspirated fractions	150
Grain, cereal, forage, fodder and hay, group 16, forage, except rice	25
Grain, cereal, forage, fodder and hay, group 16, hay, except rice	6
Grain, cereal, forage, fodder and hay, group 16, stover, except rice	30

TABLE 2 TO PARAGRAPH (a)(3)—Continued

Commodity	Parts per million
Grain, cereal, forage, fodder and hay, group 16, straw, except rice	7
Grape	1
Grape, raisin	3.5
Grass, forage, fodder and hay, group 17, forage	12
Grass, forage, fodder and hay, group 17, hay	50
Hog, fat	0.5
Hog, meat	0.01
Hog, meat byproducts	0.02
Hop, dried cones	20
Hop, vines	4
Horse, fat	2
Horse, meat	0.05
Horse, meat byproducts	0.05
Kohlrabi	2.5
Leaf petiole vegetable subgroup 22B	6
Leafy greens subgroup 4–16A	6
Milk	0.2
Milk, fat	5
Millet, grain	0.15
Nut, tree, group 14–12	0.01
Oat, bran	0.5
Oat, grain	0.15
Pea and bean, dried shelled, except soybean, subgroup 6C	0.15
Pea, dry, seed	0.15
Pea, southern, succulent	0.25
Peanut	0.01
Peanut, hay	6
Poultry, fat	0.01
Poultry, meat	0.01
Poultry, meat byproducts	0.01
Radish, roots	1
Rye, bran	0.5
Rye, grain	0.15
Sheep, fat	2
Sheep, meat	0.05
Sheep, meat byproducts	0.05
Sorghum, grain, grain	3.5
Soybean, forage	8
Soybean, hay	4
Soybean, seed	0.03
Sugarcane, cane	0.05
Sugarcane, molasses	0.2
Sunflower, forage	5
Sunflower, seed	0.02
Teosinte, grain	0.05
Tomato, paste	0.5
Tomato, pomace	5
Triticale, grain	0.15
Vegetable, brassica, head and stem, group 5–16	2.5
Vegetable, cucurbit, group 9	0.1
Vegetable, fruiting, group 8–10	0.5
Vegetable, tuberous and corm, subgroup 1C	0.01
Wheat, bran	0.5
Wheat, grain	0.15
Wheat, shorts	0.5

* * * * *

■ 9. Amend § 180.485 by:

■ a. Revising and republishing

paragraph (a)(1);

■ b. Adding the table heading “Table 2 to Paragraph (a)(2)” to the table in paragraph (a)(2); and

■ c. Adding the table heading “Table 3 to Paragraph (a)(3)” to the table in paragraph (a)(3).

The revision and addition read as follows:

§ 180.485 Cyproconazole; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the free and conjugated forms of the fungicide cyproconazole, including its metabolites and degradates, in or on the

commodities in table 1 to this paragraph (a)(1). Compliance with the proposed tolerance levels specified in table 1 to this paragraph (a)(1) is to be determined by measuring only cyproconazole (α -(4-chlorophenyl)- α -(1-cyclopropylethyl)-1H-1,2,4-triazole-1-ethanol) in or on the following commodities:

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Cattle, fat	0.01
Cattle, meat byproducts, except liver	0.01
Coffee, green bean ¹	0.1
Corn, field, forage	0.6
Corn, field, grain	0.01
Corn, field, stover	1.2
Goat, fat	0.01
Goat, meat byproducts, except liver	0.01
Grain, aspirated fractions	2.5
Horse, fat	0.01
Horse, meat byproducts, except liver	0.01
Peanut	0.01
Peanut, hay	6
Sheep, fat	0.01
Sheep, meat byproducts, except liver	0.01
Soybean, forage	1
Soybean, hay	3
Soybean, oil	0.1
Soybean, seed	0.05
Wheat, forage	0.8
Wheat, grain	0.08
Wheat, hay	1.3
Wheat, milled byproducts	0.1
Wheat, straw	0.9

¹ There are no U.S. registrations as of February 15, 2008, for use on coffee bean.

* * * * *

■ 10. Amend § 180.535 by:

■ a. Revising the introductory text in paragraph (a);

■ b. In the table to paragraph (a):

■ i. Adding the table heading “Table 1 to Paragraph (a)”;

■ ii. Removing the entry for “Barley, hay at 12.0”;

■ iii. Adding in alphabetical order the entry for “Barley, forage”;

■ iv. Revising the entry for “Barley, straw”;

■ v. Removing the entry for “Grass, forage”;

■ vi. Adding in alphabetical order the entries for “Grass, forage, fodder and

hay, group 17, forage” and “Grass, forage, fodder and hay, group 17, hay”;

■ vii. Removing the entry for “Grass, hay”;

■ viii. Revising the entries for “Millet, forage”, “Millet, hay”, “Millet, proso, straw”, “Oat, forage”, “Oat, hay”, “Oat, straw”, “Wheat, forage”, “Wheat, hay”, and “Wheat, straw”.

The revisions and additions read as follows:

§ 180.535 Fluroxypyr 1-methylheptyl ester; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide fluroxypyr 1-methylheptyl ester,

including its metabolites and degradates, in or on the commodities listed in table 1 to this paragraph (a). Compliance with the tolerance levels specified in table 1 to this paragraph (a) is to be determined by measuring only the sum of the free and conjugated forms of fluroxypyr 1-methylheptyl ester [1-methylheptyl 2-[(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetate] and its metabolite fluroxypyr [2-[(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetic acid] calculated as the stoichiometric equivalent of fluroxypyr, in or on the commodity.

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Barley, forage	12
Barley, straw	12
Grass, forage, fodder and hay, group 17, forage	120
Grass, forage, fodder and hay, group 17, hay	160
Millet, forage	12
Millet, hay	20
Millet, proso, straw	12
Oat, forage	12
Oat, hay	20
Oat, straw	12

TABLE 1 TO PARAGRAPH (a)—Continued

Commodity	Parts per million
Wheat, forage	12
Wheat, hay	20
Wheat, straw	12

* * * * *

■ 11. Amend § 180.585 by revising and republishing paragraph (a) to read as follows:

§ 180.585 Pyraflufen-ethyl; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide,

pyraflufen-ethyl, including its metabolites and degradates, in or on the plant commodities listed in table 1 to this paragraph (a)(1). Compliance with the plant commodity tolerance levels specified in the table is to be determined by measuring only the sum of the parent pyraflufen-ethyl, ethyl 2-[2-chloro-5-(4-chloro-5-

difluoromethoxy)-1-methyl-1*H*-pyrazol-3-yl]-4-fluorophenoxy] acetate, and its acid metabolite, E-1, 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1*H*-pyrazol-3-yl)-4-fluorophenoxyacetic acid, calculated as the stoichiometric equivalent of pyraflufen-ethyl in or on the commodity.

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Almond, hulls	0.02
Corn, field, forage	0.01
Corn, field, grain	0.01
Corn, field, stover	0.01
Cotton, gin byproducts	1.5
Cottonseed subgroup 20C	0.04
Fruit, pome, group 11–10	0.01
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F	0.01
Fruit, stone, group 12–12	0.01
Grass, forage, fodder and hay, group 17	1.5
Hop, dried cones	0.02
Nut, tree, group 14–1	0.01
Peanut	0.01
Peanut, hay	0.07
Pomegranate	0.01
Soybean, forage	0.05
Soybean, hay	0.1
Soybean, seed	0.01
Tropical and subtropical, small fruit, edible peel, subgroup 23A	0.01
Vegetable, tuberous and corm, subgroup 1C	0.02
Wheat, forage	0.02
Wheat, grain	0.01
Wheat, hay	0.01
Wheat, straw	0.01

(2) Tolerances are established for residues of the herbicide, pyraflufen-ethyl, including its metabolites and degradates, in or on the livestock commodities in table 2 to this paragraph (a)(2). Compliance with the livestock commodity tolerance levels specified in table 2 to this paragraph (a)(2) is to be

determined by measuring only the sum of the parent pyraflufen-ethyl, ethyl 2-[2-chloro-5-(4-chloro-5-difluoromethoxy)-1-methyl-1*H*-pyrazol-3-yl]-4-fluorophenoxy] acetate and its acid metabolites: E-1, 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1*H*-pyrazol-3-yl)-4-fluorophenoxyacetic

acid, and E-9, 2-chloro-5-(4-chloro-5-difluoromethoxy-1*H*-pyrazol-3-yl)-4-fluorophenoxyacetic acid, both calculated as the stoichiometric equivalent of pyraflufen-ethyl in or on the commodity.

TABLE 2 TO PARAGRAPH (a)(2)

Commodity	Parts per million
Cattle, fat	0.03
Cattle, meat	0.03
Cattle, meat byproducts	0.03
Goat, fat	0.03
Goat, meat	0.03
Goat, meat byproducts	0.03

TABLE 2 TO PARAGRAPH (a)(2)—Continued

Commodity	Parts per million
Horse, fat	0.03
Horse, meat	0.03
Horse, meat byproducts	0.03
Milk	0.03
Sheep, fat	0.03
Sheep, meat	0.03
Sheep, meat byproducts	0.03

* * * * *

■ 12. Amend § 180.593 by revising and republishing the table in paragraph (a) to read as follows:

§ 180.593 Etoxazole; tolerances for residues.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Almond, hulls	3
Apple, wet pomace	0.5
Avocado	0.2
Beet, sugar, leaves	1
Beet, sugar, roots	0.02
Berry, low growing, subgroup 13–07G	0.5
Caneberry subgroup 13–07A	1.5
Canistel	0.2
Cattle, fat	0.02
Cattle, liver	0.01
Cherry subgroup 12–12A	1
Corn, field, forage	0.8
Corn, field, grain	0.01
Corn, field, refined oil	0.03
Corn, field, stover	4
Corn, pop, grain	0.01
Corn, pop, stover	4
Corn, sweet, forage	1.5
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	5
Cotton, gin byproducts	1
Cottonseed subgroup 20C	0.05
Fruit, pome, group 11–10	0.2
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	0.5
Goat, fat	0.02
Goat, liver	0.01
Grape, raisin	1.5
Hop, dried cones	7
Horse, fat	0.02
Horse, liver	0.01
Mango	0.2
Melon subgroup 9A	0.2
Milk, fat	0.01
Nut, tree group 14–12	0.01
Orange ¹	0.1
Orange, oil ¹	1
Papaya	0.2
Peach subgroup 12–12B	1
Pepper/eggplant subgroup 8–10B	0.2
Peppermint, fresh leaves	15
Peppermint, oil	20
Plum, prune, dried	0.3
Plum subgroup 12–12C	0.15
Sapodilla	0.2
Sapote, black	0.2
Sapote, mamey	0.2
Sheep, fat	0.02
Sheep, liver	0.01
Soybean, seed	0.02
Spearmint, fresh leaves	15
Spearmint, oil	20
Squash/cucumber subgroup 9B	0.02
Star apple	0.2
Tangerine ²	0.1

TABLE 1 TO PARAGRAPH (a)—Continued

Commodity	Parts per million
Tea, dried ³	15
Tomato	0.2

¹ There are no U.S. registrations for orange and orange, oil as of December 2, 2015.

² There are no U.S. registrations for use of etoxazole on tangerines as of September 26, 2003.

³ There are no U.S. registrations for tea as of April 13, 2011.

* * * * *

■ 13. Amend § 180.599, in table 1 to paragraph (a), by:

■ a. Revising the entries in the table for “Almond, hulls”, “Apple, wet pomace”, “Avocado”, “Bean, succulent shelled”, “Berry, low growing, subgroup 13–07G”, “Caneberry subgroup 13–07A”, and “Cherry, subgroup 12–12A”;

■ b. Removing the entry for “Citrus, oil”;

■ c. Revising the entry for “Cowpea, forage”;

■ d. Adding in alphabetical the entry “Fruit, citrus, group 10–10, oil”; and

■ e. Revising the entries for “Fruit, pome, group 11–10”, “Guava”, “Tropical and subtropical, small fruit,

inedible peel, subgroup 24A”, “Vegetable, cucurbit, group 9”, and “Vegetable, fruiting, group 8–10”.

The revisions and addition read as follows:

§ 180.599 Acequinocyl; tolerances for residues.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Almond, hulls	2
Apple, wet pomace	1
Avocado	0.5
* * * * *	
Bean, succulent shelled	0.3
Berry, low growing, subgroup 13–07G	0.5
* * * * *	
Caneberry subgroup 13–07A	4
* * * * *	
Cherry, subgroup 12–12A	1
Cowpea, forage	6
* * * * *	
Fruit, citrus, group 10–10, oil	30
Fruit, pome, group 11–10	0.4
* * * * *	
Guava	0.9
* * * * *	
Tropical and subtropical, small fruit, inedible peel, subgroup 24A	2
Vegetable, cucurbit, group 9	0.3
Vegetable, fruiting, group 8–10	0.7

* * * * *

■ 14. Amend § 180.611 by revising and republishing paragraph (a) to read as follows:

§ 180.611 Pinoxaden; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide pinoxaden, including its metabolites and degradates, in or on the

commodities in table 1 to this paragraph (a)(1). Compliance with the tolerance levels specified in table 1 to this paragraph (a) is to be determined by measuring pinoxaden (8-(2,6-diethyl-4-methylphenyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazolo[1,2-d][1,4,5] oxadiazepin-9-yl 2,2-dimethylpropanoate) and its metabolites 8-(2,6-diethyl-4-methylphenyl)-tetrahydro-pyrazolo[1,2-

d][1,4,5]oxadiazepine-7,9-dione and free and conjugated forms of 8-(2,6-diethyl-4-hydroxymethyl-phenyl)-tetrahydro-pyrazolo[1,2-d][1,4,5] oxadiazepine-7,9-dione, and 4-(7,9-dioxo-hexahydro-pyrazolo[1,2-d] [1,4,5]oxadiazepin-8-yl)-3,5-diethyl-benzoic acid, calculated as the stoichiometric equivalent of pinoxaden, in/on the following commodities.

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Barley, bran	1.6
Barley, grain	0.9
Barley, hay	3
Barley, straw	3

TABLE 1 TO PARAGRAPH (a)(1)—Continued

Commodity	Parts per million
Egg	0.06
Poultry, fat	0.06
Poultry, meat	0.06
Poultry, meat byproducts	0.06
Wheat, bran	3
Wheat, forage	3.5
Wheat, grain	1.3
Wheat, hay	3
Wheat, straw	3

(2) Tolerances are established for residues of the herbicide pinoxaden, including its metabolites and degradates, in or on the commodities in table 2 to this paragraph (a)(2). Compliance with the tolerance levels specified in table 2 to this paragraph

(a)(2) is to be determined by measuring pinoxaden (8-(2,6-diethyl-4-methylphenyl)-1,2,4,5-tetrahydro-7-oxo-7*H*-pyrazolo[1,2-*d*][1,4,5]oxadiazepin-9-yl 2,2-dimethylpropanoate) and its metabolites 8-(2,6-diethyl-4-methylphenyl)-tetrahydro-pyrazolo[1,2-

d][1,4,5]oxadiazepine-7,9-dione and free and conjugated forms of 8-(2,6-diethyl-4-hydroxymethyl-phenyl)-tetrahydro-pyrazolo[1,2-*d*][1,4,5] oxadiazepine-7,9-dione, calculated as the stoichiometric equivalent of pinoxaden, in/on the following commodities.

TABLE 2 TO PARAGRAPH (a)(2)

Commodity	Parts per million
Cattle, fat	0.04
Cattle, meat	0.04
Cattle, meat byproducts	0.04
Goat, fat	0.04
Goat, meat	0.04
Goat, meat byproducts	0.04
Hog, fat	0.04
Hog, meat	0.04
Hog, meat byproducts	0.04
Horse, fat	0.04
Horse, meat	0.04
Horse, meat byproducts	0.04
Milk	0.02
Sheep, fat	0.04
Sheep, meat	0.04
Sheep, meat byproducts	0.04

* * * * *

■ 15. Amend § 180.613 by:

- a. Revising and republishing the table in paragraph (a)(1);

- b. Adding the table heading “Table 2 to Paragraph (a)(2)” to the table in paragraph (a)(2); and

- c. Revising the table in paragraph (c). The revisions and additions read as follows:

§ 180.613 Flonicamid; tolerances for residues.

(a) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Alfalfa, forage	10
Alfalfa, hay	7
Alfalfa, seed	1.5
Almond, hulls	9
Berry, low-growing, subgroup 13–07G	2
<i>Brassica</i> , leafy greens, subgroup 4–16B, except radish, tops	16
Bushberry subgroup 13–07B	1.5
Caneberry subgroup 13–07A	3
Celtuce	4
Cherry subgroup 12–12A	0.6
Corn, sweet, forage	9
Corn, sweet, kernel plus cob with husks removed	0.4
Corn, sweet, stover	20
Cotton, gin byproducts	6
Cotton, hulls	2
Cotton, meal	1
Cottonseed subgroup 20C	0.6

TABLE 1 TO PARAGRAPH (a)(1)—Continued

Commodity	Parts per million
Fennel, florence, fresh leaves and stalk	4
Fruit, citrus, group 10–10	1.5
Fruit, pome, group 11–10	0.2
Hop, dried cones	20
Kohlrabi	1.5
Leaf petiole vegetable subgroup 22B	4
Leafy greens subgroup 4–16A, except spinach	8
Nut, tree, group 14–12 except pistachio	0.15
Peach subgroup 12–12B	1.5
Pepper/Eggplant subgroup 8–10B	3
Peppermint, fresh leaves	7
Pistachio	0.6
Plum subgroup 12–12C	0.6
Pomegranate	0.5
Potato, granules/flakes	0.4
Prickly pear, fruit	2
Prickly pear, pads	3
Radish, tops	20
Rapeseed subgroup 20A	1.5
Small fruit vine climbing (except fuzzy kiwifruit), subgroup 13–07F	3
Spearmint, fresh leaves	7
Spinach	9
Sunflower subgroup 20B	0.7
Tea ¹	40
Tomato, paste	2
Tomato, puree	0.5
Tomato subgroup 8–10A	0.4
Vegetable, <i>brassica</i> , head and stem, group 5–16	1.5
Vegetable, cucurbit, group 9	1.5
Vegetable, legume, bean, edible podded, subgroup 6–22A	4
Vegetable, legume, bean, succulent shelled, subgroup 6–22C	7
Vegetable, legume, pea, edible podded, subgroup 6–22B	4
Vegetable, legume, pea, succulent shelled, subgroup 6–22D	7
Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E	3
Vegetable, legume, pulse, pea, dried shelled, subgroup 6–22F	3
Vegetable, root, except sugar beet, subgroup 1B	0.6
Vegetable, tuberous and corm, subgroup 1C	0.2

¹ There are no U.S. registrations for tea as of May 11, 2017.

* * * * *

(c) * * *

TABLE 3 TO PARAGRAPH (c)

Commodity	Parts per million
Clover, forage	0.9
Clover, hay	5

* * * * *

■ 16. Amend to read as follows:

§ 180.647 d-Phenothrin; tolerances for residues.

(a) *General.* A tolerance of 0.01 parts per million is established for residues of the insecticide d-phenothrin in or on all food/feed crops following wide-area mosquito adulticide applications. Compliance with the tolerance levels specified is to be determined by measuring only d-phenothrin in or on the commodity.

* * * * *

[FR Doc. 2024–13975 Filed 7–19–24; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 240716–0197; RTID 0648–XD769]

Fisheries of the Northeastern United States; Northeast Multispecies Fishery; 2024–2026 Small-Mesh Multispecies Specifications

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes small-mesh multispecies specifications for the 2024 fishing year, and projected specifications for fishing years 2025 and 2026, as recommended by the New England Fishery Management Council. This action also further reduces the recommended acceptable biological catch for southern red in order to comply with the requirements outlined in Framework Adjustment 62 to the Northeast Multispecies Fishery Management Plan. This action is necessary to establish allowable harvest levels and other management measures

consistent with the most recent scientific information. This rule also informs the public of the proposed fishery specifications and provides an opportunity for comment.

DATES: Comments must be received by August 6, 2024.

ADDRESSES: The New England Fishery Management Council (Council) has prepared a draft environmental assessment (EA) for this action that describes the proposed measures and other considered alternatives and analyzes the impacts of the proposed measures and alternatives. The Council submitted a draft of the specifications to NMFS that includes the draft EA, a description of the Council's preferred alternatives, the Council's rationale for selecting each alternative, and a Regulatory Flexibility Act (RFA) analysis. Copies of the draft of the specifications, the draft EA, RFA analysis, and information on the economic impacts of this proposed rulemaking are available upon request from: Dr. Cate O'Keefe, Executive Director; New England Fishery Management Council; 50 Water Street; Newburyport, MA 01950; and accessible via the internet in documents available at: <https://www.nefmc.org/library/2024-2026-small-mesh-multispecies-whiting-specifications>.

A plain language summary of this proposed rule is available at <https://www.regulations.gov/docket/NOAA-NMFS-2024-0077>. You may submit comments on this document, identified by NOAA–NMFS–2024–0077, by either of the following methods:

Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to <https://www.regulations.gov> and enter NOAA–NMFS–2024–0077 in the Search box (note: copying and pasting the FDMS Docket Number directly from this document may not yield search results). Click on the “Comment” icon, complete the required fields, and enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments

received are a part of the public record and will generally be posted for public viewing on <https://www.regulations.gov> without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Shannah Jaburek, Fishery Policy Analyst, (978) 282–8456.

SUPPLEMENTARY INFORMATION:

Background

The small-mesh multispecies fishery comprises three species of hakes that are managed as five stocks: Northern and southern silver hake; northern and southern red hake; and offshore hake. Southern silver hake and offshore hake are often grouped together for management purposes and collectively referred to as “southern whiting.” The New England Fishery Management Council manages the small-mesh multispecies fishery within the Northeast Multispecies Fishery Management Plan (FMP). This action proposes catch limit specifications for the 2024 small-mesh multispecies fishery, and projects specifications for fishing years 2025 and 2026, based on the Council's recommendations.

This rule proposes to implement the Council's recommended catch limits for northern silver hake, southern whiting, and northern red hake. Pursuant to section 305(d), this rule proposes to reduce the recommended acceptable biological catch (ABC) for southern red hake by 25 percent in order to comply with the requirements established in Framework Adjustment 62 to the Northeast Multispecies FMP (87 FR 3694, January 25, 2022). Framework 62 established a rebuilding plan for southern red hake that requires the ABC be set to 75 percent of the fishing mortality rate at maximum sustainable yield (F_{MSY}). However, the overfishing limit (OFL) for red hake has been unknown since the spring of 2020, when a peer review of the management

track assessment rejected a new empirical approach that would have updated the reference points for the stock. The peer review further stated that the current index-based method was inappropriate moving forward. Based on this, the Council set the 2021–2023 specifications to reduce the ABC to equal 75 percent of F_{MSY} . At its October 27, 2023, meeting, the Council's Scientific and Statistical Committee (SSC) met to discuss the specifications for small-mesh multispecies stocks. When setting the ABC for southern red hake, the SSC did not reduce the recommended ABC as required by Framework 62. The SSC's rationale for that decision was that, although exploitation is low, the low stock biomass may be a result of reduced stock productivity producing weak year classes and that the recommended ABC is not likely to result in overfishing and will support rebuilding goals for the stock. Based on the SSC's rationale, the Council submitted recommended specifications without the required reduction. This rule proposes to reduce the recommended ABCs in order to comply with the rebuilding plan for southern red hake. The fishery has not landed more than 76 percent of the proposed total allowable landings; therefore, we do not anticipate that this additional reduction to the annual catch limit (ACL) would impact the fishery as a whole.

Proposed Specifications

This action proposes the Council's recommended 2024 and projected 2025–2026 small-mesh multispecies catch specifications, with southern red hake adjusted as required by the rebuilding plan. The proposed catch limits would increase annual quotas for northern silver hake and decrease the quota for southern whiting and both red hake stocks (table 1). Specifications for fishing years 2025 and 2026 are projected to be the same as the proposed 2024 limits. These specifications are based on the most recent assessment update using the best scientific information available.

TABLE 1—SMALL-MESH MULTISPECIES SPECIFICATIONS FOR FISHING YEARS 2024–2026 (METRIC TONS), WITH THE PERCENT CHANGE IN THE TOTAL ALLOWABLE LANDINGS (TAL) FROM FISHING YEAR 2020

	OFL	ABC	Annual catch limit (ACL)	TAL	ACL percent change from 2023
Northern Red Hake	Unknown	3,129	2973	213	–9
Northern Silver Hake	79,473	40,868	38,825	31,347	+100
Southern Red Hake	Unknown	** 1,370	1,301	234	–9

TABLE 1—SMALL-MESH MULTISPECIES SPECIFICATIONS FOR FISHING YEARS 2024–2026 (METRIC TONS), WITH THE PERCENT CHANGE IN THE TOTAL ALLOWABLE LANDINGS (TAL) FROM FISHING YEAR 2020—Continued

	OFL	ABC	Annual catch limit (ACL)	TAL	ACL percent change from 2023
Southern Whiting *	35,419	20,149	19,142	13,881	– 51

* Southern whiting includes both southern silver hake and offshore hake.

** The Council recommended ABC was 1,826 mt, a 21 percent increase from 2023.

The Council did not recommend changes to any other regulations for the small-mesh multispecies fishery. Therefore, all other fishery management measures would remain unchanged under the proposed action. The Council will review the projected 2025 and 2026 specifications to determine if any changes need to be made prior to their final implementation. Changes may occur if quota overages trigger accountability measures, or if new stock information results in changes to the ABC recommendations. We will publish a notice prior to the 2025 fishing year to confirm the specifications or announce any necessary changes.

Classification

NMFS is issuing this rule pursuant to section 305(d) of the Magnuson-Stevens Fishery Conservation and Management Act (MSA). The reason for using this regulatory authority is that in a previous action taken pursuant to section 304(b), the Council designed the FMP to authorize NMFS to set specifications pursuant to section 305(d). See 50 CFR part 648.90(b). Further pursuant to MSA section 305(d), this action is necessary to carry out the Northeast Multispecies FMP because the Council-recommended specifications for southern red hake are not compliant with the rebuilding plan implemented by Framework 62 to the FMP. The NMFS Assistant Administrator has determined that this proposed rule is consistent with the Northeast Multispecies FMP and other applicable law, subject to further consideration after public comment.

This action is exempt from review under E.O. 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not

have a significant economic impact on a substantial number of small entities. The factual basis for this determination is as follows.

The proposed action would impact all permitted vessels or affiliated groups that participate in small-mesh multispecies fisheries. The Council considered any business with at least one open access Northeast multispecies K permit or other Northeast multispecies permit that allows possession of hakes in this evaluation, as well as any active entities that landed any small-mesh multispecies for commercial sale in 2022. To estimate the number of commercial business entities that may experience impacts from the proposed action on fishery specification (2024–2026), active small-mesh multispecies entities landing small-mesh multispecies are defined as those entities containing permits that are directly regulated and that landed small-mesh multispecies as recent as in 2022 for commercial sale. In 2022, there were 247 business entities landing small-mesh multispecies (southern whiting, silver, and/or red hake), of which 245 (99 percent) were small business entities, that could potentially be affected by the proposed specification measures for 2024–2026. There were two large entities landing small-mesh multispecies, but they only landed small-mesh multispecies worth about \$69,000 in aggregate (or 0.2-percent of their total income from fishing). On average, small entities derived approximately 5.37 percent of total entity fishing income from small-mesh multispecies. From 2018–2022, the number of business entities engaged in small-mesh species landings has declined but the average revenue per entity has increased.

The purpose of this action was previously outlined in the preamble to

this proposed rule and is not repeated here. As proposed, this action would decrease the available catch limits for southern whiting (51 percent from 2023) and both red hake stocks (9 percent from 2023) and increase available catch limits for northern silver hake (100-percent increase from 2023). Although three of the proposed quotas would decrease from previous years, they remain higher than landings for any of the stocks for at least the last 3 years; therefore, the reduction is not expected to be restrictive to the fishery or result in reductions in revenue.

The Council's analyses indicate that the overall economic impact of proposed action is expected to be slightly positive, and that the proposed specifications are not expected to substantially change fishing effort, risk of overfishing, prices/revenues, or fishery behavior. Therefore, the Council concluded, and NMFS agrees, that this action would not have a significant economic impact on a substantial number of small businesses. As a result, an initial regulatory flexibility analysis is not required and none has been prepared.

This action would not establish any new reporting or record-keeping requirements.

This proposed rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

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

Dated: July 16, 2024.

Samuel D. Rauch, III,

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

[FR Doc. 2024–16002 Filed 7–19–24; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 89, No. 140

Monday, July 22, 2024

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

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by August 21, 2024 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it

displays a currently valid OMB control number.

Office of Procurement and Property Management

Title: Generic Clearance for Application Information and Follow-up Information for Fellowships, Scholarships, Internships, and Training Programs.

OMB Control Number: 0503–NEW.

Summary Of Collection: This is a new generic information collection request seeking approval for 3 years. The request "Generic Clearance for Application Information and Follow-up Information for Fellowships, Scholarships, Internships, and Training Programs" supports the Office of Partnerships and Public Engagement's (OPPE) mission to connect rural and underserved communities to the education, tools, and resources available to them through Department of Agriculture programs and initiatives. OPPE coordinates outreach activities, including fellowship programs, scholarship programs, internship programs, and new initiatives that the Secretary of Agriculture deems appropriate on behalf of the Department's agencies, offices, divisions, and units (7 U.S.C. 6934(c)).

Application and supporting documentation involving fellows, scholars, interns, and trainees are necessary for OPPE to effectively coordinate services provided by the Department. In addition, follow-up surveys administered to fellows, scholars, interns, and trainees upon completion of their respective programs are necessary to ensure that USDA is designing and implementing these programs effectively.

Applicants may possess a variety of degrees including, but not limited to, high school, post-baccalaureate, graduate, and doctorates. Potential applicants may apply for a variety of USDA opportunities by submitting applications, resumes, curriculum vitae (CV), reference letters, and other related documentation to OPPE or directly to USDA offices. This information is necessary to evaluate the eligibility, merits, and quality of potential candidates and will also assist in matching potential candidates to various fellowships, scholarships, internships, and training programs.

Need and Use of the Information: This generic clearance will permit OPPE

to more efficiently collect applications and related documentation so that potential candidates may receive consideration for programs of their choice. It is important to ensure that applications are targeted, streamlined, and work in conjunction with the respective outreach efforts of USDA agencies and mission areas. This information collection will also enable USDA to collect qualitative participant feedback in an efficient, timely manner, in accordance with the Administration's commitment to providing career pathways to Federal positions. Participant feedback surveys will provide useful insights on perceptions and opinions but will not be statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into participant perceptions, experiences, and expectations; provide an early warning of issues with participant placement; or focus attention on areas where communication, training, or changes, in operations might improve program participation and conversion to Federal service. These collections will contribute directly to the improvement of program management. Finally, this generic clearance process allows programs an abbreviated PRA clearance process to gather a tailored pool of candidates to meet the education needs of a rapidly changing workforce and assess the extent to which programs are meeting participant needs. In addition, this clearance would allow for central administration of the PRA Clearance process, form sharing among programs, and potentially fewer online application and participant feedback systems at USDA.

Description of Respondents: Individuals.

Number of Respondents: 50,000.

Frequency of Responses: Annually; Semi-annually.

Total Burden Hours: 30,833.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2024–16063 Filed 7–19–24; 8:45 am]

BILLING CODE 3412–88–P

DEPARTMENT OF AGRICULTURE**Farm Service Agency****[Docket ID: FSA–2024–0008]****Information Collection Request; Direct Loan Servicing—Special****AGENCY:** Farm Service Agency, USDA.**ACTION:** Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act requirement, the Farm Service Agency (FSA) is requesting comments from all interested individuals and organizations on an extension of a currently approved information collection that supports Direct Loan Servicing—Special. The information is used in eligibility and feasibility determinations on borrower requests for disaster set-aside, primary loan servicing, buyout at market value, and homestead protection, as well as liquidation of security.

DATES: We will consider comments that we receive by September 20, 2024.

ADDRESSES: We invite you to submit comments in response to this notice. FSA prefers that the comments are submitted electronically through the Federal eRulemaking Portal, identified by Docket ID No. FSA–2024–0008. Go to <http://www.regulations.gov> and search for docket ID FSA–2024–0008. Follow the online instructions for submitting comments.

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

FOR FURTHER INFORMATION CONTACT: Lee Nault; by telephone: (202) 720–6834; or by email: lee.nault@usda.gov.

SUPPLEMENTARY INFORMATION:

Title: Farm Loan Programs; Direct Loan Servicing—Special.

OMB Control Number: 0560–0233.

OMB Expiration Date: 10/31/2024.

Type of Request: Extension.

Abstract: FSA's Farm Loan Programs provide loans to family farmers to purchase real estate and equipment and finance agricultural production. 7 CFR 766, Direct Loan Servicing-Special, provides the requirements for servicing financially distressed and delinquent direct loan borrowers. FSA's loan servicing options include disaster set-aside, primary loan servicing (including reamortization, rescheduling, deferral, write down and conservation contracts), buyout at market value, and homestead protection. FSA also services borrowers who file bankruptcy or liquidate security when available servicing options are not sufficient to produce a feasible plan. The information collections contained in the regulation

are necessary to evaluate a borrower's request for consideration of the special servicing actions.

The annual burden hours and the number of respondents and responses is estimated to remain the same in this renewal request.

When FSA is ready to implement a new servicing option for the distressed borrowers, FSA will expect to utilize the same collection already established under the Disaster Set-Aside process.

Since the last OMB approval, most special servicing activities have been stayed due to FSA's response to the Coronavirus (COVID–19) National Emergency, unless a borrower requested servicing assistance. Therefore, estimates prior to the stay are considered the most accurate and no additional revisions to the estimated annual burden hours and number of respondents have been made.

For the following estimated total annual burden on respondents, the formula used to calculate the total burden hour is the estimated average time per response multiplied by the estimated total annual responses.

Estimate of Respondent Burden: Public reporting burden for this information collection is estimated to average 0.376 hours per response to include the time for reviewing instructions, searching information, gathering and maintaining the information, and completing and reviewing the collection of information.

Respondents: Individuals or households, businesses or other for-profit farms.

Estimated Annual Number of Respondents: 32,496.

Estimated Number of Responses per Respondent: 1.00.

Estimated Total Annual Responses: 32,496.

Estimated Average Time per Response: 0.376 hours.

Estimated Total Annual Burden on Respondents: 12,221 hours.

We are requesting comments on all aspects of this information collection to help us to:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the FSA, including whether the information will have practical utility;

(2) Evaluate the accuracy of the FSA's estimate of burden including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected;

(4) Minimize the burden of the collection of information on those who are to respond, including using

appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice will be a matter of public record. Comments will be summarized and included in the submission for Office of Management and Budget approval.

USDA Non-Discrimination Policy

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

Individuals who require alternative means of communication for program information (for example, braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA TARGET Center at (202) 720–2600 (voice and text telephone (TTY)) dial 711 for Telecommunications Relay Service (both voice and text telephone users can initiate this call from any telephone). Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at <https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint> and at any USDA office or write a letter addressed to USDA and provide in the letter all the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by: (1) mail to: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; (2) fax: (202) 690–7442; or (3) email: program.intake@usda.gov.

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Zach Ducheneaux,

Administrator, Farm Service Agency.

[FR Doc. 2024–16038 Filed 7–19–24; 8:45 am]

BILLING CODE 3411–E2–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2024–0016]

Notice of Request To Renew an Approved Information Collection: Petitions for Rulemaking

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

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, FSIS is announcing its intention to renew an approved information collection regarding petitions for rulemaking. There are no changes to the existing information collection. The approval for this information collection will expire on December 31, 2024.

DATES: Submit comments on or before September 20, 2024.

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

- *Federal eRulemaking Portal:* This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to <https://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250–3700.

- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350–E, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2024–0016. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <https://www.regulations.gov>.

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

FOR FURTHER INFORMATION CONTACT: Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; 202–720–5046.

SUPPLEMENTARY INFORMATION:

Title: Petitions for Rulemaking.

OMB Number: 0583–0136.

Type of Request: Renewal of an approved information collection.

Abstract: FSIS has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53), as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*). These statutes mandate that FSIS protect the public by verifying that meat, poultry, and egg products are safe, wholesome, and properly labeled.

FSIS is requesting renewal of an approved information collection regarding petitions for rulemaking. There are no changes to the existing information collection. The approval for this information collection will expire on December 31, 2024.

The Administrative Procedure Act requires that Federal agencies give interested persons the right to petition for issuance, amendment, or repeal of a rule (5 U.S.C. 553(e)). FSIS has regulations to govern the submission to the Agency of petitions for rulemaking (9 CFR part 392). These regulations are designed to encourage the filing of well-supported petitions that contain information that the Agency needs to evaluate a requested rulemaking in a timely manner. FSIS uses the information associated with a petition to assess the merits of the requested action and to determine whether to issue, amend, or rescind regulations in response to the petition.

FSIS has made the following estimates based upon an information collection assessment:

Estimate of Burden: FSIS estimates that it takes respondents an average of 40 hours per year to complete and submit a petition.

Respondents: Official establishments, official plants, firms, trade associations, and public interest groups.

Estimated Number of Respondents: 10.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 400 hours.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record. Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; 202–720–5046.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of FSIS' functions, including whether the information will have practical utility; (b) the accuracy of FSIS' estimate of the burden of the proposed collection of information, including the validity of the method and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20253.

Additional Public Notification

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

FSIS will also announce and provide a link to this **Federal Register** publication through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <https://www.fsis.usda.gov/subscribe>.

Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

USDA Non-Discrimination Statement

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

Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (e.g., Braille, large print, audiotope, American Sign Language) should contact the responsible Mission Area, agency, or staff office; the USDA TARGET Center at (202) 720-2600 (voice and TTY); or the Federal Relay Service at (800) 877-8339.

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

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

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

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

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Paul Kiecker,
Administrator.

[FR Doc. 2024-16013 Filed 7-19-24; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

[Docket No. NRCS-2024-0008]

Proposed Revisions to Section 1 of the Field Office Technical Guide for Several States

AGENCY: Natural Resources Conservation Service (NRCS), Department of Agriculture (USDA).

ACTION: Notice of availability, request for comments.

SUMMARY: NRCS is giving notice that it is proposing revisions to Section 1—General Resource References of the Field Office Technical Guides in Connecticut, Delaware, Florida, Kentucky, Maryland, Massachusetts, New York, North Carolina, Pennsylvania, Rhode Island, South Carolina, and Virginia to include State Offsite Methods for Food Security Act Wetland Identification (SOSM). The proposed changes will replace the existing state wetland mapping conventions. The revisions are needed to clarify procedures and improve consistency in application. SOSM are used in completing wetland determinations for USDA program eligibility purposes.

DATES: We will consider comments that we receive by August 21, 2024.

ADDRESSES: We invite you to submit comments in response to this notice. You may submit your comments through:

- *Federal eRulemaking Portal*: Go to <http://www.regulations.gov> and search for Docket ID NRCS-2024-0008. Follow the online instructions for submitting comments;

All comments received will be made publicly available on <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: The appropriate person as listed below by State:

- *Connecticut*: Thomas L. Morgart; telephone: (860) 871-4011; email: thomas.morgart@usda.gov;
- *Delaware*: Jayme Arthurs; telephone: (302) 678-4160; email: jayme.arthurs@usda.gov;

- *Florida*: Walter Albarran; telephone: (352) 338-9500; email: walter.albarran@usda.gov;

- *Kentucky*: Eric Allness; telephone: (859) 224-7391; email: eric.allness@usda.gov.

- *Maryland*: Suzy Daubert; telephone: (410) 757-0861; email: suzy.daubert@usda.gov;

- *Massachusetts*: Dan Wright; telephone: (413) 253-4350; email: daniel.wright@usda.gov;

- *New York*: Blake Glover; telephone: (315) 477-6504; email: blake.glover@usda.gov;

- *North Carolina*: Julius George (Acting); telephone: (919) 873-2101; email: juliusjulius.george@usda.gov;

- *Pennsylvania*: Denise Coleman; telephone: (717) 237-2100; email: denise.coleman@usda.gov;

- *Rhode Island*: R. Phou Vongkhamdy; telephone: (401) 828-1300; email: poo.h.vongkhamdy@usda.gov;

- *South Carolina*: Jamie Keith (Acting); telephone: (803) 253-3935; email: jamie.keith@usda.gov; and

- *Virginia*: Dr. Edwin Martinez; (804) 287-1691; email: edwin.martinez@usda.gov.

SUPPLEMENTARY INFORMATION: Guidance contained in each state's SOSM will be part of the technical documents and procedures that NRCS uses to determine if wetlands are present on agricultural land as required by 16 U.S.C. 3822. NRCS is required by 16 U.S.C. 3862 to make available for public review and comment all proposed revisions to standards and procedures used to carry out highly erodible land and wetland provisions of the law.

NRCS is proposing revisions to Section 1—General Resource References of the Field Office Technical Guides in Connecticut, Delaware, Florida, Kentucky, Maryland, Massachusetts, New York, North Carolina, Pennsylvania, Rhode Island, South Carolina, and Virginia to include SOSM. The proposed SOSM will replace the following existing state wetland mapping conventions:

- “Delaware and Maryland Wetland Mapping Conventions for Agricultural Lands,” November 2007 (Delaware and Maryland);

- “New England Soil Conservation Service Wetland Mapping Conventions,” July 1994 (Connecticut and Massachusetts);

- “Food Security Act New York State Mapping Conventions for Certified Wetland Determinations on Agricultural Land,” February 2021 (New York); and

- “Rhode Island Wetland Mapping Conventions,” March 2010 (Rhode Island).

Florida, Kentucky, North Carolina, Pennsylvania, South Carolina, and Virginia do not have current state mapping conventions to be replaced.

The revisions to the Field Office Technical Guides are needed to clarify procedures and improve consistency in application. SOSM are used in completing wetland determinations for USDA program eligibility purposes.

There are separate SOSM documents for each state, except for North Carolina and South Carolina, which share a single SOSM. To fully understand the proposed revisions, commenters are encouraged to compare the SOSMs with state mapping conventions for the states listed above, as shown in Section 1 of the NRCS Field Office Technical Guide at <https://efotg.sc.egov.usda.gov/#/>. The electronic copies of each state's SOSM are available through <http://www.regulations.gov> by accessing Docket ID NRCS-2024-0008. Requests for paper versions or inquiries may be directed to the specific State Conservationist as identified in the **FOR FURTHER INFORMATION CONTACT** section above.

In general, all documents have similar language and technical methodologies with some variations based on natural resource information available and state-specific considerations.

All comments will be considered. If no comments are received, guidance contained in each state's SOSM will be considered final at the end of the comment period for this notice.

USDA Non-Discrimination Policy

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

Individuals who require alternative means of communication for program information (for example, braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or the USDA TARGET Center at (202) 720-2600 (voice and text telephone (TTY)) or dial

711 for Telecommunications Relay Service (both voice and text telephone users can initiate this call from any phone). Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD-3027, found online at <https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint> and at any USDA office or write a letter addressed to USDA and provide in the letter all the information requested in the form. To request a copy of the complaint form, call (866) 632-9992. Submit your completed form or letter to USDA by: (1) mail to: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250-9410; (2) fax: (202) 690-7442; or (3) email: program.intake@usda.gov. USDA is an equal opportunity provider, employer, and lender.

Louis Aspey,

Associate Chief, Natural Resources Conservation Service.

[FR Doc. 2024-16006 Filed 7-19-24; 8:45 am]

BILLING CODE 3410-16-P

DEPARTMENT OF AGRICULTURE

Rural Housing Service

[Docket No. RHS-24-NONE-0019]

60-Day Notice of Proposed Information Collection: Rural Housing Service Finance Office Forms; OMB Control No.: 0575-0184

AGENCY: Rural Housing Service (RHS), USDA.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the United States Department of Agriculture (USDA), RHS announces its intention to request a revision of a currently approved information collection and invites comments on this information collection.

DATES: Comments on this notice must be received by September 20, 2024 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically through the Federal eRulemaking Portal, <http://www.regulations.gov>. In the "Search for dockets and documents on agency actions" box, enter the docket number "RHS-24-NONE-0019," and click the "Search" button. From the search results: click on or locate the document title: "60-Day Notice of Proposed

Information Collection: Title Clearance and Loan Closing; OMB Control No.: 0575-0147" and select the "Comment" button. Before inputting comments, commenters may review the "Commenter's Checklist" (optional). To submit a comment: Insert comments under the "Comment" title, click "Browse" to attach files (if available), input email address, select box to opt to receive email confirmation of submission and tracking (optional), select the box "I'm not a robot," and then select "Submit Comment."

Information on using [Regulations.gov](https://www.regulations.gov), including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's "FAQ" link.

All comments will be available for public inspection online at the Federal eRulemaking Portal (<https://www.regulations.gov>).

FOR FURTHER INFORMATION CONTACT:

Crystal Pemberton, Rural Development Innovation Center—Regulations Management Division, USDA, 1400 Independence Avenue SW, South Building, Washington, DC 20250-1522. Telephone: (202) 260-8621. Email Crystal.Pemberton@usda.gov.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104-13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see, 5 CFR 1320.8(d)). This notice identifies the following information collection that RHS is submitting to OMB as extension to an existing collection with Agency adjustment.

Title: Form RD 3550-28, Authorization Agreement for Preauthorized Payments, Form RD 1951-65, Customer Initiated Payments (CIP), and Form RD 1951-66, FedWire Worksheet.

OMB Control Number: 0575-0184.

Expiration Date of Approval: January 31, 2025.

Type of Request: Revision of a currently approved information collection.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .25 hours per response. Each Rural Development borrower who elects to participate in electronic loan payments will only prepare one response for the life of their loan unless they change financial institutions or accounts.

This information collection reflects an estimate of an increase of an additional 1,464 responses and an estimate of an increase of an additional 366 hours to the burden hours due to an increase in respondents for the Single Family Housing and Community Programs and an increase in burden for Forms 3550–28/A.

Respondents: Business or other for-profit; Not-for-profit institutions; and State, Local, or Tribal Government.

Estimated Number of Respondents: 11,062.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 2,765.50 hours.

Abstract: RHS uses electronic methods (Customer Initiated Payments [CIP], FedWire, and Preauthorized Debits [PAD]) for receiving and processing loan payments and collections. These electronic collection methods provide a means for RHS borrowers to transmit loan payments from their financial institution (FI) accounts to Rural Development's Treasury Account and receive credit for their payments.

To administer these electronic loan collection methods, RHS collects the borrower's FI routing information (routing information includes the FI routing number and the borrower's account number). RHS uses Agency approved forms for collecting bank routing information for CIP, FedWire, and PAD.

Comments are invited on:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(b) The accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Copies of this information collection can be obtained from Crystal Pemberton, Innovation Center–Regulations Management Division, at Telephone: (202) 260–8621. Email Crystal.Pemberton@usda.gov.

All responses to this notice will be summarized and included in the request

for OMB approval. All comments also will become a matter of public record.

Joaquin Altoro,

Administrator, Rural Housing Service.

[FR Doc. 2024–16033 Filed 7–19–24; 8:45 am]

BILLING CODE 3410–XV–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Direct Investment Surveys: BE–10, Benchmark Survey of U.S. Direct Investment Abroad

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on 05/02/2024 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: Bureau of Economic Analysis (BEA), Commerce.

Title: Benchmark Survey of U.S. Direct Investment Abroad.

OMB Control Number: 0608–0049.

Form Number: BE–10.

Type of Request: Revision.

Number of Respondents: 29,000 respondents (U.S. parents). A complete response includes a BE–10 A form for the U.S. parent's domestic operation and one or more BE–11 B, C, or D forms for its foreign affiliates that meet the BE–10 survey requirements. BEA estimates that U.S. parents will submit 29,000 A forms, 20,100 B forms, 15,500 C forms, 29,000 D forms, and 1,700 Claim for Exemption forms.

Average Hours per Response: 29 hours per respondent (842,700 hours/29,000 U.S. parents) is the average but may vary considerably among respondents because of differences in company structure, complexity, and the number of foreign affiliates each U.S. parent must report.

Burden Hours: 842,700 hours. Total annual burden is calculated by multiplying the estimated number of

submissions of each form by the average hourly burden per form, which is 11 hours for the A form, 18.5 hours for the B form, 6 hours for the C form, 2 hours for the D form, and 0.5 hours for the Claim for Not Filing form.

Needs and Uses: The Benchmark Survey of U.S. Direct Investment Abroad (BE–10) obtains data on the financial structure and operations of U.S. parents and their foreign affiliates. The data are needed to provide reliable, useful, and timely measures of U.S. direct investment abroad, measure changes in such investment, and assess its impact on the U.S. and foreign economies. Such data are generally found in enterprise-level accounting records of respondent companies. The benchmark data provide a baseline for subsequent sample-based estimates in non-benchmark years. In particular, they serve as benchmarks for the quarterly direct investment estimates included in the U.S. international transactions, international investment position, and national income and product accounts, and for annual estimates of the U.S. direct investment abroad position and of the activities of U.S. multinational enterprises. The data collected include balance sheets; income statements; property, plant, and equipment; employment and employee compensation; merchandise trade; sales of goods and services; taxes; and research and development activity.

Affected Public: Businesses or other for-profit organizations.

Frequency: Every five years and covers years ending in 4 and 9.

Respondent's Obligation: Mandatory.

Legal Authority: International Investment and Trade in Services Survey Act (Pub. L. 94–472, 22 U.S.C. 3101–3108, as amended).

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

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function and

entering either the title of the collection or the OMB Control Number 0608–0049.

Sheleen Dumas,

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

[FR Doc. 2024–16007 Filed 7–19–24; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–803–001]

Mattresses From Kosovo: Final Affirmative Determination of Sales at Less-Than-Fair Value

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that imports of mattresses from Kosovo are being, or are likely to be, sold in the United States at less-than-fair value (LTFV). The period of investigation is July 1, 2022, through June 30, 2023.

DATES: Applicable July 22, 2024.

FOR FURTHER INFORMATION CONTACT: Sean Carey, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3964.

SUPPLEMENTARY INFORMATION:

Background

On March 1, 2024, Commerce published the preliminary determination in this LTFV investigation of mattresses from Kosovo, in which we also postponed the final determination until July 15, 2024.¹ Commerce invited interested parties to comment on the *Preliminary Determination*.²

A summary of the events that occurred since Commerce published the *Preliminary Determination*, as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.³ The Issues and Decision

Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

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

Scope Comments

During the course of this investigation, Commerce received scope comments from parties. Commerce issued a Preliminary Scope Decision Memorandum to address these comments and set aside a period of time for parties to address scope issues in scope-specific case and rebuttal briefs.⁴ We received comments from parties on the Preliminary Scope Decision Memorandum, which we address in the Final Scope Decision Memorandum.⁵ We made certain changes to the scope of the investigation from the scope published in the *Preliminary Determination*, as noted in Appendix I.

Verification

Commerce conducted verification of the information relied upon in making its final determination in this investigation, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act). Specifically, Commerce conducted on-site verifications of the sales and cost information submitted by Ventius International LLC (Ventius) for use in our final determination. We used standard verification procedures, including an examination of relevant sales and accounting records and original source documents provided by Ventius.⁶

⁴ See Memorandum, “Mattresses from Bosnia and Herzegovina, Bulgaria, Burma, India, Indonesia, Italy, Kosovo, Mexico, Philippines, Poland, Slovenia, Spain, and Taiwan: Preliminary Scope Decision Memorandum,” dated February 23, 2024 (Preliminary Scope Decision Memorandum).

⁵ See Memorandum, “Mattresses from Bosnia and Herzegovina, Bulgaria, Burma, India, Indonesia, Italy, Kosovo, Mexico, the Philippines, Poland, Slovenia, Spain, and Taiwan: Final Scope Decision Memorandum,” dated May 8, 2024 (Final Scope Decision Memorandum).

⁶ See Memoranda, “Verification of the Cost Response of Ventius International LLC in the Antidumping Duty Investigation of Mattresses from Kosovo,” dated May 7, 2024; “Verification of the Sales Response of Ventius International LLC and

Analysis of Comments Received

All issues raised in the case and rebuttal briefs submitted by interested parties in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is attached to this notice as Appendix II.

Changes Since the Preliminary Determination

We have made certain changes to the margin calculations for Ventius since the *Preliminary Determination*. For a discussion of these changes, see the Issues and Decision Memorandum.

Use of Adverse Facts Available (AFA)

As discussed in the *Preliminary Determination*, Commerce assigned to the mandatory respondent in this investigation, Nisco Thailand Co., Ltd. (Nisco Thailand), an estimated weighted-average dumping margins on the basis of AFA, pursuant to sections 776(a) and (b) of the Act.⁷ There is no new information on the record that would cause us to revisit our decision in the *Preliminary Determination*. Accordingly, for the reasons explained in the *Preliminary Determination*, and consistent with Commerce's practice, as AFA, we based the AFA rate for Nisco Thailand on the highest non-aberrational individual transaction-specific margin calculated for Ventius of 344.70 percent.⁸

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated weighted-average dumping margin for all other producers and/or exporters not individually investigated shall be equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated excluding rates that are zero, *de minimis*, or determined entirely under section 776 of the Act.

Commerce calculated an individual estimated weighted-average dumping margin for Ventius. As a result, because we have calculated only one margin and that margin is not zero, *de minimis*, or based entirely on facts otherwise available, the estimated weighted-average dumping margin calculated for

Bluechip International LLC in the Antidumping Duty Investigation of Mattresses from Kosovo,” dated May 29, 2024; and “Verification of the CEP Sales Response of Adven Group LLC in the Antidumping Duty Investigation of Mattresses from Kosovo,” dated June 5, 2024.

⁷ See *Preliminary Determination*, 89 FR at 15132, 15133.

⁸ *Id.*, PDM at 7.

¹ See *Mattresses from Kosovo: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Postponement of Final Determination, and Extension of Provisional Measures*, 89 FR 15132 (March 1, 2024).

(*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

² See *Preliminary Determination*, 89 FR at 15133.

³ See Memorandum, “Issues and Decision Memorandum for the Final Affirmative Determination of Sales at Less Than Fair Value in the Investigation of Mattresses from Kosovo,” dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Ventius is the margin assigned to all other producers and exporters, pursuant to section 735(c)(5)(A) of the Act.

Final Determination

The final estimated weighted-average dumping margins are as follows:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Ventius International LLC	63.66
Nisco Thailand Co., Ltd	* 344.70
All Others	63.66

* Rate based on facts available with adverse inferences.

Disclosure

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

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of subject merchandise as described in Appendix I of this notice, which were entered, or withdrawn from warehouse, for consumption, on or after March 1, 2024, the date of publication of the *Preliminary Determination* in the **Federal Register**.

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), upon the publication of this notice, we will instruct CBP to require a cash deposit for estimated antidumping duties for such entries as follows: (1) the cash deposit rate for the respondent listed in the table above is the company-specific estimated weighted-average dumping margin listed for the respondent in the table; (2) if the exporter is not the respondent listed in the table above, but the producer is, then the cash deposit rate is the company-specific estimated weighted-average dumping margin listed for the producer of the subject merchandise in the table above; and (3) the cash deposit rate for all other producers and exporters is the all-others estimated weighted-average dumping margin listed in the table above. These suspension of liquidation instructions will remain in effect until further notice.

U.S. International Trade Commission Notification

In accordance with section 735(d) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its final affirmative determination of sales at LTFV. Because Commerce’s final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of mattresses from Kosovo no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, all cash deposits posted will be refunded, and suspension of liquidation will be lifted. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed in the “Continuation of Suspension of Liquidation” section above.

Administrative Protective Order

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

Notification to Interested Parties

This determination is issued and published in accordance with sections 735(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: July 15, 2024.

Ryan Majerus,
Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I
Scope of the Investigation

The products covered by these investigations are all types of youth and adult mattresses. The term “mattress” denotes an assembly of materials that at a minimum

includes a “core,” which provides the main support system of the mattress, and may consist of innersprings, foam, other resilient filling, or a combination of these materials. Mattresses also may contain: (1) “upholstery,” the material between the core and the top panel of the ticking on a single-sided mattress, or between the core and the top and bottom panel of the ticking on a double-sided mattress; and/or (2) “ticking,” the outermost layer of fabric or other material (e.g., vinyl) that encloses the core and any upholstery, also known as a cover.

The scope of these investigations is restricted to only “adult mattresses” and “youth mattresses.” “Adult mattresses” are frequently described as “twin,” “extra-long twin,” “full,” “queen,” “king,” or “California king” mattresses. “Youth mattresses” are typically described as “crib,” “toddler,” or “youth” mattresses. All adult and youth mattresses are included regardless of size and size description or how they are described (e.g., frameless futon mattress and tri-fold mattress).

The scope encompasses all types of “innerspring mattresses,” “non-innerspring mattresses,” and “hybrid mattresses.” “Innerspring mattresses” contain innersprings, a series of metal springs joined together in sizes that correspond to the dimensions of mattresses. Mattresses that contain innersprings are referred to as “innerspring mattresses” or “hybrid mattresses.” “Hybrid mattresses” contain two or more support systems as the core, such as layers of both memory foam and innerspring units.

“Non-innerspring mattresses” are those that do not contain any innerspring units. They are generally produced from foams (e.g., polyurethane, memory (viscoelastic), latex foam, gel infused viscoelastic (gel foam), thermobonded polyester, polyethylene) or other resilient filling.

Mattresses covered by the scope of these investigations may be imported independently, as part of furniture or furniture mechanisms (e.g., convertible sofa bed mattresses, sofa bed mattresses imported with sofa bed mechanisms, corner group mattresses, day-bed mattresses, roll-away bed mattresses, high risers, trundle bed mattresses, crib mattresses), or as part of a set (in combination with a “mattress foundation”). “Mattress foundations” are any base or support for a mattress. Mattress foundations are commonly referred to as “foundations,” “boxsprings,” “platforms,” and/or “bases.” Bases can be static, foldable, or adjustable. Only the mattress is covered by the scope if imported as part of furniture, with furniture mechanisms, or as part of a set, in combination with a mattress foundation.

Excluded from the scope of these investigations are “futon” mattresses. A “futon” is a bi-fold frame made of wood, metal, or plastic material, or any combination thereof, that functions as both seating furniture (such as a couch, love seat, or sofa) and a bed. A “futon mattress” is a tufted mattress, where the top covering is secured to the bottom with thread that goes completely through the mattress from the top through to the bottom, and it does not

contain innersprings or foam. A futon mattress is both the bed and seating surface for the futon.

Also excluded from the scope are airbeds (including inflatable mattresses) and waterbeds, which consist of air- or liquid-filled bladders as the core or main support system of the mattress.

Also excluded is certain multifunctional furniture that is convertible from seating to sleeping, regardless of filler material or components, where such filler material or components are upholstered, integrated into the design and construction of, and inseparable from, the furniture framing, and the outermost layer of the multifunctional furniture converts into the sleeping surface. Such furniture may, and without limitation, be commonly referred to as “convertible sofas,” “sofabeds,” “sofa chaise sleepers,” “futons,” “ottoman sleepers,” or a like description.

Also excluded from the scope of these investigations are any products covered by the existing antidumping duty orders on uncovered innerspring units from the People's Republic of China, South Africa, and the Socialist Republic of Vietnam. *See Uncovered Innerspring Units from the People's Republic of China, South Africa, and Socialist Republic of Vietnam: Continuation of Antidumping Duty Orders*, 84 FR 55285 (October 16, 2019).

Also excluded from the scope of these investigations are bassinet pads with a nominal length of less than 39 inches, a nominal width of less than 25 inches, and a nominal depth of less than 2 inches.

Additionally, also excluded from the scope of these investigations are “mattress toppers.” A “mattress topper” is a removable bedding accessory that supplements a mattress by providing an additional layer that is placed on top of a mattress. Excluded mattress toppers have a height of four inches or less.

Also excluded from the scope are the following hospital and patient care setting surfaces. Products that fall within the below categories and meet all of the exclusion factors in the respective category qualify for such exclusion, regardless of whether they may be referenced as a mattress.

Air Surfaces with all of the following characteristics: with the foot end comprised of either diecut construction foam or air bladders to allow extension and retraction of the surface; enclosed in a fluid-resistant polyurethane-coated ticking with a zipper; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with the core including air bladders, with or without foam inside; with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA administered Global Unique Device Identification Database.

Stretcher Surfaces with all of the following characteristics: with a nominal thickness of 5 inches or less; with the foam core width tapered at one end; enclosed in a fluid-resistant polyurethane-coated ticking with a zipper; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a

permanent bond; with the exterior of the ticking containing a welded flap to cover the ticking zipper; with loop velcro attached to the ticking to allow for the stretcher surface to be firmly affixed to the stretcher; with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA administered Global Unique Device Identification Database.

Birthing Bed Surfaces with all of the following characteristics: with a nominal thickness of 5 inches or less; with a foam core in two pieces that have either a V-shaped cutout or U-shaped cutout; enclosed in a fluid-resistant polyurethane-coated ticking with a zipper; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with attachment fasteners extending from the bottom of the surface comprised of snaps or plastic hook(s); with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA-administered Global Unique Device Identification Database.

Foam Surfaces with all the following characteristics: with a nominal thickness of 6.5 inches or less; with a foam core that has articulation lines cut into the foam and/or die-cut construction in a portion of the foam to allow movement of the surface; enclosed in a fluid-resistant polyurethane-coated ticking with a zipper; with the ticking made of material meeting ASTM F1671B-07 requirements for porosity and ISO 10993 requirements for biocompatibility; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with brackets or attachment knobs embedded in the surface core to allow the surface to be firmly affixed to the hospital bed frame; with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA-administered Global Unique Device Identification Database, where the label includes the manufacturer's name and address as well as the product's name, date of manufacture, serial number, and Global Trade Identification Number (GTIN).

The products subject to these investigations are currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 9404.21.0010, 9404.21.0013, 9404.21.0095, 9404.29.1005, 9404.29.1013, 9404.29.1095, 9404.29.9085, 9404.29.9087, and 9404.29.9095. Products subject to these investigations may also enter under HTSUS subheadings: 9401.41.0000, 9401.49.0000, and 9401.99.9081. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to these investigations is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Changes Since the Preliminary Determination
- IV. Discussion of the Issues
 - Comment 1: Home Market Viability
 - Comment 2: Reported Corrections at Verification and Use of Facts Available

V. Recommendation

[FR Doc. 2024–15985 Filed 7–19–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–518–002]

Melamine From Qatar: Preliminary Affirmative Countervailing Duty Determination, Preliminary Negative Determination of Critical Circumstances, and Alignment of Final Determination With Final Antidumping Duty Determination

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to producers and exporters of melamine from Qatar (Qatar). The period of investigation is January 1, 2023, through December 31, 2023. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable July 22, 2024.

FOR FURTHER INFORMATION CONTACT: Samantha Kinney or Sofia Pedrelli, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2285 or (202) 482–4310, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 703(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on March 11, 2024.¹ On April 11, 2024, Commerce postponed the preliminary determination of this investigation until July 15, 2024.²

For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.³ A list of topics

¹ *See Melamine from Germany, India, Qatar, and Trinidad and Tobago: Initiation of Countervailing Duty Investigations*, 89 FR 17381 (March 11, 2024) (Initiation Notice).

² *See Melamine from Germany, India, Qatar, and Trinidad and Tobago: Postponement of Preliminary Determinations in the Countervailing Duty Investigations*, 89 FR 27714 (April 18, 2024).

³ *See* Memorandum, “Decision Memorandum for the Preliminary Affirmative Determination of the Countervailing Duty Investigation of Melamine

Continued

discussed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The product covered by this investigation is melamine from Qatar. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

In accordance with the preamble to Commerce’s regulations,⁴ the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.*, scope).⁵ No interested party commented on the scope of the investigation as it appeared in the *Initiation Notice*.

Methodology

Commerce is conducting this investigation in accordance with section 701 of the Act. For each of the subsidy programs found countervailable, Commerce preliminarily determines

that there is a subsidy, *i.e.*, a financial contribution by an “authority” that gives rise to a benefit to the recipient, and that the subsidy is specific.⁶ For a full description of the methodology underlying our preliminary determination, see the Preliminary Decision Memorandum.

Preliminary Negative Determination of Critical Circumstances

Commerce preliminarily determines that critical circumstances do not exist. For a full description of the methodology and results of Commerce’s analysis, see the “Preliminary Negative Determination of Critical Circumstances” section of the Preliminary Decision Memorandum.

Alignment

As noted in the Preliminary Decision Memorandum, in accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), Commerce is aligning the final countervailing duty (CVD) determination in this investigation with the final determination in the companion antidumping duty (AD) investigation of melamine from Qatar based on a request made by the petitioner.⁷ Consequently, the final CVD determination will be issued on the same date as the final AD determination, which is currently scheduled to be issued no later than November 25, 2024, unless postponed.⁸

All-Others Rate

Sections 703(d) and 705(c)(5)(A) of the Act provide that in the preliminary determination, Commerce shall determine an estimated all-others rate for companies not individually examined. This rate shall be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any zero and *de minimis* rates and any rates based entirely under section 776 of the Act.

In this investigation, Commerce calculated an individual estimated countervailable subsidy rate for Qatar Melamine Company (QMC)/Qatar Chemical and Petrochemical Marketing and Distribution Company (Muntajat) Q.P.J.S.C. (Muntajat) and its cross-owned companies (QMC/Muntajat), the only individually examined exporters/producers in this investigation. Because the only individually calculated rate is not zero, *de minimis*, or based entirely under section 776 of the Act, the estimated weighted-average rate calculated for QMC/Muntajat and its cross-owned companies is the rate assigned to all other producers and exporters, pursuant to section 705(c)(5)(A)(i) of the Act.

Preliminary Determination

Commerce preliminarily determines that the following estimated countervailable subsidy rates exist:⁹

Company	Subsidy rate (percent <i>ad valorem</i>)
Qatar Melamine Company; Qatar Chemical and Petrochemical Marketing and Distribution Company (Muntajat) Q.P.J.S.C.;	
Qatar Fertiliser Company (P.S.C.); Industries Qatar Q.P.S.C.; QatarEnergy	40.49
All Others	40.49

Suspension of Liquidation

In accordance with sections 703(d)(1)(B) and (d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to 19 CFR

351.205(d), Commerce will instruct CBP to require a cash deposit equal to the rates indicated above.

Disclosure

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

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination together with

from Qatar,” dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

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

⁵ See *Initiation Notice*.

⁶ See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

⁷ See Petitioner’s Letter, “Petitioner’s Request to Align Countervailing Duty Investigation Final Determination with Antidumping Duty Investigation Final Determination,” dated June 11, 2024. The petitioner is Cornerstone Chemical Company.

⁸ See *Melamine from Germany, India, Japan, the Netherlands, Qatar, and Trinidad and Tobago: Postponement of Preliminary Determinations in the*

Less-Than-Fair-Value Investigations, 89 FR 52437 (June 24, 2024).

⁹ As discussed in the Preliminary Decision Memorandum, Commerce found the following companies to be cross owned with QMC: Muntajat, Qatar Fertiliser Company (P.S.C.), Industries Qatar Q.P.S.C., and QatarEnergy.

issues raised in the case briefs or other written comments.

Verification

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

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.¹⁰ Interested parties who submit case or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.¹¹

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.¹² Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).¹³

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of

Commerce within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

U.S. International Trade Commission (ITC) Notification

In accordance with section 703(f) of the Act, Commerce will notify the ITC of its determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination, whether imports of melamine from Qatar are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act, and 19 CFR 351.205(c).

Dated: July 15, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise subject to this investigation is melamine (Chemical Abstracts Service (CAS) registry number 108–78–01, molecular formula C₃H₆N₆). Melamine is also known as 2,4,6-triamino-s-triazine; 1,3,5-Triazine-2,4,6- triamine; Cyanurotriamide; Cyanurotriamine; Cyanuramide; and by various brand names. Melamine is a crystalline powder or granule. All melamine is covered by the scope of this investigation irrespective of purity, particle size, or physical form. Melamine that has been blended with other products is included within this scope when such blends include constituent parts that have been intermingled, but that have not been chemically reacted with each other to produce a different product. For such blends, only the melamine component of the mixture is covered by the scope of this investigation. Melamine that is otherwise subject to this investigation is not excluded when commingled with melamine from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

The subject merchandise is provided for in subheading 2933.61.0000 of the Harmonized Tariff Schedule of the United States

(HTSUS). Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Injury Test
- IV. Preliminary Negative Determination of Critical Circumstances
- V. New Subsidy Allegation
- VI. Subsidies Valuation
- VII. Analysis of Programs
- VIII. Recommendation

[FR Doc. 2024–15978 Filed 7–19–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–919]

Mattresses From India: Final Affirmative Determination of Sales at Less Than Fair Value

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that imports of mattresses from India are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation is July 1, 2022, through June 30, 2023.

DATES: Applicable July 22, 2024.

FOR FURTHER INFORMATION CONTACT: Paul Senoyuit, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6106.

SUPPLEMENTARY INFORMATION:

Background

On March 1, 2024, Commerce published the preliminary determination in this LTFV investigation of mattresses from India, in which we also postponed the final determination until July 15, 2024.¹ Commerce invited interested parties to comment on the *Preliminary Determination*.² On April 1, 2024,

¹ See *Mattresses from India: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures*, 89 FR 15140 (March 1, 2024) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

² *Id.*, 89 FR at 15141.

¹⁰ See 19 CFR 351.309(d); see also *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

¹¹ See 19 CFR 351.309(c)(2) and (d)(2).

¹² We use the term “issue” here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

¹³ See *APO and Service Final Rule*.

Commerce amended its *Preliminary Determination*.³

A summary of the events that occurred since Commerce published the *Preliminary Determination* and *Amended Preliminary Determination*, as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.⁴ The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

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

Scope Comments

During the course of this investigation, Commerce received scope comments from parties. Commerce issued a Preliminary Scope Decision Memorandum to address these comments and set aside a period of time for parties to address scope issues in scope-specific case and rebuttal briefs.⁵ We received comments from parties on the Preliminary Scope Decision Memorandum, which we addressed in the Final Scope Decision Memorandum.⁶ We made changes to the scope of the investigation from the scope published in the *Preliminary Determination*, as noted in Appendix I.

Verification

Commerce conducted verification of the information relied upon in making its final determination in this investigation, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act). Specifically, Commerce conducted on-site verifications of Varahamurti Flexirub Industries Private Limited (VFI)'s home market sales, U.S. sales, and cost of production.⁷ We used standard verification procedures, including an examination of relevant sales and accounting records, and original source documents provided by VFI.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs submitted by interested parties in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is attached to this notice as Appendix II.

Changes Since the Preliminary Determination

We made certain changes to the margin calculations for VFI since the *Amended Preliminary Determination*.⁸ For a discussion of these changes, see the Issues and Decision Memorandum.

Use of Adverse Facts Available

As discussed in the *Preliminary Determination*, for two of the mandatory respondents in this investigation, Raj Mahal Fabrics (Raj Mahal) and International Comfort Technologies Private Limited (ICT), Commerce assigned estimated weighted-average dumping margins on the basis of facts otherwise available with adverse inferences (AFA), pursuant to sections 776(a) and (b) of the Act.⁹ There is no new information on the record that would cause us to revisit our decision

in the *Preliminary Determination*. Accordingly, for the reasons explained in the *Preliminary Determination*, and consistent with Commerce's practice, as AFA, we assigned Raj Mahal and ICT the highest corroborated dumping margin.¹⁰ We corroborated the highest Petition margin by comparing it to the individually calculated margins calculated for VFI (*i.e.*, the sole respondent for which a margin was calculated in the final determination of this LTFV investigation) and found the Petition margin to be within the range of the highest individually calculated margins for VFI.¹¹

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated weighted-average dumping margin for all other producers and exporters not individually investigated shall be equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated excluding rates that are zero, *de minimis*, or determined entirely under section 776 of the Act.

In this investigation, Commerce assigned a rate based entirely on facts otherwise available with adverse inferences to Raj Mahal and ICT. Therefore, the only rate that is not zero, *de minimis* or based entirely on facts otherwise available is the rate calculated for VFI. Consequently, the rate calculated for VFI is also assigned as the rate for all other producers and exporters pursuant to section 735(c)(5)(A) of the Act.

Final Determination

Commerce determines that the following estimated weighted-average dumping margins exist for the period, July 1, 2022, through June 30, 2023:¹²

³ See *Mattresses from India: Amended Preliminary Determination of Less-Than-Fair-Value Investigation*, 89 FR 22382 (April 1, 2024) (*Amended Preliminary Determination*), and accompanying Amended Preliminary Decision Memorandum.

⁴ See Memorandum, "Decision Memorandum for the Final Affirmative Determination in the Less-Than-Fair-Value Investigation of Mattresses from India," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁵ See Memorandum, "Mattresses from Bosnia and Herzegovina, Bulgaria, Burma, India, Indonesia, Italy, Kosovo, Mexico, Philippines, Poland, Slovenia, Spain, and Taiwan: Preliminary Scope Decision Memorandum," dated February 23, 2024 (Preliminary Scope Decision Memorandum).

⁶ See Memorandum, "Mattresses from Bosnia and Herzegovina, Bulgaria, Burma, India, Indonesia,

Italy, Kosovo, Mexico, the Philippines, Poland, Slovenia, Spain, and Taiwan: Final Scope Decision Memorandum," dated May 8, 2024 (Final Scope Decision Memorandum).

⁷ See Memorandum, "Verification of the Sales Response of Varahamurti Flexirub Industries Private Limited in the Antidumping Duty Investigation of Mattresses from India," dated June 7, 2024; see also Memorandum, "Verification of the Cost Response of Varahamurti Flexirub Industries Private Limited in the Less Than Fair Value Investigation of Mattresses from India," dated June 13, 2024.

⁸ See Memorandum, "Analysis for the Final Determination for Varahamurti Flexirub Industries Private Limited," dated concurrently with this notice (Analysis Memorandum).

⁹ See *Preliminary Determination*, 89 FR at 15141.

¹⁰ See PDM at 14–15 (citing *Mattresses from Bosnia and Herzegovina, Bulgaria, Burma, India,*

Italy, Kosovo, Mexico, the Philippines, Poland, Slovenia, Spain, and Taiwan: Initiation of Less-Than-Fair-Value Investigations, 88 FR 57433, 57436 (August 23, 2023); see also, e.g., *Welded Stainless Pressure Pipe from Thailand: Final Determination of Sales at Less Than Fair Value*, 79 FR 31093 (May 30, 2014), and accompanying Issues and Decision Memorandum at Comment 3.

¹¹ See Analysis Memorandum at Attachment 2.

¹² Commerce preliminarily determined that Varahamurti Flexirub Industries Private Limited, Amore International, Durfi Retail Private Limited and Springfit Marketing INC comprise a single entity. We also preliminarily determined that International Comfort Technologies Limited and Sheela Foam comprise a single entity. See *Preliminary Determination* PDM at 5–7. For this final determination, we continue to find that these aforementioned companies should be treated as single entities, respectively.

Exporter/producer	Weighted-average dumping margin (percent)
International Comfort Technologies Private Limited; Sheela Foam Limited	* 42.76
Raj Mahal Fabrics	* 42.76
Varahamurti Flexirub Industries Private Limited; Amore International, Durfi Retail Private Limited; Springfit Marketing INC ..	13.35
All Others	13.35

* Rate based on AFA.

Disclosure

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

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of subject merchandise as described in Appendix I of this notice, which were entered, or withdrawn from warehouse, for consumption, on or after March 1, 2024, the date of publication of the *Preliminary Determination* in the **Federal Register**.

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), upon the publication of this notice, we will instruct CBP to require a cash deposit for estimated antidumping duties for such entries as follows: (1) the cash deposit rates for the companies listed in the table above are the company-specific estimated weighted-average dumping margins determined in this final determination; (2) if the exporter is not a respondent listed in the table above, but the producer is, then the cash deposit rate is the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters is the all-others estimated weighted-average dumping margin listed in the table above. These suspension of liquidation instructions will remain in effect until further notice.

U.S. International Trade Commission Notification

In accordance with section 735(d) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its final affirmative determination of sales at LTFV. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final

determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of mattresses from India no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, all cash deposits posted will be refunded, and suspension of liquidation will be lifted. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed in the "Continuation of Suspension of Liquidation" section above.

Administrative Protective Order

This notice serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely notification of the return, or destruction, of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation subject to sanction.

Notification to Interested Parties

This determination and this notice are issued and published in accordance with sections 735(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: July 15, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The products covered by this investigation are all types of youth and adult mattresses. The term "mattress" denotes an assembly of materials that at a minimum includes a

"core," which provides the main support system of the mattress, and may consist of innersprings, foam, other resilient filling, or a combination of these materials. Mattresses also may contain: (1) "upholstery," the material between the core and the top panel of the ticking on a single-sided mattress, or between the core and the top and bottom panel of the ticking on a double-sided mattress; and/or (2) "ticking," the outermost layer of fabric or other material (e.g., vinyl) that encloses the core and any upholstery, also known as a cover.

The scope of this investigation is restricted to only "adult mattresses" and "youth mattresses." "Adult mattresses" are frequently described as "twin," "extra-long twin," "full," "queen," "king," or "California king" mattresses. "Youth mattresses" are typically described as "crib," "toddler," or "youth" mattresses. All adult and youth mattresses are included regardless of size and size description or how they are described (e.g., frameless futon mattress and tri-fold mattress).

The scope encompasses all types of "innerspring mattresses," "non-innerspring mattresses," and "hybrid mattresses." "Innerspring mattresses" contain innersprings, a series of metal springs joined together in sizes that correspond to the dimensions of mattresses. Mattresses that contain innersprings are referred to as "innerspring mattresses" or "hybrid mattresses." "Hybrid mattresses" contain two or more support systems as the core, such as layers of both memory foam and innerspring units.

"Non-innerspring mattresses" are those that do not contain any innerspring units. They are generally produced from foams (e.g., polyurethane, memory (viscoelastic), latex foam, gel infused viscoelastic (gel foam), thermobonded polyester, polyethylene) or other resilient filling. Mattresses covered by the scope of this investigation may be imported independently, as part of furniture or furniture mechanisms (e.g., convertible sofa bed mattresses, sofa bed mattresses imported with sofa bed mechanisms, corner group mattresses, day-bed mattresses, roll-away bed mattresses, high risers, trundle bed mattresses, crib mattresses), or as part of a set (in combination with a "mattress foundation"). "Mattress foundations" are any base or support for a mattress. Mattress foundations are commonly referred to as "foundations," "boxsprings," "platforms," and/or "bases." Bases can be static, foldable, or adjustable. Only the mattress is covered by the scope if imported as part of furniture, with furniture mechanisms, or as part of a set, in combination with a mattress foundation.

Excluded from the scope of this investigation are “futon” mattresses. A “futon” is a bi-fold frame made of wood, metal, or plastic material, or any combination thereof, that functions as both seating furniture (such as a couch, love seat, or sofa) and a bed. A “futon mattress” is a tufted mattress, where the top covering is secured to the bottom with thread that goes completely through the mattress from the top through to the bottom, and it does not contain innersprings or foam. A futon mattress is both the bed and seating surface for the futon. Also excluded from the scope are airbeds (including inflatable mattresses) and waterbeds, which consist of air- or liquid-filled bladders as the core or main support system of the mattress.

Also excluded is certain multifunctional furniture that is convertible from seating to sleeping, regardless of filler material or components, where such filler material or components are upholstered, integrated into the design and construction of, and inseparable from, the furniture framing, and the outermost layer of the multifunctional furniture converts into the sleeping surface. Such furniture may, and without limitation, be commonly referred to as “convertible sofas,” “sofabeds,” “sofa chaise sleepers,” “futons,” “ottoman sleepers,” or a like description.

Also excluded from the scope of this investigation are any products covered by the existing antidumping duty orders on uncovered innerspring units from the People’s Republic of China, South Africa, and the Socialist Republic of Vietnam. See Uncovered Innerspring Units from the People’s Republic of China, South Africa, and Socialist Republic of Vietnam: Continuation of Antidumping Duty Orders, 84 FR 55285 (October 16, 2019).

Also excluded from the scope of this investigation are bassinet pads with a nominal length of less than 39 inches, a nominal width of less than 25 inches, and a nominal depth of less than 2 inches.

Additionally, also excluded from the scope of this investigation are “mattress toppers.” A “mattress topper” is a removable bedding accessory that supplements a mattress by providing an additional layer that is placed on top of a mattress. Excluded mattress toppers have a height of four inches or less.

Also excluded from the scope are the following hospital and patient care setting surfaces. Products that fall within the below categories and meet all of the exclusion factors in the respective category qualify for such exclusion, regardless of whether they may be referenced as a mattress.

Air Surfaces with all of the following characteristics: with the foot end comprised of either diecut construction foam or air bladders to allow extension and retraction of the surface; enclosed in a fluid-resistant polyurethane-coated ticking with a zipper; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with the core including air bladders, with or without foam inside; with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA-administered Global Unique Device Identification Database.

Stretcher Surfaces with all of the following characteristics: with a nominal thickness of 5 inches or less; with the foam core width tapered at one end; enclosed in a fluid-resistant polyurethane-coated ticking with a zipper; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with the exterior of the ticking containing a welded flap to cover the ticking zipper; with loop velcro attached to the ticking to allow for the stretcher surface to be firmly affixed to the stretcher; with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA-administered Global Unique Device Identification Database.

Birthing Bed Surfaces with all of the following characteristics: with a nominal thickness of 5 inches or less; with a foam core in two pieces that have either a V-shaped cutout or U-Shaped cutout; enclosed in a fluid-resistant polyurethane-coated ticking with a zipper; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with attachment fasteners extending from the bottom of the surface comprised of snaps or plastic hook(s); with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA-administered Global Unique Device Identification Database.

Foam Surfaces with all the following characteristics: with a nominal thickness of 6.5 inches or less; with a foam core that has articulation lines cut into the foam and/or die-cut construction in a portion of the foam to allow movement of the surface; enclosed in a fluid-resistant polyurethane-coated ticking with a zipper; with the ticking made of material meeting ASTM F1671B–07 requirements for porosity and ISO 10993 requirements for biocompatibility; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with brackets or attachment knobs embedded in the surface core to allow the surface to be firmly affixed to the hospital bed frame; with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA-administered Global Unique Device Identification Database, where the label includes the manufacturer’s name and address as well as the product’s name, date of manufacture, serial number, and Global Trade Identification Number (GTIN).

The products subject to this investigation are currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 9404.21.0010, 9404.21.0013, 9404.21.0095, 9404.29.1005, 9404.29.1013, 9404.29.1095, 9404.29.9085, 9404.29.9087, and 9404.29.9095. Products subject to this investigation may also enter under HTSUS subheadings: 9401.41.0000, 9401.49.0000, and 9401.99.9081. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to this investigation is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Changes Since the *Preliminary Determination*
- IV. Discussion of the Issues
 - Comment 1: Whether to Continue to Collapse All VFI Affiliates
 - Comment 2: Whether to Apply Total or Partial Adverse Facts Available to VFI
- V. Recommendation

[FR Doc. 2024–15984 Filed 7–19–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–560–839]

Mattresses From Indonesia: Final Negative Countervailing Duty Determination

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are not being provided to producers and exporters of mattresses from Indonesia. The period of investigation is January 1, 2022, through December 31, 2022.

DATES: Applicable July 22, 2024.

FOR FURTHER INFORMATION CONTACT: Natasia Harrison or Harriston Tanchuck, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1240 or (202) 482–7421, respectively.

SUPPLEMENTARY INFORMATION:

Background

On January 2, 2024, Commerce published the *Preliminary Determination* in the **Federal Register**.¹ Subsequently, on April 3, 2024, Commerce released its Post-Preliminary Analysis.² For a complete description of the events that followed the *Preliminary Determination*, see the Issues and Decision Memorandum.³ The Issues and

¹ See *Mattresses from Indonesia: Preliminary Negative Countervailing Duty Determination and Alignment of Final Determination with the Final Antidumping Duty Determination*, 89 FR 57 (January 2, 2024) (*Preliminary Determination*).

² See Memorandum, “Post-Preliminary Analysis,” dated April 3, 2024.

³ See Memorandum, “Issues and Decision Memorandum for the Final Negative Determination in the Countervailing Duty Investigation of Mattresses from Indonesia,” dated concurrently

Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <http://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

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

Scope Comments

During the course of this investigation, Commerce received scope comments from parties. Commerce issued a Preliminary Scope Decision Memorandum to address these comments and set aside a period of time for parties to address scope issues in scope-specific case and rebuttal briefs.⁴ We received comments from parties on the Preliminary Scope Decision Memorandum, which we addressed in the Final Scope Decision Memorandum.⁵ We made changes to the scope of the investigation from the

scope published in the *Preliminary Determination*, as noted in Appendix I.

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation, and the issues raised in the case and rebuttal briefs that were submitted by parties in this investigation, are discussed in the Issues and Decision Memorandum. For a list of the issues raised by interested parties and addressed in the Issues and Decision Memorandum, see Appendix II.

Verification

Commerce conducted verification of the information relied upon in making its final determination in this investigation, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act). Specifically, we conducted on-site verifications of the Government of Indonesia, PT Grantec Jaya Indonesia (Grantec), and PT Zinus Global Indonesia (PT Zinus) between February 19 and March 1, 2024, as well as of the Government of Korea and Zinus Inc. (Korea) in May 2024, using standard verification procedures, including an examination of relevant sales and accounting records, and

original source documents provided by the respondents.⁶

Methodology

Commerce conducted this investigation in accordance with section 701 of the Act. For each of the subsidy programs found to be countervailable, Commerce determines that there is a subsidy, *i.e.*, a financial contribution by an "authority" that gives rise to a benefit to the recipient, and that the subsidy is specific.⁷ For a full description of the methodology underlying our final determination, see the Issues and Decision Memorandum.

Changes Since the Preliminary Determination and Post-Preliminary Analysis

Based on our findings at verification, and our review and analysis of the comments received from parties, for this final determination, we made certain changes to the countervailable subsidy rate calculations for Grantec. For a discussion of these changes, see the Issues and Decision Memorandum.

Final Determination

Commerce determines that the following estimated countervailable subsidy rates exist for the period January 1, 2022, through December 31, 2022:

Company	Subsidy rate (<i>ad valorem</i> percent)
PT Grantec Jaya Indonesia ⁸	0.19 (<i>de minimis</i>).
PT Zinus Global Indonesia	0.03 (<i>de minimis</i>).

Consistent with section 703(d) of the Act, Commerce has not calculated an estimated weighted-average subsidy rate for all other producers and exporters because it has not made an affirmative final determination.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this final determination within five days of any

public announcement, or if there is no public announcement, within five days of the date of the publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

In the *Preliminary Determination*, the total net countervailable subsidy rates for the individually examined respondents were *de minimis* and, therefore, we did not suspend

liquidation of entries of mattresses from Indonesia.⁹ Because Commerce determines that no countervailable subsidies are being provided to the production or exportation of subject merchandise, Commerce will not direct U.S. Customs and Border Protection to suspend liquidation of any such entries.

with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁴ See Memorandum, "Mattresses from Bosnia and Herzegovina, Bulgaria, Burma, India, Indonesia, Italy, Kosovo, Mexico, Philippines, Poland, Slovenia, Spain, and Taiwan: Preliminary Scope Decision Memorandum," dated February 23, 2024.

⁵ See Memorandum, "Mattresses from Bosnia and Herzegovina, Bulgaria, Burma, India, Indonesia, Italy, Kosovo, Mexico, Philippines, Poland,

Slovenia, Spain, and Taiwan: Final Scope Decision Memorandum," dated May 8, 2024.

⁶ See Memoranda, "Verification of PT Grantec Jaya Indonesia Questionnaire Responses," dated April 9, 2024; "Verification of PT Zinus Global Indonesia Questionnaire Responses," dated April 9, 2024; "Verification of the Government of Indonesia Questionnaire Responses," dated April 9, 2024; "Verification of the Government of the Republic of Korea's New Subsidy Allegations Questionnaire Response," dated June 5, 2024; and "Verification of PT Zinus Global Indonesia New Subsidy

Allegations Questionnaire Responses regarding Zinus Inc. (Korea)," dated June 5, 2024.

⁷ See sections 771(5)(B) and (D) of the Act regarding financial contribution; see also section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

⁸ As discussed in the Issues and Decision Memorandum, Commerce determines PT Grantec Jaya Indonesia is cross-owned with PT Ecos Jaya Indonesia.

⁹ See *Preliminary Determination*, 89 FR at 58.

International Trade Commission (ITC) Notification

In accordance with section 705(d) of the Act, Commerce will notify the ITC of its final determination that countervailable subsidies are not being provided to producers and exporters of mattresses from Indonesia. Because Commerce's final determination is negative, this proceeding is terminated in accordance with section 705(c)(2) of the Act.

Administrative Protective Order

This notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO, in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: July 15, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The products covered by this investigation are all types of youth and adult mattresses. The term "mattress" denotes an assembly of materials that at a minimum includes a "core," which provides the main support system of the mattress, and may consist of innersprings, foam, other resilient filling, or a combination of these materials. Mattresses also may contain: (1) "upholstery," the material between the core and the top panel of the ticking on a single-sided mattress, or between the core and the top and bottom panel of the ticking on a double-sided mattress; and/or (2) "ticking," the outermost layer of fabric or other material (e.g., vinyl) that encloses the core and any upholstery, also known as a cover.

The scope of this investigation is restricted to only "adult mattresses" and "youth mattresses." "Adult mattresses" are frequently described as "twin," "extra-long twin," "full," "queen," "king," or "California king" mattresses. "Youth mattresses" are typically described as "crib," "toddler," or "youth" mattresses. All adult and youth mattresses are included regardless of size and size description or how they are described (e.g., frameless futon mattress and tri-fold mattress).

The scope encompasses all types of "innerspring mattresses," "non-innerspring mattresses," and "hybrid mattresses." "Innerspring mattresses" contain innersprings, a series of metal springs joined together in sizes that correspond to the dimensions of mattresses. Mattresses that contain innersprings are referred to as "innerspring mattresses" or "hybrid mattresses." "Hybrid mattresses" contain two or more support systems as the core, such as layers of both memory foam and innerspring units.

"Non-innerspring mattresses" are those that do not contain any innerspring units. They are generally produced from foams (e.g., polyurethane, memory (viscoelastic), latex foam, gel infused viscoelastic (gel foam), thermobonded polyester, polyethylene) or other resilient filling.

Mattresses covered by the scope of this investigation may be imported independently, as part of furniture or furniture mechanisms (e.g., convertible sofa bed mattresses, sofa bed mattresses imported with sofa bed mechanisms, corner group mattresses, day-bed mattresses, roll-away bed mattresses, high risers, trundle bed mattresses, crib mattresses), or as part of a set (in combination with a "mattress foundation"). "Mattress foundations" are any base or support for a mattress. Mattress foundations are commonly referred to as "foundations," "boxsprings," "platforms," and/or "bases." Bases can be static, foldable, or adjustable. Only the mattress is covered by the scope if imported as part of furniture, with furniture mechanisms, or as part of a set, in combination with a mattress foundation.

Excluded from the scope of this investigation are "futon" mattresses. A "futon" is a bi-fold frame made of wood, metal, or plastic material, or any combination thereof, that functions as both seating furniture (such as a couch, love seat, or sofa) and a bed. A "futon mattress" is a tufted mattress, where the top covering is secured to the bottom with thread that goes completely through the mattress from the top through to the bottom, and it does not contain innersprings or foam. A futon mattress is both the bed and seating surface for the futon.

Also excluded from the scope are airbeds (including inflatable mattresses) and waterbeds, which consist of air- or liquid-filled bladders as the core or main support system of the mattress.

Also excluded is certain multifunctional furniture that is convertible from seating to sleeping, regardless of filler material or components, where such filler material or components are upholstered, integrated into the design and construction of, and inseparable from, the furniture framing, and the outermost layer of the multifunctional furniture converts into the sleeping surface. Such furniture may, and without limitation, be commonly referred to as "convertible sofas," "sofabeds," "sofa chaise sleepers," "futons," "ottoman sleepers," or a like description.

Also excluded from the scope of this investigation are any products covered by the existing antidumping duty orders on

uncovered innerspring units from the People's Republic of China, South Africa, and the Socialist Republic of Vietnam. See *Uncovered Innerspring Units from the People's Republic of China, South Africa, and Socialist Republic of Vietnam: Continuation of Antidumping Duty Orders*, 84 FR 55285 (October 16, 2019).

Also excluded from the scope of this investigation are bassinet pads with a nominal length of less than 39 inches, a nominal width of less than 25 inches, and a nominal depth of less than 2 inches.

Additionally, also excluded from the scope of this investigation are "mattress toppers." A "mattress topper" is a removable bedding accessory that supplements a mattress by providing an additional layer that is placed on top of a mattress. Excluded mattress toppers have a height of four inches or less.

Also excluded from the scope are the following hospital and patient care setting surfaces. Products that fall within the below categories and meet all the exclusion factors in the respective category qualify for such exclusion, regardless of whether they may be referenced as a mattress.

Air Surfaces with all of the following characteristics: with the foot end comprised of either diecut construction foam or air bladders to allow extension and retraction of the surface; enclosed in a fluid-resistant polyurethane-coated ticking with a zipper; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with the core including air bladders, with or without foam inside; with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA administered Global Unique Device Identification Database.

Stretcher Surfaces with all of the following characteristics: with a nominal thickness of 5 inches or less; with the foam core width tapered at one end; enclosed in a fluid-resistant polyurethane coated ticking with a zipper; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with the exterior of the ticking containing a welded flap to cover the ticking zipper; with loop velcro attached to the ticking to allow for the stretcher surface to be firmly affixed to the stretcher; with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA administered Global Unique Device Identification Database.

Birthing Bed Surfaces with all of the following characteristics: with a nominal thickness of 5 inches or less; with a foam core in two pieces that have either a V-shaped cutout or U-Shaped cutout; enclosed in a fluid-resistant polyurethane-coated ticking with a zipper; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with attachment fasteners extending from the bottom of the surface comprised of snaps or plastic hook(s); with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA-administered Global Unique Device Identification Database.

Foam Surfaces with all the following characteristics: with a nominal thickness of

6.5 inches or less; with a foam core that has articulation lines cut into the foam and/or die-cut construction in a portion of the foam to allow movement of the surface; enclosed in a fluid-resistant polyurethane coated ticking with a zipper; with the ticking made of material meeting ASTM F1671B-07 requirements for porosity and ISO 10993 requirements for biocompatibility; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with brackets or attachment knobs embedded in the surface core to allow the surface to be firmly affixed to the hospital bed frame; with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA-administered Global Unique Device Identification Database, where the label includes the manufacturer's name and address as well as the product's name, date of manufacture, serial number, and Global Trade Identification Number (GTIN).

The products subject to this investigation are currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 9404.21.0010, 9404.21.0013, 9404.21.0095, 9404.29.1005, 9404.29.1013, 9404.29.1095, 9404.29.9085, 9404.29.9087, and 9404.29.9095. Products subject to this investigation may also enter under HTSUS subheadings: 9401.41.0000, 9401.49.0000, and 9401.99.9081. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to this investigation is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Investigation
- IV. Subsidies Valuation
- V. Changes Since the *Preliminary Determination*
- VI. Analysis of Programs
- VII. Discussion of the Issues
 - Comment 1: Whether Commerce Should Have Investigated the Exemption of Value-Added Tax (VAT) on Imported and Domestically-Sourced Machinery for Bonded Zone Companies
 - Comment 2: Whether to Attribute to PT Zinus Subsidies Received by PT Zinus Dream Indonesia (Zinus Dream)
 - Comment 3: Whether the Government of the Republic of Korea (GOK) Provided Export Subsidies and Subsidized Loans to PT Zinus Through GOK-Owned Banks
- VIII. Recommendation

[FR Doc. 2024-15983 Filed 7-19-24; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-428-853]

Melamine From Germany: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination With Final Antidumping Duty Determination

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to producers and exporters of melamine from Germany. The period of investigation is January 1, 2023, through December 31, 2023. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable July 22, 2024.

FOR FURTHER INFORMATION CONTACT: Bob Palmer or Faris Montgomery, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-9068 or (202) 482-1537, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 703(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on March 11, 2024.¹ On April 11, 2024, Commerce postponed the preliminary determination of this investigation until July 15, 2024.²

For a complete description of the events that followed the initiation of this investigation, see the Preliminary Decision Memorandum.³ A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically

¹ See *Melamine from Germany, India, Qatar and Trinidad and Tobago: Initiation of Countervailing Duty Investigations*, 89 FR 17381 (March 11, 2024) (*Initiation Notice*).

² See *Melamine from Germany, India, Qatar and Trinidad and Tobago: Postponement of Preliminary Determinations of Antidumping Duty Investigations*, 89 FR 27714 (April 18, 2024).

³ See Memorandum, "Decision Memorandum for the Preliminary Affirmative Determination of the Countervailing Duty Investigation of Melamine from Germany," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The product covered by this investigation is melamine from Germany. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,⁴ the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.*, scope).⁵ No interested party commented on the scope of the investigation as it appeared in the *Initiation Notice*.

Methodology

Commerce is conducting this investigation in accordance with section 701 of the Act. For each of the subsidy programs found countervailable, Commerce preliminarily determines that there is a subsidy, *i.e.*, a financial contribution by an "authority" that gives rise to a benefit to the recipient, and that the subsidy is specific.⁶

Commerce notes that, in making these findings, it relied, in part, on facts available and, because it finds that one or more respondents did not act to the best of their ability to respond to Commerce's requests for information, it drew an adverse inference where appropriate in selecting from among the facts otherwise available.⁷ For further information, see the "Use of Facts Otherwise Available and Adverse Inferences" section in the Preliminary Decision Memorandum.

Alignment

As noted in the Preliminary Decision Memorandum, in accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), Commerce is aligning the final countervailing duty (CVD) determination in this investigation with the final determination in the companion antidumping duty (AD)

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

⁵ See *Initiation Notice*.

⁶ See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

⁷ See sections 776(a) and (b) of the Act.

investigation of melamine from Germany based on a request made by the petitioner.⁸ Consequently, the final CVD determination will be issued on the same date as the final AD determination, which is currently scheduled to be issued no later than November 25, 2024, unless postponed.

All-Others Rate

Sections 703(d) and 705(c)(5)(A) of the Act provide that in the preliminary determination, Commerce shall determine an estimated all-others rate for companies not individually examined. This rate shall be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any zero and *de minimis* rates and any rates based entirely under section 776 of the Act.

Pursuant to section 705(c)(5)(A)(ii) of the Act, if the individual estimated countervailable subsidy rates established for all exporters and producers individually examined are zero, *de minimis*, or determined based entirely on facts otherwise available, Commerce may use any reasonable method to establish the estimated subsidy rate for all other producers or exporters. Commerce has preliminarily determined the individually estimated subsidy rate for the individually examined respondent under section 776 of the Act. Consequently, as a reasonable method, Commerce is determining the all-others rate based on the rate determined for LAT Nitrogen Piesteritz GmbH (LAT Nitrogen), the mandatory respondent in this investigation, as determined under section 776 of the Act.⁹ For a full description of the methodology

underlying Commerce's analysis, see the Preliminary Decision Memorandum.

Preliminary Determination

Commerce preliminarily determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent <i>ad valorem</i>)
LAT Nitrogen Piesteritz GmbH	29.72
All Others	29.72

Suspension of Liquidation

In accordance with sections 703(d)(1)(B) and (d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the rates indicated above.

Disclosure

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

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination together with issues raised in the case briefs or other written comments.

Verification

Because the examined respondents in this investigation did not provide information requested by Commerce and Commerce preliminarily determines each of the examined respondents to have been uncooperative, it will not conduct verification.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and

Compliance no later than 30 days after the date of publication of the preliminary determination. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.¹⁰ Interested parties who submit case or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.¹¹

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.¹² Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).¹³

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

⁸ See Petitioner's Letter, "Petitioner's Request to Align Countervailing Duty Investigation Final Determination with Antidumping Duty Investigation Final Determination," dated June 11, 2024. The petitioner is Cornerstone Chemical Company.

⁹ See, e.g., *Notice of Preliminary Determination of Sales at Less Than Fair Value: Sodium Nitrite from the Federal Republic of Germany*, 73 FR 21909, 21912 (April 23, 2008), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: Sodium Nitrite from the Federal Republic of Germany*, 73 FR 38986, 38987 (July 8, 2008), and accompanying Issues and Decision Memorandum at Comment 2; see also *Notice of Final Determination of Sales at Less Than Fair Value: Raw Flexible Magnets from Taiwan*, 73 FR 39673, 39674 (July 10, 2008); and *Steel Threaded Rod from Thailand: Preliminary Determination of Sales at Less Than Fair Value and Affirmative Preliminary Determination of Critical Circumstances*, 78 FR 79670, 79671 (December 31, 2013), unchanged in *Steel Threaded Rod from Thailand: Final Determination of Sales at Less Than Fair Value and Affirmative Final Determination of Critical Circumstances*, 79 FR 14476, 14477 (March 14, 2014).

¹⁰ See 19 CFR 351.309(d); see also *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

¹¹ See 19 CFR 351.309(c)(2) and (d)(2).

¹² We use the term "issue" here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

¹³ See *APO and Service Final Rule*.

location of the hearing two days before the scheduled date.

U.S. International Trade Commission (ITC) Notification

In accordance with section 703(f) of the Act, Commerce will notify the ITC of its determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether imports of melamine from Germany are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act, and 19 CFR 351.205(c).

Dated: July 15, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise subject to this investigation is melamine (Chemical Abstracts Service (CAS) registry number 108–78–01, molecular formula C₃H₆N₆). Melamine is also known as 2,4,6-triamino-s-triazine; 1,3,5-Triazine-2,4,6-triamine; Cyanurotriamide; Cyanurotriamine; Cyanuramide; and by various brand names. Melamine is a crystalline powder or granule. All melamine is covered by the scope of this investigation irrespective of purity, particle size, or physical form. Melamine that has been blended with other products is included within this scope when such blends include constituent parts that have been intermingled, but that have not been chemically reacted with each other to produce a different product. For such blends, only the melamine component of the mixture is covered by the scope of this investigation. Melamine that is otherwise subject to this investigation is not excluded when commingled with melamine from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

The subject merchandise is provided for in subheading 2933.61.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Injury Test

- IV. Use of Facts Otherwise Available and Adverse Inferences
- V. Recommendation

[FR Doc. 2024–15980 Filed 7–19–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–925]

Melamine From India: Preliminary Affirmative Countervailing Duty Determination, Preliminary Affirmative Critical Circumstances Determination, and Alignment of Final Determination With the Final Antidumping Duty Determination

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to producers and exporters of melamine from India. The period of investigation (POI) is January 1, 2023, through December 31, 2023. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable July 22, 2024.

FOR FURTHER INFORMATION CONTACT: Paul Kebker or Dylan Hill, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2254 or (202) 482–1197, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 703(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on March 11, 2024.¹ On April 18, 2024, Commerce postponed the preliminary determination in this investigation until July 15, 2024.²

For a complete description of the events that followed the initiation of this investigation, see the Preliminary Decision Memorandum.³ A list of topics

discussed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The product covered by this investigation is melamine from India. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,⁴ the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage, (i.e., scope).⁵ No interested party commented on the scope of the investigation as it appeared in the *Initiation Notice*.

Methodology

Commerce is conducting this investigation in accordance with section 701 of the Act. For each of the subsidy programs found to be countervailable, Commerce preliminarily determines that there is a subsidy, i.e., a financial contribution by an "authority" that gives rise to a benefit to the recipient, and that the subsidy is specific.⁶

In making its determination, Commerce relied, in part, on adverse facts available. For further information, see the "Use of Adverse Facts Available" section in the Preliminary Decision Memorandum.

Preliminary Affirmative Determination of Critical Circumstances

In accordance with section 703(e)(1) of the Act, Commerce preliminarily determines that critical circumstances exist with respect to U.S. imports of subject merchandise from Gujarat State Fertilizers and Chemicals Limited (Gujarat Fertilizers) and all other exporters or producers not individually

Countervailing Duty Investigation of Melamine from India," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

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

⁵ See *Initiation Notice*, 89 FR at 17381–82.

⁶ See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

¹ See *Melamine from Germany, India, Qatar, and Trinidad and Tobago: Initiation of Countervailing Duty Investigations*, 89 FR 17381 (March 11, 2024) (*Initiation Notice*).

² See *Melamine from Germany, India, Qatar, and Trinidad and Tobago: Postponement of Preliminary Determinations in the Countervailing Duty Investigations*, 89 FR 27714 (April 18, 2024).

³ See Memorandum, "Decision Memorandum for the Preliminary Affirmative Determination in the

examined. For a full description of the methodology and results of Commerce's analysis, see the "Preliminary Determination of Critical Circumstances" section in the Preliminary Decision Memorandum.

Alignment

As noted in the Preliminary Decision Memorandum, in accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), Commerce is aligning the final countervailing duty (CVD) determination in this investigation with the final determination in the companion antidumping duty (AD) investigation of melamine from India based on a request made by the petitioner.⁷ Consequently, the final CVD determination will be issued on the same date as the final AD determination, which is currently scheduled to be issued no later than November 25, 2024, unless postponed.⁸

All-Others Rate

Sections 703(d) and 705(c)(5)(A) of the Act provide that in the preliminary determination, Commerce shall determine an estimated all-others rate for companies not individually examined. This rate shall be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any zero and *de minimis* rates and any rates determined entirely under section 776 of the Act.

In this investigation, Commerce calculated an individual estimated countervailable subsidy rate for Gujarat Fertilizers, the only individually examined exporter/producer in this investigation. Because the only individually calculated rate is not zero, *de minimis*, or determined entirely under section 776 of the Act, we have assigned the rate calculated for Gujarat Fertilizers to all other producers and exporters, pursuant to section 705(c)(5)(A)(i) of the Act.

Preliminary Determination

Commerce preliminarily determines that the following estimated countervailable subsidy rates exists:

Company	Subsidy rate (percent <i>ad valorem</i>)
Gujarat State Fertilizers and Chemicals Limited	17.09
All Others	17.09

Suspension of Liquidation

In accordance with section 703(d)(1)(B) and (d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in Appendix I to this notice entered, or withdrawn from warehouse, for consumption on or after the date described below. Further, pursuant to 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the rate indicated in the table above.

Section 703(e)(2) of the Act provides that, given an affirmative determination of critical circumstances, any suspension of liquidation shall apply to unliquidated entries of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the later of: (a) the date which is 90 days before the date on which the suspension of liquidation was first ordered; or (b) the date on which notice of initiation of the investigation was published in the **Federal Register**. As noted above, Commerce preliminarily finds that critical circumstances exist for imports of subject merchandise produced and/or exported by Gujarat Fertilizers and all other producers and/or exporters not individually examined. In accordance with section 703(e)(2)(A) of the Act, suspension of liquidation shall apply to unliquidated entries of subject merchandise from the exporters/producers identified in this paragraph that were entered, or withdrawn from warehouse, for consumption on or after the date which is 90 days before the publication of this notice in the **Federal Register**.

Disclosure

Commerce intends to disclose its calculations and analysis performed in this preliminary determination to parties to the proceeding within five days of public announcement of the determination, or if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.244(b).

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent

with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination together with issues raised in the case briefs or other written comments.

Verification

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

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. Rebuttal briefs, limited to issues raised in case briefs, may be filed not later than five days after the date for filing case briefs.⁹ Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.¹⁰

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide, at the beginning of their briefs, a public executive summary for each issue raised in their briefs.¹¹ Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis for the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).¹²

⁷ See Petitioner's Letter, "Petitioner's Request to Align Countervailing Duty Investigation Final Determination with Antidumping Duty Investigation Final Determination," dated June 11, 2024. The petitioner is Cornerstone Chemical Company.

⁸ See *Melamine From Germany, India, Japan, the Netherlands, Qatar, and Trinidad and Tobago: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations*, 89 FR 52437 (June 24, 2024).

⁹ See 19 CFR 351.309(d); see also *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

¹⁰ See 19 CFR 351.309(c)(2) and (d)(2).

¹¹ We use the term "issue" here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

¹² See *APO and Service Final Rule*.

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

U.S. International Trade Commission Notification

In accordance with section 703(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine, before the later of 120 days after the date of this preliminary determination or 45 days after the final determination, whether imports of melamine from India are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act, and 19 CFR 351.205(c).

Dated: July 15, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise subject to this investigation is melamine (Chemical Abstracts Service (CAS) registry number 108-78-01, molecular formula C₃H₆N₆). Melamine is also known as 2,4,6-triamino-s-triazine; 1,3,5-Triazine-2,4,6-triamine; Cyanurotriamide; Cyanurotriamine; Cyanuramide; and by various brand names. Melamine is a crystalline powder or granule. All melamine is covered by the scope of this investigation irrespective of purity, particle size, or physical form. Melamine that has been blended with other products is included within this scope when such blends include constituent parts that have been intermingled, but that have not been

chemically reacted with each other to produce a different product. For such blends, only the melamine component of the mixture is covered by the scope of this investigation. Melamine that is otherwise subject to this investigation is not excluded when commingled with melamine from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

The subject merchandise is provided for in subheading 2933.61.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Injury Test
- IV. Preliminary Determination of Critical Circumstances
- V. Use of Adverse Facts Available (AFA)
- VI. Subsidies Valuation
- VII. Benchmarks
- VIII. Diversification of India's Economy
- IX. Analysis of Programs
- X. Recommendation

[FR Doc. 2024-15981 Filed 7-19-24; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-274-811]

Melamine From Trinidad and Tobago: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination With Final Antidumping Duty Determination

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to producers and exporters of melamine from Trinidad and Tobago. The period of investigation is January 1, 2023, through December 31, 2023. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable July 22, 2024.

FOR FURTHER INFORMATION CONTACT: Colin Thrasher, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-3004.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 703(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on March 11, 2024.¹ On April 18, 2024, Commerce postponed the preliminary determination of this investigation until July 15, 2024.²

For a complete description of the events that followed the initiation of this investigation, see the Preliminary Decision Memorandum.³ A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

The product covered by this investigation is melamine from Trinidad and Tobago. For a complete description of the scope of this investigation, see Appendix I.

Scope Comments

In accordance with the *Preamble* to Commerce's regulations,⁴ the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage, (*i.e.*, scope).⁵ No interested party commented on the scope of the investigation as it appeared in the *Initiation Notice*.

Methodology

Commerce is conducting this investigation in accordance with section 701 of the Act. For each of the subsidy programs found countervailable, Commerce preliminarily determines

¹ See *Melamine from Germany, India, Qatar, and Trinidad and Tobago: Initiation of Countervailing Duty Investigations*, 89 FR 17381 (March 11, 2024) (*Initiation Notice*).

² See *Melamine from Germany, India, Qatar, and Trinidad and Tobago: Postponement of Preliminary Determinations in the Countervailing Duty Investigations*, 89 FR 27714 (April 18, 2024).

³ See Memorandum, "Decision Memorandum for the Preliminary Affirmative Determination in the Countervailing Duty Investigation of Melamine from Trinidad and Tobago," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

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

⁵ See *Initiation Notice*.

that there is a subsidy, *i.e.*, a financial contribution by an “authority” that gives rise to a benefit to the recipient, and that the subsidy is specific.⁶

Commerce notes that, in making these findings, it relied on facts available and, because it finds that one or more respondents did not act to the best of their ability to respond to Commerce’s requests for information, it drew an adverse inference where appropriate in selecting from among the facts otherwise available.⁷ For further information, *see* the “Use of Facts Otherwise Available and Adverse Inferences” section in the Preliminary Decision Memorandum.

Alignment

As noted in the Preliminary Decision Memorandum, in accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), Commerce is aligning the final countervailing duty (CVD) determination in this investigation with the final determination in the companion antidumping duty (AD) investigation of melamine from Trinidad and Tobago based on a request made by the petitioner.⁸ Consequently, the final CVD determination will be issued on the same date as the final AD determination, which is currently scheduled to be issued no later than November 25, 2024, unless postponed.

All-Others Rate

Sections 703(d) and 705(c)(5)(A) of the Act provide that in the preliminary determination, Commerce shall determine an estimated all-others rate for companies not individually examined. This rate shall be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any zero and *de minimis* rates and any rates based entirely under section 776 of the Act.

Pursuant to section 705(c)(5)(A)(ii) of the Act, if the individual estimated countervailable subsidy rates established for all exporters and producers individually examined are zero, *de minimis*, or determined based entirely on facts otherwise available, Commerce may use any reasonable method to establish the estimated subsidy rate for all other producers or

exporters. Commerce has preliminarily determined the individually estimated subsidy rate for the individually examined respondent, Methanol Holdings (Trinidad) Ltd. (MHTL), under section 776 of the Act. There is no other exporter/producer under investigation. Consequently, the rate calculated for MHTL is also assigned as the rate for all other producers and exporters.

Preliminary Determination

Commerce preliminarily determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent <i>ad valorem</i>)
Methanol Holdings (Trinidad) Ltd	5.13
All Others	5.13

Suspension of Liquidation

In accordance with section 703(d)(1)(B) and (d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the rates indicated above.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of its public announcement, or if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). However, because Commerce preliminarily applied total adverse facts available (AFA) to the respondent in this investigation, in accordance with section 776 of the Act, and the applied AFA rates are based on rates calculated in prior proceedings, there are no calculations to disclose.

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations

in the final determination together with issues raised in the case briefs or other written comments.

Verification

Because the examined respondent in this investigation did not provide information requested by Commerce and Commerce preliminarily determines the examined respondent failed to cooperate by not acting to the best of its ability to respond to Commerce’s request for information pursuant to section 776(b) of the Act, it will not conduct verification.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 30 days after the date of publication of the preliminary determination. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.⁹ Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.¹⁰

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.¹¹ Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).¹²

⁶ See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

⁷ See sections 776(a) and (b) of the Act.

⁸ See Petitioner’s Letter, “Petitioner’s Request to Align Countervailing Duty Investigation Final Determination with Antidumping Duty Investigation Final Determination,” dated June 11, 2024. The petitioner is Cornerstone Chemical Company.

⁹ See 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

¹⁰ See 19 CFR 351.309(c)(2) and (d)(2).

¹¹ We use the term “issue” here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

¹² See *APO and Service Final Rule*.

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

U.S. International Trade Commission Notification

In accordance with section 703(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether imports of melamine from Trinidad and Tobago are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: July 15, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise subject to this investigation is melamine (Chemical Abstracts Service (CAS) registry number 108-78-01, molecular formula C₃H₆N₆). Melamine is also known as 2,4,6-triamino-s-triazine; 1,3,5-Triazine-2,4,6-triamine; Cyanurotriarnide; Cyanurotriarnine; Cyanuramide; and by various brand names. Melamine is a crystalline powder or granule. All melamine is covered by the scope of this investigation irrespective of purity, particle size, or physical form. Melamine that has been blended with other products is included within this scope when such blends include constituent parts that have been intermingled, but that have not been chemically reacted with each other to produce a different product. For such blends, only the melamine component of the mixture is covered by the scope of this investigation.

Melamine that is otherwise subject to this investigation is not excluded when commingled with melamine from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

The subject merchandise is provided for in subheading 2933.61.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Injury Test
- IV. Use of Facts Otherwise Available and Adverse Inferences
- V. Recommendation

[FR Doc. 2024-15979 Filed 7-19-24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A-469-826]

Mattresses From Spain: Final Affirmative Determination of Sales at Less Than Fair Value

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that imports of mattresses from Spain are being, or are likely to be, sold in the United States at less than fair value (LTFV). The period of investigation is July 1, 2022, through June 30, 2023.

DATES: Applicable July 22, 2024.

FOR FURTHER INFORMATION CONTACT: Joy Zhang or Matthew Palmer, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-1168 or (202) 482-1678, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 1, 2024, Commerce published the preliminary determination in this LTFV investigation of mattresses from Spain, in which we also postponed the final determination until July 15, 2024.¹

¹ See *Mattresses from Spain: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination*,

Commerce invited interested parties to comment on the *Preliminary Determination*.²

A summary of the events that occurred since Commerce published the *Preliminary Determination*, as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.³ The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

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

Scope Comments

During the course of this investigation, Commerce received scope comments from parties. Commerce issued a Preliminary Scope Decision Memorandum to address these comments and set aside a period of time for parties to address scope issues in scope-specific case and rebuttal briefs.⁴ We received comments from parties on the Preliminary Scope Decision Memorandum, which we addressed in the Final Scope Decision Memorandum.⁵ We made changes to the scope of the investigation from the scope published in the *Preliminary Determination*, as noted in Appendix I.

Verification

Commerce conducted verification of the information relied upon in making

and Extension of Provisional Measures, 89 FR 15126 (March 1, 2024) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

² See *Preliminary Determination*, 89 FR at 15127.

³ See Memorandum, "Issues and Decision Memorandum for the Final Affirmative Determination of Sales at Less Than Fair Value in the Investigation of Mattresses from Spain," dated concurrently with this notice (Issues and Decision Memorandum).

⁴ See Memorandum, "Mattresses from Bosnia and Herzegovina, Bulgaria, Burma, India, Indonesia, Italy, Kosovo, Mexico, Philippines, Poland, Slovenia, Spain, and Taiwan: Preliminary Scope Decision Memorandum," dated February 23, 2024 (Preliminary Scope Decision Memorandum).

⁵ See Memorandum, "Mattresses from Bosnia and Herzegovina, Bulgaria, Burma, India, Indonesia, Italy, Kosovo, Mexico, the Philippines, Poland, Slovenia, Spain, and Taiwan: Final Scope Decision Memorandum," dated May 8, 2024 (Final Scope Decision Memorandum).

its final determination in this investigation, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act). Specifically, Commerce conducted on-site verifications of the information and data on Healthcare Foam, S.I. Unipersonal's (HC Foam) home market sales, U.S. sales, and cost of production.⁶ We used standard verification procedures, including an examination of relevant sales and accounting records, and original source documents provided by HC Foam.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs submitted by interested parties in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is attached to this notice as Appendix II.

Changes Since the Preliminary Determination

We have made certain changes to the margin calculations for HC Foam since the *Preliminary Determination*. For a discussion of these changes, see the Issues and Decision Memorandum.

Use of Adverse Facts Available

As discussed in the *Preliminary Determination*, Commerce assigned to one of the mandatory respondent in this investigation, Interplasp Fabrica de Espuma de Poliuretano (Interplasp), an estimated weighted-average dumping margin on the basis of adverse facts available (AFA), pursuant to sections 776(a) and (b) of the Act.⁷ There is no new information on the record that would cause us to revisit our decision in the *Preliminary Determination*. Accordingly, for the reasons explained in the *Preliminary Determination*, and consistent with Commerce's practice, as AFA, we assigned Interplasp the highest corroborated dumping margin alleged in the petition.⁸

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated weighted-average dumping margin for all other producers and/or exporters not individually investigated shall be equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated excluding rates that are zero, *de minimis*, or determined entirely under section 776 of the Act.

In this investigation, Commerce assigned a rate based entirely on facts available to Interplasp. Therefore, the only rate that is not zero, *de minimis*, or based entirely on facts otherwise available is the rate calculated for HC Foam. Consequently, the rate calculated for HC Foam is also assigned as the rate for all other producers and/or exporters.

Final Determination

The final estimated weighted-average dumping margins are as follows:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Healthcare Foam, S.L. Unipersonal/Comotex Sistemas Del Descanso, S.L. Unipersonal ⁹	4.61
Interplasp Fabrica de Espuma de Poliuretano	* 280.28
All Others	4.61

* Rate based on AFA.

Disclosure

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

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of subject merchandise as described in Appendix I of this notice, which were entered, or withdrawn from

warehouse, for consumption, on or after March 1, 2024, the date of publication of the *Preliminary Determination* in the **Federal Register**.

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), upon the publication of this notice, we will instruct CBP to require a cash deposit for estimated antidumping duties for such entries as follows: (1) the cash deposit rate for the respondents listed in the table above will be equal to the company-specific estimated weighted-average dumping margin determined in this final determination; (2) if the exporter is not the respondent listed in the table above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin

listed for the producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin listed in the table above. These suspension of liquidation instructions will remain in effect until further notice.

U.S. International Trade Commission Notification

In accordance with section 735(d) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its final affirmative determination of sales at LTFV. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States

⁶ See Memoranda, "Verification of the Sales Response of HC Foam in the Antidumping Investigation of Mattresses from Spain," dated April 5, 2024; and "Verification of the Cost Response of Healthcare Foam, S.L. Unipersonal in the Antidumping Duty Investigation of Mattresses from Spain," dated April 18, 2024.

⁷ See *Preliminary Determination*, 88 FR at 33387.

⁸ See *Mattresses from Bosnia and Herzegovina, Bulgaria, Burma, India, Italy, Kosovo, Mexico, the*

Philippines, Poland, Slovenia, Spain, and Taiwan: Initiation of Less-Than-Fair-Value Investigations, 88 FR 57433 (August 23, 2023); see also Checklist, "Enforcement and Compliance Trade Remedy Counseling and Initiations Antidumping Duty Investigation Initiation Checklist," dated August 17, 2023, at 7.

⁹ In the *Preliminary Determination*, Commerce preliminarily determined that HC Foam and its affiliate Comotex Sistemas Del Descanso, S.L.

Unipersonal (Comotex) should be collapsed and treated as a single entity. For further discussion, see the *Preliminary Determination* PDM; see also Memorandum, "Preliminary Affiliation and Collapsing Memorandum," dated February 23, 2024. We received no comments on this preliminary determination; thus, we continue to treat HC Foam and Comotex as a single entity for purposes of this final determination.

is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of mattresses from Spain no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, all cash deposits posted will be refunded, and suspension of liquidation will be lifted. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed in the "Continuation of Suspension of Liquidation" section above.

Administrative Protective Order

This notice serves as the final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return, or destruction, of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation subject to sanction.

Notification to Interested Parties

This determination is issued and published in accordance with sections 735(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: July 15, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The products covered by this investigation are all types of youth and adult mattresses. The term "mattress" denotes an assembly of materials that at a minimum includes a "core," which provides the main support system of the mattress, and may consist of innersprings, foam, other resilient filling, or a combination of these materials. Mattresses also may contain: (1) "upholstery," the material between the core and the top panel of the ticking on a single-sided mattress, or between the core and the top and bottom panel of the ticking on a double-sided mattress; and/or (2) "ticking," the outermost layer of fabric or other material (e.g., vinyl) that encloses the core and any upholstery, also known as a cover.

The scope of this investigation is restricted to only "adult mattresses" and "youth mattresses." "Adult mattresses" are frequently described as "twin," "extra-long twin," "full," "queen," "king," or "California king" mattresses. "Youth mattresses" are typically described as "crib," "toddler," or "youth" mattresses. All adult and youth mattresses are included regardless of size and size description or how they are described (e.g., frameless futon mattress and tri-fold mattress).

The scope encompasses all types of "innerspring mattresses," "non-innerspring mattresses," and "hybrid mattresses." "Innerspring mattresses" contain innersprings, a series of metal springs joined together in sizes that correspond to the dimensions of mattresses. Mattresses that contain innersprings are referred to as "innerspring mattresses" or "hybrid mattresses." "Hybrid mattresses" contain two or more support systems as the core, such as layers of both memory foam and innerspring units.

"Non-innerspring mattresses" are those that do not contain any innerspring units. They are generally produced from foams (e.g., polyurethane, memory (viscoelastic), latex foam, gel infused viscoelastic (gel foam), thermobonded polyester, polyethylene) or other resilient filling.

Mattresses covered by the scope of this investigation may be imported independently, as part of furniture or furniture mechanisms (e.g., convertible sofa bed mattresses, sofa bed mattresses imported with sofa bed mechanisms, corner group mattresses, day-bed mattresses, roll-away bed mattresses, high risers, trundle bed mattresses, crib mattresses), or as part of a set (in combination with a "mattress foundation"). "Mattress foundations" are any base or support for a mattress. Mattress foundations are commonly referred to as "foundations," "boxsprings," "platforms," and/or "bases." Bases can be static, foldable, or adjustable. Only the mattress is covered by the scope if imported as part of furniture, with furniture mechanisms, or as part of a set, in combination with a mattress foundation.

Excluded from the scope of this investigation are "futon" mattresses. A "futon" is a bi-fold frame made of wood, metal, or plastic material, or any combination thereof, that functions as both seating furniture (such as a couch, love seat, or sofa) and a bed. A "futon mattress" is a tufted mattress, where the top covering is secured to the bottom with thread that goes completely through the mattress from the top through to the bottom, and it does not contain innersprings or foam. A futon mattress is both the bed and seating surface for the futon.

Also excluded from the scope are airbeds (including inflatable mattresses) and waterbeds, which consist of air- or liquid-filled bladders as the core or main support system of the mattress.

Also excluded is certain multifunctional furniture that is convertible from seating to sleeping, regardless of filler material or components, where such filler material or components are upholstered, integrated into

the design and construction of, and inseparable from, the furniture framing, and the outermost layer of the multifunctional furniture converts into the sleeping surface. Such furniture may, and without limitation, be commonly referred to as "convertible sofas," "sofabeds," "sofa chaise sleepers," "futons," "ottoman sleepers," or a like description.

Also excluded from the scope of this investigation are any products covered by the existing antidumping duty orders on uncovered innerspring units from the People's Republic of China, South Africa, and the Socialist Republic of Vietnam. See *Uncovered Innerspring Units from the People's Republic of China, South Africa, and Socialist Republic of Vietnam: Continuation of Antidumping Duty Orders*, 84 FR 55285 (October 16, 2019).

Also excluded from the scope of this investigation are bassinet pads with a nominal length of less than 39 inches, a nominal width of less than 25 inches, and a nominal depth of less than 2 inches.

Additionally, also excluded from the scope of this investigation are "mattress toppers." A "mattress topper" is a removable bedding accessory that supplements a mattress by providing an additional layer that is placed on top of a mattress. Excluded mattress toppers have a height of four inches or less.

Also excluded from the scope are the following hospital and patient care setting surfaces. Products that fall within the below categories and meet all of the exclusion factors in the respective category qualify for such exclusion, regardless of whether they may be referenced as a mattress.

Air Surfaces with all of the following characteristics: with the foot end comprised of either die-cut construction foam or air bladders to allow extension and retraction of the surface; enclosed in a fluid-resistant polyurethane-coated ticking with a zipper; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with the core including air bladders, with or without foam inside; with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA administered Global Unique Device Identification Database.

Stretcher Surfaces with all of the following characteristics: with a nominal thickness of 5 inches or less; with the foam core width tapered at one end; enclosed in a fluid-resistant polyurethane-coated ticking with a zipper; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with the exterior of the ticking containing a welded flap to cover the ticking zipper; with loop velcro attached to the ticking to allow for the stretcher surface to be firmly affixed to the stretcher; with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA administered Global Unique Device Identification Database.

Birthing Bed Surfaces with all of the following characteristics: with a nominal thickness of 5 inches or less; with a foam core in two pieces that have either a V-shaped cutout or U-Shaped cutout; enclosed

in a fluid-resistant polyurethane-coated ticking with a zipper; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with attachment fasteners extending from the bottom of the surface comprised of snaps or plastic hook(s); with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA-administered Global Unique Device Identification Database.

Foam Surfaces with all the following characteristics: with a nominal thickness of 6.5 inches or less; with a foam core that has articulation lines cut into the foam and/or die-cut construction in a portion of the foam to allow movement of the surface; enclosed in a fluid-resistant polyurethane-coated ticking with a zipper; with the ticking made of material meeting ASTM F1671B-07 requirements for porosity and ISO 10993 requirements for biocompatibility; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with brackets or attachment knobs embedded in the surface core to allow the surface to be firmly affixed to the hospital bed frame; with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA-administered Global Unique Device Identification Database, where the label includes the manufacturer's name and address as well as the product's name, date of manufacture, serial number, and Global Trade Identification Number (GTIN).

The products subject to this investigation are currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 9404.21.0010, 9404.21.0013, 9404.21.0095, 9404.29.1005, 9404.29.1013, 9404.29.1095, 9404.29.9085, 9404.29.9087, and 9404.29.9095. Products subject to this investigation may also enter under HTSUS subheadings: 9401.41.0000, 9401.49.0000, and 9401.99.9081. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to this investigation is dispositive.

Appendix II

List of Topics Discussed in the Final Decision Memorandum

- I. Summary
- II. Background
- III. Changes Since the *Preliminary Determination*
- IV. Discussion of the Issues
 - Comment 1: Level of Trade (LOT)
 - Comment 2: Whether to Use Comotex Sistemas Del Descanso, S.L. Unipersonal's (Comotex) Reported General and Administrative (G&A) Expense
 - Comment 3: Whether to Use the Revised Sales and Cost Databases
 - Comment 4: Whether to Exclude Home Market Sample Sales
- V. Recommendation

[FR Doc. 2024-15987 Filed 7-19-24; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-201-859]

Mattresses From Mexico: Final Affirmative Determination of Sales at Less-Than-Fair Value

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that imports of mattresses from Mexico are being, or are likely to be, sold in the United States at less-than-fair value (LTFV). The period of investigation is July 1, 2022, through June 30, 2023.

DATES: Applicable July 22, 2024.

FOR FURTHER INFORMATION CONTACT: Dakota Potts or Benjamin Blythe, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-0223 and (202) 482-3457, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 1, 2024, Commerce published the preliminary determination in this LTFV investigation of mattresses from Mexico.¹ Commerce invited interested parties to comment on the *Preliminary Determination*.²

A summary of the events that occurred since Commerce published the *Preliminary Determination*, as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.³ The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed

¹ See *Mattresses from Mexico: Preliminary Affirmative Determination of Sales at Less Than Fair Value*, 89 FR 15152 (March 1, 2024) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

² See *Preliminary Determination*, 89 FR at 15153.

³ See Memorandum, "Issues and Decision Memorandum for the Final Affirmative Determination of Sales at Less Than Fair Value in the Investigation of Mattresses from Mexico," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Investigation

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

Scope Comments

During the course of this investigation, Commerce received scope comments from parties. Commerce issued a Preliminary Scope Decision Memorandum to address these comments and set aside a period of time for parties to address scope issues in scope-specific case and rebuttal briefs.⁴ We received comments from parties on the Preliminary Scope Decision Memorandum, which we addressed in the Final Scope Decision Memorandum.⁵ We made changes to the scope of the investigation from the scope published in the *Preliminary Determination*, as noted in Appendix I.

Verification

Commerce conducted verification of the information relied upon in making its final determination in this investigation, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act). Specifically, we conducted on-site verifications of the home market sales, U.S. sales, and cost of production responses submitted by Ureblock S.A. de C.V. and Espumas de Oriente S.A. de C.V. (collectively, Ureblock/Espumas), using standard verification procedures, including an examination of relevant sales and accounting records, and original source documents provided by the respondents.⁶

Analysis of Comments Received

All issues raised in the case and rebuttal briefs submitted by the interested parties in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues

⁴ See Memorandum, "Mattresses from Bosnia and Herzegovina, Bulgaria, Burma, India, Indonesia, Italy, Kosovo, Mexico, Philippines, Poland, Slovenia, Spain, and Taiwan: Preliminary Scope Decision Memorandum," dated February 23, 2024 (Preliminary Scope Decision Memorandum).

⁵ See Memorandum, "Mattresses from Bosnia and Herzegovina, Bulgaria, Burma, India, Indonesia, Italy, Kosovo, Mexico, Philippines, Poland, Slovenia, Spain, and Taiwan: Final Scope Decision Memorandum," dated May 8, 2024 (Final Scope Decision Memorandum).

⁶ See Memoranda, "Verification of the Sales Response of Ureblock S.A. de C.V. and its affiliates in the Less-Than-Fair-Value Investigation of Mattresses from Mexico," and "Verification of the Cost Response of Ureblock S.A. de C.V. in the Antidumping Duty Investigation of Mattresses from Mexico," dated April 16 and 23, 2024, respectively.

addressed in the Issues and Decision Memorandum is attached to this notice as Appendix II.

Changes Since the Preliminary Determination

We have made certain changes to the margin calculations for Ureblock/Espumas since the *Preliminary Determination*. For a discussion of these changes, see the Issues and Decision Memorandum.

Use of Adverse Facts Available (AFA)

As discussed in the *Preliminary Determination*, Commerce assigned a mandatory respondent in this investigation, GAIM Regiomontana S.A. de C.V. (GAIM), and a voluntary respondent in this investigation, Colchones Wendy S.A. de C.V. (Wendy), an estimated weighted-average dumping margin on the basis of AFA, pursuant to sections 776(a) and (b) of the Act.⁷ There is no new information on the record that would cause us to revisit our decision in the *Preliminary Determination*. Accordingly, for the reasons explained in the *Preliminary Determination*, and consistent with Commerce's practice, as AFA, we assigned GAIM and Wendy the highest corroborated dumping margin alleged in the petition.⁸

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated weighted-average dumping margin for all other producers and exporters not individually investigated shall be equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated excluding rates that are zero, *de minimis*, or determined entirely under section 776 of the Act.

In this investigation, Commerce assigned a rate based entirely on facts available to Wendy and GAIM. Therefore, the only rate that is not zero, *de minimis*, or based entirely on facts otherwise available is the rate calculated for Ureblock/Espumas. Consequently, the rate calculated for Ureblock/Espumas is also assigned as the rate for all other producers and exporters.

Final Determination

The final estimated dumping margins are as follows:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Ureblock S.A. de C.V./Espumas de Oriente S.A. de C.V	37.59
GAIM Regiomontana S.A. de C.V	*61.97
Colchones Wendy S.A. de C.V ..	*61.97
All Others	37.59

* Rate based on facts available with adverse inferences.

Disclosure

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

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of subject merchandise as described in Appendix I of this notice, which were entered, or withdrawn from warehouse, for consumption, on or after March 1, 2024, the date of publication of the *Preliminary Determination* in the **Federal Register**.

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), upon the publication of this notice, we will instruct CBP to require a cash deposit for estimated antidumping duties for such entries as follows: (1) the cash deposit rates for the respondents listed in the table above are the company-specific estimated weighted-average dumping margins listed for the respondents in the table; (2) if the exporters are not the respondents listed in the table above, but the producers are, then the cash deposit rate will be the company-specific estimated weighted-average dumping margins listed for the producer of the subject merchandise in the table above; and (3) the cash deposit rate for all other producers and exporters is the all-others estimated weighted-average dumping margin listed in the table above.

These suspension of liquidation instructions will remain in effect until further notice.

International Trade Commission (ITC) Notification

In accordance with section 735(d) of the Act, Commerce will notify the ITC of its final affirmative determination of sales at LTFV. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of mattresses no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, all cash deposits posted will be refunded, and suspension of liquidation will be lifted. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed in the "Continuation of Suspension of Liquidation" section above.

Administrative Protective Order (APO)

This notice serves as the only reminder to parties subject to an APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely notification of the return, or destruction, of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation subject to sanction.

Notification to Interested Parties

This determination is issued and published in accordance with sections 735(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: July 15, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The products covered by this investigation are all types of youth and adult mattresses. The term "mattress" denotes an assembly of materials that at a minimum includes a "core," which provides the main support system of the mattress, and may consist of innersprings, foam, other resilient filling, or

⁷ See *Preliminary Determination*, 89 FR at 15153.

⁸ See, e.g., *Welded Stainless Pressure Pipe from Thailand: Final Determination of Sales at Less Than Fair Value*, 79 FR 31093 (May 30, 2014), and accompanying Issues and Decision Memorandum (IDM) at Comment 3; see also Petitioners' Letter, "Antidumping and Countervailing Duty Petitions," dated July 28, 2023, at 16–19; and Checklist, "Antidumping Duty Investigation Initiation Checklist," dated August 17, 2023; and Petitioner's Letter, "Mattress Petitioners' Response to the Department of Commerce's Supplemental Questions," dated August 7, 2023, at Exhibit 3.

a combination of these materials. Mattresses also may contain: (1) “upholstery,” the material between the core and the top panel of the ticking on a single-sided mattress, or between the core and the top and bottom panel of the ticking on a double-sided mattress; and/or (2) “ticking,” the outermost layer of fabric or other material (e.g., vinyl) that encloses the core and any upholstery, also known as a cover.

The scope of this investigation is restricted to only “adult mattresses” and “youth mattresses.” “Adult mattresses” are frequently described as “twin,” “extra-long twin,” “full,” “queen,” “king,” or “California king” mattresses. “Youth mattresses” are typically described as “crib,” “toddler,” or “youth” mattresses. All adult and youth mattresses are included regardless of size and size description or how they are described (e.g., frameless futon mattress and tri-fold mattress).

The scope encompasses all types of “innerspring mattresses,” “non-innerspring mattresses,” and “hybrid mattresses.” “Innerspring mattresses” contain innersprings, a series of metal springs joined together in sizes that correspond to the dimensions of mattresses. Mattresses that contain innersprings are referred to as “innerspring mattresses” or “hybrid mattresses.” “Hybrid mattresses” contain two or more support systems as the core, such as layers of both memory foam and innerspring units.

“Non-innerspring mattresses” are those that do not contain any innerspring units. They are generally produced from foams (e.g., polyurethane, memory (viscoelastic), latex foam, gel infused viscoelastic (gel foam), thermobonded polyester, polyethylene) or other resilient filling.

Mattresses covered by the scope of this investigation may be imported independently, as part of furniture or furniture mechanisms (e.g., convertible sofa bed mattresses, sofa bed mattresses imported with sofa bed mechanisms, corner group mattresses, day-bed mattresses, roll-away bed mattresses, high risers, trundle bed mattresses, crib mattresses), or as part of a set (in combination with a “mattress foundation”). “Mattress foundations” are any base or support for a mattress. Mattress foundations are commonly referred to as “foundations,” “boxsprings,” “platforms,” and/or “bases.” Bases can be static, foldable, or adjustable. Only the mattress is covered by the scope if imported as part of furniture, with furniture mechanisms, or as part of a set, in combination with a mattress foundation.

Excluded from the scope of this investigation are “futon” mattresses. A “futon” is a bi-fold frame made of wood, metal, or plastic material, or any combination thereof, that functions as both seating furniture (such as a couch, love seat, or sofa) and a bed. A “futon mattress” is a tufted mattress, where the top covering is secured to the bottom with thread that goes completely through the mattress from the top through to the bottom, and it does not contain innersprings or foam. A futon mattress is both the bed and seating surface for the futon.

Also excluded from the scope are airbeds (including inflatable mattresses) and waterbeds, which consist of air- or liquid-filled bladders as the core or main support system of the mattress.

Also excluded is certain multifunctional furniture that is convertible from seating to sleeping, regardless of filler material or components, where such filler material or components are upholstered, integrated into the design and construction of, and inseparable from, the furniture framing, and the outermost layer of the multifunctional furniture converts into the sleeping surface. Such furniture may, and without limitation, be commonly referred to as “convertible sofas,” “sofabeds,” “sofa chaise sleepers,” “futons,” “ottoman sleepers,” or a like description.

Also excluded from the scope of this investigation are any products covered by the existing antidumping duty orders on uncovered innerspring units from the People’s Republic of China, South Africa, and the Socialist Republic of Vietnam. See *Uncovered Innerspring Units from the People’s Republic of China, South Africa, and Socialist Republic of Vietnam: Continuation of Antidumping Duty Orders*, 84 FR 55285 (October 16, 2019).

Also excluded from the scope of this investigation are bassinet pads with a nominal length of less than 39 inches, a nominal width of less than 25 inches, and a nominal depth of less than 2 inches.

Additionally, also excluded from the scope of this investigation are “mattress toppers.” A “mattress topper” is a removable bedding accessory that supplements a mattress by providing an additional layer that is placed on top of a mattress. Excluded mattress toppers have a height of four inches or less.

Also excluded from the scope are the following hospital and patient care setting surfaces. Products that fall within the below categories and meet all of the exclusion factors in the respective category qualify for such exclusion, regardless of whether they may be referenced as a mattress.

Air Surfaces with all of the following characteristics: with the foot end comprised of either die-cut construction foam or air bladders to allow extension and retraction of the surface; enclosed in a fluid-resistant polyurethane-coated ticking with a zipper; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with the core including air bladders, with or without foam inside; with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA-administered Global Unique Device Identification Database.

Stretcher Surfaces with all of the following characteristics: with a nominal thickness of 5 inches or less; with the foam core width tapered at one end; enclosed in a fluid-resistant polyurethane-coated ticking with a zipper; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with the exterior of the ticking containing a welded flap to cover the ticking zipper; with loop velcro attached to the ticking to allow for the stretcher surface

to be firmly affixed to the stretcher; with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA-administered Global Unique Device Identification Database.

Birthing Bed Surfaces with all of the following characteristics: with a nominal thickness of 5 inches or less; with a foam core in two pieces that have either a V-shaped cutout or U-Shaped cutout; enclosed in a fluid-resistant polyurethane-coated ticking with a zipper; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with attachment fasteners extending from the bottom of the surface comprised of snaps or plastic hook(s); with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA-administered Global Unique Device Identification Database.

Foam Surfaces with all the following characteristics: with a nominal thickness of 6.5 inches or less; with a foam core that has articulation lines cut into the foam and/or die-cut construction in a portion of the foam to allow movement of the surface; enclosed in a fluid-resistant polyurethane-coated ticking with a zipper; with the ticking made of material meeting ASTM F1671B–07 requirements for porosity and ISO 10993 requirements for biocompatibility; with welded seams on the ticking, which are two or more layers of coated material thermally fused together with a permanent bond; with brackets or attachment knobs embedded in the surface core to allow the surface to be firmly affixed to the hospital bed frame; with a unique device identifier label for medical devices issued by an FDA-accredited agency and listed in the FDA-administered Global Unique Device Identification Database, where the label includes the manufacturer’s name and address as well as the product’s name, date of manufacture, serial number, and Global Trade Identification Number (GTIN).

The products subject to this investigation are currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 9404.21.0010, 9404.21.0013, 9404.21.0095, 9404.29.1005, 9404.29.1013, 9404.29.1095, 9404.29.9085, 9404.29.9087, and 9404.29.9095. Products subject to this investigation may also enter under HTSUS subheadings: 9401.41.0000, 9401.49.0000, and 9401.99.9081. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to this investigation is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Period of Investigation
- IV. Scope of Investigation
- V. Changes Since the *Preliminary Determination*
- VI. Affiliation/Single Entity
- VII. Discussion of the Issues

Comment 1: Whether Commerce Should Make a Level of Trade (LOT) Adjustment for Certain Retail Sales in the Home Market

Comment 2: Whether Certain Ureblock/
Espumas Record Data Issues Warrant the
Use of Adverse Facts Available (AFA)
Comment 3: Whether Commerce Should
Correct Two Ministerial Errors in its
Analysis of Ureblock's Databases
Comment 4: Whether Commerce Should
Apply GAIM's AFA Rate to Kuka
Comment 5: Whether Commerce Should
Select Kuka as the Second Mandatory
Respondent in the Investigation

VIII. Recommendation

[FR Doc. 2024–15986 Filed 7–19–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric
Administration

[RTID 0648- XE064]

Magnuson-Stevens Fishery
Conservation and Management Act;
General Provisions for Domestic
Fisheries; Applications for Exempted
Fishing Permits

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

ACTION: Notice; request for comments.

SUMMARY: In the spring of 2024, two
exempted fishing permits (EFP)
applications were submitted to NMFS to
request exemption from regulations
pertaining to the use of authorized gear
types under the Fishery Management
Plan for U.S. West Coast Fisheries for
Highly Migratory Species (HMS FMP).
The applicants propose to test the
effects and economic viability of using
alternative fishing practices to harvest
swordfish and other HMS off the U.S.
West Coast. Specifically, the
applications propose fishing with
standard and linked deep-set buoy gear
(DSBG) at night, a practice otherwise
known as night-set buoy gear (NSBG).
During the June 2024 Pacific Fishery
Management Council (Council) meeting,
the Council made recommendations to
NMFS regarding the two applications
for EFPs. NMFS has determined that
these applications warrant
consideration and is requesting public
comment on them.

DATES: Comments must be submitted in
writing by August 21, 2024.

ADDRESSES: You may submit comments
on this document, identified by NOAA–
NMFS–2024–0080, by any of the
following methods:

Electronic Submission: Submit all
electronic public comments via the
Federal e-Rulemaking Portal. Go to
<https://www.regulations.gov> and enter
NOAA–NMFS–2024–0080 in the Search

box. Click on the “Comment” icon,
complete the required fields, and enter
or attach your comments.

Mail: Submit written comments to
Chris Fanning, NMFS West Coast
Region, 501 W Ocean Blvd., Suite 4200,
Long Beach, CA 90802. Include the
identifier “NOAA–NMFS–2024–0080”
in the comments.

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

FOR FURTHER INFORMATION CONTACT:

Chris Fanning, NMFS, West Coast
Region, 562–980–4198, Chris.Fanning@noaa.gov.

SUPPLEMENTARY INFORMATION: On May 8,
2023, NMFS published a final rule
implementing amendment 6 to the HMS
FMP (88 FR 29545). These regulations,
which became effective on June 7, 2023,
authorize the use of standard and linked
DSBG for targeting swordfish and other
HMS in Federal waters off of California
and Oregon. The regulations include
various gear specification requirements
and operational requirements (e.g.,
prohibiting vessels from deploying their
gear at night). See 50 CFR 660.715.

The two applications¹ specifically
request exemption from 50 CFR
660.715(c)(3) that limits gear
deployment and retrieval to daytime
hours between sunrise and sunset.
Aside from the regulatory exemptions
being sought for the proposed activities
in the applications described above,
vessels fishing under an EFP would be
subject to all other regulations
implemented at 50 CFR part 660,
subpart K and 50 CFR part 300, subpart
C. This includes measures to protect sea
turtles, marine mammals, and seabirds.

At this time, NMFS is requesting
public comment on the two NSBG EFP
applications discussed above. NMFS
will consider the Council's
recommendation, along with public
comments, when determining whether
to issue these EFPs.

¹ <https://www.pcouncil.org/documents/2024/05/g-3-attachment-1.pdf/>, and <https://www.pcouncil.org/documents/2024/05/g-3-attachment-2.pdf/>.

NMFS will consider all public
comments submitted in response to this
Federal Register notice prior to issuance
of any EFP. NMFS has already analyzed
the effects of issuing EFPs for NSBG, in
accordance with the National
Environmental Policy Act and NOAA's
Administrative Order 216–6A. NMFS
has also evaluated the proposed fishing
practices for compliance with other
applicable laws, including section
7(a)(2) of the Endangered Species Act
(16 U.S.C. 1531 *et seq.*), which requires
the agency to consider whether the
proposed action is likely to jeopardize
the continued existence and recovery of
any endangered or threatened species or
result in the destruction or adverse
modification of critical habitat.

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

Dated: July 16, 2024.

Lindsay Fullenkamp,

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

[FR Doc. 2024–16004 Filed 7–19–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2023–OS–0071]

Submission for OMB Review;
Comment Request

AGENCY: Office of the Under Secretary of
Defense for Personnel and Readiness
(OUSD(P&R)), Department of Defense
(DoD).

ACTION: 30-Day information collection
notice.

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

DATES: Consideration will be given to all
comments received by August 21, 2024.

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

FOR FURTHER INFORMATION CONTACT:

Reginald Lucas, (571) 372–7574,
[whs.mc-alex.esd.mbx.dd-dod-
information-collections@mail.mil](mailto:whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil).

SUPPLEMENTARY INFORMATION: Title;
Associated Form; And Omb Number:

Overcoming Barriers to Safe Firearms Storage Among Different Groups; OMB Control Number 0704–OBFS.

Type of Request: New.

Number of Respondents: 1,400.

Responses per Respondent: 1.

Annual Responses: 1,400.

Average Burden per Response: 20 minutes.

Annual Burden Hours: 467 hours.

Needs And Uses: The Defense Suicide Prevention Office (DSPO) has contracted with CNA to conduct a study titled “Overcoming Barriers to Safe Firearms Storage Among Different Groups.” The goal of the study is to assist the services in meeting the requirements set forth in DoD Instruction 6490.16 that all suicide prevention activities are developed from a relevant evidence-base and have an evaluation capability prior to implementation. DSPO wants to craft safe firearm storage messages that will be persuasive to servicemembers of varying races and genders, in response to changing demographics of firearm owners and suicides completed using a firearm. To do so, CNA has developed a survey that will address the following issues:

- What are the barriers to safe firearm storage practices among different groups?

- Do different demographic groups respond to messages differently, and if so, how should messaging be targeted? For example, would these servicemembers respond more positively if their demographic group were featured in safety appeals?

- What principles could be introduced to OSD lethal means safety messaging to make it better resonate across demographic groups?

This survey will provide unique information to help DoD (a) determine what attitudinal and other barriers prevent servicemembers from adopting safe firearms storage practices, (b) decide which aspects of a safe storage message are most persuasive in overcoming those barriers, and (c) learn whether female and Black servicemembers respond differently to safe storage messaging. The findings from the survey will support DoD Instruction 6400.09’s mandate to focus suicide prevention efforts on research-based programs, policies, and practices. They will also assist in executing data-informed actions to reduce and stop self-directed harm (Section 1.2.b), promoting an understanding of lethal means safety among the military community (Section 4.3.b), and addressing the needs of high-risk groups (Section 4.7.a.).

Affected Public: Individuals or households.

Frequency: Once.

Respondent’s Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

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

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

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

DOD Clearance Officer: Mr. Reginald Lucas.

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

Dated: July 17, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–16066 Filed 7–19–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2024–OS–0014]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

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

DATES: Consideration will be given to all comments received by August 21, 2024.

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

for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Reginald Lucas, 571–372–7574, or whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION: The Status of Forces Active Duty Survey (SOFS–A) is a DoD-wide annual survey of active duty members that is used to evaluate existing policies and programs, establishing baseline measures before implementing new policies and programs, and monitoring the progress of established policies/programs. The survey assesses topics such as financial well-being, satisfaction, readiness, stress, and retention intention.

Title; Associated Form; and OMB

Number: Status of the Forces Survey of Active Duty Members; OMB Control Number 0704–0624.

Type of Request: Revision.

Number of Respondents: 16,500.

Responses per Respondent: 1.

Annual Responses: 16,500.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 4,125.

Needs and Uses: The Status of Forces Active Duty Survey (SOFS–A) is an annual DoD-wide large-scale survey of active duty members that is used in evaluating existing policies and programs, establishing baseline measures before implementing new policies and programs, and monitoring the progress of existing policies/programs. The survey assesses topics such as financial well-being, retention intention, stress, tempo, readiness, food security and suicide awareness. Data are aggregated by appropriate demographics, including Service, paygrade, gender, race/ethnicity, and other indicators. The legal requirements for the SOFS–A can be found in the Fiscal Year 2016 National Defense Authorization Act, Title VI, Subtitle F, Subpart 661. This legal requirement mandates that the SOFS–A solicit information on financial literacy and preparedness. Results will be used by the Service Secretaries to evaluate and update financial literacy training and will be submitted in a report to the Committees on Armed Services of the Senate and the House of Representatives.

Affected Public: Individuals and households.

Frequency: Annually.

Respondent’s Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

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

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

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

DOD Clearance Officer: Mr. Reginald Lucas.

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

Dated: July 17, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–16068 Filed 7–19–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2024–OS–0016]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)), Department of Defense (DoD).

ACTION: 30-day information collection notice.

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

DATES: Consideration will be given to all comments received by August 21, 2024.

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

FOR FURTHER INFORMATION CONTACT: Reginald Lucas, (571) 372–7574, whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Department of Defense Telework Agreement; DD Form 2946; OMB Control Number 0704–0611.

Type of Request: Revision.

Number of Respondents: 310,000.

Responses per Respondent: 1.

Annual Responses: 310,000.

Average Burden per Response: 19.8 minutes.

Annual Burden Hours: 102,300 hours.

Needs and Uses: In accordance with and prescribed by DoDI 1035.01, information is collected to register individuals as participants in the DoD alternative workplace program; to manage and document the duties of participants; and to fund, evaluate and report on program activity. The records may be used by Information Technology offices to determine equipment needs, to ensure appropriate safeguards are in place to protect government information, and for assessing and managing technological risks and vulnerabilities. All employees who are authorized to telework shall complete a DD Form 2946. The DD Form 2946 shall be signed and dated by the employee and supervisor and maintained by the employee’s supervisor. Components are encouraged to include a DD Form 2946 in the new employee on-boarding packages for those employees occupying telework eligible positions to ensure that they are aware of their telework responsibilities, should telework be offered or requested. Information on telework responsibilities should be posted throughout the workplace and included in periodic training events.

Affected Public: Individuals or households.

Frequency: Biennially. Telework agreements shall be reviewed by the supervisor and teleworker, revalidated at least every two years, and revised when appropriate. A new DD Form 2946 should be completed when a new supervisor is responsible for the employee.

Respondent’s Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

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

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

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

www.regulations.gov as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Reginald Lucas.

Dated: July 17, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–16067 Filed 7–19–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2024–OS–0013]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)), Department of Defense, (DoD).

ACTION: 30-Day information collection notice.

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

DATES: Consideration will be given to all comments received by August 21, 2024.

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

FOR FURTHER INFORMATION CONTACT:

Reginald Lucas, (571) 372–7574, whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB

Number: Status of the Forces Survey of Reserve Component Members: OMB Control Number 0704–0616.

Type of Request: Revision.

Number of Respondents: 16,515.

Responses per Respondent: 1.

Annual Responses: 16,515.

Average Burden per Response: 0.33 hours.

Annual Burden Hours: 5,450.

Needs and Uses: The Status of Forces Reserve Survey (SOFs–R) is a DoD-wide survey of Reserve and National Guard used in evaluating existing policies and programs, establishing baseline

measures before implementing new policies and programs, and monitoring the progress of policies/programs that make a difference in the lives of Reserve component members and their families. The survey assesses topics such as stress, satisfaction, retention, tempo, readiness, and financial well-being. Data are aggregated by appropriate demographics, including Service, paygrade, gender, race/ethnicity, activation status, and other indicators. In order to be able to meet reporting requirements for DoD leadership, the Military Services, and Congress, the survey needs to be completed annually. The Undersecretary of Defense for Personnel and Readiness uses the SOFS-R to suggest changes to services supporting Reserve component members' ability to return to their families and their civilian jobs following activation/deployment as well as addressing retention and family life issues.

Affected Public: DoD Reservists/ National Guard Members.

Frequency: Annually.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

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

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

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

DOD Clearance Officer: Mr. Reginald Lucas.

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

Dated: July 17, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024-16065 Filed 7-19-24; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD-2024-OS-0053]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense (Comptroller)/Chief Financial Officer, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

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

DATES: Consideration will be given to all comments received by August 21, 2024.

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

FOR FURTHER INFORMATION CONTACT:

Reginald Lucas, (571) 372-7574, whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Claim Certification and Voucher for Death Gratuity Payment; DD Form 397; OMB Control Number 0730-0017

Type of Request: Extension.
Number of Respondents: 500.
Responses per Respondent: 1.
Annual Responses: 500.
Average Burden per Response: 30 minutes.

Annual Burden Hours: 250.

Needs and Uses: The information collection requirement allows the government to collect the signatures and information needed to pay a death gratuity. Pursuant to 10 U.S.C. 1475-1480, a designated beneficiary or next-of-kin can receive a death gratuity payment for a deceased service member. This form serves as a record of the disbursement. The DoD Financial Management Regulation (FMR), Volume 7A, Chapter 36, defines the eligible beneficiaries and procedures for payment. To provide internal controls for this benefit, and to comply with the above-cited statutes, the information requested is needed to substantiate the receipt of the benefit.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

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

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

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

DOD Clearance Officer: Mr. Reginald Lucas.

Requests for copies of the information collection proposal should be sent to Mr. Reginald Lucas, at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Dated: July 17, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024-16069 Filed 7-19-24; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2024-SCC-0053]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Evaluation of Transition Supports for Youth With Disabilities

AGENCY: Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

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

DATES: Interested persons are invited to submit comments on or before August 21, 2024.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link www.reginfo.gov/public/do/PRAMain to access the site. Find this information collection request (ICR) by

selecting “Department of Education” under “Currently Under Review,” then check the “Only Show ICR for Public Comment” checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the “View Information Collection (IC) List” link. Supporting statements and other supporting documentation may be found by clicking on the “View Supporting Statement and Other Documents” link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Yumiko Sekino, (202) 219–2046.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Evaluation of Transition Supports for Youth with Disabilities.

OMB Control Number: 1850–0979.

Type of Review: Revision of a currently approved ICR.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 6,090.

Total Estimated Number of Annual Burden Hours: 3,217.

Abstract: This study will examine the effectiveness, implementation, and costs of two new strategies for supporting youth with disabilities and their families to prepare for a successful transition from high school to adult life. The first strategy is based on a model of self-determination instruction designed to help students develop skills such as goal setting, decision making, planning and apply those skills to plan and pursue their transition goals. The second strategy not only teaches self-determination skills but also provides individual mentoring to help students engage in and take active steps toward their post-school goals. The study will compare the intermediate and post-school outcomes for approximately 3,000 students who have an

individualized education program and are approximately two years from high school graduation. Participating students in up to 100 schools and 16 districts will be randomly assigned to receive one of the study’s strategies or continue with the regular transition supports they receive from their school. This revised information collection request adds instruments to measure outcomes and assess the implementation and cost-effectiveness of each strategy.

Dated: July 16, 2024.

Juliana Pearson,

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

[FR Doc. 2024–16016 Filed 7–19–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Technical Assistance on State Data Collection—National Technical Assistance Center To Improve State Capacity To Collect, Report, Analyze, and Use Accurate Early Childhood IDEA Data

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for new awards for fiscal year (FY) 2024 for a National Technical Assistance Center To Improve State Capacity To Collect, Report, Analyze, and Use Accurate Early Childhood IDEA Data.

DATES: *Applications Available:* July 22, 2024.

Deadline for Transmittal of Applications: August 21, 2024.

Deadline for Intergovernmental Review: November 19, 2024.

Pre-Application Webinar Information: No later than July 29, 2024, the Office of Special Education Programs and Rehabilitative Services will post pre-recorded informational webinars designed to provide technical assistance (TA) to interested applicants. The webinars may be found at <https://www2.ed.gov/fund/grant/apply/osep/new-osep-grants.html>.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the

Federal Register on December 7, 2022 (87 FR 75045) and available at www.federalregister.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs.

FOR FURTHER INFORMATION CONTACT:

Meredith Miceli, U.S. Department of Education, 400 Maryland Avenue SW, Room 4A10, Washington, DC 20202. Telephone: (202) 987–0135. Email: Meredith.Miceli@ed.gov.

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the Technical Assistance on State Data Collection program is to improve the capacity of States to meet IDEA data collection and reporting requirements. Funding for the program is authorized under section 611(c)(1) of the Individuals with Disabilities Education Act (IDEA), which gives the Secretary authority to reserve not more than one-half of one percent of the amounts appropriated under Part B for each fiscal year to provide TA activities, where needed, to improve the capacity of States to meet the data collection and reporting requirements under Parts B and C of IDEA. The maximum amount the Secretary may reserve under this set-aside for any fiscal year is \$25,000,000, cumulatively adjusted by the rate of inflation. Section 616(i) of IDEA requires the Secretary to review the data collection and analysis capacity of States to ensure that data and information determined necessary for implementation of sections 616 and 642 of IDEA are collected, analyzed, and accurately reported to the Secretary. It also requires the Secretary to provide TA, where needed, to improve the capacity of States to meet the data collection requirements, which include the data collection and reporting requirements in sections 616 and 618 of IDEA. In addition, the Further Consolidated Appropriations Act, 2024, Public Law 118–47, gives the Secretary authority to use funds reserved under section 611(c) of IDEA to “administer and carry out other services and activities to improve data collection, coordination, quality, and use under Parts B and C of the IDEA.” Further Consolidated Appropriations Act, 2024, Public Law 118–47, Div. D, Title III, 138 Stat. 460, 685 (2024).

Assistance Listing Number: 84.373Z.

OMB Control Number: 1820–0028.

Priority: This competition includes two absolute priorities. These priorities are from the notice of final priorities and requirements (NFP) for this program published elsewhere in this issue of the **Federal Register**.

Absolute Priority: For FY 2024 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3), we consider only applications that meet both Absolute Priorities 1 and 2.

These priorities are:

Absolute Priority 1: National Technical Assistance Center To Improve State Capacity To Collect, Report, Analyze, and Use Accurate Early Childhood IDEA Data.

Background:

The purpose of this priority is to establish a TA center to improve State capacity to meet the early childhood data collection and reporting requirements for children with disabilities under Parts C and B of the IDEA.¹ State-level staff in Part C early intervention and Part B preschool special education programs are expected to report high quality data; be able to provide in-depth explanations of the data; use the data to improve programs, compliance, and general supervision of Part C early intervention and Part B preschool special education programs; and present the data in an understandable fashion to all data users, including novice data users. Under the ED*Facts* Modernization Project, which began with the submission of the 2022–23 IDEA section 618 data, the Office of Special Education Programs (OSEP) is expecting States to undertake more data quality initiatives before the deadline for data submission, a task previously completed by OSEP after the due date. Additionally, beginning with the Federal fiscal year (FFY) 2022 State Performance Plan/Annual Performance Report (SPP/APR) (submitted in 2024), State Part C early intervention programs must report additional data and information to substantiate that the reported data for indicator C4 (Family Involvement)² accurately represent infants and toddlers with disabilities and their families receiving services

within their State. Also, State-level staff in Part C early intervention and Part B preschool special education programs are expected to analyze and use data to report on how they are both ensuring compliance with IDEA requirements and improving results for children with disabilities through OSEP's Differentiated Monitoring and Support as part of the results-driven accountability system. Lastly, States are expected to present their data in a manner that fosters stakeholder engagement, encouraging active participation in important discussions regarding program improvement and accountability compliance.

As expectations surrounding IDEA have evolved and intensified, there is a growing imperative to provide support for both seasoned and new data personnel operating within Part C early intervention and Part B preschool special education programs. In 2023, approximately 17 percent of the State data managers for Part C early intervention programs had less than a year experience while approximately 23 percent had been in the role for only one to three years. According to the 2023 IDEA Infants and Toddlers Coordinators Association (ITCA) Tipping Points Survey, approximately 49 percent of Part C coordinators had served in their position for two years or less (ITCA, 2023).³ Similarly, in 2023, approximately 59 percent of Part B preschool special education coordinators possessed three years or less experience (Early Childhood Technical Assistance Center, 2023).⁴ Given the persistent turnover among staff in Part C early intervention and Part B preschool special education programs, there is a critical need to support new and novice staff in effectively collecting, reporting, analyzing, and using IDEA data.

Given the heightened demands placed on the collection, reporting, analysis, and use of IDEA data, coupled with staff turnover, there is a need to find efficient, effective, and user-friendly approaches to conducting the early childhood IDEA data work. Improved data management processes, alongside the growing development of linked and integrated child-level data across Part C data systems, Part B preschool special

education data systems, other early learning program data systems, and statewide longitudinal data systems for school-aged children, are key approaches for States to meet these heightened expectations. States need to establish and implement effective early childhood data management policies and procedures, including, where appropriate, integration of data systems to bolster program improvement, compliance accountability, and Federal and public reporting. Improved policies and procedures would enable States, where applicable, to link or integrate child-level data across Part C data systems, Part B preschool special education data systems, other early learning program data systems, and statewide longitudinal data systems for school-aged children. An early childhood integrated data system (ECIDS) could assist States in identifying optimal strategies to improve outcomes for young children within their jurisdictions. For instance, an ECIDS offers States the opportunity to assess which service characteristics correlate with improved outcomes for children and families, as well as explore the relationship between early childhood settings and outcomes. Moreover, an ECIDS that includes data from across various early care and education programs could also improve child find activities in the State by identifying strong referral sources and areas requiring increased outreach efforts. An ECIDS could also aid States in identifying other early care and education programs in which young children with disabilities and their families participate, thereby enabling States to maximize the efficiency of inclusive service delivery for young children with disabilities and their families.

Building robust ECIDSs, incorporating both Part C early intervention and Part B preschool special education data, would improve responses to critical policy questions, facilitate program improvement, and reinforce compliance accountability for Part C early intervention and Part B preschool special education programs. This level of integration would help ensure that States report high-quality IDEA data to the Department and the public. Despite some progress over the past decade in linking and integrating Part C early intervention and Part B preschool special education data with data from other early learning programs, K–12 systems, and the workforce, as well as longitudinally over time, the proportion of State programs capable of making these changes remains low. In response

¹ This notice describes infants, toddlers and/or children with disabilities as “children with disabilities” or “young children with disabilities to include children referred to both Parts C and B of the IDEA, birth through age five.

² Indicator C4 requires States to report on the percent of families participating in Part C who report that early intervention services have helped the family: (a) know their rights; (b) effectively communicate their children's needs; and (c) help their children develop and learn.

³ For more information on ITCA's 2023 Tipping Points Survey, please go to 2023 Tipping Points Survey (ideainfanttoddler.org). www.ideainfanttoddler.org/pdf/2023-Tipping-Points-Survey.pdf.

Early Childhood Technical Assistance Center. (2023). Part B, Section 619 National Survey 2023. <https://ectacenter.org/sec619/sec619survey.asp>.

⁴ Early Childhood Technical Assistance Center. (2023). Part B, Section 619 National Survey 2023. <https://ectacenter.org/sec619/sec619survey.asp>.

to a survey on their State data systems, less than 40 percent of Part C early intervention and Part B preschool special education programs indicated the ability to link their child-level data to their workforce data. Moreover, less than 30 percent of Part C early intervention programs that responded reported linking Part C child-level data to Early Head Start, Head Start, State Pre-K, childcare programs, home visiting programs, or other early care or education programs. Most Part C early intervention programs that responded stated they have never linked their Part C data to their Part B preschool special education data.⁵

This priority will directly address the increased expectations and capacity challenges Part C early intervention and Part B preschool special education programs face with respect to effectively and efficiently collecting, reporting, analyzing, and using high-quality IDEA data.

Priority:

The purpose of this priority is to fund a cooperative agreement to establish and operate a National Technical Assistance Center To Improve State Capacity To Collect, Report, Analyze, and Use Accurate Early Childhood IDEA Data (Center). The Center will provide TA to (1) improve State capacity to collect, report, analyze, and use high-quality IDEA Part C early intervention data (including IDEA section 618 Part C data and IDEA section 616 Part C data) and IDEA Part B preschool special education data on children with disabilities; and (2) enhance and streamline Part C and Part B preschool special education data systems by sharing, linking, and integrating statewide, child-level early childhood data (including Part C and Part B preschool special education data) to improve the analyses of IDEA data to address critical policy questions that will facilitate program improvement, improve compliance accountability, and improve outcomes or results for children served under Part C and Part B preschool special education programs. These Part C early intervention and Part B preschool special education data systems must allow the States to (1) effectively and efficiently respond to all IDEA-related data submission requirements (e.g., Part C section 616 and 618 data and Part B preschool special education data); (2) improve the analyses of IDEA data to the extent these analyses respond to critical policy questions that will facilitate program

improvement and compliance accountability; and (3) comply with applicable privacy requirements, including the privacy and confidentiality requirements under Parts B and C of IDEA and applicable provisions of the Family Educational Rights and Privacy Act (20 U.S.C. 1232g) and its regulations at 34 CFR part 99.⁶

The Center must achieve, at a minimum, the following expected outcomes:

(a) Increased capacity of States to collect, report, analyze, and use high-quality IDEA Part C early intervention data (including IDEA section 616 Part C data⁷ and section 618 Part C data⁸);

(b) Increased capacity of States to collect, report, analyze, and use high-quality IDEA Part B preschool special education data;

(c) Increased number of States with plans to share, link, or integrate Part C early intervention and Part B preschool special education data (that comply with all applicable privacy laws) and use such shared, linked, or integrated Part C early intervention and Part B preschool special education data to improve program compliance and accountability;

(d) Increased number of States that use their Part C early intervention and Part B preschool special education data system to identify and answer critical State-determined policy questions to drive program improvement, improve results for children with disabilities, and improve compliance accountability;

(e) Increased number of States who consider engaging in data sharing, linking, or integration activities related to Part C and Part B preschool special education data/data systems to other statewide longitudinal and early learning data/data systems (e.g., Early Head Start, Head Start, child care, publicly funded preschool, and home visiting programs) and identify how to enable such sharing, linkages, or

integration so that it would comply with all applicable privacy laws;

(f) Increased capacity of States to implement and document Part C early intervention and Part B preschool special education data management policies and procedures, including data sharing, linking, and integration activities, used to collect, report, analyze, and use high-quality IDEA Part C early intervention and Part B preschool special education data;

(g) Increased capacity of States to address data leadership and personnel training needs to collect, report, analyze, and use the Part C early intervention and Part B preschool special education data collection through development of effective tools and resources, as well as providing opportunities for in-person and virtual cross-State training for data leaders and personnel in State and local programs and agencies to collect, report, analyze, and use Part C early intervention and Part B preschool special education;

(h) Increased capacity of States to collect, report, analyze, and use Part C and Part B preschool special education data to support equitable identification, access, services, outcomes, and impact of early intervention and preschool special education and related services on infants, toddlers, and young children receiving services under IDEA; and

(i) Increased capacity of States to collect, report, analyze, and use Part C early intervention and Part B preschool special education data to improve State IDEA data analyses regarding results and functional outcomes for all infants, toddlers, and young children with disabilities to demonstrate and improve how public agencies meet the program requirements under Parts B and C of IDEA, with a particular emphasis on those requirements that are most closely related to improving early intervention results for infants and toddlers with disabilities and educational results for children with disabilities as monitored by OSEP via its Differentiated Monitoring and Support process.

Absolute Priority 2: Technical Assistance To Improve State Capacity To Collect, Report, Analyze, and Use Accurate Child Find Data For Infants and Toddlers.

Background:

The purpose of this priority is to establish a TA center to provide TA to increase the capacity of States to collect, report, analyze, and use data available to States to improve their Part C child find data and efforts that they report through their Part C SPP/APR.

On October 5, 2023, the U.S. Government Accountability Office (GAO) issued a report "Special

⁶ The Center must review the need for additional resources (with input from the Department) and disseminate existing resources developed by the Department, such as: (1) *Understanding the Confidentiality Requirements Applicable to IDEA Early Childhood Programs* (October 2016); (2) *IDEA/FERPA Crosswalk* (Surprenant & Miller, August 24, 2022); (3) Webinars such as *Navigating IDEA and FERPA To Protect Privacy in Today's Early Childhood World* (September 22, 2023); and (4) Data sharing agreement template.

⁷ The IDEA section 616 Part C data includes Indicator 1 through 12 as discussed in the Part C State Performance Plan (SPP) and Annual Performance Report (APR) Indicator Measurement Table.

⁸ The IDEA section 618 Part C data includes Part C Child Count and Settings data collection, Part C Exiting data collection, and the Part C Dispute Resolution data collection.

⁵ Perez, N., & Mercier, B. (2022). 2021 DaSy data systems (State of the States) survey findings. SRI International. https://dasycenter.org/wp-content/uploads/2022/12/DaSy_2021DaSyDataSystemsSurveyFindings_Acc.pdf.

Education: Additional Data Could Help Early Intervention Programs Reach More Eligible Infants and Toddlers” noting variation across racial groups at each step of the identification and enrollment process for early intervention services under Part C of IDEA (GAO–24–106019)(2023 GAO IDEA Part C Child Find Report).⁹ Based on an analysis of data from 16 States, GAO found that the percentage of infants and toddlers who were referred and evaluated differed widely by race. However, the percentage of infants and toddlers who were found eligible and began receiving Part C services looked similar across races. For example, the percentage of infants and toddlers who were referred and subsequently received an evaluation ranged from 59 percent for American Indian and Alaska Native children to 86 percent for Asian children. In contrast, the percentage of those determined eligible and subsequently began receiving Part C services ranged from 91 percent for American Indian or Alaska Native children to 95 percent for Asian and White children.

Specifically, the 2023 GAO IDEA Part C Child Find Report identified one matter for Congress and one recommendation for the Department, to which the Department agreed. GAO recommended that the Department encourage all States to use demographic data they already collect to maximize children’s access to Part C early intervention services. In its September 13, 2023, response, the Department noted its plans to implement this recommendation. Starting with the FFY 2023 SPP/APR, which States will submit on February 3, 2025, all States are encouraged to include the root cause analysis of their child find efforts for indicators C–5 and C–6,¹⁰ utilizing all available data rather than solely relying on the child find data reported under SPP/APR C–5 and C–6 and must report this root cause analysis if the State shows slippage in the FFY 2023 data it reports under SPP/APR indicators C–5 and C–6.¹¹

⁹ The GAO Report and the Department’s response concurring with the recommendation can be found at www.gao.gov/assets/d24106019.pdf.

¹⁰ Per the Part C State Performance Plan and Annual Performance Report (Part C SPP/APR) General Instructions, “If a State is required to report on the reasons for slippage, then the State must include the results of its analysis under the “Additional Information” section of Indicators 5 and 6.” Part C State Performance Plan and Annual Performance Report (Part C SPP/APR)—General Instructions—For Federal Fiscal Year 2023 Submission.

¹¹ For the FFY 2023 SPP/APR Indicators C–5 and C–6, the Department noted that “to improve the analysis of whether States are identifying children who need services as early as possible, States should conduct root cause analyses of child find

While many State Part C early intervention programs currently use demographic data for infants and toddlers to identify disparities in the provision of, and improve access to, Part C services, not all States have implemented similar analyses of other data influencing child find identification rates. Analyzing child find data beyond race and ethnicity data reported under IDEA section 618 is crucial. This broader analysis should encompass factors such as geographic location, family income, and primary language. By conducting analyses of these additional child find-related data, all State Part C early intervention programs can more effectively identify and serve infants and toddlers eligible for services under Part C of IDEA. To promote equitable access to early intervention services under Part C of IDEA, this priority provides needed TA to States as they embark on reporting root cause analyses using all available child find–related data to improve their data analyses, child find efforts, and children’s access to early intervention services under Part C of IDEA.

Priority:

The purpose of this priority is to fund TA to increase the capacity of States to collect, report, analyze, and use available data to improve the Part C child find data they report through their Part C SPP/APR.

The Center must achieve, at a minimum, the following expected outcomes:

(a) Increased capacity of States to collect, report, analyze, and use available data to improve the root cause analysis of their Part C child find data (including IDEA section 616 Part C data for indicators C5 and C6 and section 618 Part C data);

(b) Increased number of States that have the capacity to identify, for children served under IDEA Part C, other data they may collect (such as number of infants and toddlers referred, screened, evaluated, eligible, and enrolled in early intervention services under Part C) by various characteristics

identification rates, including reviewing data (if available) on the number of children referred, evaluated, and identified. This root cause analysis may include examining not only demographic data (such as race and ethnicity data reported under IDEA section 618 and Indicators C–5 and C–6), but also other child-find related data available to the State (such as geographic location, family income, primary language, etc.). The State should report the results of its analysis under the “Additional Information” section of the Indicators C–5 and C–6. Furthermore, if a State is required to report on the reasons for slippage, then the State must include the results of its analysis under the “Additional Information” section of the Indicators C–5 and C–6.” See, <https://omb.report/icr/202305-1820-001/doc/131687100>.

of the child, including race, ethnicity, home language, gender, socio-economic status, and geographic location;

(c) Increased number of States that have the capacity to conduct a root cause analysis of available child find data to better identify disparities among demographic groups and potential barriers to enrollment in early intervention services under Part C of IDEA; and

(d) Increased number of States that have the capacity to use their IDEA and non-IDEA Part C child find data to improve their IDEA child find processes at the State and local program levels.

In addition to the program requirements contained in both priorities, to be considered for funding, applicants must meet the application and administrative requirements. We may apply these requirements in any year in which this program is in effect.

Applicants must—

(a) Demonstrate, in the narrative section of the application under “Significance,” how the proposed project will—

(1) Address State challenges associated with early childhood data management and data sharing, linking, and integration, including implementing early childhood data system integration and improvements; enhancing and streamlining Part C early intervention and Part B preschool special education data systems to respond to critical policy questions; using ECIDS for program improvement and compliance accountability for Part C early intervention and Part B preschool special education programs; reporting high-quality IDEA Part C data (including IDEA section 616 Part C data and section 618 Part C data) and IDEA Part B preschool special education data to the Department and the public; and analyzing Part C child find data to improve equitable access to Part C early intervention services. To meet this requirement the applicant must—

(i) Present applicable national, State, or local data demonstrating the challenges of States to implement effective early childhood data management policies and procedures and data sharing, linking, and integration activities, including integrating early childhood data systems across IDEA programs, other early learning programs, and other educational programs for school-aged students; link Part C and Part B preschool special education program data; use their Part C and Part B preschool special education data systems to respond to critical State-determined policy questions for program improvement and compliance

accountability; and collect, report, analyze, and use Part C child find data to improve equitable access to Part C early intervention services;

(ii) Demonstrate knowledge of current educational and technical issues and policy initiatives relating to early childhood data management and data sharing, linking, and integration; data use; data privacy; Part C IDEA sections 616 and 618 data; Part C child find data; Part B preschool special education data; and Part C and Part B preschool special education data systems; and

(iii) Present information about the current level of implementation of sharing, linking, and integrating Part C and Part B preschool special education data; sharing, linking, or integrating Part C and/or Part B preschool special education data systems with other early learning data systems; using Part C and Part B preschool special education data systems to respond to critical State-determined policy questions; and collecting, reporting, analyzing, and using high-quality IDEA Part C data (including IDEA section 616 Part C data and section 618 Part C data) and IDEA Part B preschool special education data; and

(2) Improve early childhood data management policies and procedures and data sharing, linking, and integration practices to: collect, report, and analyze high-quality Part C and Part B preschool special education data (including Part C child find data); share, link, or integrate Part C and Part B preschool special education data; share, link, or integrate these data with data on children participating in other early learning programs and data on school-aged children; and use robust early childhood data systems to improve the analyses of IDEA data to the extent these analyses answer critical State-determined policy questions. Include the likely magnitude or importance of the improvements.

(b) Demonstrate, in the narrative section of the application under "Quality of project services," how the proposed project will—

(1) Ensure equal access and treatment for members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. To meet this requirement, the applicant must describe how it will—

(i) Identify the needs of the intended recipients for TA and information; and

(ii) Ensure that products and services meet the needs of the intended recipients of the grant;

(2) Achieve its goals, objectives, and intended outcomes. To meet this

requirement, the applicant must provide—

(i) Measurable intended project outcomes; and

(ii) In Appendix A, the logic model (as defined in 34 CFR 77.1) by which the proposed project will achieve its intended outcomes that depicts, at a minimum, the goals, activities, outputs, and intended outcomes of the proposed project;

(3) Use a conceptual framework (and provide a copy in Appendix A) to develop project plans and activities, describing any underlying concepts, assumptions, expectations, beliefs, or theories, as well as the presumed relationships or linkages among these variables, and any empirical support for this framework;

Note: The following websites provide more information on logic models and conceptual frameworks: https://osepideasthatwork.org/sites/default/files/2021-12/ConceptualFramework_Updated.pdf and www.osepideasthatwork.org/resources-grantees/program-areas/ta-ta/tad-project-logic-model-and-conceptual-framework.

(4) Be based on current research and make use of evidence-based¹² practices (EBPs). To meet this requirement, the applicant must describe—

(i) The current research on early childhood data management and data sharing, linking, and integration, and related EBPs; and

(ii) How the proposed project will incorporate current research and EBPs in the development and delivery of its products and services;

(5) Develop products and provide services that are of high quality and sufficient intensity and duration to achieve the intended outcomes of the proposed project. To address this requirement, the applicant must describe—

(i) How it proposes to identify and develop the knowledge base on early childhood data management and data system integration;

(ii) Its proposed approach to universal, general TA,¹³ which must

¹² For purposes of these requirements, "evidence-based" means, at a minimum, demonstrating a rationale (as defined in 34 CFR 77.1) based on high-quality research findings or positive evaluation that such activity, strategy, or intervention is likely to improve student outcomes or other relevant outcomes.

¹³ "Universal, general TA" means TA and information provided to independent users through their own initiative, resulting in minimal interaction with TA center staff and including one-time, invited or offered conference presentations by TA center staff. This category of TA also includes information or products, such as newsletters, guidebooks, or research syntheses, downloaded

identify the intended recipients, including the type and number of recipients, that will receive the products and services under this approach;

(iii) The proposed approach to targeted, specialized TA,¹⁴ which must identify—

(A) The intended recipients, including the type and number of recipients, that will receive the products and services;

(B) The proposed approach to measure the readiness of potential TA recipients to work with the project, assessing, at a minimum, their current infrastructure, available resources, and ability to build capacity at the State and local level; and

(C) The process by which the proposed project will collaborate with OSEP-funded centers and other federally funded TA centers to develop and implement a coordinated TA plan when the work of the center or centers overlaps with the proposed project; and

(iv) Its proposed approach to intensive, sustained TA,¹⁵ which must identify—

(A) The intended recipients, including the type and number of recipients, that will receive the products and services under this approach;

(B) Its proposed approach to addressing States' challenges associated with limited resources to engage in early childhood data sharing, linking, and integration and enhancement activities that streamline the established Part C and Part B preschool special education data systems to respond to critical policy questions and to report high-quality IDEA data to the Department and the public, which must, at a minimum, include providing on-site consultants to the State lead agency

from the TA center's website by independent users. Brief communications by TA center staff with recipients, either by telephone or email, are also considered universal, general TA.

¹⁴ "Targeted, specialized TA" means TA services based on needs common to multiple recipients and not extensively individualized. A relationship is established between the TA recipient and one or more TA center staff. This category of TA includes one-time, labor-intensive events, such as facilitating strategic planning or hosting regional or national conferences. It can also include episodic, less labor-intensive events that extend over a period of time, such as facilitating a series of conference calls on single or multiple topics that are designed around the needs of the recipients. Facilitating communities of practice can also be considered targeted, specialized TA.

¹⁵ "Intensive, sustained TA" means TA services often provided on-site and requiring a stable, ongoing relationship between the TA center staff and the TA recipient. "TA services" are defined as negotiated series of activities designed to reach a valued outcome. This category of TA should result in changes to policy, program, practice, or operations that support increased recipient capacity or improved outcomes at one or more systems levels.

(LA) or State educational agency (SEA) to—

(1) Model and document data management and data sharing, linking, and integration policies, procedures, processes, and activities within the State;

(2) Develop and adapt tools and provide technical solutions to meet State-specific data needs; and

(3) Develop a sustainability plan for the State to continue the data management and data sharing, linking, and integration work in the future;

(C) Its proposed approach to measure the readiness of State LA and SEA personnel to work with the project, including their commitment to the initiative, alignment of the initiative to their needs, current infrastructure, available resources, and ability to build capacity at the State and local levels;

(D) Its proposed approach to prioritizing TA recipients with a primary focus on meeting the needs of States with known ongoing data quality issues, as measured by OSEP's review of the quality of the IDEA sections 616 and 618 data;

(E) Its proposed plan for assisting State LAs and SEAs to build or enhance training systems that include professional development based on adult learning principles and coaching;

(F) Its proposed plan for working with appropriate levels of the education system (*e.g.*, State LAs, SEAs, regional TA providers, districts, local programs, families) to ensure that there is communication between each level and that there are systems in place to support the collection, reporting, analysis, and use of high-quality IDEA Part C data (including IDEA section 616 Part C data, section 618 Part C data, and Part C child find data) and IDEA Part B preschool special education data as well as early childhood data management and data system integration; and

(G) Its proposed plan for collaborating and coordinating with the National Technical Assistance Center to Improve State Capacity to Collect, Report, Analyze, and Use Accurate IDEA Part B Data, the Early Childhood Technical Assistance Center, other Department-funded TA investments, other federally funded TA investments, and Institute of Education Sciences/National Center for Education Statistics research and development investments, where appropriate, in order to align complementary work and jointly develop and implement products and services to meet the purposes of this priority and to develop and implement a coordinated TA plan when they are involved in a State; and

(6) Develop products and implement services that maximize efficiency. To address this requirement, the applicant must describe—

(i) How the proposed project will use technology to achieve the intended project outcomes;

(ii) With whom the proposed project will collaborate and the intended outcomes of this collaboration; and

(iii) How the proposed project will use non-project resources to achieve the intended project outcomes.

(c) In the narrative section of the application under "Quality of the project evaluation," include an evaluation plan for the project developed in consultation with and implemented by a third-party evaluator.¹⁶ The evaluation plan must—

(1) Articulate formative and summative evaluation questions, including important process and outcome evaluation questions. These questions should be related to the project's proposed logic model required in paragraph (b)(2)(ii) of these application and administrative requirements;

(2) Describe how progress in and fidelity of implementation, as well as project outcomes will be measured to answer the evaluation questions.

Specify the measures and associated instruments or sources for data appropriate to the evaluation questions. Include information regarding reliability and validity of measures where appropriate;

(3) Describe strategies for analyzing data and how data collected as part of this plan will be used to inform and improve service delivery over the course of the project and to refine the proposed logic model and evaluation plan, including subsequent data collection;

(4) Provide a timeline for conducting the evaluation, and include staff assignments for completing the plan. The timeline must indicate that the data will be available annually for the annual performance report (APR) and at the end of Year 2; and

(5) Dedicate sufficient funds in each budget year to cover the costs of developing or refining the evaluation plan in consultation with a "third-party" evaluator, as well as the costs associated with the implementation of the evaluation plan by the third-party evaluator.

¹⁶ A "third-party" evaluator is an independent and impartial program evaluator who is contracted by the grantee to conduct an objective evaluation of the project. This evaluator must not have participated in the development or implementation of any project activities, except for the evaluation activities, or have any financial interest in the outcome of the evaluation.

(d) Demonstrate, in the narrative section of the application under "Adequacy of resources," how—

(1) The proposed project will encourage applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability, as appropriate;

(2) The proposed key project personnel, consultants, and subcontractors have the qualifications and experience to carry out the proposed activities and achieve the project's intended outcomes;

(3) The applicant and any key partners have adequate resources to carry out the proposed activities;

(4) The proposed costs are reasonable in relation to the anticipated results and benefits and funds will be spent in a way that increases their efficiency and cost-effectiveness, including by reducing waste or achieving better outcomes.

(e) Demonstrate, in the narrative section of the application under "Quality of the management plan," how—

(1) The proposed management plan will ensure that the project's intended outcomes will be achieved on time and within budget. To address this requirement, the applicant must describe—

(i) Clearly defined responsibilities for key project personnel, consultants, and subcontractors, as applicable; and

(ii) Timelines and milestones for accomplishing the project tasks;

(2) Key project personnel and any consultants and subcontractors will be allocated to the project and how these allocations are appropriate and adequate to achieve the project's intended outcomes;

(3) The proposed management plan will ensure that the products and services provided are of high quality, relevant, and useful to recipients; and

(4) The proposed project will benefit from a diversity of perspectives, including those of families, educators, TA providers, researchers, and policy makers, among others, in its development and operation.

(f) Address the following application requirements. The applicant must—

(1) Include, in Appendix A, personnel-loading charts and timelines, as applicable, to illustrate the management plan described in the narrative;

(2) Include, in the budget, attendance at the following:

(i) A one and one-half day kick-off meeting in Washington, DC, after receipt of the award, and an annual planning

meeting in Washington, DC, with the OSEP project officer and other relevant staff during each subsequent year of the project period.

(ii) A three-day project directors' conference in Washington, DC, during each year of the project period, provided that, if the conference is conducted virtually, the project must reallocate unused travel funds no later than the end of the third quarter of each budget period.

(iii) Three annual two-day trips to attend Department briefings, Department-sponsored conferences, and other meetings, as requested by OSEP;

(3) Provide an assurance that the project will—

(i) Reallocate unused travel funds no later than the end of the third quarter if the kick-off or planning meetings are conducted virtually; and

(ii) Within 30 days of receipt of the award, participate in a post-award teleconference between the OSEP project officer and the grantee's project director or other authorized representative;

(4) Include, in the budget, a line item for an annual set-aside of 5 percent of the grant amount to support emerging needs that are consistent with the proposed project's intended outcomes, as those needs are identified in consultation with, and approved by, the OSEP project officer. With approval from the OSEP project officer, the project must reallocate any remaining funds from this annual set-aside no later than the end of the third quarter of each budget period;

(5) Budget at least 50 percent of the grant award for providing targeted and intensive TA to States;

(6) Provide an assurance that it will maintain a high-quality website, with an easy-to-navigate design, that meets government or industry-recognized standards for accessibility; and

(7) Include, in Appendix A, an assurance to assist OSEP with the transfer of pertinent resources and products and to maintain the continuity of services to States during the transition to these new award period and at the end of this award period, as appropriate.

Program Authority: 20 U.S.C. 1411(c), 1416(i), 1418(c), 1418(d), 1442; Further Consolidated Appropriations Act, 2024, Public Law 118–47, Div. D, Title III, 138 Stat. 460, 685 (2024).

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General

Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget (OMB) Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Guidance for Federal Financial Assistance in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The NFP.

Note: The U.S. Department of Education will implement the provisions included in the Office of Management and Budget (OMB) final rule, *OMB Guidance for Federal Financial Assistance*, which amends 2 CFR parts 25, 170, 175, 176, 180, 182, 183, 184, and 200, on October 1, 2024. Grant applicants that anticipate a performance period start date on or after October 1, 2024, should follow the provisions stated in the OMB Guidance for Federal Financial Assistance (89 FR 30046, April 22, 2024) when preparing an application. For more information about these updated regulations please visit: www.cfo.gov/resources/uniform-guidance/. The Department will continue to provide more resources on our web page as they become available.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian Tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Cooperative agreement.

Estimated Available Funds: \$6,250,000 in year one, \$6,750,000 in years two and three, and \$7,000,000 in years four and five.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2025 from the list of unfunded applications from this competition.

Maximum Award: We will not make an award exceeding \$6,250,000 for a single budget period of 12 months in year one, \$6,750,000 for a single budget period of 12 months in years two and three, and \$7,000,000 for a single budget period of 12 months in years four and five.

Estimated Number of Awards: 1.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. **Eligible Applicants:** SEAs; State lead agencies under Part C of the IDEA;

local educational agencies (LEAs), including public charter schools that are considered LEAs under State law; institutions of higher education (IHEs); other public agencies; private nonprofit organizations; freely associated States and outlying areas; Indian Tribes or Tribal organizations; and for-profit organizations.

Note: If you are a nonprofit organization, under 34 CFR 75.51, you may demonstrate your nonprofit status by providing: (1) proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code; (2) a statement from a State taxing body or the State attorney general certifying that the organization is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual; (3) a certified copy of the applicant's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the applicant; or (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate.

2. a. **Cost Sharing or Matching:** This competition does not require cost sharing or matching.

b. **Indirect Cost Rate Information:** This program uses an unrestricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see <https://www2.ed.gov/about/offices/list/ocfo/intro.html>.

c. **Administrative Cost Limitation:** This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Guidance for Federal Financial Assistance.

3. **Subgrantees:** Under 34 CFR 75.708(b) and (c), a grantee under this competition may award subgrants—to directly carry out project activities described in its application—to the following types of entities: IHEs, nonprofit organizations suitable to carry out the activities proposed in the application, and other public agencies. The grantee may award subgrants to entities it has identified in an approved application or that it selects through a competition under procedures established by the grantee, consistent with 34 CFR 75.708(b)(2).

4. **Other General Requirements:**

(a) Recipients of funding under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Applicants for, and recipients of, funding must, with respect to the aspects of their proposed project relating to the absolute priority, involve individuals with disabilities, or parents of individuals with disabilities ages birth through 26, in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. Application Submission

Instructions: Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045) and available at www.federalregister.gov/content/pkg/FR-2022-12-07/pdf/2022-26554.pdf, which contain requirements and information on how to submit an application.

2. **Intergovernmental Review:** This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

3. **Funding Restrictions:** We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

4. **Recommended Page Limit:** The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 70 pages and (2) use the following standards:

- A “page” is 8.5” x 11”, on one side only, with 1” margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.

- Use a font that is 12 point or larger.
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the abstract (follow the

guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the recommended page limit does apply to all of the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

V. Application Review Information

1. **Selection Criteria:** The selection criteria for this competition are from 34 CFR 75.210 and are as follows:

(a) **Significance (10 points).**

(1) The Secretary considers the significance of the proposed project.

(2) In determining the significance of the proposed project, the Secretary considers the following factors:

(i) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses.

(ii) The importance or magnitude of the results or outcomes likely to be attained by the proposed project.

(b) **Quality of project services (35 points).**

(1) The Secretary considers the quality of the services to be provided by the proposed project.

(2) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable.

(ii) The extent to which there is a conceptual framework underlying the proposed research or demonstration activities and the quality of that framework.

(iii) The extent to which the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice.

(iv) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services.

(v) The extent to which the TA services to be provided by the proposed

project involve the use of efficient strategies, including the use of technology, as appropriate, and the leveraging of non-project resources.

(vi) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project.

(c) **Quality of the project evaluation (15 points).**

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the following factors:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project.

(ii) The extent to which the methods of evaluation provide for examining the effectiveness of project implementation strategies.

(iii) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

(iv) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

(d) **Adequacy of resources and quality of project personnel (20 points).**

(1) The Secretary considers the adequacy of resources for the proposed project and the quality of the personnel who will carry out the proposed project.

(2) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The qualifications, including relevant training and experience, of the project director or principal investigator.

(ii) The qualifications, including relevant training and experience, of key project personnel.

(iii) The qualifications, including relevant training and experience, of project consultants or subcontractors.

(iv) The qualifications, including relevant training, experience, and independence, of the evaluator.

(v) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization.

(vi) The relevance and demonstrated commitment of each partner in the proposed project to the implementation and success of the project.

(vii) The extent to which the budget is adequate to support the proposed project.

(viii) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project.

(e) *Quality of the management plan (20 points).*

(1) The Secretary considers the quality of the management plan for the proposed project.

(2) In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(i) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(ii) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(iii) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project.

(iv) How the applicant will ensure that a diversity of perspectives are brought to bear in the operation of the proposed project, including those of parents, teachers, the business community, a variety of disciplinary and professional fields, recipients or beneficiaries of services, or others, as appropriate.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:* In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications.

4. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions, and under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently \$250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds \$10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed \$10,000,000.

6. *In General:* In accordance with the Office of Management and Budget's guidance for Federal Financial Assistance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with:

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN), or we may send you an email containing a link to access an electronic version of your GAN. We also may notify you informally.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved

application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to www.ed.gov/fund/grant/apply/appforms/appforms.html.

5. *Performance Measures:* For the purposes of Department reporting under 34 CFR 75.110, the Department has established a set of performance measures that are designed to yield information on various aspects of the effectiveness and quality of the Technical Assistance on State Data Collection program. These measures are:

- *Program Performance Measure #1:* The percentage of TA and dissemination products and services deemed to be of high quality by an independent review panel of experts qualified or individuals with appropriate expertise to review the substantive content of the products and services.

- *Program Performance Measure #2:* The percentage of TA and dissemination products and services deemed by an independent review panel of qualified experts or members of the target audiences to be of high relevance to educational and early intervention policy or practice.

- *Program Performance Measure #3:* The percentage of TA and dissemination products and services deemed by an independent review panel of qualified experts or members of the target audiences to be useful in improving educational or early intervention policy or practice.

- *Program Performance Measure #4:* The cost efficiency of the Technical Assistance on State Data Collection Program includes the percentage of milestones achieved in the current annual performance report period and the percentage of funds spent during the current fiscal year.

The measures apply to projects funded under this competition, and grantees are required to submit data on these measures as directed by OSEP.

Grantees will be required to report information on their project's performance in annual and final performance reports to the Department (34 CFR 75.590).

The Department will also closely monitor the extent to which the products and services provided by the Center meet needs identified by stakeholders and may require the project to report on such alignment in its annual and final performance reports.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at www.govinfo.gov. At this site you can view this document, as well as all other Department documents published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access Department documents published in the **Federal Register** by using the article search feature at www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Danté Allen,

Commissioner, Rehabilitation Services Administration, Office of Special Education and Rehabilitative Services.

[FR Doc. 2024-16116 Filed 7-18-24; 11:15 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

Extension of the Application Deadline Date; Applications for New Awards; Expanding Opportunity Through Quality Charter Schools Program (CSP)-State Charter School Facilities Incentive Grant (SFIG) Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

SUMMARY: On April 24, 2024, we published in the **Federal Register** a notice inviting applications (NIA) for the fiscal year (FY) 2024 SFIG Program, Assistance Listing Number 84.282D. The NIA established a deadline date of July 23, 2024, for the transmittal of applications. For eligible applicants located in counties in Texas that are covered by a major disaster declaration issued by the President, this notice extends the deadline date for transmittal of applications until Monday, July 29,

2024, and extends the date of intergovernmental review until September 27, 2024.

DATES:

Deadline for Transmittal of Applications: July 29, 2024.

Deadline for Intergovernmental Review: September 27, 2024.

FOR FURTHER INFORMATION CONTACT:

Clifton Jones. Telephone: (202) 205-2204. Email: charter.facilities@ed.gov.

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7-1-1.

SUPPLEMENTARY INFORMATION: On April 24, 2024, we published the NIA in the **Federal Register** (89 FR 31151). Under the NIA, applications are due on July 23, 2024. We are extending the deadline for transmittal of applications for affected applicants (as defined under *Eligibility*) to allow these applicants more time—until July 29, 2024—to prepare and submit their applications.

Eligibility: The application deadline extension applies only to eligible applicants under the FY 2024 SFIG Program competition that are affected applicants. An eligible applicant for this competition is defined in the NIA. To qualify as an affected applicant, the applicant must have a mailing address that is located in the federally declared disaster area and must provide appropriate supporting documentation, if requested.

The applicable federally declared disaster area under this declaration is the area in which assistance to individuals or public assistance has been authorized under FEMA's disaster declaration for Texas Hurricane Beryl DR-4798-TX. See the disaster declaration available at <https://www.fema.gov/disaster/4798>.

Affected applicants that have already timely submitted applications under the FY 2024 SFIG Program competition may resubmit applications on or before the extended application deadline of July 29, 2024, but are not required to do so. If a new application is not submitted, the Department will use the application that was submitted by the original deadline. If a new application is submitted, the Department will consider the application that is last submitted and timely received by 11:59:59 p.m., Eastern Time, on July 29, 2024.

Any application submitted by an affected applicant under the extended deadline must contain evidence (e.g., the applicant organization mailing address) that the applicant is located in the applicable federally declared disaster area and, if requested, the

applicant must provide appropriate supporting documentation.

The application period is not extended for all applicants. Applications from applicants that are not affected, as defined above, will not be accepted past the original July 23, 2024 deadline.

Note: All information in the NIA for this competition remains the same, except for the deadline for the transmittal of applications and the deadline for intergovernmental review.

Program Authority: Title IV, Part C Section 4304 of the ESEA, as amended (20 U.S.C. 7221(c)).

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this notice, the NIA, and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at www.govinfo.gov. At this site you can view this document, as well as all other Department documents published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access Department documents published in the **Federal Register** by using the article search feature at www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Adam Schott,

Principal Deputy Assistant Secretary, Delegated the Authority to Perform the Functions and Duties of the Assistant Secretary, Office of Elementary and Secondary Education.

[FR Doc. 2024-16175 Filed 7-18-24; 4:15 pm]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Staff Attendance at North American Electric Reliability Corporation Security Integration and Technology Enablement Subcommittee Quarterly Meeting

The Federal Energy Regulatory Commission hereby gives notice ¹ that members of the Commission and/or Commission staff may attend the following meetings:

North American Electric Reliability Corporation: Security Integration and Technology Enablement Subcommittee Quarterly Meeting, WebEx

July 23, 2024 | 12:00 p.m.–2:00 p.m. Eastern

Further information regarding this meeting and how to join remotely may be found at: <https://www.nerc.com/pa/RAPA/Lists/RAPA/DispForm.aspx?ID=690>.

The discussions at the meetings, which are open to the public, may address matters at issue in the following Commission proceedings:

Docket No. RR24-2-000—North American Electric Reliability Corporation

For further information, please contact Leigh Anne Faugust at (202) 502-6396 or leigh.faugust@ferc.gov.

Dated: July 11, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024-15738 Filed 7-19-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

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

Filings Instituting Proceedings

Docket Numbers: PR24-84-000.

Applicants: Southern California Gas Company.

Description: § 284.123(g) Rate Filing: Offshore Delivery Service Rate Revision July 2024 to be effective 7/1/2024.

Filed Date: 7/12/24.

Accession Number: 20240712-5188.

Comment Date: 5 p.m. ET 8/2/24.

§ 284.123(g) Protest: 5 p.m. ET 9/10/24.

¹ 18 CFR 385.2009 (2023).

Docket Numbers: RP24–904–000.
Applicants: Transcontinental Gas
 Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: List of
 Non-Conforming Service Agreements
 (REA Interim Firm—Jul 2024) to be
 effective 8/12/2024.

Filed Date: 7/12/24.

Accession Number: 20240712–5065.

Comment Date: 5 p.m. ET 7/24/24.

Any person desiring to intervene, to
 protest, or to answer a complaint in any
 of the above proceedings must file in
 accordance with Rules 211, 214, or 206
 of the Commission's Regulations (18
 CFR 385.211, 385.214, or 385.206) on or
 before 5:00 p.m. Eastern time on the
 specified comment date. Protests may be
 considered, but intervention is
 necessary to become a party to the
 proceeding.

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

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

The Commission's Office of Public
 Participation (OPP) supports meaningful
 public engagement and participation in
 Commission proceedings. OPP can help
 members of the public, including
 landowners, environmental justice
 communities, Tribal members and
 others, access publicly available
 information and navigate Commission
 processes. For public inquiries and
 assistance with making filings such as
 interventions, comments, or requests for
 rehearing, the public is encouraged to
 contact OPP at (202) 502–6595 or [OPP@
 ferc.gov](mailto:OPP@ferc.gov).

Dated: July 15, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024–15991 Filed 7–19–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24–88–000]

Rover Pipeline LLC; Notice of Availability of the Environmental Assessment for the Proposed Rover— Bulger Delivery Meter Station Project

The staff of the Federal Energy
 Regulatory Commission (FERC or

Commission) has prepared an
 environmental assessment (EA) for the
 Rover—Bulger Delivery Meter Station
 Project, proposed by Rover Pipeline LLC
 (Rover) in the above-referenced docket.
 Rover requests authorization to
 construct, own, and operate a new
 pipeline delivery point interconnection,
 the Rover-Bulger Delivery Meter Station,
 entirely within Rover's existing Bulger
 Compressor Station at milepost 0.0 of
 Rover's Burgettstown Lateral in
 Washington County, Pennsylvania.

The EA assesses the potential
 environmental effects of the
 construction and operation activities
 associated with the Rover—Bulger
 Delivery Meter Station Project in
 accordance with the requirements of the
 National Environmental Policy Act
 (NEPA). The FERC staff concludes that
 approval of the proposed project would
 not constitute a major federal action
 significantly affecting the quality of the
 human environment.

The proposed Rover—Bulger Delivery
 Meter Station Project includes the
 following facilities:

- one-16-inch-diameter hot tap;
- one tap valve;
- two Ultrasonic Meter Skids;
- two flow control valves;
- a gas quality/measurement
 building;
- satellite communications; and
- associated interconnect piping.

The Commission mailed a copy of the
Notice of Availability of the EA to
 federal, state, and local government
 representatives and agencies; elected
 officials; environmental and public
 interest groups; Native American tribes;
 potentially affected landowners and
 other interested individuals and groups;
 and newspapers and libraries in the
 project area. The EA is only available in
 electronic format. It may be viewed and
 downloaded from the FERC's website
 (www.ferc.gov), on the natural gas
 environmental documents page ([https://
 www.ferc.gov/industries-data/natural-
 gas/environment/environmental-
 documents](https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents)). In addition, the EA may be
 accessed by using the eLibrary link on
 the FERC's website. Click on the
 eLibrary link ([https://elibrary.ferc.gov/
 eLibrary/search](https://elibrary.ferc.gov/eLibrary/search)), select "General
 Search" and enter the docket number in
 the "Docket Number" field, excluding
 the last three digits (*i.e.*, CP24–88). Be
 sure you have selected an appropriate
 date range. For assistance, please
 contact FERC Online Support at
FercOnlineSupport@ferc.gov or toll free
 at (866) 208–3676, or for TTY, contact
 (202) 502–8659.

The EA is not a decision document.
 It presents Commission staff's
 independent analysis of the

environmental issues for the
 Commission to consider when
 addressing the merits of all issues in
 this proceeding. Any person wishing to
 comment on the EA may do so. Your
 comments should focus on the EA's
 disclosure and discussion of potential
 environmental effects, reasonable
 alternatives, and measures to avoid or
 lessen environmental impacts. The more
 specific your comments, the more useful
 they will be. To ensure that the
 Commission has the opportunity to
 consider your comments prior to
 making its decision on this project, it is
 important that we receive your
 comments in Washington, DC on or
 before 5:00 p.m. Eastern Time on
 August 14, 2024.

For your convenience, there are three
 methods you can use to file your
 comments to the Commission. The
 Commission encourages electronic filing
 of comments and has staff available to
 assist you at (866) 208–3676 or
FercOnlineSupport@ferc.gov. Please
 carefully follow these instructions so
 that your comments are properly
 recorded.

(1) You can file your comments
 electronically using the *eComment*
 feature on the Commission's website
 (www.ferc.gov) under the link to *FERC
 Online*. This is an easy method for
 submitting brief, text-only comments on
 a project;

(2) You can also file your comments
 electronically using the *eFiling* feature
 on the Commission's website
 (www.ferc.gov) under the link to *FERC
 Online*. With eFiling, you can provide
 comments in a variety of formats by
 attaching them as a file with your
 submission. New eFiling users must
 first create an account by clicking on
 "eRegister." You must select the type of
 filing you are making. If you are filing
 a comment on a particular project,
 please select "Comment on a Filing"; or

(3) You can file a paper copy of your
 comments by mailing them to the
 Commission. Be sure to reference the
 project docket number (CP24–88–000)
 on your letter. Submissions sent via the
 U.S. Postal Service must be addressed
 to: Debbie-Anne A. Reese, Acting
 Secretary, Federal Energy Regulatory
 Commission, 888 First Street NE, Room
 1A, Washington, DC 20426.
 Submissions sent via any other carrier
 must be addressed to: Debbie-Anne A.
 Reese, Acting Secretary, Federal Energy
 Regulatory Commission, 12225 Wilkins
 Avenue, Rockville, MD 20852.

Filing environmental comments will
 not give you intervenor status, but you
 do not need intervenor status to have
 your comments considered. Only
 intervenors have the right to seek

rehearing or judicial review of the Commission's decision. At this point in this proceeding, the timeframe for filing timely intervention requests has expired. Any person seeking to become a party to the proceeding must file a motion to intervene out-of-time pursuant to Rule 214(b)(3) and (d) of the Commission's Rules of Practice and Procedures (18 CFR 385.214(b)(3) and (d)) and show good cause why the time limitation should be waived. Motions to intervene are more fully described at <https://www.ferc.gov/how-intervene>.

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208-FERC, or on the FERC website (www.ferc.gov) using the eLibrary link. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to <https://www.ferc.gov/ferc-online/overview> to register for eSubscription.

Dated: July 15, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-15989 Filed 7-19-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

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

Docket Numbers: ER23-1851-008.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Second Status Report—Amended ISA—CSA, SA Nos. 6917-6918; Queue No. AD1-031 to be effective 10/26/2023.

Filed Date: 7/15/24.

Accession Number: 20240715-5106.

Comment Date: 5 p.m. ET 8/5/24.

Docket Numbers: ER24-2052-001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: 4225 Algodon Solar Energy & SPS Facilities Service Agr to be effective 7/16/2024.

Filed Date: 7/15/24.

Accession Number: 20240715-5083.

Comment Date: 5 p.m. ET 8/5/24.

Docket Numbers: ER24-2518-000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of ISA, SA No. 4395; Queue No. AA1-092 to be effective 7/19/2024.

Filed Date: 7/15/24.

Accession Number: 20240715-5045.

Comment Date: 5 p.m. ET 8/5/24.

Docket Numbers: ER24-2519-000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original GIA Service Agreement No. 7304, AG1-100 to be effective 6/14/2024.

Filed Date: 7/15/24.

Accession Number: 20240715-5058.

Comment Date: 5 p.m. ET 8/5/24.

Docket Numbers: ER24-2520-000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions to Add the Multi-Day Economic Commitment Process to be effective 12/31/9998.

Filed Date: 7/15/24.

Accession Number: 20240715-5095.

Comment Date: 5 p.m. ET 8/5/24.

Docket Numbers: ER24-2521-000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amended WMPA, Service Agreement No. 6062; AG1-253 to be effective 9/16/2024.

Filed Date: 7/15/24.

Accession Number: 20240715-5118.

Comment Date: 5 p.m. ET 8/5/24.

Docket Numbers: ER24-2522-000.

Applicants: Public Service Company of New Hampshire.

Description: § 205(d) Rate Filing: Wok, LLC Interconnection Study Agreement to be effective 7/16/2024.

Filed Date: 7/15/24.

Accession Number: 20240715-5123.

Comment Date: 5 p.m. ET 8/5/24.

Docket Numbers: ER24-2523-000.

Applicants: The Connecticut Light and Power Company.

Description: § 205(d) Rate Filing: Vineyard Northeast LLC Engineering Review Agreement to be effective 7/16/2024.

Filed Date: 7/15/24.

Accession Number: 20240715-5126.

Comment Date: 5 p.m. ET 8/5/24.

Docket Numbers: ER24-2524-000.

Applicants: Poblano Energy Storage, LLC.

Description: Baseline eTariff Filing: Application for Market Based Rate Authority to be effective 7/16/2024.

Filed Date: 7/15/24.

Accession Number: 20240715-5167.

Comment Date: 5 p.m. ET 8/5/24.

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

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

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

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

Dated: July 15, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-15993 Filed 7-19-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY**Western Area Power Administration****Central Valley Project/Power, Transmission, and Ancillary Services and California-Oregon Transmission Project Transmission Service—Rate Order No. WAPA–207**

AGENCY: Western Area Power Administration, Department of Energy (DOE).

ACTION: Notice of rate order concerning power, transmission, and ancillary services formula rates.

SUMMARY: The formula rates for the Sierra Nevada Region (SN) Central Valley Project (CVP) power, transmission, and ancillary services and California-Oregon Transmission Project (COTP) transmission service have been confirmed, approved, and placed into effect on an interim basis. These new formula rates replace the existing formula rates which expire on September 30, 2024, and December 31, 2024. There are no changes to the existing formula rates for these services and there are no material changes aside from updating the effective dates.

DATES: The Provisional Formula Rates under Rate Schedules CV–F14, CPP–3, CV–T4, CV–NWT6, COTP–T4, CV–TPT8, CV–UUP2, CV–SPR5, CV–SUR5, CV–RFS5, CV–EID6, CV–GID3, CV–SSP3, CV–EIM1S1, CV–EIM4S1, and CV–EIM9S1 are effective on the first day of the first full billing period beginning on or after October 1, 2024, and will remain in effect through September 30, 2029, pending confirmation and approval by the Federal Energy Regulatory Commission (FERC) on a final basis or until superseded.

FOR FURTHER INFORMATION CONTACT: Michelle Williams, Regional Manager, Sierra Nevada Region, Western Area Power Administration, 114 Parkshore Drive, Folsom, CA 95630, or Autumn Wolfe, Rates Manager, Sierra Nevada Region, Western Area Power Administration, (916) 353–4686, or email: SNR-RateCase@wapa.gov.

SUPPLEMENTARY INFORMATION: On December 2, 2011, FERC confirmed and approved Rate Schedules for CVP power, transmission, and ancillary services; COTP transmission; and Pacific Alternating Current Intertie (PACI) transmission under Rate Order No. WAPA–156. That rate order was extended by Rate Order Nos. WAPA–173 and WAPA–185. These rates are set

to expire on September 30, 2024.¹ The formula rate schedules are:

- CV–F13 Base Resource and First Preference Power
- CPP–2 Custom Product Power
- CV–T3 Firm and Non-Firm Point-to-Point Transmission Service
- CV–NWT5 Network Integration Transmission Service
- COTP–T3 Firm and Non-Firm Point-to-Point Transmission Service
- PACI–T3 Firm and Non-Firm Point-to-Point Transmission Service (to be handled in a separate rate case)
- CV–TPT7 Third-Party Transmission Service
- CV–UUP1 Unreserved Use Penalties
- CV–RFS4 Regulation and Frequency Response
- CV–SPR4 Spinning Reserves
- CV–SUR4 Supplemental Reserves

On April 27, 2021, FERC confirmed and approved Rate Order No. WAPA–194, which placed into effect formula rates for the Energy Imbalance Market (EIM) services, Sale of Surplus Products, and revisions to existing rate schedules for Energy Imbalance and Generator Imbalance services. These rates are being superseded as they were not set to expire until December 31, 2024.² The formula rate schedules are:

- CV–EIM1S EIM Administrative Service Charge
- CV–EIM4S EIM Energy Imbalance Service
- CV–EIM9S EIM Generator Imbalance Service
- CV–SSP2 Sale of Surplus Products
- CV–EID5 Energy Imbalance Service
- CV–GID2 Generator Imbalance Service

Western Area Power Administration (WAPA) published a **Federal Register** notice (Proposed FRN) on August 30, 2023 (88 FR 59909), proposing new formula rates for CVP power, transmission, and ancillary services and COTP transmission service. The Proposed FRN also initiated a 90-day public consultation and comment period (which was subsequently extended another 30-days)³ and set forth the date and location of the public information and public comment forums. The rates continue the formula-based methodology that includes an annual update to the financial, load, and other data in the rate formulas.

¹ See Docket No. EF11–9–00 (137 FERC ¶ 62,201) (2011). Extended by Docket No. EF16–3–000 (156 FERC ¶ 62,039) (2016). Extended by Docket No. EF19–4–000 (168 FERC ¶ 62,150) (2019).

² See Docket No. EF21–1–000 (86 FERC ¶ 11760) (2021).

³ 88 FR 80293 (Nov. 17, 2023).

Legal Authority

By Delegation Order No. S1–DEL–RATES–2016, effective November 19, 2016, the Secretary of Energy delegated: (1) the authority to develop power and transmission rates to the WAPA–SN Administrator; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, or to remand or disapprove such rates, to FERC. By Delegation Order No. S1–DEL–S3–2023, effective April 10, 2023, the Secretary of Energy also delegated the authority to confirm, approve, and place such rates into effect on an interim basis to the Under Secretary for Infrastructure. By Redelegation Order No. S3–DEL–WAPA1–2023, effective April 10, 2023, the Under Secretary for Infrastructure further redelegated the authority to confirm, approve, and place such rates into effect on an interim basis to WAPA’s Administrator. This rate action is issued under Redelegation Order No. S3–DEL–WAPA1–2023 and Department of Energy procedures for public participation in rate adjustments set forth at 10 CFR part 903.⁴

Following review of WAPA–SN’s proposal, Rate Order No. WAPA–207, which provides the formula rates for CVP power, transmission, and ancillary services and COTP transmission service, is hereby confirmed, approved, and placed into effect on an interim basis. WAPA–SN will submit Rate Order No. WAPA–207 to FERC for confirmation and approval on a final basis.

DEPARTMENT OF ENERGY**Administrator, Western Area Power Administration**

In the Matter of: Western Area Power Administration, Sierra Nevada Region, Rate Adjustment for the Central Valley Project Power, Transmission, and Ancillary Services; and California-Oregon Transmission Project Transmission Service Formula Rates, Rate Order No. WAPA–207

Order Confirming, Approving, and Placing the Formula Rates for Central Valley Project and California-Oregon Transmission Project Into Effect on an Interim Basis

The formula rates in Rate Order No. WAPA–207 are established following section 302 of the Department of Energy (DOE) Organization Act (42 U.S.C. 7152).¹

⁴ 50 FR 37835 (Sept. 18, 1985) and 84 FR 5347 (Feb. 21, 2019).

¹ This Act transferred to, and vested in, the Secretary of Energy the power marketing functions

By Delegation Order No. S1–DEL–RATES–2016, effective November 19, 2016, the Secretary of Energy delegated: (1) the authority to develop power and transmission rates to the Western Area Power Administration (WAPA) Administrator; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, or to remand or disapprove such rates, to the Federal Energy Regulatory Commission (FERC). By Delegation Order No. S1–DEL–S3–2023, effective April 10, 2023, the Secretary of Energy also delegated the authority to confirm, approve, and place such rates into effect on an interim basis to the Under Secretary for Infrastructure. By Redelegation Order No. S3–DEL–WAPA1–2023, effective April 10, 2023, the Under Secretary for Infrastructure further redelegated the authority to confirm, approve, and place such rates into effect on an interim basis to WAPA's Administrator. This rate action is issued under Redelegation Order No. S3–DEL–WAPA1–2023 and DOE procedures for public participation in rate adjustments set forth at 10 CFR part 903.²

Acronyms, Terms, and Definitions

As used in this Rate Order, the following acronyms, terms, and definitions apply:

BA: As defined in WAPA's Open Access Transmission Tariff (OATT), is Balancing Authority and is the responsible entity that integrates resource plans ahead of time, maintains load Interchange-generation balance within a Balancing Authority Area, and supports interconnection frequency in real time.

BAA: As defined in WAPA's OATT, is Balancing Authority Area; the term Balancing Authority Area shall have the same meaning as "Control Area."

BANC: Balancing Authority of Northern California is a joint powers authority that provides BA and other services to its members and other entities within the BAA. Members/entities of BANC may in turn provide transmission service to customers.

BR: Base Resource, as defined in Central Valley Project's 2025 Marketing Plan is the Central Valley and Washoe

Project power (capacity and energy) output determined by WAPA–SN to be available for marketing, including the environmental attributes, after meeting the requirements of project use and first preference customers, and any adjustments for maintenance, reserves, system losses, and certain ancillary services.

CAISO: As defined in WAPA's OATT, is the California Independent System Operator. A state-chartered, California, non-profit public benefit corporation that operates the transmission facilities of all CAISO participating transmission owners and dispatches certain generating units and loads. The CAISO is the Market Operator (MO) for the EIM.

Capacity: The electric capability of a generator, transformer, transmission circuit, or other equipment. It is expressed in kilowatts (kW) or megawatts (MW).

Conforming Load: The term is not officially defined by CAISO at this time and will be addressed in the future. The following description reasonably aligns with the CAISO's use of the term in defining load forecasting requirements under EIM: it is the load that changes in a reasonably predictable, uniform manner that is environmentally driven. A conforming load has a load profile that is similar to the aggregated load profile. Due to conventional weather- and temperature-based patterns, conforming loads can be forecast with a high level of accuracy using historical and meteorological data.

CVP: As defined in Central Valley Project's 2025 Marketing Plan, is Central Valley Project. The multipurpose Federal water development project extending from the Cascade Range in northern California to the plains along the Kern River south of the city of Bakersfield, California.

EI Service: Energy Imbalance Service is an ancillary service that provides for the difference between the scheduled and the actual delivery of energy to a load within the Transmission Provider's Sub-BAA.

EIM: As defined in CAISO's Business Practice Manual, means Energy Imbalance Market and is the rules and procedures in Section 29 of the CAISO Tariff governing the CAISO's operation of the Real-Time Market in BAAs outside of the CAISO BAA and the participation of EIM Market Participants in the Real-Time Market.

EIM Administrative Charge: As defined in CAISO's Business Practice Manual, is the fee imposed on transaction in the energy imbalance market as described in section 29.11(i)(1) of the CASIO Tariff.

EIM Entity: As defined in WAPA's OATT, Attachment S, is a BAA that enters into the MO's EIM Entity Agreement to enable the EIM to occur in its BAA. BANC is the EIM Entity for the BANC EIM Entity BAA. For the purposes of this Attachment S, the EIM Entity is the BANC EIM Entity, or the entity selected by the BANC EIM Entity who is certified by the MO. WAPA–SN participates in the CAISO EIM under the BANC EIM Entity.

EIM Non-Participating Resource: As defined on CAISO's website: EIM Resource that does not participate in the Real-Time Market but is required to be identified in the EIM BAA for settling charges and payments related to nonparticipating load and nonparticipating resources.

EIM Participating Resource: As defined in WAPA's OATT, Attachment S, is a resource or a portion of a resource: (1) that meets the Transmission Provider's eligibility requirements; (2) has been certified by the BANC EIM Entity for participation in the EIM; and (3) for which the generation owner and/or operator enters into the MO's EIM Participating Resource Agreement and any agreements as may be required by BANC and/or the BANC EIM Entity.

EIM Participating Resource Scheduling Coordinator: As defined in WAPA's OATT, Attachment S, an entity with one or more BANC EIM Participating Resource(s) or a third-party designated by the Transmission Customer with one or more BANC EIM Participating Resource(s), that is certified by the MO and enters into the MO's EIM Participating Resource Scheduling Coordinator Agreement.

Energy: As defined in Central Valley Project's 2025 Marketing Plan, is measured in terms of the work it is capable of doing over a period of time; electric energy is usually measured in kilowatt-hours or megawatt-hours.

Firm Point-To-Point Transmission Service: As defined in WAPA's OATT, is transmission service reserved and/or scheduled between specified Points of Receipt and Delivery pursuant to Part II of the Tariff.

First Preference Customers/Entity: As defined in Central Valley Project's 2025 Marketing Plan, is a preference customer and/or a preference entity (an entity qualified to use, but not using, preference power) within a country or origin (Trinity, Calaveras, and Tuolumne) as specified under the Trinity River Division Act (69 Sta. 719) and the New Melones Project provisions of the Flood Control Act of 1962 (76 Stat. 1173, 1191–1192).

of the Secretary of the Department of the Interior and the Bureau of Reclamation (Reclamation) under the Reclamation Act of 1902 (ch. 1093, 32 Stat. 388), as amended and supplemented by subsequent laws, particularly section 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)), and other acts that specifically apply to the projects involved.

² 50 FR 37835 (Sept. 18, 1985) and 84 FR 5347 (Feb. 21, 2019).

FRR: Frequency Response Reserve, as defined in Sacramento Municipal Utility District's (SMUD's) Operating Reserves OP-114, "NERC/WECC does not have an official definition for Frequency Response Reserve (FRR) yet. BANC is defining the FRR as an amount of reserve in MW that is synchronized to the system and can automatically respond to system frequency deviation. BANC in coordination with WAPA-SN and SMUD procures and monitors sufficient FRR in both Day-Ahead scheduling process and Real-Time operations to ensure that BANC meets NERC Reliability Standard BAL0031.1 R1."

FY: WAPA's fiscal year, October 1 to September 30.

Generating Unit: As defined in CAISO Tariff, is an individual electric generator and its associated plant and apparatus whose electrical output is capable of being separately identified and metered or a Physical Scheduling Plant that, in either case, is: located within the CAISO BAA (which includes a Pseudo-Tie of a generating unit to the CAISO BAA) or, for purposes of scheduling and operating the Real-Time Market only, an EIM Entity BAA; connected to the CAISO Controlled Grid, either directly or via interconnected transmission, or distribution facilities or via a Pseudo-Tie; and capable of producing and delivering net energy (energy in excess of a generating station's internal power requirements).

GI Service: Generator Imbalance Service is an ancillary service that provides for the difference between the output of a generator and the delivery schedule from that generator to: (1) another BAA, (2) the BANC BAA, or (3) a load within the Transmission Provider's Sub-BAA. GI Service during EIM participation is that associated with a generator that is not an EIM Participating Resource located in the Transmission Provider's Sub-BAA.

kW: Kilowatt—the electrical unit of capacity that equals 1,000 watts.

LAP: Load Aggregation Point is a set of Pricing Nodes as specified in Section 27.2 of the CAISO Tariff that are used for the submission of Bids and Settlement of Demand.

Load Ratio Share: As defined in WAPA's OATT, is the ratio of a Transmission Customer's Network Load to the Transmission Provider's total load computed in accordance with Sections 34.2 and 34.3 of the Network Integration Transmission Service under Part III of the Tariff and calculated on a rolling twelve-month basis.

Long-Term Firm Point-to-Point Transmission Service: As defined in WAPA's OATT, is Firm Point-to-Point

Transmission Service under Part II of the Tariff with a term of one year or more.

MO: As defined in WAPA's OATT, Attachment S, is Market Operator. The entity responsible for operation, administration, settlement, and oversight of the EIM. The CAISO is the current MO of the EIM.

MO Tariff: As defined in WAPA's OATT, Attachment S, is those portions of the MO's approved tariff, as such tariff may be modified from time to time, that specifically apply to the operation, administration, settlement, and oversight of the EIM.

NERC: The North American Electric Reliability Corporation.

New Rate: As defined in WAPA's OATT, means the modification of a rate for transmission or ancillary services provided by the Transmission Provider which has been promulgated pursuant to the rate development process outlined in Power and Transmission Rates, 10 CFR part 903 (2006).

NITS: Network Integration Transmission Service, as defined in WAPA's OATT, is the transmission service provided under Part III of the Tariff.

Non-conforming Load: The term is not officially defined by CAISO at this time and will be addressed in the future. The following description reasonably aligns with the CAISO's use of the term in defining load forecasting requirements under EIM: it is the load with unpredictable load pattern, e.g., pumps, industrial plants, etc., that makes it difficult for the CAISO model to accurately forecast. CAISO's load forecasting model uses historical actual conforming load data and meteorological data determined necessary to accurately forecast the conforming load. When non-conforming load causes more than 5% deviation (hourly) from the total actual load, it should be modeled separately from the load that CAISO will forecast for the EIM Entity (the conforming load). This requirement is part of the EIM Readiness Criteria in accordance with CAISO Tariff section 29.2(b)(7)(A)(iv).

Non-Firm Point-to-Point Transmission Service: As defined in WAPA's OATT, is Point-to-Point Transmission Service under the Tariff that is reserved and scheduled on an as-available basis and is subject to Curtailment or Interruption as set forth in Section 14.7 under Part II of the Tariff. Non-Firm Point-to-Point Transmission Service is available on a stand-alone basis for periods ranging from one hour to one month. The Transmission Provider may offer Non-Firm Point-to-Point Transmission Service for periods longer than one

month. If offered, the terms and conditions will be consistent with Part II of the Tariff and will be posted on the Transmission Provider's OASIS.

OASIS: As defined in WAPA's OATT, is Open Access Same-Time Information System. The information system and standards of conduct contained in Part 37 of FERC's regulations and all additional requirements implemented by subsequent FERC orders dealing with OASIS.

OATT: The Open Access Transmission Tariff, including all schedules or attachments thereto, of the Transmission Provided as amended from time to time, and approved by FERC.

Preference: As defined in Central Valley Project's 2025 Marketing Plan, is the requirements of Reclamation Law that provide for preference in the sale of Federal power be given to certain entities, such as governments (state, Federal and Native American), municipalities and other public corporations or agencies, and cooperatives and other nonprofit organizations financed in whole or in part by loans made pursuant to the Rural Electrification Act of 1936 (See, e.g., Reclamation Project Act of 1939, Section 9(c), 43 U.S.C. 485h(c)).

Point-to-Point Transmission Service: As defined in WAPA's OATT, is the reservation and transmission of capacity and energy on either a firm or non-firm basis from the Point(s) of Receipt to the Point(s) of Delivery under Part II of the Tariff.

Project Use: As defined in Central Valley Project's 2025 Marketing Plan, is power as defined by Reclamation Law and/or used to operate CVP and Washoe Project facilities.

Power: Capacity and energy.

Provisional Formula Rates: The formula rates confirmed, approved, and placed into effect on an interim basis by the Deputy Secretary of Energy or designee.

PRR: Power Revenue Requirement is revenue required by the PRS to recover annual expenses (such as operation and maintenance, purchase power, transmission service expenses, interest, and deferred expenses) and repay Federal investments and other assigned costs.

PRS: Power Repayment Study, is defined in Order RA 6120.2 as a study portraying the annual repayment of power production and transmission costs of a power system through the application of revenues over the repayment period of the power system. The study shows, among other items, estimated revenues and expenses, year by year, over the remainder of the power

system's repayment period (based upon conditions prevailing over the cost evaluation period), the estimated amount of Federal investment amortized during each year, and the total estimated amount of Federal investment remaining to be amortized.

Rate: As defined in WAPA's OATT, means the monetary charge or the formula for computing such a charge for any electric service provided by a Transmission Provider as defined in 10 CFR part 903.

Rate Adjustment: Rate Adjustment means a change in an existing rate or rates, or the establishment of a rate or rates for a new service. It does not include a change in rate schedule provisions or in contract terms, other than changes in the price per unit of service, nor does it include changes in the monetary charge pursuant to a formula stated in a rate schedule or a contract as defined in 10 CFR part 903.

Regulation: As defined in CAISO's Tariff, is the service provided either by resources certified by the CAISO as equipped and capable of responding to the CAISO's direct digital control signals, or by System Resources that have been certified by the CAISO as capable of delivering such service to the CAISO BAA, in an upward and downward direction to match, on a real-time basis, demand and resources, consistent with established NERC and Western Electricity Coordinating Council (WECC) reliability standards and any requirements of the Nuclear Regulatory Commission, or its successor. Regulation is used to control the operating level of a resource within a prescribed area in response to a change in system frequency, tie line loading, or the relation of these to each other so as to maintain the target system frequency and/or the established Interchange with other BAAs within the predetermined Regulation Limits. Regulation includes both an increase in energy production by a resource or decrease in energy consumption by a resource (Regulation Up) and a decrease in energy production by a resource or increase in energy consumption by a resource (Regulation Down). Regulation Up and Regulation Down are distinct capacity products, with separately stated requirements and Ancillary Service Marginal Pricings in each Settlement Period.

Resource Sufficiency: CAISO defines and proposes resource sufficiency evaluation that require all BAAs offer sufficient resources to meet their bid-in demand, reliability capacity to meet forecasted net load, provide ramp capability to meet their 24-hour net demand variation, and their forecasted

ancillary service and imbalance reserve requirements (adjusted for diversity benefit).

Short-Term Firm Point-to-Point Transmission Service: As defined in WAPA's OATT, is Firm Point-to-Point Transmission Service under Part II of the Tariff with a term of less than one year.

Sub-BAA: As defined in WAPA's OATT, is Sub-Balancing Authority Area. An electric power system operating within a host BAA that is bounded by meters and is responsible for BAA-like performance of generation, load, and transmission. WAPA-SN is a Sub-BAA within the BANC BAA.

Tariff: As defined in WAPA's OATT, is the Open Access Transmission Tariff, including all schedules or attachments thereto, of the Transmission Provided as amended from time to time, and approved by FERC.

TO: As defined in WAPA's OATT, means Transmission Owner and is the entity that owns, leases or otherwise possesses an interest in the portion of the Transmission System at the Point of Interconnection and may be a Party to the Small Generator Interconnection Agreement to the extent necessary.

Transmission Customer: As defined in WAPA's OATT, is any Eligible Customer (or its Designated Agent) that (i) executes a Service Agreement, or (ii) requests in writing that the Transmission Provider provide transmission service without a Service Agreement, pursuant to section 15.3 of the Tariff. This term is used in the Part I Common Service Provisions to include customers receiving transmission service under Part II and Part III of this Tariff.

Transmission Customer Base Schedule: As defined in WAPA's OATT, Attachment S, is an energy schedule that provides Transmission Customer hourly-level forecast data and other information used as the baseline by which to measure Imbalance Energy for purposes of EIM settlement. The term "Transmission Customer Base Schedule" as used in this Tariff is synonymous with the term "EIM Participant Base Schedule" used in the EIM Entity's business practices and may refer collectively to the components of such schedule (resource, Interchange, Intrachange, and load determined pursuant to the EIM Entity's business practices) or any individual components of such schedule. This term is synonymous to "Base Schedule."

Transmission Provider: As defined in WAPA's OATT, is the regional office within WAPA-SN that owns, controls, or operates the facilities used for the transmission of electric energy in

interstate commerce and provides transmission service under the Tariff.

Transmission System: As defined in WAPA's OATT, is the facilities owned, controlled, or operated by the Transmission Provider that are used to provide transmission service under Part II and Part III of the Tariff.

UIE: As defined in WAPA's OATT, Attachment S, is Uninstructed Imbalance Energy. Settlement charges incurred by the Transmission Provider on behalf of Transmission Customers due to uninstructed deviations of supply or demand.

WECC: The Western Electricity Coordinating Council.

Effective Date

The Provisional Formula Rate Schedules CV-F14, CPP-3, CV-T4, CV-NWT6, COTP-T4, CV-TPT8, CV-UUP2, CV-SPR5, CV-SUR5, CV-RFS5, CV-EID6, CV-GID3, CV-SSP3, CV-EIM1S1, CV-EIM4S1, and CV-EIM9S1 will take effect on the first day of the first full billing period beginning on or after October 1, 2024, and will remain in effect through September 30, 2029, pending approval by FERC on a final basis or until superseded.

Public Notice and Comment

WAPA-SN followed the Procedures for Public Participation in Power and Transmission Rate Adjustments and Extensions, 10 CFR part 903, in developing these formula rates. WAPA-SN took the following steps to involve interested parties in the rate process:

1. On August 30, 2023, a **Federal Register** notice (88 FR 59909) (Proposed FRN) announced the proposed formula rates and initiated a 90-day public consultation and comment period.

2. On August 31, 2023, WAPA-SN notified Preference Customers and interested parties of the proposed rates and provided a copy of the Proposed FRN.

3. On November 15, 2023, WAPA-SN held a public information forum via Microsoft Teams. WAPA-SN's representatives explained the proposed formula rates, answered questions, and gave notice that more information was available in the Customer Rate Brochure.

4. On November 15, 2023, WAPA-SN held a public comment forum via Microsoft Teams to provide an opportunity for customers and other interested parties to comment for the record.

5. SN established a public website to post information about the rate process. The website is located at: www.wapa.gov/about-wapa/regions/sn/sn-rates.

6. On November 17, 2023, a **Federal Register** notice (88 FR 80293) announced that WAPA–SN extended the public comment period for an additional 30-days, through December 28, 2023.

7. During the 120-day consultation and comment period, WAPA–SN received three oral comment submissions and no written comment letters. The comments and WAPA–SN's responses are addressed in the "Comments" section. All comments have been considered in the preparation of this Rate Order.

Oral Comments Were Received From the Following Organization

Northern California Power Agency, California.

Power Revenue Requirement and Allocation to Preference Customers

Before the start of each FY, WAPA–SN will continue to calculate and publish an annual Power Revenue Requirement (PRR) to determine the total cost of power. The total cost of power is allocated to WAPA–SN's preference customers, namely, First Preference (FP) customers based on their FP percentages, and the remaining amount to Base Resource (BR) customers based on their BR allocation, adjusted for programs, such as hourly exchange. The Trinity River Division Act of 1955 (69 Stat. 719) and the Flood Control Act of 1962 (76 Stat. 1173, 1191–1192) accorded FP to CVP power customers in Trinity, Tuolumne, and Calaveras counties. A BR customer, under the 2004 and 2025 Marketing Plans, is an entity that has executed a BR contract and is allocated a percentage of the BR.

WAPA–SN prepares a Power Repayment Study (PRS) each FY to determine if revenue will be sufficient to repay, within the required periods, all costs assigned to the commercial power function. Project repayment is measured over the long term to ensure repayment is met and to maintain rate stability. The PRR is an estimate of revenues and expenses including investment and repayment projections from the PRS. Any variance from estimate to actual will increase or decrease annual project repayment. Generally, the PRR includes Operation and Maintenance (O&M) expenses, purchased power for Project Use and FP customers' loads, interest, and other expenses (including any other statutorily required costs or charges), investment repayment, and the Washoe Project transfer. Revenues from Project Use, transmission, ancillary services, and other services offset expenses in the PRR; and the remainder is collected

from BR and FP customers. The PRR is reviewed during March of each year; and if such review results in a change of \$5 million or more to the annual PRR, collections are adjusted over the remaining 6-month period.

For WAPA–SN to meet the load requirements beyond delivered BR for Full Load Service (FLS) customers and Variable Resource (VR) customers, WAPA–SN may make Supplemental Power (SP) purchases pursuant to the Custom Product Power (CPP) rate schedule. FLS and VR customers who contract with WAPA–SN for such service will pay all SP costs. FLS customers pay a portfolio management charge according to their contract, whereas VR customers pay a scheduling charge per the rate schedule.

Transmission and Ancillary Services Revenue Requirements and Formula Rates

At least annually, WAPA–SN will apply the formula rates to calculate and then post the CVP transmission rates for point-to-point and Network Integration Transmission Service (NITS), the California Oregon Transmission Project (COTP) transmission rates, and CVP regulation and frequency response service rates. WAPA–SN prepares a detailed cost-of-service study to determine the costs, by project, that support the transfer capability of each transmission system and the cost that supports the generation capability of the CVP system. Generally, the costs allocated through the cost-of-service study for the transmission systems include O&M, interest, and depreciation expenses. WAPA–SN's costs for scheduling, system control and dispatch service associated with CVP and COTP transmission service are included and recovered through the respective transmission system's revenue requirement. Third-party transmission service costs are passed through directly to each requesting customer.

The unreserved use penalties continue to be assessed at 200percent of the effective point-to-point transmission rate when transmission service is used and not reserved, or when used in excess of the reservation. The required spinning and supplemental reserves charges are based on a price consistent with the California Independent System Operator's (CAISO) market price plus all costs incurred for the sale of these reserves. Customers who have a contractual obligation to provide spinning and supplemental reserves and do not fulfill their obligation will be assessed a penalty equal to the greater of WAPA–SN's actual cost or 150percent of the market price.

For Energy Imbalance (EI) service, when the EIM is suspended, customers outside of their contractual bandwidth (under delivery) will pay the greater of 150percent of the market price or WAPA–SN's actual cost. Given WAPA–SN's EI customers are and will continue to operate under existing agreements, WAPA–SN will continue its existing rate methodology for EI. The GI rate uses the same tiered methodology as WAPA–SN's EI service rate.

Sale of Surplus Products Formula Rates

The provisional rates are for the sale of surplus energy and/or capacity products. This includes Energy, Frequency Response Reserve, Regulation, Reserves, and Resource Sufficiency. If CVP surplus products are available, WAPA–SN will make the product(s) available for sale, provided entities enter into separate agreement(s) which would specify the terms of sale(s).

EIM Service Formula Rates

WAPA–SN will continue participation in the EIM as a Transmission Service Provider and Participating Resource Scheduling Coordinator within the Balancing Authority of Northern California (BANC) Balancing Authority Area (BAA). WAPA–SN is continuing formula rate schedules for: (1) EIM Administrative Service, (2) EIM EI Service, and (3) EIM GI Service. In EIM, CAISO economically dispatches energy under its EIM Tariff to meet the imbalances for loads and resources over multiple BAAs. CAISO provides a centralized, automated, and region-wide dispatch for imbalances. The EIM Administrative Services formula rate continues to allow WAPA–SN to pass through administrative costs incurred by WAPA–SN resulting from its participation in EIM as a Participating Resource Scheduling Coordinator. The formula rates and cost allocation for Administrative, EI, and GI services will be in effect when WAPA–SN is participating in the EIM, and to the extent WAPA–SN incurs associated settlements during market suspension or contingency.

Comments

WAPA–SN received three separate oral comments during the public consultation and comment period. The comments expressed have been paraphrased and/or combined, where appropriate, without compromising the meaning of the comments.

Comment: Commenter questioned the reasoning behind changing the COTP rate period from three seasonal rates to

one annual rate. Commenter inquired if there was variation between seasons.

Response: The reasoning for the seasonal change to one annual period is that there is very little change between the seasonal rates.

Comment: Commenter questioned whether there has been any recent change to the percentage losses that are charged on the COTP?

Response: While transmission loss factors are outside the scope of the rate process, there have been no recent changes to the percentage loss factors.

Comment: Commentor stated that WAPA-SN has an agreement with Pacific Gas and Electric (PG&E) for distribution through their transmission lines through 2024. They asked if there is any reason to expect issues with the renewal, and to elaborate on the implications for WAPA-SN customers if this contract with PG&E is not renewed.

Response: While transmission distribution agreements are outside the scope of the rate process, WAPA-SN does have an existing agreement with PG&E through 2024 and is in negotiations for an extension or a renegotiation of those arrangements.

Certification of Rates

I have certified that the Provisional Formula Rates for Central Valley Project power, transmission, and ancillary services; and California-Oregon Transmission Project transmission service under Rate Schedules CV-F14, CPP-3, CV-T4, CV-NWT6, COTP-T4, CV-TPT8, CV-UUP2, CV-SPR5, CV-SUR5, CV-RFS5, CV-EID6, CV-GID3, CV-SSP3, CV-EIM1S1, CV-EIM4S1, and CV-EIM9S1, are the lowest possible rates, consistent with sound business principles. The Provisional Formula Rates were developed following administrative policies and applicable laws.

Availability of Information

Information used by WAPA-SN to develop the Provisional Formula Rates is available for inspection and copying at the WAPA-SN Regional Office, 114 Parkshore Drive, Folsom, California. Many of these documents are also available on WAPA-SN's website at www.wapa.gov/about-wapa/regions/sn/sn-rates.

Ratemaking Procedure Requirements Environmental Compliance

WAPA-SN has determined that this action fits within the following categorical exclusion listed in appendix B to subpart D of 10 CFR part 1021.410:

B4.3 (Electric power marketing rate changes). Categorically excluded projects and activities do not require preparation of either an environmental impact statement or an environmental assessment.³ A copy of the categorical exclusion determination is available on WAPA's website at: www.wapa.gov/about-wapa/regions/sn/environment.

Determination Under Executive Order 12866

WAPA-SN has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

Submission to the Federal Energy Regulatory Commission

The Provisional Formula Rates herein confirmed, approved, and placed into effect on an interim basis, together with supporting documents, will be submitted to FERC for confirmation and final approval.

Order

In view of the above and under the authority delegated to me, I hereby confirm, approve, and place into effect, on an interim basis, Rate Order No. WAPA-207. The rates will remain in effect on an interim basis until: (1) FERC confirms and approves them on a final basis; (2) subsequent rates are confirmed and approved; or (3) such rates are superseded.

Signing Authority

This document of the Department of Energy was signed on July 15, 2024, by Tracey A. LeBeau, Administrator, Western Area Power Administration, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on July 17, 2024.

Treena V. Garrett,

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

Rate Schedule CV-F14

(Supersedes Schedule CV-F13)

UNITED STATES DEPARTMENT OF ENERGY

Western Area Power Administration

Central Valley Project

Base Resource and First Preference Power

(Approved Under Rate Order No. WAPA-207)

Effective

October 1, 2024, through September 30, 2029, or until superseded, whichever occurs earlier.

Available

In the area served by the Western Area Power Administration (WAPA), Sierra Nevada Region (SN).

Applicable

To the Base Resource (BR) and First Preference (FP) Power Customers.

Character and Conditions of Service

Alternating current, 60-hertz, three-phase, delivered and metered at the voltages and points established by contract. This service includes the Central Valley Project (CVP) transmission (to include reactive supply and voltage control from Federal generation sources needed to support the transmission service), spinning reserve service, and supplemental reserve service.

Formula Rate

The formula rate includes three components.

Component 1

Power Revenue Requirement (PRR):

WAPA-SN will develop the PRR before the start of each fiscal year (FY). The PRR will be divided into two 6-month periods, October through March, and April through September, based on FP and BR percentages. The PRR will be reviewed in March of each year. If there is a change of \$5 million or more, the PRR will be recalculated for the entire FY. The PRR is allocated to FP Customers and BR Customers based on formula rates, as adjusted for Hourly Exchange (HE), FP true-up calculation and midyear adjustments.

FP Power Formula Rate:

The annual FP customer allocation is equal to the annual PRR multiplied by the relevant FP percentage.

³ The determination was done in compliance with NEPA (42 U.S.C. 4321-4347); the Council on

Environmental Quality Regulations for implementing NEPA (40 CFR parts 1500-1508); and

DOE NEPA Implementing Procedures and Guidelines (10 CFR part 1021).

$$\text{FP Revenue Requirement} = \text{PRR} \times \text{FP Customer Percentage (FP \%)}$$

$$\text{FP \%} = \frac{\text{FP Customer Load}}{\text{Gen} + \text{Power Purchases} - \text{Project Use}}$$

Where:

FP Customer Load = FP Customer's
forecasted annual load (MWh)

Gen = Forecasted annual CVP and Washoe
generation (MWh)

Power Purchases = Power purchases for
Project Use and FP loads (MWh)

Project Use = Forecasted annual Project Use
loads (MWh)

WAPA–SN will develop each FP customer's percentage before the start of each FY, and review in March every year. If there is a change of more than one-half of 1 percent, the percentage will be revised for the full FY and billing will be adjusted over the remaining 6 months.

In addition, WAPA–SN will perform a true-up each year to ensure FP Customers pay their proportionate share of the PRR. The FP customers' percentage is limited to a percentage of the PRR. The table below shows the maximum percentages for each FP customer that will be applied to the PRR. FP percentages cannot exceed the maximum except in instances where a FP customers' percentage increases due to load growth. If maximum percentages are exceeded for more than one year, WAPA–SN will reevaluate and update customer maximum percentages.

FP MAXIMUM PERCENTAGES

FP customer	Maximum FP customer percentage applied to the PRR
Sierra Conservation Center .. Calaveras Public Power Agency	1.58 3.81 12.01
Trinity Public Utilities District Tuolumne Public Power Agency	3.16 0.96
Chicken Ranch Rancheria	
Total	21.52

BR Formula Rate:

The annual BR customer allocation is equal to the annual PRR multiplied by the relevant BR percentage.

BR Customer Allocation = (PRR × BR%)

Where:

BR% = BR percentage for each customer as indicated in the BR contract after

adjustments for programs, such as HE, if applicable

After the FP Customers' share of the annual PRR has been determined, including a prior period true-up from the FP formula rate, the remainder of the annual PRR is recovered from the BR Customers. The BR Revenue Requirement will be collected in two 6-month periods: 25% for October through March and 75% for April through September.

Component 2

Any charges or credits associated with the creation, termination, or modification to any tariff, contract, or rate schedule accepted or approved by FERC or other regulatory body will be passed on to each relevant customer. The charges or credits apply to the service to which this rate methodology applies. When possible, WAPA–SN will pass through charges or credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Component 3

Any charges or credits from the Host Balancing Authority for providing this service will be passed on to each relevant customer. When possible, WAPA–SN will pass through charges and credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Billing

Billing for BR and FP power will occur monthly using the respective formula rate. Any adjustment made at midyear applies to the entire FY and is billed over the remainder of the FY.

Adjustment for Losses

Losses will be accounted for under this rate schedule as stated in the service agreement.

Audit Adjustments

Financial audit adjustments that apply to the formula rate under this rate

schedule will be evaluated on a case-by-case basis to determine the appropriate treatment for repayment and cash flow management.

Rate Schedule CPP–3

(Supersedes Schedule CPP–2)

UNITED STATES DEPARTMENT OF ENERGY

Western Area Power Administration

Central Valley Project

Custom Product Power

Effective

October 1, 2024, through September 30, 2029, or until superseded, whichever occurs earlier.

Available

In the area served by the Western Area Power Administration (WAPA), Sierra Nevada Region (SN).

Applicable

To Sierra Nevada Region (SN) customers that contract for Custom Product Power (CPP). CPP means capacity and energy, provided by WAPA–SN, in addition to a customer's Base Resource, to meet its load.

To WAPA–SN Variable Resources (VR) Customers requesting scheduling for this service. A scheduling charge is applicable to VR customers requesting WAPA–SN to schedule CPP purchases.

Character and Conditions of Service

Alternating current, 60-hertz, three-phase, delivered and metered at the voltages and points established by contract, in accordance with approved policies and procedures.

Formula Rate

The formula rate includes three components.

Component 1

All charges and credits incurred in providing CPP will be passed through to the customer. WAPA–SN will assess a VR scheduling charge per schedule per day to cover the administrative costs for procuring and scheduling CPP.

Daily Charge Per Schedule = $\frac{\text{Fully Burdened Hourly Rate} \times \text{Minutes Per Schedule}}{60 \text{ Minutes}}$

If the actual number of schedules for the month is not available, WAPA–SN will estimate the number of schedules for the month and apply the VR scheduling charge to the estimated number of schedules.

Component 2

Any charges or credits associated with the creation, termination, or modification to any tariff, contract, or rate schedule accepted or approved by FERC or other regulatory body will be passed on to each relevant customer. The charges or credits apply to the service to which this rate methodology applies. When possible, WAPA–SN will pass through charges or credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Component 3

Any charges or credits from the Host Balancing Authority for providing this service will be passed on to each relevant customer. When possible, WAPA–SN will pass through charges and credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Billing

Billing for CPP and VR scheduling charge occurs monthly.

Adjustments for Losses

All losses incurred for the delivery of CPP under this rate schedule shall be the responsibility of the customer that has contracted for this service.

Audit Adjustments

Financial audit adjustments that apply to the formula rate under this rate schedule will be evaluated on a case-by-case basis to determine the appropriate treatment for repayment and cash flow management.

Rate Schedule CV–T4

(Supersedes Schedules CV–T3)

UNITED STATES DEPARTMENT OF ENERGY

Western Area Power Administration

Central Valley Project

Point-To-Point Transmission Service

Effective

October 1, 2024, through September 30, 2029, or until superseded, whichever occurs earlier.

Available

In the area served by the Western Area Power Administration (WAPA), Sierra Nevada Region (SN).

Applicable

To customers receiving Central Valley Project (CVP) firm and/or non-firm Point-to-Point (PTP) transmission service.

Character and Conditions of Service

Transmission service for three-phase, alternating current at 60 hertz, delivered and metered at the voltages and points of delivery or receipt, adjusted for losses, and delivered to points of delivery. This service includes scheduling and system control and dispatch service needed to support the transmission service.

Formula Rate

The formula rate for CVP firm and non-firm PTP transmission includes three components.

Component 1

CVP Transmission Revenue Requirement (TRR) = Contracted PTP Transmission Capacity (PTPc) + Network Integration Transmission Service Capacity (NITSc)

Where:

CVP TRR = the cost associated with facilities that support the transfer capability of the CVP transmission system, excluding generation facilities and radial lines

PTPc = the total PTP transmission capacity (kW) under long-term contract between WAPA–SN and other parties

NITSc = the 12-month average coincident peaks (kW) of Network Integrated Transmission Service (NITS) customers at the time of the monthly CVP transmission system peak (kW)

WAPA–SN may revise the rate from Component 1 based on either of the following conditions: (1) updated financial data available in March of each year; or (2) a change in the numerator or denominator that results in a rate change of at least \$0.05 per kilowatt

month (kW month). Rate change notifications will be posted on WAPA–SN's Open Access Same-Time Information System (OASIS) website.

Component 2

Any charges or credits associated with the creation, termination, or modification to any tariff, contract, or rate schedule accepted or approved by FERC or other regulatory body will be passed on to each relevant customer. The charges or credits apply to the service to which this rate methodology applies. When possible, WAPA–SN will pass through charges or credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Component 3

Any charges or credits from the Host Balancing Authority for providing this service will be passed on to each relevant customer. When possible, WAPA–SN will pass through charges and credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Billing

The formula rate above applies to the maximum amount of capacity reserved for periods ranging from 1 hour to 1 month, payable whether used or not. Billing will occur monthly.

Adjustment for Losses

Losses incurred for service under this rate schedule will be accounted for as agreed to by the parties in accordance with the service agreements.

Audit Adjustments

Financial audit adjustments that apply to the formula rate under this rate schedule will be evaluated on a case-by-case basis to determine the appropriate treatment for repayment and cash flow management.

Rate Schedule CV–NWT6

(Supersedes Schedule CV–NWT5)

UNITED STATES DEPARTMENT OF ENERGY

Western Area Power Administration
Central Valley Project

Network Integration Transmission Service

Effective

October 1, 2024, through September 30, 2029, or until superseded, whichever occurs earlier.

Available

In the area served by the Western Area Power Administration (WAPA), Sierra Nevada Region (SN).

Applicable

To customers receiving Central Valley Project (CVP) Network Integration Transmission Service (NITS).

Character and Conditions of Service

Transmission service for three-phase, alternating current at 60 hertz, delivered and metered at the voltages and points of delivery or receipt, adjusted for losses, and delivered to points of

delivery. This service includes scheduling and system control and dispatch service needed to support the transmission service.

Formula Rate

The formula rate for CVP NITS includes three components:

Component 1

The NITS revenue requirement equals the CVP Transmission Revenue Requirement (TRR) less the CVP firm point-to-point revenue. Each NITS customer's allocation is based on the following formula:

NITS Monthly Charge

=

NITS Customer's

x

Annual NITS TRR

12

Load-Ratio Share

Where:

NITS customer's load ratio share = The NITS customer's load, hourly, or in accordance with approved policies or procedures, (including behind the meter generation minus the NITS customer's adjusted Base Resource) coincident with the monthly CVP transmission system peak, averaged over a 12-month rolling period, expressed as a ratio.

Annual Network TRR = The total CVP TRR less revenue from long-term contracts for the CVP transmission between WAPA-SN and other parties.

The Annual Network TRR will be revised when the formula rate from Component 1 of the CVP transmission rate under Rates Schedule CV-T4 is revised.

Component 2

Any charges or credits associated with the creation, termination, or modification to any tariff, contract, or rate schedule accepted or approved by FERC or other regulatory body will be passed on to each relevant customer. The charges or credits apply to the service to which this rate methodology applies. When possible, WAPA-SN will pass through charges or credits directly to the customer in the same manner WAPA-SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Component 3

Any charges or credits from the Host Balancing Authority for providing this service will be passed on to each

relevant customer. When possible, WAPA-SN will pass through charges and credits directly to the customer in the same manner WAPA-SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Billing

NITS will be billed monthly under the formula rate.

Adjustment for Losses

Losses incurred for service under this rate schedule will be accounted for as agreed to by the parties in accordance with the service agreement.

Audit Adjustments

Financial audit adjustments that apply to the formula rate under this rate schedule will be evaluated on a case-by-case basis to determine the appropriate treatment for repayment and cash flow management.

Rate Schedule COTP-T4
(Supersedes Schedule COTP-T3)

UNITED STATES DEPARTMENT OF ENERGY

Western Area Power Administration
California-Oregon Transmission Project
Point-To-Point Transmission Service

Effective

October 1, 2024, through September 30, 2029, or until superseded, whichever occurs earlier.

Available

In the area served by the Western Area Power Administration (WAPA), Sierra Nevada Region (SN).

Applicable

To customers receiving California-Oregon Transmission Project (COTP) firm and/or non-firm point-to-point (PTP) transmission service.

Character and Conditions of Service

Transmission service for three-phase, alternating current at 60 hertz, delivered and metered at the voltages and points of delivery or receipt, adjusted for losses, and delivered to points of delivery. This service includes scheduling and system control and dispatch service needed to support the transmission service.

Formula Rate

The formula rate for COTP firm and non-firm PTP transmission service includes three components.

Component 1

COTP Transmission Revenue Requirement
WAPA-SN's COTP Capacity

Where:

COTP Transmission Revenue Requirement

(TRR) = WAPA-SN's costs associated

with facilities that support the transfer capability of the COTP.

WAPA–SN's COTP Capacity = WAPA–SN's share of COTP transmission capacity, subject to curtailment under the current California-Oregon Intertie (COI) transfer capability.

WAPA–SN will update the rate from Component 1 at least 15 days before the start of the rate period. Rate change notifications will be posted on WAPA–SN's Open Access Same-Time Information System (OASIS) website.

Component 2

Any charges or credits associated with the creation, termination, or modification to any tariff, contract, or rate schedule accepted or approved by FERC or other regulatory body will be passed on to each relevant customer. The charges or credits apply to the service to which this rate methodology applies. When possible, WAPA–SN will pass through charges or credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Component 3

Any charges or credits from the Host Balancing Authority for providing this service will be passed on to each relevant customer. When possible, WAPA–SN will pass through charges and credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Billing

The formula rate above applies to the maximum amount of capacity reserved for periods ranging from 1 hour to 1 month, payable whether used or not. Billing will occur monthly.

Adjustment for Losses

Losses incurred for service under this rate schedule will be accounted for as agreed to by the parties in accordance with the service agreement.

Audit Adjustments

Financial audit adjustments that apply to the formula rate under this rate schedule will be evaluated on a case-by-case basis to determine the appropriate treatment for repayment and cash flow management.

Rate Schedule CV–TPT8

(Supersedes Schedule CV–TPT7)

UNITED STATES DEPARTMENT OF ENERGY

Western Area Power Administration Central Valley Project

Transmission of WAPA–SN Power By Others

Effective

October 1, 2024, through September 30, 2029, or until superseded, whichever occurs earlier.

Available

In the area served by the Western Area Power Administration (WAPA), Sierra Nevada Region (SN).

Applicable

To WAPA–SN's power service customers who require transmission service by a third-party to receive power sold by WAPA–SN.

Character and Conditions of Service

Transmission service for three-phase, alternating current at 60 hertz, delivered and metered at the voltages and points of delivery or receipt, adjusted for losses, and delivered to points as agreed to by the parties.

Formula Rate

The formula rate for transmission of WAPA–SN's power by others includes three components.

Component 1

When WAPA–SN uses transmission facilities other than its own in supplying WAPA–SN power and costs are incurred by WAPA–SN for the use of such facilities, the customer will pay all costs, including transmission losses, incurred in the delivery of such power.

Component 2

Any charges or credits associated with the creation, termination, or modification to any tariff, contract, or rate schedule accepted or approved by FERC or other regulatory body will be passed on to each relevant customer. The charges or credits apply to the service to which this rate methodology applies. When possible, WAPA–SN will pass through charges or credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Component 3

Any charges or credits from the Host Balancing Authority for providing this service will be passed on to each relevant customer. When possible, WAPA–SN will pass through charges

and credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Billing

Third-party transmission will be billed monthly under the formula rate.

Adjustments for Losses

All losses incurred for delivery of power under this rate schedule will be the responsibility of the customer that received the power.

Audit Adjustments

Financial audit adjustments that apply to the formula rate under this rate schedule will be evaluated on a case-by-case basis to determine the appropriate treatment for repayment and cash flow management.

Rate Schedule CV–UUP2

(Supersedes Rate Schedule CV–UUP1)

UNITED STATES DEPARTMENT OF ENERGY

Western Area Power Administration Central Valley Project

Unreserved Use Penalties

Effective

October 1, 2024, through September 30, 2029, or until superseded, whichever occurs earlier.

Available

In the area served by the Western Area Power Administration (WAPA), Sierra Nevada Region (SN).

Applicable

To unreserved use of transmission service for the Central Valley Project, California-Oregon Transmission Project, and Pacific Alternating Current Intertie. This penalty is applicable to point-to-point (PTP) transmission customers using transmission not reserved or more than reserved, or network customers when they schedule delivery of off-system non-designated purchases using transmission capacity reserved for designated network resources.

Character and Conditions of Service

Transmission service for three-phase, alternating current at 60 hertz, delivered and metered at the voltages and points of delivery or receipt, adjusted for losses, and delivered to points of delivery. This service includes scheduling and system control and dispatch service needed to support the transmission service.

Penalty Rate

The formula rate for Unreserved Use Penalty (UUP) has three components.

Component 1

A transmission customer that has not reserved capacity or exceeds its firm or non-firm reserved capacity at any point of receipt or any point of delivery will be assessed UUP.

The penalty charge for a transmission customer who engages in unreserved use is 200 percent of WAPA–SN's approved transmission service rate for PTP transmission service assessed as follows: (1) the UUP for a single hour of unreserved use will be based upon the rate for daily firm PTP service; (2) the UUP for more than one assessment for a given duration (e.g., daily) will increase to the next longest duration (e.g., weekly); and (3) the UUP for multiple instances of unreserved use (e.g., more than 1 hour) within a day will be based on the rate for daily firm PTP service. The penalty charge for multiple instances of unreserved use isolated to one-calendar week would result in a penalty based on the charge for weekly firm PTP service. The penalty charge for multiple instances of unreserved use during more than one week within a calendar month is based on the charge for monthly firm PTP service.

The UUP will not apply to transmission customers utilizing PTP transmission service under WAPA's Open Access Transmission Tariff (OATT) because of action taken to support reliability. Such actions include reserve activations or uncontrolled event response as directed by the responsible reliability authority such as Sub-Balancing Authority, Host Balancing Authority (HBA), Reliability Coordinator, or Transmission Operator.

A transmission customer that exceeds its firm or non-firm reserved capacity is required to pay for all ancillary services identified in WAPA's OATT associated

with the unreserved use of transmission service. The transmission customer or eligible customer will pay for ancillary services, in accordance with existing rate schedules, based on the amount of transmission service it used but did not reserve.

The UUP collected over and above the base PTP rate will be distributed to customers as a credit on future transmission revenue requirements.

Component 2

Any charges or credits associated with the creation, termination, or modification to any tariff, contract, or rate schedule accepted or approved by FERC or other regulatory body will be passed on to each relevant customer. The charges or credits apply to the service to which this rate methodology applies. When possible, WAPA–SN will pass through charges or credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Component 3

Any charges or credits from the HBA for providing this service will be passed on to each relevant customer. When possible, WAPA–SN will pass through charges and credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Billing

The UUP will be billed monthly under the formula rate.

Adjustment for Losses

Losses incurred for delivery of power under this rate schedule shall be the responsibility of the customer that received the power.

Audit Adjustments

Financial audit adjustments that apply to the formula rate will be evaluated on a case-by-case basis to determine the appropriate treatment for repayment and cash flow management. Rate Schedule CV–RFS5 (Supersedes Schedule CV–RFS4)

UNITED STATES DEPARTMENT OF ENERGY**Western Area Power Administration
Central Valley Project****Regulation and Frequency Response Service****Effective**

October 1, 2024, through September 30, 2029, or until superseded, whichever occurs earlier.

Available

In the area served by the Western Area Power Administration (WAPA), Sierra Nevada Region (SN).

Applicable

To customers receiving Regulation and Frequency Response Service (Regulation).

Character and Conditions of Service

Regulation is necessary to provide for the continuous balancing of resources and interchange with load and for maintaining scheduled interconnection frequency at 60 cycles per second. Regulation is accomplished by committing on-line generation whose output is raised or lowered, predominantly using automatic generating control equipment, as necessary, to follow the moment-by-moment changes in load.

Formula Rate

The formula rate for regulation includes three components:

Component 1

$$\text{Regulation Rate} = \frac{\text{Annual Regulation Revenue Requirement}}{\text{Annual Regulating Capacity (kW)}}$$

Where:

The annual regulation revenue requirement includes: (1) the Central Valley Project generation costs associated with providing regulation, and (2) the non-facility costs allocated to regulation; and is calculated by dividing the Generation Revenue Requirement by the prior year plant capacity usage times the Regulation capacity.

The annual regulating capacity is one-half of the total regulating capacity bandwidths

provided by WAPA–SN under the Interconnected Operations Agreements with Sub-Balancing Authority (SBA) members.

The penalty for non-performance by an SBA customer who has committed to self-provision for their regulating capacity requirement will be the greater of 150 percent of WAPA–SN's actual costs or 150 percent of the market price.

WAPA–SN will revise the formula rate resulting from Component 1 based on either of the following two

conditions: (1) updated financial data available in March of each year; or (2) a change in the numerator or denominator that results in a rate change of at least \$0.25 per kW month.

Component 2

Any charges or credits associated with the creation, termination, or modification to any tariff, contract, or rate schedule accepted or approved by

FERC or other regulatory body will be passed on to each relevant customer. The charges or credits apply to the service to which this rate methodology applies. When possible, WAPA–SN will pass through charges or credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Component 3

Any charges or credits from the Host Balancing Authority for providing this service will be passed on to each relevant customer. When possible, WAPA–SN will pass through charges and credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Billing

The formula rate above will be applied to the regulating capacity bandwidth contained in the service agreement. Billing will occur monthly.

Audit Adjustments

Financial audit adjustments that apply to the formula rate under this rate schedule will be evaluated on a case-by-case basis to determine the appropriate treatment for repayment and cash flow management.

Rate Schedule CV–SPR5
(Supersedes Schedule CV–SPR4)

UNITED STATES DEPARTMENT OF ENERGY

Western Area Power Administration Central Valley Project

Operating Reserve–Spinning Reserve Service

Effective

October 1, 2024, through September 30, 2029, or until superseded, whichever occurs earlier.

Available

In the area served by the Western Area Power Administration (WAPA), Sierra Nevada Region (SN).

Applicable

To customers receiving spinning reserve service.

Character and Conditions of Service

Spinning Reserve Service supplies capacity that is available immediately to serve load and is synchronized with the power system.

Formula Rate

The formula rate for spinning reserve includes three components:

Component 1

The formula rate for spinning reserve service is the price consistent with the California Independent System Operator's (CAISO) market plus all costs incurred from the sale of spinning reserves, such as WAPA–SN's scheduling costs.

For customers that have a contractual obligation to provide spinning reserve to WAPA–SN and do not fulfill that obligation, the penalty for non-performance is the greater of 150 percent of WAPA–SN's actual cost or 150 percent of the market price.

Component 2

Any charges or credits associated with the creation, termination, or modification to any tariff, contract, or rate schedule accepted or approved by FERC or other regulatory body will be passed on to each relevant customer. The charges or credits apply to the service to which this rate methodology applies. When possible, WAPA–SN will pass through charges or credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula.

Component 3

Any charges or credits from the Host Balancing Authority for providing this service will be passed on to each relevant customer. When possible, WAPA–SN will pass through charges and credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Billing

The formula rate above will be applied to the amount of spinning reserve sold. Billing will occur monthly.

Audit Adjustments

Financial audit adjustments that apply to the formula rate under this rate schedule will be evaluated on a case-by-case basis to determine the appropriate treatment for repayment and cash flow management.

Rate Schedule CV–SUR5
(Supersedes Schedule CV–SUR4)

UNITED STATES DEPARTMENT OF ENERGY

Western Area Power Administration Central Valley Project

Operating Reserve–Supplemental Reserve Service

Effective

October 1, 2024, through September 30, 2029, or until superseded, whichever occurs earlier.

Available

In the area served by the Western Area Power Administration (WAPA), Sierra Nevada Region (SN).

Applicable

To customers receiving supplemental reserve service.

Character and Conditions of Service

Supplemental reserve service supplies capacity that is available within the first 10 minutes to take load and is synchronized with the power system.

Formula Rate

The formula rate for supplemental reserve service includes three components:

Component 1

The formula rate for supplemental reserve service is the price consistent with the California Independent System Operator's (CAISO) market plus all costs incurred as a result of the sale of supplemental reserves, such as WAPA–SN's scheduling costs.

For customers that have a contractual obligation to provide supplemental reserve service to WAPA–SN and do not fulfill that obligation, the penalty for non-performance is the greater of 150 percent of WAPA–SN's actual cost or 150 percent of the market price.

Component 2

Any charges or credits associated with the creation, termination, or modification to any tariff, contract, or rate schedule accepted or approved by FERC or other regulatory body will be passed on to each relevant customer. The charges or credits apply to the service to which this rate methodology applies. When possible, WAPA–SN will pass through charges or credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Component 3

Any charges or credits from the Host Balancing Authority for providing this

service will be passed on to each relevant customer. When possible, WAPA–SN will pass through charges and credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Billing

The formula rate above will be applied to the amount of supplemental reserve service sold. Billing will occur monthly.

Audit Adjustments

Financial audit adjustments that apply to the formula rate under this rate schedule will be evaluated on a case-by-case basis to determine the appropriate treatment for repayment and cash flow management.

Rate Schedule CV–EID6
(Supersedes Schedule CV–EID5)

UNITED STATES DEPARTMENT OF ENERGY

Western Area Power Administration

Central Valley Project

Energy Imbalance Service

Effective

October 1, 2024, through September 30, 2029, or until superseded, whichever occurs earlier.

Available

In the area served by the Western Area Power Administration (WAPA), Sierra Nevada Region (SN).

Applicable

To customers receiving Energy Imbalance (EI) Service.

Character and Conditions of Service

EI Service is provided when a difference occurs between the scheduled and the actual delivery of energy to a load within the Sub-Balancing Authority (SBA) over an hour or in accordance with approved policies and procedures. The deviation, in megawatts, is the net scheduled amount of energy minus the net metered (actual delivered) amount.

EI Service uses the deviation bandwidth that is established in the service agreement or Interconnected Operations Agreements.

Formula Rate

The formula rate for EI Service includes three components:

Component 1

EI Service charges are applied to deviations as follows unless otherwise

dictated by contract or policy: (1) deviations within the bandwidth will be tracked and settled financially, at the greater of the California Independent System Operator (CAISO) market price, or WAPA–SN's actual cost; (2) negative deviations (under-delivery), outside the deviation bandwidth, will be charged the greater of 150 percent of the CAISO market price or 150 percent of WAPA–SN's actual cost; and (3) positive deviations (over-delivery), outside the deviation bandwidth, will be lost to the system, except for any hour when WAPA–SN incurs a cost to dispose of the energy, in which event the responsible party will bear that cost.

Deviations that occur due to actions taken to support reliability will be resolved in accordance with existing contractual requirements. Such actions include reserve activations or uncontrolled event responses as directed by the responsible reliability authority such as SBA, Host Balancing Authority (HBA), Reliability Coordinator, or Transmission Operator.

Component 2

Any charges or credits associated with the creation, termination, or modification to any tariff, contract, or rate schedule accepted or approved by FERC or other regulatory body will be passed on to each relevant customer. The charges or credits apply to the service to which this rate methodology applies. When possible, WAPA–SN will pass through charges or credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Component 3

Any charges or credits from the HBA for providing this service will be passed on to each relevant customer. When possible, WAPA–SN will pass through charges and credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Billing

Billing for negative deviations outside the bandwidth, or as otherwise required, will occur monthly.

Audit Adjustments

Financial audit adjustments that apply to the formula rate under this rate schedule will be evaluated on a case-by-case basis to determine the appropriate treatment for repayment and cash flow management.

Rate Schedule CV–GID3
(Supersedes Schedule CV–GID2)

UNITED STATES DEPARTMENT OF ENERGY

Western Area Power Administration

Central Valley Project

Generator Imbalance Service

Effective

October 1, 2024, through September 30, 2029, or until superseded, whichever occurs earlier.

Available

In the area served by the Western Area Power Administration (WAPA), Sierra Nevada Region (SN).

Applicable

To generators receiving Generator Imbalance (GI) Service.

Character and Conditions of Service

GI Service is provided when a difference occurs between the scheduled and actual delivery of energy from an eligible generation resource within the Sub-Balancing Authority (SBA), over an hour, or in accordance with approved policies. The deviation in megawatts is the net scheduled amount of generation minus the net metered output from the generator's (actual generation) amount.

GI Service is subject to the deviation bandwidth established in the service agreement or Interconnected Operations Agreements.

Formula Rate

The formula rate for the GI Service has three components:

Component 1

GI Service is applied to deviations as follows unless otherwise dictated by contract or policy: (1) deviations within the bandwidth will be tracked and settled financially at the greater of the California Independent System Operator (CAISO) market price or WAPA–SN's actual cost; (2) negative deviations (under-delivery), outside the deviation bandwidth, will be charged the greater of 150 percent of the CAISO market price or 150 percent of WAPA–SN's actual cost; and (3) positive deviations (over-delivery), outside the deviation bandwidth, will be lost to the system, except for any hour when WAPA–SN incurs a cost to dispose of the energy, in which event the responsible party will bear that cost.

Deviations that occur due to actions taken to support reliability will be resolved in accordance with existing contractual requirements. Such actions include reserve activations or

uncontrolled event responses as directed by the responsible reliability authority such as SBA, Host Balancing Authority (HBA), Reliability Coordinator, or Transmission Operator.

To the extent that an entity incorporates intermittent resources, deviations will be charged as follows unless otherwise dictated by contract or policy: (1) deviations within the bandwidth will be tracked and settled financially at the greater of the CAISO market price or WAPA-SN's actual cost; (2) negative deviations (under-delivery), outside the deviation bandwidth, will be charged the greater of market price or actual cost (no penalty); and (3) positive deviations (over-delivery), outside the deviation bandwidth, will be lost to the system, except for any hour where WAPA-SN incurs a cost, then that cost will be borne by the responsible party.

Intermittent generators serving load outside of WAPA-SN's SBA will be required to dynamically schedule or dynamically meter their generation to another Balancing Authority. An intermittent resource, for the limited purpose of these rate schedules, is an electric generator that is not dispatchable and cannot store its output, and therefore, cannot respond to changes in demand or respond to transmission security constraints.

Component 2

Any charges or credits associated with the creation, termination, or modification to any tariff, contract, or rate schedule accepted or approved by FERC or other regulatory body will be passed on to each relevant customer. The charges or credits apply to the service to which this rate methodology applies. When possible, WAPA-SN will pass through charges or credits directly to the customer in the same manner WAPA-SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Component 3

Any charges or credits from the HBA for providing this service will be passed on to each relevant customer. When possible, WAPA-SN will pass through charges and credits directly to the customer in the same manner WAPA-SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Billing

Billing for negative deviations outside the bandwidth will occur monthly.

Audit Adjustments

Financial audit adjustments that apply to the formula rate under this rate schedule will be evaluated on a case-by-case basis to determine the appropriate treatment for repayment and cash flow management.

Rate Schedule CV-SSP3
(Supersedes Schedule CV-SSP2)

UNITED STATES DEPARTMENT OF ENERGY

Western Area Power Administration

Central Valley Project

Sale of Surplus Products

Effective

October 1, 2024, through September 30, 2029, or until superseded by another rate schedule, whichever occurs earlier.

Available

In the area served by the Western Area Power Administration (WAPA), Sierra Nevada Region (SN).

Applicable

To WAPA-SN customers participating in the Sale of Surplus Products.

Character and Conditions of Service

Sale of Surplus Products occurs when there is a sale of surplus energy and/or capacity products. This includes: (1) Energy, (2) Frequency Response Service, (3) Regulation, (4) Reserves, and (5) Resource Sufficiency. If any of the surplus products are available, WAPA-SN could make the product(s) available for sale, provided entities enter into separate agreement(s) which will specify the terms of sale(s).

Formula Rate

The formula rate for Sale of Surplus Products service includes three components:

Component 1

WAPA-SN will determine the charge for each product at the time of sale to be the greater of WAPA-SN's cost or market rates, to include transmission charges. WAPA-SN will use a separate agreement(s) to specify the terms of sale(s). The customer may be responsible for acquiring additional transmission service necessary to deliver the product(s), for which a separate charge may be incurred from the transmission provider.

Component 2

Any charges or credits associated with the creation, termination, or modification to any tariff, contract, or rate schedule accepted or approved by

FERC or other regulatory body will be passed on to each relevant customer. The charges or credits apply to the service to which this rate methodology applies. When possible, WAPA-SN will pass through charges or credits directly to the customer in the same manner WAPA-SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Component 3

Any charges or credits from the Host Balancing Authority for providing this service will be passed on to each relevant customer. When possible, WAPA-SN will pass through charges and credits directly to the customer in the same manner WAPA-SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Billing

The formula rate above will be applied to the Sale of Surplus product(s) sold. Billing will occur monthly.

Audit Adjustments

Financial audit adjustments that apply to the formula rate under this rate schedule will be evaluated on a case-by-case basis to determine the appropriate treatment for repayment and cash flow management.

Rate Schedule CV-EIM1S1
(Supersedes Rate Schedule CV-EIM1S)

UNITED STATES DEPARTMENT OF ENERGY

Western Area Power Administration

Central Valley Project

Energy Imbalance Market

Administrative Service

Effective

October 1, 2024, through September 30, 2029, or until superseded, whichever occurs earlier.

Available

In the area served by the Western Area Power Administration (WAPA), Sierra Nevada Region (SN).

Applicable

This rate applies to WAPA-SN customers when WAPA-SN, as the Transmission Provider, is participating in Energy Imbalance Market (EIM) and when the EIM has not been suspended. To the extent WAPA-SN incurs EIM Administrative Service-related costs from the EIM Entity during periods of market suspension or contingency, this schedule will also apply to ensure that

WAPA–SN, as Transmission Provider, remains revenue neutral for its participation in EIM.

Character and Conditions of Service

The EIM Administrative Service rate recovers the administrative costs for participating in the EIM by WAPA–SN as a Transmission Provider, including but not limited to such administrative charges as may be incurred by WAPA–SN from California Independent System Operator (CAISO) as the EIM Market Operator (MO) and/or Balancing Authority of Northern California (BANC) as the EIM Entity.

Unless such charges are allocated to the Transmission Customer directly by BANC, all Transmission Customers purchasing Long-Term Firm Point-to-Point Transmission Service, Short-Term Firm Point-to-Point Transmission Service, Non-Firm Point-to-Point Transmission Service, or Network Integration Transmission Service from WAPA–SN shall incur an EIM Administrative Service Charge from WAPA–SN.

CAISO's Administrative Service Charge, as defined in the MO Tariff, is included in this rate. This rate also includes administrative charges assessed to WAPA–SN by BANC based on net energy load within the WAPA–SN Sub-Balancing Authority Area.

Formula Rate

The formula rate for EIM Administrative Service includes three components:

Component 1

EIM Administrative Service costs shall be sub-allocated to WAPA–SN's transmission customers based on load ratio share for the time in which WAPA–SN incurs EIM administrative costs.

Component 2

Any charges or credits associated with the creation, termination, or modification to any tariff, contract, or rate schedule accepted or approved by FERC or other regulatory body will be passed on to each relevant customer. The charges or credits apply to the service to which this rate methodology applies. When possible, WAPA–SN will pass through charges or credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Component 3

Any charges or credits from the Host Balancing Authority for providing this

service will be passed on to each relevant customer. When possible, WAPA–SN will pass through charges and credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Billing

Billing will occur monthly.

Audit Adjustments

Financial audit adjustments that apply to the formula rate under this rate schedule will be evaluated on a case-by-case basis to determine the appropriate treatment for repayment and cash flow management.

Rate Schedule CV–EIM4S1
(Supersedes Rate Schedule CV–EIM4S)

UNITED STATES DEPARTMENT OF ENERGY

Western Area Power Administration

Central Valley Project

Energy Imbalance Market

Energy Imbalance Service

Effective

October 1, 2024, through September 30, 2029, or until superseded, whichever occurs earlier.

Available

In the area served by the Western Area Power Administration (WAPA), Sierra Nevada Region (SN).

Applicable

This rate applies to WAPA–SN customers receiving Energy Imbalance (EI) Service when WAPA–SN, as the Transmission Provider, is participating in Energy Imbalance Market (EIM) and when the EIM has not been suspended. To the extent WAPA–SN incurs EIM Administrative Service-related costs from the EIM Entity during periods of market suspension or contingency, this schedule will also apply to ensure that WAPA–SN, as Transmission Provider, remains revenue neutral for its participation in EIM.

Character and Conditions of Service

EI Service is provided when a difference occurs between the scheduled and the actual delivery of energy to a load located within the WAPA–SN Sub-Balancing Authority Area (Sub-BAA). WAPA–SN offers this service when transmission service is used to serve load within the WAPA–SN Sub-BAA.

Unless subsequently imposed by California Independent System Operator

(CAISO) as the Market Operator (MO) as part of the MO Tariff and promulgated by WAPA–SN through rate proceedings, there shall be no incremental transmission charge assessed for transmission use related to the EIM. Transmission customers must have transmission service rights, as set forth in Attachment S of WAPA's Tariff.

Formula Rate

The formula rate for EI Service includes three components:

Component 1

EI Service is the deviation of the transmission customer's metered load compared to the load component of the Transmission Customer Base Schedule settled as Uninstructed Imbalance Energy (UIE) for the period of the deviation at the applicable Load Aggregation Point (LAP) price where the load is located.

EI Service penalties are applied to deviations as follows unless otherwise dictated by contract or policy: (1) negative deviations (under-delivery), outside the deviation bandwidth, will be charged the greater of 50 percent of the CAISO market price or 50 percent of WAPA–SN's actual cost; and (2) positive deviations (over-delivery), outside the deviation bandwidth, will be lost to the system, except for any hour when WAPA–SN incurs a cost to dispose of the energy, in which event the responsible party will bear that cost.

Deviations that occur due to actions taken to support reliability will be resolved in accordance with existing contractual requirements. Such actions include reserve activations or uncontrolled event responses as directed by the responsible reliability authority such as SBA, Host Balancing Authority (HBA), Reliability Coordinator, or Transmission Operator.

Component 2

Any charges or credits associated with the creation, termination, or modification to any tariff, contract, or rate schedule accepted or approved by FERC or other regulatory body will be passed on to each relevant customer. The charges or credits apply to the service to which this rate methodology applies. When possible, WAPA–SN will pass through charges or credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Component 3

Any charges or credits from the HBA for providing this service will be passed

on to each relevant customer. When possible, WAPA–SN will pass through charges and credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Billing

Billing will occur monthly.

Audit Adjustments

Financial audit adjustments that apply to the formula rate under this rate schedule will be evaluated on a case-by-case basis to determine the appropriate treatment for repayment and cash flow management.

Rate Schedule CV–EIM9S1

(Supersedes Rate Schedule CV–EIM9S)

UNITED STATES DEPARTMENT OF ENERGY

Western Area Power Administration

Central Valley Project

Energy Imbalance Market

Generator Imbalance Service

Effective

October 1, 2024, through September 30, 2029, or until superseded, whichever occurs earlier.

Available

In the area served by the Western Area Power Administration (WAPA), Sierra Nevada Region (SN).

Applicable

This rate applies to WAPA–SN customers receiving Generator Imbalance (GI) Service when WAPA–SN, as the Transmission Provider, is participating in Energy Imbalance Market (EIM) and when the EIM has not been suspended. To the extent WAPA–SN incurs EIM Administrative Service-related costs from the EIM Entity during periods of market suspension or contingency, this schedule will also apply to ensure that WAPA–SN, as Transmission Provider, remains revenue neutral for its participation in EIM.

Character and Conditions of Service

GI Service is provided when a difference occurs between the output of EIM Non-Participating Resource located in the WAPA–SN Sub-Balancing Authority (Sub-BAA), as reflected in the resource component of the Transmission Customer Base Schedule, and the delivery schedule from that generator to (1) another BAA, (2) the Balancing Authority of Northern California (BANC) BAA, or (3) a load within the WAPA–SN Sub-BAA.

Unless subsequently imposed by California Independent System Operator (CAISO) as the Market Operator (MO) as part of the MO Tariff and promulgated by WAPA–SN through rate proceedings, there shall be no incremental transmission charge assessed for transmission use related to the EIM. Transmission customers must have transmission service rights, as set forth in Attachment S of WAPA's Tariff.

Formula Rate

The formula rate for GI Service includes three components:

Component 1

GI Service penalties are applied to deviations as follows unless otherwise dictated by contract or policy: (1) negative deviations (under-delivery), outside the deviation bandwidth, will be charged the greater of 50 percent of the CAISO market price or 50 percent of WAPA–SN's actual cost; and (2) positive deviations (over-delivery), outside the deviation bandwidth, will be lost to the system, except for any hour when WAPA–SN incurs a cost to dispose of the energy, in which event the responsible party will bear that cost.

Deviations that occur due to actions taken to support reliability will be resolved in accordance with existing contractual requirements. Such actions include reserve activations or uncontrolled event responses as directed by the responsible reliability authority such as SBA, Host Balancing Authority (HBA), Reliability Coordinator, or Transmission Operator.

To the extent that an entity incorporates intermittent resources, deviations will be charged as follows unless otherwise dictated by contract or policy: (1) negative deviations (under-delivery), outside the deviation bandwidth, will be charged the greater of market price or actual cost (no penalty); and (2) positive deviations (over-delivery), outside the deviation bandwidth, will be lost to the system, except for any hour where WAPA–SN incurs a cost, then that cost will be borne by the responsible party.

Intermittent generators serving load outside of WAPA–SN's SBA will be required to dynamically schedule or dynamically meter their generation to another Balancing Authority. An intermittent resource, for the limited purpose of these rate schedules, is an electric generator that is not dispatchable and cannot store its output, and therefore, cannot respond to changes in demand or respond to transmission security constraints.

Component 2

Any charges or credits associated with the creation, termination, or modification to any tariff, contract, or rate schedule accepted or approved by FERC or other regulatory body will be passed on to each relevant customer. The charges or credits apply to the service to which this rate methodology applies. When possible, WAPA–SN will pass through charges or credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Component 3

Any charges or credits from the HBA for providing this service will be passed on to each relevant customer. When possible, WAPA–SN will pass through charges and credits directly to the customer in the same manner WAPA–SN is charged or credited. When not possible, the charges or credits will be passed through using Component 1 of the formula rate.

Billing

Billing will occur monthly.

Audit Adjustments

Financial audit adjustments that apply to the formula rate under this rate schedule will be evaluated on a case-by-case basis to determine the appropriate treatment for repayment and cash flow management.

[FR Doc. 2024–16029 Filed 7–19–24; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–12076–01–OA]

Farm, Ranch, and Rural Communities Advisory Committee (FRRCC); Call for Nominations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice request for nominations.

SUMMARY: The Environmental Protection Agency (EPA) is inviting nominations for membership on the Farm, Ranch, and Rural Communities Advisory Committee (FRRCC). The purpose of the FRRCC is to provide policy advice, information, and recommendations to the EPA Administrator on a range of environmental issues and policies that are of importance to agriculture and rural communities.

DATES: To be considered for 2024 appointments, nominations should be

submitted no later than September 5, 2024.

ADDRESSES: Submit nominations electronically with the subject line “FRRCC Membership 2024” to FRRCC@epa.gov.

General information regarding the FRRCC can be found on the EPA website at: www.epa.gov/faca/frrcc. General information about federal advisory committees at EPA is available at www.epa.gov/faca.

FOR FURTHER INFORMATION CONTACT: Dr. Venus Welch-White, designated federal officer for the FRRCC, U.S. EPA, 1200 Pennsylvania Avenue NW, Mail Code 1101A, Washington, DC 20460; telephone number: 202-564-7719; email address: FRRCC@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

EPA established the FRRCC in 2008 pursuant to the Federal Advisory Committee Act, Public Law 92-463, in order to help EPA build a more positive and proactive relationship with the agricultural industry in furtherance of EPA’s mission to protect human health and the environment. The FRRCC serves as part of EPA’s efforts to expand cooperative working relationships with the agriculture community and others who are interested in agricultural issues and achieving greater progress in environmental protection. The FRRCC provides advice and recommendations to the EPA Administrator on environmental issues and programs that impact, or are of concern to, farms, ranches, and rural communities. Topics addressed may include climate change, water or air quality issues, pesticides, toxics, food loss and waste, environmental justice, emergency response, enforcement and compliance, technology and innovation, and other topics of environmental importance pertaining to agriculture and rural communities. The charter for the FRRCC was renewed in January 2024. EPA is currently seeking members for the committee, who will be appointed for two- or three-year terms and may be eligible for reappointment. The membership of this committee will include a balanced representation of interested persons with relevant experience to contribute to the functions of the committee, and will be drawn from relevant sectors, including but not limited to academia, agricultural industry, nongovernmental organizations, and state, local, and tribal governments.

The full committee expects to meet approximately twice a year, or as needed and approved by the designated

federal officer (DFO). Meetings will be hybrid, with the in person conducted in Washington, DC, and/or within the EPA regions. The Administrator may ask members to serve on subcommittees and workgroups to develop reports and recommendations to address specific policy issues, reflecting the priorities of the administration. The average workload for members is approximately five hours per month. Members serve on the committee in a voluntary capacity. Although we are unable to offer compensation or an honorarium, members may receive travel and per diem allowances, according to applicable Federal travel regulations and the agency’s budget.

II. Eligibility

Because of the nature of the issues to be discussed, it is the intent of the Agency for the majority of Committee members- to be actively engaged in farming or ranching. The membership of this committee will include a balanced representation of interested persons with relevant experience to contribute to the functions of the committee and will be drawn from a variety of relevant sectors. Members may represent farmers, ranchers, and rural communities (can include large, small, crop, livestock, commodity, and specialty producers from various regions)—and their allied industries (farm groups, rural suppliers, marketers, processors, etc.) as well as the academic/research community who research environmental issues impacting agriculture, tribal agriculture groups, state, local, and tribal government, and environmental/conservation and other nongovernmental organizations. Individuals are generally appointed to serve on the FRRCC as “Representative” members and are thus expected to represent the points of view of a particular group (e.g., an industry sector), rather than provide independent judgment and expertise. Other Federal agencies and other sectors as appropriate may be invited to attend or provide presentations at committee meetings as non-members.

In accordance with Executive Order 14035 (June 25, 2021) and consistent with law, EPA values and welcomes opportunities to increase diversity, equity, inclusion, and accessibility on its federal advisory committees. EPA’s federal advisory committees have a workforce that reflects the diversity of the American people.

In selecting committee members, EPA will consider each candidate’s qualifications including, but not limited to, on whether the candidate is:

- Is actively engaged in farming
- Occupies a senior position within their organization
- Holds leadership positions in ag-related organizations, businesses and/or workgroups
- Has broad agricultural experience regardless of their current position
- Has experience working on issues where building consensus is necessary
- Has membership in professional societies, broad-based networks or the equivalent
- Has extensive experience in the environmental field dealing with agricultural issues
- Provides services to producers
- Is involved in processing, retailing, manufacturing, and distribution of agricultural products
- Possesses a professional knowledge of agricultural issues and environmental policy
- Possesses a demonstrated ability to examine and analyze complicated environmental issues with objectivity and integrity
- Possesses excellent interpersonal as well as oral and written communication skills
- Possesses an ability and willingness to participate in a deliberative and collaborative process

In addition, well-qualified applicants must be prepared to process a substantial amount of complex and technical information and the ability to volunteer several hours per month to the committee’s activities, including participation in teleconference meetings and preparation of text for committee reports.

III. Nominations

Any interested person or organization may submit the names of qualified persons, including themselves. To be considered, all nominations should include the information requested below:

- Current contact information for the nominee, including the nominee’s name, organization (and position within that organization), business address, email address, and daytime telephone number(s).
- A brief statement describing the nominee’s interest and availability in serving on the FRRCC. Please also include the following information, as available: (1) The nominee’s ability to serve as a “Representative” member and represent the point of view of a group (e.g., an industry sector) rather than provide independent judgment and expertise; (2) if the nominee has any prior/current service on Federal

advisory committees, and the number of years.

- **Résumé or curriculum vitae** detailing the nominee's background, experience and qualifications and other relevant information.

Letters of support and recommendation will be accepted but are not mandatory. To help the agency evaluate the effectiveness of its outreach efforts, please indicate how you learned of this nomination opportunity.

Other sources, in addition to this **Federal Register** notice, may be utilized in the solicitation of nominees. EPA expressly values diversity, equity, and inclusion, and encourages the nominations of interested individuals from diverse backgrounds. Individuals may self-nominate.

Venus Welch-White,

Acting Deputy Director, Office of Agriculture and Rural Affairs.

[FR Doc. 2024-15982 Filed 7-19-24; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as

confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than August 6, 2024.

A. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198-0001. Comments can also be sent electronically to KCApplicationComments@kc.frb.org:

1. Andrew Hoffman Legacy Trust dated January 3, 2022, Peoples Bank and Trust Company as trustee, Wise & Reber L.C. as trust protector, Andrew Hoffman as voting beneficiary, all of McPherson, Kansas; Caleb Houghton Legacy Trust dated January 3, 2022, Peoples Bank and Trust Company as trustee, Wise & Reber L.C. as trust protector, Caleb Houghton as voting beneficiary, all of McPherson, Kansas; Hannah Nesbitt Legacy Trust dated January 3, 2022, Peoples Bank and Trust Company as trustee, Wise & Reber L.C. as trust protector, all of McPherson, Kansas, and Hannah Nesbitt, Andover, Kansas, as voting beneficiary; and Paige Moore Legacy Trust dated January 3, 2022, Peoples Bank and Trust Company as trustee, Wise & Reber L.C. as trust protector, all of McPherson, Kansas, and Paige Moore, Wichita, Kansas, as voting beneficiary; to join the Houghton Family Group, a group acting in concert, to retain the voting shares of PBT Bancshares Inc., McPherson, Kansas, and thereby indirectly retain voting shares of Peoples Bank and Trust Company.

Board of Governors of the Federal Reserve System.

Erin Cayce,

Assistant Secretary of the Board.

[FR Doc. 2024-16062 Filed 7-19-24; 8:45 am]

BILLING CODE P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090-0287; Docket No. 2024-0001; Sequence No. 11]

Information Collection; Background Investigations for Child Care Workers; GSA Form 176

AGENCY: Office of Mission Assurance, General Services Administration (GSA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, and the Office of Management and Budget (OMB) regulations, GSA invites the public to comment on a request to review and approve an extension of a previously approved information collection requirement regarding the collection of personal data for background investigations for childcare workers accessing GSA owned and leased controlled facilities.

DATES: Submit comments on or before: September 20, 2024.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link "Submit a Comment" that corresponds with "Information Collection 3090-0287, Background Investigations for Child Care Workers". Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 3090-0287, Background Investigations for Child Care Workers" on your attached document.

If your comment cannot be submitted using [regulations.gov](http://www.regulations.gov), call or email the points of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Please submit comments only and cite Information Collection 3090-0287, Background Investigations for Child Care Workers, in all correspondence related to this collection. Comments received generally will be posted without change to [regulations.gov](http://www.regulations.gov), including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check [regulations.gov](http://www.regulations.gov) approximately two-to-three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Mr. Phil Ahn, Security Officer, Office of Mission Assurance, GSA, 202-219-0273, or via email at phillip.ahn@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

Homeland Security Presidential Directive (HSPD) 12 "Policy for a Common Identification Standard for Federal Employees and Contractors" requires the implementation of a governmentwide standard for secure and reliable forms of identification for Federal employees and contractors.

OMB's implementing instructions requires all contract employees requiring routine access to federally controlled facilities for greater than six (6) months to receive a background investigation. The minimum background investigation is Tier 1 and the Office of Personnel Management offers a Tier 1C for child care.

However, there is no requirement in the law or HSPD-12 that requires childcare employees to be subject to the Tier 1C since employees of childcare providers are neither government employees nor government contractors. The childcare providers are required to complete the criminal history background checks mandated in the Crime Control Act of 1990, Public Law 101-647, dated November 29, 1990, as amended by Public Law 102-190, dated December 5, 1991. These statutes require that each employee of a childcare center located in a Federal building or in leased space must undergo a background check.

According to GSA policy, childcare workers (as described above) will need to submit the following:

1. An original signed copy of a *Basic National Agency Check Criminal History*, GSA Form 176; and
2. Two sets of fingerprints on FBI Fingerprint Cards, for SF-87 and/or electronic prints from an enrollment center.
3. Electronically submit the e-qip (SF85) application for completion of the Tier 1C.

This is not a request to collect new information; this is a request to change the form that is currently being used to collect this information.

B. Annual Reporting Burden

Respondents: 1,200.

Responses per Respondent: 1.

Hours per Response: 1.

Total Burden Hours: 1,200.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202-501-4755 or emailing GSARegSec@gsa.gov. Please cite

Background Investigations for Child Care Workers, in all correspondence.

Lois Mandell,

*Director, Regulatory Secretariat Division,
General Services Administration.*

[FR Doc. 2024-16031 Filed 7-19-24; 8:45 am]

BILLING CODE 6820-23-P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090-0319; Docket No. 2024-0001; Sequence No. 8]

Information Collection; CDP Supply Chain Climate Change Information Request

AGENCY: Office of Government-wide Policy (OGP), General Services Administration (GSA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, and the Office of Management and Budget (OMB), GSA will invite the public to comment on a renewal and extension concerning the CDP Supply Chain Climate Change Information Request.

DATES: GSA will consider all comments received by September 20, 2024.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching for "Information Collection 3090-0319; CDP Supply Chain Climate Change Information Request." Select the link "Comment Now" that corresponds with "Information Collection 3090-0319; CDP Supply Chain Climate Change Information Request." Follow the instructions provided on the screen. Please include your name, company name (if any), and "Information Collection 3090-0319; CDP Supply Chain Climate Change Information Request" on your attached document. If your comment cannot be submitted using [regulations.gov](http://www.regulations.gov), call or email the point of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Please submit comments only and cite "Information Collection 3090-0319; CDP Supply Chain Climate Change Information Request", in all correspondence related to this collection. Comments received generally will be posted without change to [regulations.gov](http://www.regulations.gov), including any personal and/or business confidential information provided. To confirm

receipt of your comment(s), please check [regulations.gov](http://www.regulations.gov), approximately two-to-three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Mr. Jed Ela, Sustainability Advisor, Office of Government-wide Policy, at jed.ela@gsa.gov, 202-854-8804.

SUPPLEMENTARY INFORMATION:

A. Purpose

The CDP Supply Chain Climate Change Information Request is an electronic questionnaire designed to collect information that is widely used by large private and public sector organizations to understand, assess, and mitigate potentially disruptive and costly supply chain risks, investment risks, and environmental impacts. The questionnaire is administered by CDP North America, Inc., a 501(c)(3) nonprofit organization ("CDP"). CDP administers the questionnaire annually on behalf of over 700 institutional investors, 300 major corporations, and several large governmental purchasing organizations in addition to GSA. CDP's most recent annual survey was directed to over 40,000 companies, with over 23,000 electing to respond.

Under previously approved information collection requests, GSA has directed CDP since 2017 to include several hundred major Federal contractors annually among its potential survey respondents. In accordance with 31 U.S.C. 3512(c)(1)(b), GSA uses information received from these companies via CDP to inform and develop purchasing policies and contract requirements necessary to safeguard Federal assets against waste, loss, and misappropriation resulting from unmitigated exposure to physical, market, regulatory, legal, and other types of risks in Federal supply chains. GSA also uses the information in accordance with Executive Orders 13990, 14008, 14030, and 14057 to inform development of policies and programs to reduce similar risks and environmental impacts associated with federal procurement activities.

For example, GSA has used CDP information in recent years to perform critical market research in connection with multi-billion-dollar strategic contracting efforts. In one case, GSA determined that data center facilities used by potential network infrastructure providers could be at risk due to flooding, extreme heat, or lack of available cooling water sources, placing Federal client operations at risk. In another case, GSA used information from the CDP survey to research potential contractors' existing risk

mitigation and greenhouse gas reduction practices and to design appropriate contract requirements to ensure that contractors assess and mitigate these risks and reduce greenhouse gases associated with their federal contract activities. In another case, GSA determined that energy savings practices available to potential information technology service providers could significantly lower their overhead costs and that this would likely reduce contract costs for GSA and other Federal agencies. GSA uses the information collected to research development of similar policies and programs and to verify contractor compliance with existing programs.

B. Annual Burden Hours

GSA expects to direct CDP to request voluntary survey responses from up to 1000 large and medium-sized businesses per year. Estimates of response time per respondent vary greatly depending on whether each requested respondent (a) elects not to respond; (b) responds, but would have responded to CDP regardless of GSA's request (because the respondent was also requested to respond to CDP by other customer and/or investor stakeholders); or (c) responds to CDP because of GSA's request. Analysis of total response time is thus based on estimates for each of these categories.

(a) Requested respondents who elect not to respond.

Based on historical CDP response rates and GSA's intended recipients, GSA estimates that 680 out of 1000 annual requested respondents will be in this category. Hour burden for this category: 680 non-responses; time per respondent 0; total time 0.

(b) Respondents who would have responded to CDP regardless of GSA's request. These respondents will complete some or all of the collection instrument, but would have done so regardless of GSA's request. In addition, some of these respondents will answer a small number of additional questions (requiring a small fraction of their overall response time to CDP) based on GSA's request. In addition, all of these respondents will need to complete one additional question in order to direct CDP to share their responses with GSA. Based on historical CDP response rates and GSA's intended recipients, GSA estimates that 250 out of 1000 annual requested respondents will be in this category. Hour burden for this category: 250 responses; average time per respondent 5 minutes; total burden 21 hours.

(c) Respondents who respond to CDP because of GSA's request. These

respondents may need to invest significant time drafting their responses and gathering facts, including searching and compiling existing data sources such as utility bills, and completing and reviewing the collection instrument. Based on historical CDP response rates and GSA's intended recipients, GSA estimates that 70 out of 1000 annual requested respondents will be in this category. Based on discussions with several dozen previous respondents to CDP's questionnaire, as well as public input received in response to a related information collection request notice (see 82 FR 3794), time burden for this collection is estimated to average 120 hours per response. Hour burden for this category: 70 responses; average time per respondent 120 hours; total burden 8400 hours.

Based on the individual category response times above, the total estimated response burden for all 1000 requested respondents is summarized below.

Frequency: Annual.

Affected Public: Federal contractors.

Number of Respondents: 1,000.

Responses per Respondent: 1.

Total Annual Responses: 320.

Estimated Time per Respondent: 26.3.

Total Burden Hours: 8,421.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary, whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Lois Mandell,

*Director, Regulatory Secretariat Division,
General Services Administration.*

[FR Doc. 2024-16032 Filed 7-19-24; 8:45 am]

BILLING CODE 6820-14-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Reorganization of the National Center for Immunization and Respiratory Diseases

AGENCY: Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: CDC has modified its structure. This notice announces the reorganization of the National Center for Immunization and Respiratory Diseases (NCIRD). NCIRD has abolished offices, retitled divisions and branches, and modified mission and function statements.

DATES: This reorganization of NCIRD was approved by the Director of CDC on July 17, 2024 and became effective on July 17, 2024.

FOR FURTHER INFORMATION CONTACT: Rebecca Greco Kone, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24-9, Atlanta, GA 30329; Telephone 800-232-4636; Email: pmoncird@cdc.gov.

SUPPLEMENTARY INFORMATION: Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 89 FR 56753, dated July 10, 2024) is amended to reflect the reorganization of National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention. Specifically, the changes are as follows:

I. Under Part C, Section C-B, Organization and Functions, make the following changes:

- Update the Office of the Director (CJ1) mission/function statements
- Abolish the Office of Informatics (CJ12)
- Abolish the Office of Policy (CJ13)
- Abolish the Office of Health Communications Science (CJ14)
- Abolish the Office of Management and Operations (CJ15)
- Abolish the Office of Science (CJ16)
- Abolish the Office of Global Health, Preparedness, and Response (CJ17)
- Update the Division of Bacterial Diseases (CJE) mission/function statements
- Retitle and update the mission/function statement for the Respiratory

Disease Branch to the Pneumonia and Streptococcus Epidemiology Branch (CJEB)

- Retitle and update the mission/function statement for the Meningitis and Vaccine Preventable Disease Branch to the Meningitis, Pertussis, and Diphtheria Epidemiology Branch (CJEC)
- Establish the Pneumonia and Streptococcus Laboratory Branch (CJED)
- Establish the Meningitis, Pertussis, and Diphtheria Laboratory Branch (CJEE)

II. Under Part C, Section C–B, Organization and Functions, within the National Center for Immunization and Respiratory Diseases, delete the mission or function statements for and replace with the following:

Office of the Director (CJ1). (1) provides leadership, expertise, and service in laboratory and epidemiological sciences for respiratory and vaccine-preventable diseases and in immunization program delivery; (2) provides diagnostic and reference laboratory services to relevant partnerships; (3) works with agency and other CIOs to ensure spending plans, budget planning, and budget execution are in line with the overall infectious disease strategies and priorities; (4) ensures that NCIRD's strategy is executed by the divisions and aligned with overall CDC goals, including leadership for and guidance for strategic planning and performance measurement; (5) co-develops execution strategies for NCIRD with the division directors;

(6) provides program and science quality oversight; (7) builds leadership at the division and branch levels; (8) evaluates the strategies, focus, and prioritization of the division research, program, and budget activities; (9) identifies and coordinates synergies between NCIRD and relevant partners; (10) ensures that policy development is consistent and appropriate; (11) facilitates research and program activities by providing leadership support; (12) proposes resource priorities throughout the budget cycle; (13) ensures scientific quality, ethics, and regulatory compliance; (14) fosters an integrated approach to research, program, and policy activities; (15) liaises with HHS and other domestic and international immunization and respiratory disease partners, as well as with NCIRD divisions; (16) coordinates center's emergency response activities related to immunization issues and complex acute respiratory infectious disease emergencies; (17) applies

communication science, media principles, and web design to support NCIRD and CDC's efforts to reduce morbidity and mortality caused by vaccine-preventable and respiratory diseases; ensuring that communication distributed by the center is timely, accurate, clear and relevant to intended audiences; (18) provides guidance for key scientific and laboratory services in the functional areas of extramural research (research and non-research), human studies oversight and review, regulatory affairs; activities in the areas of space planning, advising, coordination and evaluation, safety management and coordination, and shared services in controlled correspondence, and programmatic services in the area of workforce and career development; (19) provides and coordinates center-wide administrative, management, and support services in the areas of fiscal management, personnel, travel, procurement, facility management, and other administrative services; (20) manages the coordination of workforce development and succession planning activities, and provides human capital management, planning, and training consultation services; (21) develops and implements a coordinated healthcare provider strategy across NCIRD programs that maximizes public health outcomes; (22) directs the cultivation of clinical partnerships aimed at enhancing the reach and effectiveness of NCIRD programs; (23) leads the coordination and guidance of Advisory Committee on Immunization Practices (ACIP) related work; (24) designs and operationalize s cross-cutting public health strategies that improve outcomes for high risk groups; (25) provides advice to NCIRD leadership in developing policies, programs, implementation guidance, and strategic initiatives; (26) works with NCIRD programs, other CIOs, and agency to ensure NCIRD programs and priorities are incorporated into priority initiatives; (27) monitors and evaluates effectiveness of strategic plans and priorities, including linkages of resources to priorities and identification of public health outcomes to track effectiveness; (28) provides strategic guidance and direction, technical assistance and support for NCIRD's health equity portfolio; (29) tracks progress towards advancing health equity in the areas of science, intervention, and partnerships as aligned with CDC's CORE Health Equity framework; (30) advises NCIRD and CDC leadership on global health related to current and known respiratory threats and to emerging respiratory pandemic

threats; (31) provides strategic leadership for NCIRD in the areas of global health related to respiratory and vaccine-preventable diseases, including establishing NCIRD priorities, promoting science, policies, and new programs; (32) coordinates NCIRD efforts related to funding and budgets for global health security; and (33) supports NCIRD's work across CDC and the federal government on global health security, respiratory diseases.

Division of Bacterial Diseases (CJE). The mission of the Division of Bacterial Diseases (DBD) is to prevent and control illness and death from vaccine-preventable and other respiratory bacterial diseases, in the United States and worldwide, through leadership in epidemiologic and laboratory science and vaccine policy. DBD's cross-cutting functions include laboratory science, epidemiologic science, vaccine science, and partner support. (1) Provides laboratory support for surveillance and epidemiologic studies and reference diagnostic services to state, tribal, local, and territorial health departments, other federal agencies, and national and international health organizations; (2) develops, analyzes, and improves diagnostic methods and reagents; (3) facilitates development and evaluation of immunologic compounds, and vaccines; (4) conducts laboratory studies of the biological, biochemical, genetic, and antigenic characteristics, immunology, and pathogenesis of disease; (5) participates in and supports investigations of outbreaks, clusters, epidemics, and other public health problems in the United States and internationally, and recommends and evaluates appropriate control measures; (6) conducts surveillance for bacteria under the division's purview, including surveillance for antimicrobial resistance; assists state, tribal, local, and territorial health departments with conducting surveillance; prepares and distributes surveillance information; (7) conducts epidemiologic studies to define etiology, patterns of disease, disease burden, and risk factors; (8) provides consultation on the use of bacterial vaccines and other measures to prevent infections; identifies and evaluates other (non-vaccine) prevention strategies; and evaluates other aspects of vaccination practices; (9) determines the effectiveness and cost effectiveness of vaccines through the evaluation of scientific evidence; (10) supports the development and evaluation of vaccination policy and programs, and helps prepare statements on bacterial vaccines for ACIP and other groups in the United States; (11)

provides guidance and technical expertise on vaccine-preventable disease policy development in international settings; (12) supports CDC's Immunization Safety Office in vaccine safety risk assessment and leadership in vaccine safety risk management; (13) advises the World Health Organization (WHO) on global vaccine policies and strategies via the Strategic Advisory Group of Experts on Immunization; (14) provides technical support to state immunization programs for all aspects of vaccine-preventable diseases and their vaccines; (15) assists internal and external partners with other public health problems of national and international significance when needed; and (16) provides assistance with professional training for both internal and external partners.

Office of the Director (CJE1). (1) directs, coordinates, and manages the programs and activities of the division; (2) provides leadership and guidance on scientific strategy, policy, communications, partnerships, program planning and development, program management, and operations; (3) coordinates or assures coordination with the appropriate CDC and NCIRD offices on administrative and program matters; (4) reviews, prepares, and coordinates congressional testimony and briefing documents related to bacterial respiratory and vaccine-preventable diseases, and analyzes programmatic and policy implications of legislative proposals; (5) serves as CDC and NCIRD's primary internal and external communications contact regarding bacterial respiratory and vaccine-preventable disease issues; (6) advises CDC and NCIRD on policy and communications matters concerning the division's programs and activities; (7) assures the overall quality and integrity of the science conducted by the division; (8) coordinates division activities on cross-cutting agency initiatives; (9) guides and coordinates with division laboratory branches to implement quality management systems and maintain safety; (10) guides and facilitates efficient coordination and cooperation for administrative, programmatic, and scientific activities within the division, and with other groups in and outside of CDC; (11) provides statistical consultation for epidemiologic and laboratory research studies conducted by the division, including developing new methods for statistical applications; and (12) provides overall leadership, guidance, support, and coordination for the division's global health activities.

Pneumonia and Streptococcus Epidemiology Branch (CJEB). (1)

provides epidemiologic subject matter expertise and technical assistance for surveillance, prevention and control of respiratory and other syndromes caused by *Streptococcus pneumoniae*, group A and group B streptococci, and atypical respiratory bacteria (*Legionella*, *Mycoplasma*, and *Chlamydia* species), including outbreaks and antimicrobial-resistant infections, as well as community-acquired pneumonia, otitis media, and neonatal sepsis; (2) conducts surveillance and epidemiologic research for these diseases; (3) develops, implements, and evaluates prevention methods for these diseases, including vaccine and non-vaccine strategies; (4) supports development of vaccine policy through the ACIP process; (5) provides consultation and support to domestic and international partners on the use of vaccines and other prevention measures for bacterial respiratory diseases; (6) coordinates activities within and outside the division related to Active Bacterial Core surveillance with the Emerging Infections Program sites, and leverages other surveillance platforms that include bacterial respiratory diseases; and (7) collaborates with other CDC groups, other federal agencies, state, tribal, local, and territorial groups, ministries of health, WHO, private industry, academia, and other governmental and non-governmental organizations involved in public health.

Meningitis, Pertussis, and Diphtheria Epidemiology Branch (CJEC). (1) provides laboratory subject matter expertise and technical assistance for surveillance, prevention, and control of bacterial illness, including meningococcal disease, *Haemophilus influenzae* disease, diphtheria, pertussis, tetanus, and bacterial meningitis syndrome; (2) provides reference and diagnostic testing support for agents causing these diseases; (3) develops and evaluates new diagnostic methods for these bacterial pathogens; (4) develops, maintains, and implements genomic analyses of bacteria to enhance surveillance programs, outbreak investigations, and public health research; (5) provides leadership and expertise for the study of immunologic response to infection, vaccination, and therapeutic interventions against bacterial respiratory diseases; (6) ensures that the laboratory quality management system functions according to CDC policy and other regulatory requirements, *e.g.*, Clinical Laboratory Improvement Amendments (CLIA); maintains laboratory safety practices and provides guidance to ensure a safe work environment; (7) collaborates with other

CDC groups; other federal agencies; state, tribal, local, and territorial groups; ministries of health; WHO; private industry; academia; and other governmental and non-governmental organizations involved in public health; and (8) maintains World Health Organization Collaborating Center for Control and Prevention of Epidemic Meningitis.

Pneumonia and Streptococcus Laboratory Branch (CJED). (1) provides laboratory subject matter expertise and technical assistance for surveillance, prevention, and control of respiratory and other syndromes caused by *Streptococcus pneumoniae*, group A and group B streptococci, and atypical respiratory bacteria (*Legionella*, *Mycoplasma*, and *Chlamydia* species), including outbreaks and antimicrobial-resistant infections, as well as community-acquired pneumonia, otitis media, and neonatal sepsis; (2) provides reference and diagnostic testing support for bacterial respiratory diseases and for the identification of unknown gram-positive cocci; (3) develops and evaluates new diagnostic methods for bacterial respiratory pathogens; (4) develops, maintains, and implements genomic analyses of bacteria to enhance surveillance programs, outbreak investigations, and public health research; (5) maintains the World Health Organization Collaborating Center for Streptococcal Infections; (6) ensures that the laboratory quality management system functions according to CDC policy and other regulatory requirements, *e.g.*, CLIA; maintains laboratory safety practices and provides guidance to ensure a safe work environment; and (7) collaborates with other CDC groups; other federal agencies; state, tribal, local, and territorial groups; ministries of health; WHO; private industry; academia; and other governmental and non-governmental organizations involved in public health.

Meningitis, Pertussis, and Diphtheria Laboratory Branch (CJEE). (1) provides laboratory subject matter expertise and technical assistance for surveillance, prevention, and control of bacterial illness, including meningococcal disease, *Haemophilus influenzae* disease, diphtheria, pertussis, tetanus, and bacterial meningitis syndrome; (2) provides reference and diagnostic testing support for agents causing these diseases; (3) develops and evaluates new diagnostic methods for these bacterial pathogens; (4) develops, maintains, and implements genomic analyses of bacteria to enhance surveillance programs, outbreak investigations, and public health

research; (5) provides leadership and expertise for the study of immunologic response to infection, vaccination, and therapeutic interventions against bacterial respiratory diseases; (6) ensures that the laboratory quality management system functions according to CDC policy and other regulatory requirements, *e.g.* CLIA; maintains laboratory safety practices and provides guidance to ensure a safe work environment; (7) collaborates with other CDC groups; other federal agencies; state, tribal, local, and territorial groups, ministries of health, WHO, private industry, academia, and other governmental and non-governmental organizations involved in public health; and (8) maintains World Health Organization Collaborating Center for Control and Prevention of Epidemic Meningitis.

Delegations of Authority

All delegations and redelegations of authority made to officials and

employees of affected organizational components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.
(Authority: 44 U.S.C. 3101)

Robin D. Bailey,
Chief Operating Officer, Centers for Disease Control and Prevention.
[FR Doc. 2024–16027 Filed 7–19–24; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9149–N]

Medicare and Medicaid Programs;
Quarterly Listing of Program
Issuances—April Through June 2024

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published in the 3-month period, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone No.
I CMS Manual Instructions	Ismael Torres	(410) 786–1864
II Regulation Documents Published in the Federal Register	Terri Plumb	(410) 786–4481
III CMS Rulings	Tiffany Lafferty	(410)786–7548
IV Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786–7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786–6877
VI Collections of Information	William Parham	(410) 786–4669
VII Medicare-Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786–2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites.	Sarah Fulton, MHS	(410) 786–2749
IX Medicare’s Active Coverage-Related Guidance Documents	Lori Ashby, MA	(410) 786–6322
X One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786–7205
XI National Oncologic Positron Emission Tomography Registry Sites	David Dolan, MBA	(410) 786–3365
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities.	David Dolan, MBA	(410) 786–3365
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XIV Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	David Dolan, MBA	(410) 786–3365
All Other Information	Annette Brewer	(410) 786–6580

SUPPLEMENTARY INFORMATION:

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners

(NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and “real time” accessibility. In addition, many of the

websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

III. How To Use the Notice

This notice is organized into 15 addenda so that a reader may access the

subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at <http://www.cms.gov/manuals>.

The Director of the Office of Strategic Operations and Regulatory Affairs of the Centers for Medicare & Medicaid Services (CMS), Kathleen Cantwell,

having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Trenesha Fultz-Mimms,

Federal Register Liaison, Department of Health and Human Services.

BILLING CODE 4120-01-P

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: August 4, 2023 (88 FR 51814), October 26, 2023 (88 FR 73591), January 30, 2024 (89 FR 5897) and April 29, 2024 (89 FR 33356). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (April through June 2024)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: <http://cms.gov/manuals>.

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at <http://www.gpo.gov/libraries/>

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government

publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual Updates for Clarification on Services Under the Medicare Hospice Benefit for Dually Eligible Veterans (CMS-Pub. 100-02) Transmittal No. 12589.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual.

Fee-For Service Transmittal Numbers

Please Note: Beginning Friday, March 20, 2020, there will be the following change regarding the Advance Notice of Instructions due to a CMS internal process change. Fee-For Service Transmittal Numbers will no longer be determined by Publication. The Transmittal numbers will be issued by a single numerical sequence beginning with Transmittal Number 10000.

For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

Transmittal Number	Manual/Subject/Publication Number
Medicare General Information (CMS-Pub. 100-01)	
12566	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12568	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12637	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12638	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
Medicare Benefit Policy (CMS-Pub. 100-02)	
12589	Manual Updates for Clarification on Services Under the Medicare Hospice Benefit for Dually Eligible Veterans
12599	A Social Determinants of Health Risk Assessment in the Annual Wellness Visit Policy Update in the Calendar Year 2024 Physician Fee Schedule Final Rule
12600	Expand Diabetes Screening and Diabetes Definitions Policy Update in the Calendar Year 2024 Physician Fee Schedule Final Rule
Medicare National Coverage Determination (CMS-Pub. 100-03)	
12571	National Coverage Determination (NCD) 20.7 Percutaneous Transluminal

	Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting Percutaneous Transluminal Angioplasty (PTA) (Various Effective Dates Below)
12590	Technical Revision Only to the National Coverage Determination (NCD) Manual, Publication (Pub) 100-03, Chapter 1, Part 4, section 310.1
12627	Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndromes (MDS) National Coverage Determination (NCD) 110.23
Medicare Claims Processing (CMS-Pub. 100-04)	
12565	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12570	CY 2024 Home Infusion Therapy (HIT) Payment Rates and Instructions for Retrieving the January 2024 Home Infusion Therapy (HIT) Services Payment Rates Through the CMS Mainframe Telecommunications System
12571	National Coverage Determination (NCD) 20.7 Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting
12573	Manual Update to Section 20.7 in Chapter 23 of Publication (Pub) 100-04
12575	Internet Only Manual Updates to Publication 100-04 to Implement Updates to Policy (Inpatient Rehabilitation Facility (IRF))
12576	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12577	Additional Enforcement of Required County Codes on Home Health Claims
12578	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
12584	April Quarterly Update for 2024 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
12586	Additional Implementation Edits on Hospice Claims for Hospice Certifying Physician Medicare Enrollment Notice of Election (NOE) Remove Modify Notice of Termination/Revocation (NOTR) Change of Provider/Transfer Notice Cancellation of an Election Change of Ownership Notice Data Required on the Institutional Claim to A/B MAC (HHH)
12587	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12594	Outlier Reconciliation and Cost-to-Charge Ratio (CCR) Updates for the Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) PPS
12596	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
12599	A Social Determinants of Health Risk Assessment in the Annual Wellness Visit Policy Update in the Calendar Year 2024 Physician Fee Schedule Final Rule
12600	Expand Diabetes Screening and Diabetes Definitions Policy Update in the Calendar Year 2024 Physician Fee Schedule Final Rule
12601	Update to Several Sections of the Internet-only Manual (IOM) Publication (Pub.) 100-04, Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements
12604	Internet-Only Manual (IOM) Updates for Split (or Shared) Evaluation and Management Visits
12606	Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment
12607	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12608	Enhancements to Home Health Consolidated Billing Edits

12609	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12610	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12611	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12612	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
12614	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
12615	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
12621	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12627	Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndromes (MDS) National Coverage Determination (NCD) 110.23
12628	Quarterly Update to the End-Stage Renal Disease Prospective Payment System (ESRD PPS)
12629	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - July 2024 Update
12635	Additional Implementation Edits on Hospice Claims for Hospice Certifying Physician Medicare Enrollment
12644	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12646	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12649	National Coverage Determination (NCD) 200.3 - Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD)1
12650	Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports
12652	October 2024 (2025 File) Update of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)
12653	Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits
12654	Quarterly Update to Home Health (HH) Grouper
12655	October 2024 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder
12657	Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment
12659	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
12660	Combined Common Edits/Enhancements Modules (CCEM) Code Set Update
12661	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
12662	Implement Operating Rules – Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): Committee on Operating Rules for Information Exchange (CORE) 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Claim Adjustment Group Code (CAGC) Rule - Update from Council for Affordable Quality Healthcare (CAQH) CORE
12664	Changing the Frequency of No-Pay Medicare Summary Notice (MSN) Mailings from Every 90 Days to Every 120 Days

12665	July 2024 Update of the Hospital Outpatient Prospective Payment System (OPPS)
12666	July 2024 Integrated Outpatient Code Editor (I/OCE) Specifications Version 25.2
12670	July 2024 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
12671	Billing and Payment for Telehealth Services with Place of Service (POS) 10
12677	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12682	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 30.3, Effective October 1, 2024
12683	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 32, Section 150.3 for Coding Revisions to the National Coverage Determinations (NCDs)--October 2024 Change Request (CR)13596
12685	July Quarterly Update for 2024 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
12686	Instructions for Downloading the Medicare ZIP Code File for October 2024 Files
12687	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
12688	Fiscal Year (FY) 2025 Annual Update to the Medicare Code Editor (MCE) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) and Procedure Coding System (ICD-10-PCS)
12690	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12691	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2024
12692	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12693	October 2024 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
12694	Expand Diabetes Screening and Diabetes Definitions Policy Update in the Calendar Year 2024 Physician Fee Schedule Final Rule - This CR Rescinds and Fully Replaces CR 13487.
Medicare Secondary Payer (CMS-Pub. 100-05)	
12564	Changes to The Electronic Correspondence Referral System (ECRS) Web Includes Updates to Submitting Duplicate and Overlapping Drug Records; Addition of Action Code (DR) to Investigate Deleted Drug Records and Updates to the Electronic Data Interchange (EDI) and Coordination of Benefits Voluntary Agreement (COBVA) Email Addresses
12568	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
12648	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
Medicare Financial Management (CMS-Pub. 100-06)	
12583	Notice of New Interest Rate for Medicare Overpayments and Underpayments -3rd Quarter Notification for FY 2024
12597	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files to the Provider and Statistical Reimbursement (PS&R) System
Medicare State Operations Manual (CMS-Pub. 100-07)	
219	Revisions to the State Operations Manual (SOM) Appendix B – Home Health Agencies
220	Revisions to State Operations Manual (SOM) Appendix A-Hospitals

221	Revisions to the State Operations Manual (SOM) Chapter 10 –Informal Dispute Resolution (IDR) and Enforcement Procedures for Home Health Agencies and Hospice Programs
222	Revisions to the State Operations Manual (SOM) Appendix M-Hospice
223	Revisions to the State Operations Manual (SOM) Appendix G – RHC
224	Revisions to State Operations Manual (SOM), Chapter 2, section 2779A1 – CCN for Medicare Providers
Medicare Program Integrity (CMS-Pub. 100-08)	
12580	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12581	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12582	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12591	Stay of Enrollment
12592	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12593	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12602	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12603	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12633	Medical Review Policies for Signature Requirements
12656	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12663	Medical Review Policies for Signature Requirements
12679	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12680	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12681	Fraud Prevention System (FPS) Edit – FPS14 – Denial of Pacemaker, Cardioverter, and Cardiovascular Monitoring Services Frequency - This CR Rescinds and Fully Replaces CR 11594.
12700	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
	None
Medicare Quality Improvement Organization (CMS- Pub. 100-10)	
	None
Medicare Program of All-Inclusive Care for the Elderly (CMS- Pub. 100-11)	
	None
Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)	
	None
Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)	
	None
Medicare Managed Care (CMS-Pub. 100-16)	
	None
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None
Medicare Prescription Drug Benefit (CMS-Pub. 100-18)	
	None
Demonstrations (CMS-Pub. 100-19)	
12563	Guiding an Improved Dementia Experience (GUIDE) Model Implementation
12567	Making Care Primary (MCP) Model Implementation

12596	Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
12598	Create APIs to Support ACO REACH Model - Full Agile Pilot
12620	Primary Care First (PCF) Model: Updated Appendix B - Prohibited Healthcare Common Procedure Coding System (HCPCS) Codes
12622	Extension of Payment Period for Pennsylvania Rural Health Model
12643	Making Care Primary (MCP) Model Implementation
12647	Guiding an Improved Dementia Experience (GUIDE) Model Implementation
12651	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
One Time Notification (CMS-Pub. 100-20)	
12605	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12613	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
12616	Fiscal Intermediary Shared System (FISS) - User Enhancement Change Request (UECR) - Create a Beneficiary Liable Reason Code for National Coverage Determination (NCD) 210.14
12617	User Enhancement Change Request (UECR) - Enhance the MCS Desktop Tool (MCSDT) Table Manager and Customer Service Representative (CSR) Security Table
12619	User Enhancement Change Request (UECR) - Enhance the Multi-Carrier System Desktop Tool (MCSDT) to Export Tables
12623	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12625	Fiscal Intermediary Shared System (FISS) User Enhancement Change Request (UECR) - Expiration of a Unique Tracking Number (UTN) on the Prior Authorization (PA) Tracking File
12626	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs) October 2024
12630	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
12631	Fiscal Intermediary Shared System (FISS) - New Process to Create and Use Overridable Reason Codes
12632	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
12634	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12636	Implement Edits on Hospice Claims
12640	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12641	Updates to the Recovery Audit Contractor Data Warehouse (RACDW) Suppression Upload File Format
12658	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
12667	Clarification of Liability for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Claims Overlapping Inpatient Hospital Stays
12668	User Enhancement Change Request (UECR) - Enhance the Multi-Carrier System Desktop Tool (MCSDT) to Export Tables
12669	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
12672	Replacement Wheelchair Equipment When the Manufacturer Exits Wheelchair Business

12675	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
12678	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12689	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
12698	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
12701	New State Codes for Arizona, California, Nevada, and Texas
12703	Fiscal Intermediary Shared System (FISS) - User Enhancement Change Request (UECR) - Create a Beneficiary Liable Reason Code for National Coverage Determination (NCD) 210.14
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
	None
State Payment of Medicare Premiums (CMS-Pub.100-24)	
	None
Information Security Acceptable Risk Safeguards (CMS Pub. 100-25)	
	None

For questions or additional information, contact Ismael Torres (410-786-1864).

Addendum II: Regulation Documents Published in the Federal Register (April through June 2024) **Regulations and Notices**

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register**, contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through **GPO Access**. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at <http://www.gpoaccess.gov/fr/index.html>. The following website <http://www.archives.gov/federal-register/> provides information on how to access electronic editions, printed editions, and reference copies.

For questions or additional information, contact Terri Plumb (410-786-4481).

Addendum III: CMS Rulings (April through June 2024)

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare,

Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings>.

For questions or additional information, contact Tiffany Lafferty (410-786-7548).

Addendum IV: Medicare National Coverage Determinations (April through June 2024)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice, there were no specific updates to national coverage determinations (NCDs), or reconsiderations of completed NCDs published in the 3-month period. This information is available at: www.cms.gov/medicare-coverage-database/.

For questions or additional information, contact Wanda Belle, MPA (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndromes (MDS) National Coverage Determination (NCD) 110.23	NCD 110.23	12627	05/09/2024	03/06/2024

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (April through June 2024)
(Inclusion of this addenda is under discussion internally.)

Addendum VI: Approval Numbers for Collections of Information (April through June 2024)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain.

For questions or additional information, contact William Parham (410-786-4669).

Addendum VII: Medicare-Approved Carotid Stent Facilities (April through June 2024)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. There were no additions, deletions, or editorial changes to the listing for Medicare-approved carotid stent facilities for this 3-month period. This information is available at: <http://www.cms.gov/MedicareApprovedFacilities/CASF/list.asp#TopOfPage>

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (April through June 2024)

The initial data collection requirement through the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) has served to develop and improve the evidence base for the use of ICDs in certain Medicare beneficiaries. The data collection requirement ended with the posting of the final decision memo for Implantable Cardioverter Defibrillators on February 15, 2018.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum IX: Active CMS Coverage-Related Guidance Documents (April through June 2024)

CMS issued a guidance document on November 20, 2014 titled “Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document”. Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS’s implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27>.

CMS published three proposed guidance documents on June 22, 2023 to provide a framework for more predictable and transparent evidence development and encourage innovation and accelerate beneficiary access to new items and services. The documents are available at:

<https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=35&docTypeId=1&sortBy=title&bc=16>

<https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=34&docTypeId=1&sortBy=title&bc=16>

<https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=33&docTypeId=1&sortBy=title&bc=16>

For questions or additional information, contact Lori Ashby, MA (410 786 6322).

Addendum X:

List of Special One-Time Notices Regarding National Coverage Provisions (April through June 2024)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at <http://www.cms.gov>.

For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (April through June 2024)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography (PET) scans**, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET

scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilities/NOPR/list.asp#TopOfPage>.

For questions or additional information, contact David Dolan, MBA (410-786-3365).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (April through June 2024)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at

<http://www.cms.gov/MedicareApprovedFacilities/VAD/list.asp#TopOfPage>.

For questions or additional information, contact David Dolan, MBA, (410-786-3365).

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
The following facility is a new listing.				
Virginia Mason Medical Center 1100 Ninth Avenue Seattle, WA 98101 Other information: DNV ID #: C667499 Previous Re-certification Dates: n/a	50-0005	03/07/2024	n/a	WA
The following facilities have editorial changes (in bold).				
Shands Teaching Hospitals & Clinics, Inc. 1600 SW Archer Road Gainesville, FL 32608	100113	11/26/2003	01/31/2024	FL

Other information: Joint Commission ID #6804 Previous Re-certification Dates: 11/18/2008; 02/08/2011; 02/12/2013; 01/27/2015; 02/14/2017; 04/24/2019; 12/16/2021				
Stanford Health Care 300 Pasteur Drive Stanford, CA 94305 Other information: Joint Commission ID #10010 Previous Re-certification Dates: 11/24/2010; 12/12/2012; 12/09/2014; 03/14/2017; 08/28/2019; 12/15/2021	050441	12/22/2003	01/31/2024	CA
Cedars-Sinai Health System 8700 Beverly Boulevard Los Angeles, CA 90048 Other information: Joint Commission ID #9792 Previous Re-certification Dates: 12/11/2008; 06/21/2011; 06/11/2013; 05/29/2015; 07/11/2017; 09/11/2019; 02/26/2022	050625	12/29/2003	04/12/2024	CA
Wellstar Kennestone Hospital 677 Church Street Marietta, GA 30060 Other information: Joint Commission ID #6711 Previous Re-certification Dates: 11/07/2017; 11/22/2019; 01/15/2022	110035	11/07/2017	02/07/2024	GA
University of Chicago Medical Center 5841 South Maryland Avenue Chicago, IL 60637 Other information: Joint Commission ID #7315 Previous Re-certification Dates: 02/24/2009; 08/17/2011; 09/04/2013; 09/15/2015; 10/24/2017; 12/17/2019; 01/22/2022	140088	02/24/2009	02/07/2024	IL
Emory University Hospital 1364 Clifton Road NE	110010	08/18/2009	02/14/2024	GA

Atlanta, GA 30322 Other information: Joint Commission ID #6689 Previous Re-certification Dates: 08/18/2009; 09/09/2011; 08/29/2013; 08/11/2015; 09/26/2017; 11/20/2019; 02/12/2022				
Northeast Georgia Medical Center 743 Spring Street Gainesville, GA 30501 Other information: DNV ID #: C690194 Previous Re-certification Dates: 04/26/2018; 05/05/2021	110029	04/26/2018	05/05/2024	GA
Pitt County Memorial Hospital, Inc. DBA Vidant Medical Center 2100 Stantonsburg Road Greenville, NC 27835-6028 Other information: Joint Commission ID #6506 Previous Re-certification Dates: 09/26/2017; 12/17/2019; 02/09/2022	340040	09/26/2017	02/21/2024	NC
Florida Health Sciences Center Inc. 1 Tampa General Circle Tampa, FL 33606 Other information: Joint Commission ID #6934 Previous Re-certification Dates: 12/19/2008; 04/05/2011; 04/09/2013; 04/21/2015; 06/06/2017; 7/24/2019; 01/20/2022	100128	12/18/2008	02/28/2024	FL
Baptist Memorial Hospital - Memphis 6019 Walnut Grove Road Memphis, TN 38120 Other information: Joint Commission ID #7869 Previous Re-certification Dates: 01/27/2009; 05/20/2011; 04/17/2013;	440048	04/07/2007	03/13/2024	TN

06/02/2015; 07/25/2017; 09/17/2019; 02/19/2022				
UT Southwestern Medical Center/William P. Clements Jr. University Hospital 6201 Harry Hines Boulevard Dallas, TX 75390-9262 Other information: Joint Commission ID #9013 Previous Re-certification Dates: 12/17/2008; 06/07/2011; 06/04/2013; 06/23/2015; 08/08/2017; 10/11/2019; 02/12/2022	450044	12/10/2003	03/13/2024	TX
University Hospital Cleveland Medical Center 11100 Euclid Avenue Cleveland, OH 44106 Other information: DNV ID #: C669039 Previous Re-certification Dates: 02/09/2010; 01/24/2012; 01/30/2014; 02/23/2016; 02/09/2018; 01- 21-2021; 08/17/2022	36-0137	02/09/2010	04/17/2024	OH
UofL Health - Louisville, Inc. 200 Abraham Flexner Way Louisville, KY 40202 Other information: Joint Commission ID #7765 Previous Re-certification Dates: 11/14/2008; 03/22/2011; 02/26/2013; 03/24/2015; 05/23/2017; 8/6/2019; 02/23/2022	180040	11/14/2008	03/13/2024	KY
Keck Hospital of USC 1500 San Pablo Street Los Angeles, CA 90033 Other information: Joint Commission ID #5033 Previous Re-certification Dates: 03/13/2009; 08/16/2011; 09/10/2013; 10/06/2015; 10/20/2017; 12/4/2019; 02/02/2022	050696	03/13/2009	03/14/2024	CA
Methodist Hospital 7700 Floyd Curl Drive San Antonio, TX 78229	450388	01/27/2009	03/08/2024	TX

Other information: Joint Commission ID #: 9219 Previous Re-certification Dates: 01/27/2009; 07/12/2011; 07/09/2013; 07/07/2015; 08/08/2017; 10/23/2019; 01/22/2022				
Riverside Methodist Hospital 3535 Olentangy River Road Columbus, OH 43214-3998 Other information: Joint Commission ID #: 7030 Previous Re-certification Dates: 07/14/2015; 08/29/2017; 10/23/2019; 02/26/2022	360006	07/14/2015	03/23/2024	OH
Texas Heart Hospital of the Southwest LLP 1100 Allied Drive Plano, TX 75093-5348 Other information: Joint Commission ID #: 440319 Previous Re-certification Dates: 06/15/2011; 07/09/2013; 07/14/2015; 08/22/2017; 9/7/2019; 01/28/2022	670025	06/15/2011	03/16/2024	TX
Christiana Care Health Services, Inc. 4755 Ogletown-Stanton Road Newark, DE 19718 Other information: Joint Commission ID #6237 Previous Re-certification Dates: 07/25/2013; 07/21/2015; 10/24/2017; 12/21/2019; 03/03/2022	080001	07/25/2013	04/10/2024	DE
Thomas Jefferson University Hospitals, Inc. 111 South 11th Street Philadelphia, PA 19107 Other information: Joint Commission ID #6132 Previous Re-certification Dates: 07/09/2009; 09/13/2011; 10/17/2013;	390174	07/09/2009	03/27/2024	PA

09/22/2015; 09/20/2017; 11/6/2019; 02/24/2022				
Banner-University Medical Center Tucson Campus 1625 North Campbell Avenue Tucson, AZ 85719 Other information: Joint Commission ID #: 9514 Previous Re-certification Dates: 02/04/2009; 04/27/2011; 03/15/2013; 02/24/2015; 04/18/2017; 7/12/2019; 03/05/2022	030064	02/04/2009	04/04/2024	AZ
Baylor Scott and White All Saints – Fort Worth 1400 8th Avenue Fort Worth, TX 76104 Other information: DNV ID #: 10000469761 Previous Re-certification Dates: 5/26/2021	450137	5/26/2021	5/26/2024	TX
Banner - University Medical Center Phoenix 1111 East McDowell Road Phoenix, AZ 85006 Other information: Joint Commission ID #9489 Previous Re-certification Dates: 05/19/2011; 05/07/2013; 06/09/2015; 07/25/2017; 07-10-2019; 03/03/2022	030002	05/19/2011	04/06/2024	AZ
Ronald Reagan UCLA Medical Center 757 Westwood Plaza Los Angeles, CA 90095 Other information: Joint Commission ID #9944 Previous Re-certification Dates: 02/06/2009; 08/09/2011; 08/13/2013; 09/15/2015; 10/06/2017; 12/04/2019; 04/09/2022	050262	02/06/2009	05/08/2024	CA
Baylor University Medical Center 3500 Gaston Avenue Dallas, TX 75246-2017 Other information:	450021	08/21/2007	04/17/2024	TX

Joint Commission ID #8993 Previous Re-certification Dates: 08/21/2007; 08/27/2009; 10/07/2011; 11/20/2013; 11/10/2015; 10/31/2017; 12/18/2019; 03/24/2022				
Ochsner Medical Center 1516 Jefferson Highway New Orleans, LA 70121 Other information: Joint Commission ID # Previous Re-certification Dates: 05/28/2009; 11/09/2011; 12/12/2013; 01/05/2016; 12/12/2017; 03/12/2020; 03/10/2022	190036	05/28/2009	04/03/2024	LA
Morristown Medical Center 100 Madison Avenue Morristown, NJ 07960 Other information: Joint Commission ID #5958 Previous Re-certification Dates: 06/16/2009; 09/28/2011; 10/31/2013; 11/17/2015; 12/12/2017; 1/25/2020; 03/23/2022	310015	06/16/2009	04/17/2024	NJ

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (April through June 2024)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. For the purposes of this quarterly notice, there are no additions and deletions to a listing of Medicare-approved facilities that are eligible to receive coverage for lung

volume reduction surgery. This information is available at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (April through June 2024)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASBMS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (April through June 2024)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage.

For questions or additional information, contact David Dolan, MBA (410-786-3365).

[FR Doc. 2024-16040 Filed 7-19-24; 8:45 am]
BILLING CODE 4120-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity: Administration of Psychotropic Medication to Unaccompanied Children (New Collection)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services is inviting public comment on the proposed collection. The request consists of two forms that will allow the Unaccompanied Children (UC) Bureau to obtain informed consent from authorized consenters and informed assent or agreement from unaccompanied children for the

administration of psychotropic medication.

DATES: *Comments due* September 20, 2024. In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The ORR UC Bureau is proposing two new forms: *Psychotropic Medication Informed Consent* (Form MMH-1) and *Psychotropic Medication Assent Notice* (Form MMH-2). The proposed information collection is necessary to allow the ORR UC Bureau to comply with a court order and improve processes for the administration of psychotropic medication. On June 29, 2018, Plaintiffs filed their federal class action lawsuit in the Central District of California, western division, captioned *Lucas R. et al. v. Becerra et al.* (Case No. 2:18-CV-05741 DMG-PLA), asserting claims under the Flores consent decree, the Trafficking Victims Protection

Reauthorization Act, the Due Process clause, and the First Amendment. Plaintiffs allege violation of unaccompanied children rights in decisions regarding family reunification, placement in restrictive facilities, services for children with disabilities, administration of psychotropic medication, and access to legal assistance. On May 3, 2024, the Court granted final approval for the settlement agreements of the Plaintiffs' claims for disabilities, psychotropic medication, and legal assistance. As part of the settlement agreement for the psychotropic medication claim, ORR is required, whenever possible, to obtain informed consent for the administration of psychotropic medication and provide certain information to the authorized consenter. Additionally, ORR is required to provide a written notice and obtain informed assent or agreement from children aged 14 or older before administering psychotropic medication. The psychotropic medication settlement agreement must be fully implemented by August 3, 2026, but data collection must be implemented by February 3, 2025, to ensure compliance with the Agreement.

Respondents: Care provider grantees and contractors

Annual Burden Estimates:

Form	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Psychotropic Medication Informed Consent (Form MMH-1)	300	2	1.50	900
Psychotropic Medication Assent Notice (Form MMH-2)	300	1	0.75	225

Estimated Total Annual Burden Hours: 1,125.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; 45 CFR 410; *Flores v. Reno Settlement Agreement*, No. CV85-4544-RJK (C.D. Cal. 1996); *Lucas R. et al. v. Becerra et al.* (Case No. 2:18-CV-05741 DMG PLA) Psychotropic Medication Settlement Agreement.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024-16043 Filed 7-19-24; 8:45 am]

BILLING CODE 4184-45-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-D-2442]

Recommendations for Investigational and Licensed COVID-19 Convalescent Plasma; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for immediate implementation entitled "Recommendations for Investigational and Licensed COVID-19 Convalescent Plasma; Guidance for Industry." The purpose of this guidance is to provide FDA's recommendations to blood establishments for the submission of a Biologics License Application (BLA) for the manufacture of COVID-19

convalescent plasma intended for transfusion in patients with immunosuppressive disease or receiving immunosuppressive treatment in either the outpatient or inpatient setting. The guidance also provides FDA's recommendations for investigational new drug applications (INDs) for investigational COVID-19 convalescent plasma for transfusion.

DATES: The announcement of the guidance is published in the **Federal Register** on July 22, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as

well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2024-D-2442 for "Recommendations for Licensed COVID-19 Convalescent Plasma; Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts

and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive labels to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for blood establishments entitled “Recommendations for Investigational and Licensed COVID-19 Convalescent Plasma; Guidance for Industry.” We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (see § 10.115(g)(2) and section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C))). We made this determination because the revisions to the guidance reflect the current epidemiology of COVID-19 and provide updated recommendations needed by blood establishments and sponsors. Specifically, we are issuing this guidance to ensure that blood establishments and sponsors are aware of our current recommendations to expedite the timely development of COVID-19 convalescent plasma. Immediate implementation of the guidance is required to facilitate the licensure of COVID-19 convalescent plasma to protect the public health. Although this guidance document is being implemented immediately, it remains subject to comment in accordance with FDA’s GGP regulation (§ 10.115(g)(3)(D)).

COVID-19 convalescent plasma is plasma containing antibodies to SARS-CoV-2 intended for transfusion that is collected from individuals who have recovered from COVID-19. FDA first issued an emergency use authorization (EUA) on August 23, 2020, for COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19, pursuant to section 564 of the FD&C Act (21 U.S.C. 360bbb-3). FDA has subsequently reissued the EUA with revisions. Most recently, on December 28, 2021, FDA revised the EUA to limit authorization to the use of COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies for the treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment in either the outpatient or inpatient setting. The purpose of this guidance is to provide FDA’s recommendations on two regulatory pathways for the manufacture of COVID-19 convalescent plasma. Specifically, the guidance provides recommendations to blood establishments for the submission of a BLA for the manufacture of COVID-19 convalescent plasma for transfusion intended to treat patients with immunosuppressive disease or receiving immunosuppressive treatment in either the outpatient or inpatient setting. The guidance also provides FDA’s recommendations for INDs for investigational COVID-19 convalescent plasma for transfusion.

The guidance represents the current thinking of FDA on investigational and licensed COVID-19 convalescent plasma. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

FDA has also issued a separate guidance entitled “Investigational COVID-19 Convalescent Plasma,” which was most recently updated in October 2023 (88 FR 15417). The “Investigational COVID-19 Convalescent Plasma” guidance provides recommendations and additional information related to the EUA for COVID-19 convalescent plasma, as well as recommendations for administering COVID-19 convalescent plasma under the IND pathway in accordance with 21 CFR part 312. The recommendations in section III.A.2 of the guidance being announced today pertaining to investigational new drug applications for COVID-19 convalescent plasma supersede the recommendations in section III.C. of the “Investigational COVID-19 Convalescent Plasma”

guidance. We intend to revise the “Investigational COVID-19 Convalescent Plasma” guidance to reflect this change.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338; the collections of information in 21 CFR part 606 have been approved under OMB control number 0910-0116; and the collections of information in 21 CFR part 630 have been approved under OMB control number 0910-0795.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: July 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-16046 Filed 7-19-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-1298]

Agency Information Collection Activities; Proposed Collection; Comment Request; Diversity Action Plans for Clinical Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each

proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collections of information related to Diversity Action Plans for Clinical Studies.

DATES: Either electronic or written comments on the collection of information must be submitted by September 20, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 20, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and

identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2024-N-1298 for "Diversity Action Plans To Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New

Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002; or Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collections of information as set forth in the draft guidance for industry "Diversity Action Plans To Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies."

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use

of automated collection techniques, when appropriate, and other forms of information technology.

Diversity Action Plans (DAPs) for Clinical Studies

OMB Control No. 0910–NEW

This information collection supports the implementation of sections 3601 and 3602 of the Food and Drug Omnibus Reform Act of 2022 (FDORA) included as part of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328). In the **Federal Register** of June 28, 2024 (89 FR 54010), FDA announced the availability of a draft guidance for industry entitled “Diversity Action Plans To Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies,” as required under FDORA. The guidance is available from our website at [https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-action-plans-improve-enrollment-participants-underrepresented-populations-clinical-](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-action-plans-improve-enrollment-participants-underrepresented-populations-clinical-studies)

studies. Statutory requirements in sections 505(z) and 520(g) of the FD&C Act (21 U.S.C. 355(z) and 360j(g)) are discussed in the draft guidance document, including the content of a DAP (guidance Section V), applicable timelines (guidance Section VI), procedures for submitting a DAP and receiving feedback (guidance Section VII), and requesting a DAP waiver (guidance Section VIII).

A DAP must include the sponsor’s goals for enrollment in the clinical study disaggregated by race, ethnicity, sex, and age group of clinically relevant study populations, the sponsor’s rationale for those goals, including sufficient information and analysis to explain how the goals were determined, and an explanation of how the sponsor intends to meet such goals. The appropriate submission for a medical product type (investigational new drug application (IND) for drugs and biological products, and investigational device exemptions (IDE), premarket notification (510(k)), premarket

approval application (PMA), and de novo classification request (De Novo) for devices) should include a cover letter identifying the submission as a DAP and whether the DAP submission is for an initial or a revised plan.

DAP Waiver Requests should be submitted with a cover letter identifying the submission as a Diversity Action Plan—Waiver request. The waiver request should also identify the submission number, applicable clinical study name or identification number, and a justification for the waiver request, including relevant data and information. DAP submission and waiver requests should be submitted electronically.

DAP submissions and waiver requests are processed through FDA’s Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and Center for Devices and Radiological Health (CDRH) according to product type.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ONE-TIME RECORDKEEPING BURDEN ¹

Review guidance to comply with FDORA sections 3601/3602	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER (sec. 505(z)(3) of the FD&C Act)	200	1	200	1	200
CBER (sec. 505(z)(3) of the FD&C Act)	40	1	40	1	40
CDRH (sec. 520(g)(9) of the FD&C Act)	488	1	488	1	488
Total			728		728

¹ There are no operating and maintenance costs associated with this collection of information.

We are expanding the scope of our currently approved collection inventory to acknowledge the establishment of DAP requirements under FDORA and to account for burden that may be attendant to the submission of a DAP or for requesting a waiver. As explained in

the draft guidance document Section VII (Procedures for Submitting the Diversity Action Plan and Receiving Feedback), the submission process will vary depending on the medical product type.

As reflected in table 1, we estimate a one-time burden of 728 hours and 728

responses, cumulatively, with regard to reviewing the guidance and to any necessary adjustment respondents may need to make in complying with applicable requirements.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Information collection activity; statutory authority	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER DAP Submission—sec. 505(z)(3) of the FD&C Act	146	1.37	200	100	20,000
CBER DAP Submission—sec. 505(z)(3) of the FD&C Act	35	1.14	40	100	4,000
CDRH—sec. 520(g)(9)(A) of the FD&C Act	488	1	488	40	19,520
Waiver request CDER—sec. 505(z)(4) of the FD&C Act	4	1	4	16	72
Waiver request CBER—sec. 505(z)(4) of the FD&C Act	1	1	1	16	16
Waiver request CDRH—sec. 520(g)(9)(C) of the FD&C Act	5	1	5	16	80
Total			738		43,688

¹ There are no operating and maintenance costs associated with this collection of information.

As reflected in table 2, we assume recurring activities to include the

preparation, submission, and retention of information consistent with statutory

requirements and discussed in the draft guidance and, therefore, estimate an

annual recordkeeping burden of 738 responses and 43,688 hours, including the submission of DAPs and waiver requests to FDA. We discuss these revisions and adjustments with regard to drugs and devices, respectively.

A. Section 505(z)(1) of the FD&C Act (21 U.S.C. 355(z)(1))—Drugs and Biological Products

Regulations establishing procedures and requirements governing clinical investigations for investigational new drugs and biological products are found in part 312 (21 CFR part 312). Specifically, regulations in part 312, subpart D, establish responsibilities for sponsors and investigators of new drugs, including requirements applicable to the investigational plans. Relatedly, regulations in 21 CFR 312.2(e) and 312.145 provide for the issuance of Agency guidance to assist respondents who must comply with part 312 and other requirements applicable to the clinical investigation of new drugs and biological products. The intent of the current draft guidance is to increase enrollment of participants who are members of historically underrepresented populations in clinical studies to help improve the strength and generalizability of the evidence for the intended use population. We have developed and issued other guidance documents also intended to enhance the representativeness of clinical trial populations and to improve enrollment of participants from underrepresented populations in clinical trials.¹

As outlined in Section VII of the guidance, DAPs for drug and biological products must be submitted to the IND under which the applicable clinical study is to be conducted and, for applicable submissions, must be submitted in eCTD format through FDA's Electronic Submissions Gateways (ESG and ESG-NextGen). Based on our experience with current IND submissions, we estimate receipt of 240 DAPs annually, for FDA's drug and biological product programs. We assume an average of 100 hours are necessary to prepare and submit a DAP.

As noted in Section VIII of the guidance, the appropriateness of a DAP waiver is case-specific and depends on factors relevant to a specific development program. Sponsors should submit their DAP waiver requests

electronically to the applicable IND for consideration by FDA. We estimate receipt of 5 waiver requests annually for CDER and CBER combined and estimate that each waiver request would require 16 hours to prepare and submit.

Related information collection activities are currently approved under OMB control number 0910–0014. We intend to revise the scope of the information collection to account for DAP submissions and waiver requests and to adjust our estimated burden for the activities in the relevant information collection after evaluating DAP submissions received.

B. Section 520(g)(9) of the FD&C Act (21 U.S.C. 360j(g))—Devices

Regulations that govern the clinical investigation of medical devices are found in part 812 (21 CFR part 812) (investigational device exemptions (IDE)), where regulations in subpart B set forth content elements, and 21 CFR 812.20 specifically requires the submission of an investigational plan. Consistent with Section VII of the draft guidance, a DAP submission should be accompanied by a cover letter and submitted as part of the IDE application for clinical studies of significant risk devices, or for device studies that require development of a Diversity Action Plan but do not require an IDE (see Section III of the guidance), the DAP must be submitted as part of a 510(k), PMA, or De Novo. Currently, CDRH maintains dedicated IT systems intended to facilitate the uniform submission of information by respondents (CDRH Customer Collaboration Portal, <https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal>). Although electronic submission is not mandatory for all device submissions, most forms are completed and submitted electronically.

In estimating the burden per response for a DAP submitted to CDRH, we considered the differences in requirements for the specific development programs (*i.e.*, IDE, IND, PMA, De Novo, and 510(k)) and the content and number of clinical studies that may be included in a submission. The burden to submit a DAP for a device may vary to the extent that submitters have already considered the enrollment of participants from underrepresented populations, as recommended in existing guidance documents related to improving clinical studies.² We assume a range of 16 to 40

hours is necessary to prepare and submit a DAP to CDRH. Based on our experience with current submissions, we estimate 488 DAP submissions annually.

Similarly, requests for waivers from any requirement in part 812 are provided for in § 812.10, and requests for waivers from applicable requirements under § 812.28(a)(1) and (b) are provided for in § 812.28(c). As discussed in Section VIII of the draft guidance, requests to waive the requirement to submit a DAP should be submitted electronically as a stand-alone submission for consideration by FDA. Further, the appropriateness of a waiver is case-specific and depends on factors relevant to a specific development program. We assume a range of 8 to 16 hours is necessary to prepare and submit a DAP waiver, and we assume 5 DAP waiver requests annually.

Under section 520(g)(9)(A)(ii) of the FD&C Act, the sponsor of a device for which submission of an application for an IDE is not required must develop a diversity action plan for any clinical study with respect to the device, except for a device being studied as described in § 812.2(c). Such diversity action plan must be submitted in any 510(k), De Novo, or PMA for such device. Regulations that govern 510(k), De Novo, and PMA are found in 21 CFR parts 807 subpart E, 860 subpart D, and 814 subparts A through E, respectively. Related information collection activities are currently approved under OMB control numbers 0910–0078 (IDE), 0910–0231 (PMA), 0910–0844 (De Novo), and 0910–0120 (510(k)), respectively. We intend to revise the scope of the information collections to account for DAP submissions and waiver requests. We will adjust our estimated burden in these information collections after evaluating the DAP submissions we receive.

The draft guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR part 314 relating to new drug marketing applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 relating to biological product development and marketing applications have been

Device Clinical Studies,” <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/evaluation-and-reporting-age-race-and-ethnicity-specific-data-medical-device-clinical-studies>, and “Evaluation of Sex-Specific Data in Medical Device Clinical Studies,” <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/evaluation-sex-specific-data-medical-device-clinical-studies-guidance-industry-and-food-and-drug>.

¹ “Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial>.

² See *e.g.*, “Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical

approved under OMB control number 0910–0338. The collections of information pertaining to submission of a biologics license application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) have been approved under OMB control number 0910–0718. The collections of information in 21 CFR part 50 for protection of human subjects have been approved under OMB control number 0910–0130. The collections of information pertaining to the Q-Submission program for medical devices have been approved under OMB control number 0910–0756.

Dated: July 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15988 Filed 7–19–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–E–3130 and FDA–2023–E–3135]

Determination of Regulatory Review Period for Purposes of Patent Extension; XENPOZYME; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is correcting a notice that appeared in the *Federal Register* of July 2, 2024. The document announced the determination of the regulatory review period for XENPOZYME (olipudase alfa-rpcp) for purposes of patent extension. The document was published with an incorrect patent number. This notice corrects the patent number.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of Tuesday, July 2, 2024 (89 FR 54829), appearing on pg. 54830, in the first paragraph of the third column, under Section I. Background of the **SUPPLEMENTARY INFORMATION** section, the patent numbers are corrected to read “U.S. Patent Nos. 8,349,319 and 8,658,162.”

Dated: July 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15998 Filed 7–19–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Renewal/for the Advisory Commission on Childhood Vaccines

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act (FACA), the Department of Health and Human Services is hereby giving notice that the charter for the Advisory Commission on Childhood Vaccines (ACCV) has been renewed. The effective date of the renewed charter is July 21, 2024.

FOR FURTHER INFORMATION CONTACT: Pita Gomez, Principal Staff Liaison, Division of Injury Compensation Programs, HRSA, 5600 Fishers Lane, 8W–25A, Rockville, MD 20857; 800–338–2382; or ACCV@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACCV provides advice and recommendations to the Secretary of Health and Human Services (Secretary) on policy, program development, and other matters of significance concerning the activities under 2119 of the Public Health Service Act (the Act) (42 U.S.C. 300aa–19), as enacted by Public Law 99–660, and as subsequently amended. ACCV advises the Secretary on issues related to the implementation of the National Vaccine Injury Compensation Program. Other activities of ACCV include: recommending changes in the Vaccine Injury Table at its own initiative or as the result of the filing of a petition; advising the Secretary in implementing section 2127 of the Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying federal, state, and local programs and activities related to gathering information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b) of the Act; advising the Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions

associated with childhood vaccines; consulting on the development or revision of Vaccine Information Statements; and recommending to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the National Vaccine Injury Compensation Program.

The recharter for ACCV was approved on July 8, 2024. Renewal of the ACCV charter gives authorization for the Commission to operate until July 21, 2026.

A copy of the ACCV charter is available on the ACCV website at <https://www.hrsa.gov/advisory-committees/vaccines/index.html>. A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is <http://www.facadatabase.gov/>.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–16025 Filed 7–19–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before September 20, 2024.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–New–60D and project title for reference, to Sherrette A. Funn, email: Sherrette.Funn@hhs.gov, or call (202) 795–7714 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of

information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Evaluation of the Certified Community Behavioral Health Clinic Demonstration in Accordance with the Bipartisan Safer Communities Act.

Type of Collection: New.

OMB No.: 0990–XXXX.

Abstract: The Office of the Assistant Secretary for Planning and Evaluation (ASPE) at the U.S. Department of Health and Human Services (HHS) is requesting Office of Management and Budget (OMB) approval for new data collection activities to support its evaluation of the Certified Community Behavioral Health Clinic (CCBHC) demonstration program in accordance

with the Bipartisan Safer Communities Act.

Section 223 of the Protecting Access to Medicare Act (Pub. L. 113–93; PAMA) authorized the Certified Community Behavioral Health Clinic (CCBHC) demonstration to allow states to test a different strategy for delivering and reimbursing a comprehensive array of services provided in community behavioral health clinics. The demonstration aims to improve the availability, quality, and outcomes of outpatient services provided in these clinics by establishing a standard definition for CCBHCs and develops a new Medicaid prospective payment system (PPS) in each state that accounts for the total cost of providing nine types of services to all people who seek care. The PPS in each state is designed to provide CCBHCs with the financial support and stability necessary to deliver these required services. The demonstration also aims to incentivize quality through quality bonus payments to clinics and requires CCBHCs to report quality measures and costs. The demonstration was originally authorized for two years.

Need and Proposed Use of the Information: PAMA mandates that HHS submit reports to Congress about the Section 223 demonstration that assess (1) access to community-based mental health services under Medicaid in the area or areas of a state targeted by a demonstration program as compared to other areas of the state, (2) the quality and scope of services provided by certified community behavioral health clinics as compared to community-based mental health services provided in states not participating in a demonstration program and in areas of a demonstration state that are not participating in the demonstration, and (3) the impact of the demonstration on the federal and state costs of a full range of mental health services (including inpatient, emergency, and ambulatory services). The ability of ASPE to provide this information to Congress requires a rigorously designed and independent evaluation of the CCBHC demonstration.

The total annual burden hours estimated for this information collection request are summarized in the table below.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondent	Average burden per response	Total burden hours
Interviews	State officials	75	1	1.5	113
Interviews	CCBHC staff	20	1	1.5	30
Survey	CCBHC staff	231	1	4	924
Focus groups	CCBHC clients	8	1	1.5	12
Total		334	1		1,079

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024–16005 Filed 7–19–24; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS 4040–0018]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before September 20, 2024.

ADDRESSES: Submit your comments to Narmada.Dacherla@hhs.gov

FOR FURTHER INFORMATION CONTACT:

When submitting comments or requesting information, please include the document identifier 4040–0018–60D and project title for reference to Narmada Dacherla, the Reports Clearance Officer, at Narmada.Dacherla@hhs.gov, or call (202) 430–1710.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to

enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: SF–428 Tangible Personal Property Report.

Type of Collection: Extension.

OMB No.: 4040–0018.

Abstract: Reporting on the status of Federally-owned property, including disposition, is necessitated in 2 CFR part 215, the “Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations”, and the “Uniform Administrative Requirements for Grants and Agreements with State and Local Governments”, Additionally, Public Law 106–107, the Federal Financial Assistance Management Improvement Act requires that agencies “simplify Federal financial assistance application

and reporting requirements.” 31 U.S.C. 6101 3.

Agencies are currently using a variety of forms to account for both Federally-owned and grantee owned equipment and property. During the public consultation process mandated by Public Law 106–107, grant recipients requested a standard form to help them

submit appropriate property information when required. The Public Law 106–107 Post Awards Subgroup developed a new standard form, the Tangible Personal Property Report, for submission of the required data. The form consists of the cover sheet (SF–428), three attachments to be used as required: Annual Report, SF–428–A;

Final Report, SF–428–B; Disposition Request/Report, SF–428–C and a Supplemental Sheet, SF–428S to provide detailed individual item information when required. This IC expires on November 30, 2024. *Grants.gov* seeks a three-year clearance of this collection.

ANNUALIZED BURDEN HOUR TABLE

Forms	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
SF–428 Tangible Personal Property Report.	Grant applicants	2,000	1	1	2,000
Total		2,000	1	1	2,000

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024–16051 Filed 7–19–24; 8:45 am]

BILLING CODE 4150–AE–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Metabolism.

Date: August 13, 2024.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301–435–1154, dianne.hardy@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine;

93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 16, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–16019 Filed 7–19–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; NIDA–K Alternate SEP.

Date: August 1, 2024.

Time: 12:00 p.m. to 12:45 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892.

Contact Person: Marisa Srivareerat, Ph.D., Scientific Review Officer, Scientific Review

Branch, Office of Extramural Policy, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 435–1258, marisa.srivareerat@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: July 2, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–16053 Filed 7–19–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Pharmacokinetic Analysis Resource Center.

Date: August 14, 2024.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892.

Contact Person: Meysam Yazdankhah, Ph.D., Scientific Review Officer, National Institutes of Health, National Institute on Drug Abuse, Scientific Review Branch, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 402-6965, meysam.yazdankhah@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: July 16, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-16020 Filed 7-19-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Tolerance and Transplant Immunology.

Date: August 15, 2024.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Philip Owens, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Dr., Bethesda, MD 20892, (301) 594-7394, owensp2@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 16, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-16017 Filed 7-19-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Minority Health and Health Disparities Special Emphasis Panel; Limited Competition: NIMHD Initiative for Improving American Indian and Alaska Native Cancer Outcomes (U19—Clinical Trial Optional).

Date: August 28-29, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, NIMHD, DEM II, Suite 800, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Maryline Laude, Ph.D., Scientific Review Officer, Office of Extramural Research Administration, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Boulevard, Suite 800, Bethesda, MD 20892, (301) 451-9536, mllaudesharp@mail.nih.gov.

Dated: July 16, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-16018 Filed 7-19-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Heart, Lung, and Blood Institute Special Emphasis Panel, Catalyze Product Definition, August 15, 2024, 10:00 a.m. to 2:00 p.m., National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on July 16, 2024, 89 FR 57916.

This meeting is being amended due to a change the meeting date. The meeting will be held on September 13, 2024, from 10:00 a.m. to 2:00 p.m. The meeting is closed to the public.

Dated: July 17, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-16054 Filed 7-19-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2024 Notice of Supplemental Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services (HHS).

ACTION: Notice of intent to award supplemental funding.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) is supporting administrative supplements in scope of the parent award for the 10 eligible grant recipients funded under the FY 2022 Rural Opioid Technical Assistance Regional Centers (ROTA-R), Notice of Funding Opportunity (NOFO) TI-22-012. Each recipient may receive up to \$650,000, for a total of \$6,500,000. This supplemental funding will extend the project period by one-year. The supplemental funding will be used to continue to implement regional centers of excellence to develop and disseminate training and technical assistance addressing opioid and stimulant misuse affecting rural communities. Recipients will continue the identification of model programs, develop and update materials related to

the prevention, harm reduction, treatment, and recovery activities for opioid use disorder (OUD) and/or stimulant use disorder, and ensure that high-quality training is provided.

FOR FURTHER INFORMATION CONTACT:

Humberto Carvalho, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857, telephone 240-276-2974; email: humberto.carvalho@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION:

Funding Opportunity Title: FY 2024 Rural Opioid Technical Assistance Regional Centers (ROTA-R) TI-22-012.

Assistance Listing Number: 93.243.

Authority: Section 509 of the of the Public Health Service Act.

Justification: The 10 SAMHSA-funded ROTA-R grant recipients have the capacity and expertise to provide training and technical assistance addressing opioid and stimulant misuse affecting rural communities. This supplement is to continue providing training and technical assistance in FY 2024 to rural communities.

This is not a formal request for application. Assistance will only be provided to the 10 ROTA-R grant recipients funded in FY 2022 under the Rural Opioid Technical Assistance Regional Centers (ROTA-R) NOFO TI-22-012 based on the receipt of a satisfactory application and associated budget that is approved by a review group.

Dated: July 16, 2024.

Ann Ferrero,

Public Health Analyst.

[FR Doc. 2024-16014 Filed 7-19-24; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2024-0388]

National Offshore Safety Advisory Committee; Vacancy

AGENCY: United States Coast Guard, Department of Homeland Security.

ACTION: Notice; request for application.

SUMMARY: The U.S. Coast Guard is accepting applications to fill one vacancy on the National Offshore Safety Advisory Committee (Committee). This Committee advises the Secretary of Homeland Security, via the Commandant of the U.S. Coast Guard on matters relating to activities directly involved with, or in support of, the

exploration of offshore mineral and energy resources, to the extent that such matters are within the jurisdiction of the U.S. Coast Guard.

DATES: Completed applications must reach the U.S. Coast Guard on or before September 20, 2024.

ADDRESSES: Applications must include: (a) a cover letter expressing interest in an appointment to the National Offshore Safety Advisory Committee, (b) a resume detailing the applicant's relevant experience for the position applied for, and (c) a brief biography. Applications should be submitted via email with subject line "NOSAC Vacancy Application" to Justin.P.Goff@uscg.mil.

FOR FURTHER INFORMATION CONTACT:

Lieutenant Justin Goff, Alternate Designated Federal Officer of the National Offshore Safety Advisory Committee; telephone 571-610-0130 or email at Justin.P.Goff@uscg.mil.

SUPPLEMENTARY INFORMATION: The National Offshore Safety Advisory Committee is a Federal advisory committee. The Committee was established by section 601 of the *Frank LoBiondo Coast Guard Authorization Act of 2018* (Pub. L. 115-282, 132 Stat. 4192), and amended by section 8331 of the *Elijah E. Cummings Coast Guard Authorization Act of 2020* (Pub. L. 116-283, 134 Stat. 4702) and is codified in 46 U.S.C. 15106. The Committee operates under the provisions of the *Federal Advisory Committee Act* and 46 U.S.C. 15109. The Committee provides advice and recommendations to the Secretary of Homeland Security on matters relating to activities directly involved with, or in support of, the exploration of offshore mineral and energy resources, to the extent that such matters are within the jurisdiction of the U.S. Coast Guard.

The Committee is required to meet at least once a year in accordance with 46 U.S.C. 15109(a). We expect the Committee to meet at least twice a year, but it may meet more frequently. The meetings are generally held in Houston, Texas and New Orleans, Louisiana.

Under provisions in 46 U.S.C. 15109(f)(6), if you are appointed as a member of the Committee, your membership term will expire on December 31st of the third full year after the effective date of your appointment. Under provisions in 46 U.S.C. 15109(f)(4), the Secretary of Homeland Security may require an individual to have passed an appropriate security background examination before appointment to the Committee.

All members serve at their own expense and receive no salary or other

compensation from the Federal Government. If you are appointed as a member of the Committee, you will be required to sign a Non-Disclosure Agreement and a Gratuitous Services Agreement.

In this solicitation for Committee Members, we will consider applications for the following position:

One member representing entities engaged in the support, by offshore supply vessels or other vessels, of offshore operations; The member who will fill the position described above will be appointed to represent the interest of their respective groups and viewpoints and are not Special Government Employees as defined in 18 U.S.C. 202(a).

In order for the Department, to fully leverage broad-ranging experience and education, the National Offshore Safety Advisory Committee must be diverse with regard to professional and technical expertise. The Department is committed to pursuing opportunities, consistent with applicable law, to compose a committee that reflects the diversity of the Nation's people.

The U.S. Coast Guard will not consider incomplete or late applications.

Privacy Act Statement

Purpose: To obtain qualified applicants to fill one vacancy on the National Offshore Safety Advisory Committee. When you apply for appointment to the DHS' National Offshore Safety Advisory Committee, DHS collects your name, contact information, and any other personal information that you submit in conjunction with your application. DHS will use this information to evaluate your candidacy for Committee membership. If you are chosen to serve as a Committee member, your name will appear in publicly-available Committee documents, membership lists, and Committee reports.

Authorities: 14 U.S.C. 504; 46 U.S.C. 15106 and 15109; and 18 U.S.C. 202(a), and Department of Homeland Security Delegation No. 00915.

Routine Uses: Authorized U.S. Coast Guard personnel will use this information to consider and obtain qualified candidates to serve on the Committee. Any external disclosures of information within this record will be made in accordance with DHS/ALL-009, Department of Homeland Security Advisory Committee (73 FR 57639, October 3, 2008).

Consequences of Failure to Provide Information: Furnishing this information is voluntary. However, failure to furnish the requested

information may result in your application not being considered for the Committee.

Dated: July 15, 2024.

Jeffrey G. Lantz,

Director of Commercial Regulations and Standards.

[FR Doc. 2024–16036 Filed 7–19–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. CUSTOMS AND BORDER PROTECTION

[CBP Dec. 24–11]

Customs User Fees To Be Adjusted for Inflation in Fiscal Year 2025

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This document announces that U.S. Customs and Border Protection (CBP) is adjusting certain customs user fees and corresponding limitations established by the Consolidated Omnibus Budget Reconciliation Act (COBRA) for Fiscal Year 2025 in accordance with the Fixing America's Surface Transportation Act (FAST Act) as implemented by the CBP regulations.

DATES: The adjusted amounts of customs COBRA user fees and their corresponding limitations set forth in this notice for Fiscal Year 2025 are required as of October 1, 2024.

FOR FURTHER INFORMATION CONTACT: Kari Deppe, Assistant Director—User Fee and Reimbursable Controls Branch, Office of Finance, 317–294–2144, UserFeeNotices@cbp.dhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. Adjustments of Customs COBRA User Fees and Corresponding Limitations for Inflation

On December 4, 2015, the Fixing America's Surface Transportation Act (FAST Act, Pub. L. 114–94) was signed into law. Section 32201 of the FAST Act amended section 13031 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (19 U.S.C. 58c) by requiring the Secretary of the Treasury (Secretary) to adjust certain

customs COBRA user fees and corresponding limitations to reflect certain increases in inflation.

Sections 24.22 and 24.23 of title 19 of the Code of Federal Regulations (19 CFR 24.22 and 24.23) describe the procedures that implement the requirements of the FAST Act. Specifically, paragraph (k) in section 24.22 (19 CFR 24.22(k)) sets forth the methodology to determine the change in inflation as well as the factor by which the fees and limitations will be adjusted, if necessary. The fees and limitations subject to adjustment, which are set forth in Appendix A and Appendix B of part 24, include the commercial vessel arrival fees, commercial truck arrival fees, railroad car arrival fees, private vessel arrival fees, private aircraft arrival fees, commercial aircraft and vessel passenger arrival fees, dutiable mail fees, customs broker permit user fees, barges and other bulk carriers arrival fees, and merchandise processing fees, as well as the corresponding limitations.

B. Determination of Whether an Adjustment Is Necessary for Fiscal Year 2025

In accordance with 19 CFR 24.22, CBP must determine annually whether the fees and limitations must be adjusted to reflect inflation. For Fiscal Year 2025, CBP is making this determination by comparing the average of the Consumer Price Index—All Urban Consumers, U.S. All items, 1982–1984 (CPI-U) for the current year (June 2023–May 2024) with the average of the CPI-U for the comparison year (June 2022–May 2023) to determine the change in inflation, if any. If there is an increase in the CPI-U of greater than one (1) percent, CBP must adjust the customs COBRA user fees and corresponding limitations using the methodology set forth in 19 CFR 24.22(k). Following the steps provided in paragraph (k)(2) of section 24.22, CBP has determined that the increase in the CPI-U between the most recent June to May twelve-month period (June 2023–May 2024) and the comparison year (June 2022–May 2023) is 3.35¹ percent. As the increase in the CPI-U is greater than one (1) percent,

¹ The figures provided in this notice may be rounded for publication purposes only. The calculations for the adjusted fees and limitations were made using unrounded figures, unless otherwise noted.

the customs COBRA user fees and corresponding limitations must be adjusted for Fiscal Year 2025.

C. Determination of the Adjusted Fees and Limitations

Using the methodology set forth in section 24.22(k)(2) of the CBP regulations (19 CFR 24.22(k)), CBP has determined that the factor by which the base fees and limitations will be adjusted is 30.849 percent (base fees and limitations can be found in Appendices A and B to part 24 of title 19). In reaching this determination, CBP calculated the values for each variable found in paragraph (k) of 19 CFR 24.22 as follows:

- The arithmetic average of the CPI-U for June 2023–May 2024, referred to as (A) in the CBP regulations, is 308.815;
- The arithmetic average of the CPI-U for Fiscal Year 2014, referred to as (B), is 236.009;
- The arithmetic average of the CPI-U for the comparison year (June 2022–May 2023), referred to as (C), is 298.952;
- The difference between the arithmetic averages of the CPI-U of the comparison year (June 2022–May 2023) and the current year (June 2023–May 2024), referred to as (D), is 9.863;
- This difference rounded to the nearest whole number, referred to as (E), is 10;
- The percentage change in the arithmetic averages of the CPI-U of the comparison year (June 2022–May 2023) and the current year (June 2023–May 2024), referred to as (F), is 3.35 percent;
- The difference in the arithmetic average of the CPI-U between the current year (June 2023–May 2024) and the base year (Fiscal Year 2014), referred to as (G), is 72.806; and
- Lastly, the percentage change in the CPI-U from the base year (Fiscal Year 2014) to the current year (June 2023–May 2024), referred to as (H), is 30.849 percent.

D. Announcement of New Fees and Limitations

The adjusted amounts of customs COBRA user fees and their corresponding limitations for Fiscal Year 2025, as adjusted by 30.849 percent, and set forth below, are required as of October 1, 2024.

Table 1 provides the fees and limitations found in 19 CFR 24.22 as

adjusted for Fiscal Year 2025, and Table 2 provides the fees and limitations

found in 19 CFR 24.23 as adjusted for Fiscal Year 2025.

TABLE 1—CUSTOMS COBRA USER FEES AND LIMITATIONS FOUND IN 19 CFR 24.22 AS ADJUSTED FOR FISCAL YEAR 2025

19 U.S.C. 58c	19 CFR 24.22	Customs COBRA user fee/limitation	New fee/limitation adjusted in accordance with the FAST Act
(a)(1)	(b)(1)(i)	Fee: Commercial Vessel Arrival Fee	\$571.81
(b)(5)(A)	(b)(1)(ii)	Limitation: Calendar Year Maximum for Commercial Vessel Arrival Fees.	7,792.05
(a)(8)	(b)(2)(i)	Fee: Barges and Other Bulk Carriers Arrival Fee	143.93
(b)(6)	(b)(2)(ii)	Limitation: Calendar Year Maximum for Barges and Other Bulk Carriers Arrival Fees.	1,962.73
(a)(2)	(c)(1)	Fee: Commercial Truck Arrival Fee ^{2 3}	7.20
(b)(2)	(c)(2) and (3)	Limitation: Commercial Truck Calendar Year Prepayment Fee ⁴	130.85
(a)(3)	(d)(1)	Fee: Railroad Car Arrival Fee	10.80
(b)(3)	(d)(2) and (3)	Limitation: Railroad Car Calendar Year Prepayment Fee	130.85
(a)(4)	(e)(1) and (2)	Fee and Limitation: Private Vessel or Private Aircraft First Arrival/Calendar Year Prepayment Fee.	35.98
(a)(6)	(f)	Fee: Dutiable Mail Fee	7.20
(a)(5)(A)	(g)(1)(i)	Fee: Commercial Vessel or Commercial Aircraft Passenger Arrival Fee	7.20
(a)(5)(B)	(g)(1)(ii)	Fee: Commercial Vessel Passenger Arrival Fee (from one of the territories and possessions of the United States).	2.53
(a)(7)	(h)	Fee: Customs Broker Permit User Fee	180.57

TABLE 2—CUSTOMS COBRA USER FEES AND LIMITATIONS FOUND IN 19 CFR 24.23 AS ADJUSTED FOR FISCAL YEAR 2025

19 U.S.C. 58c	19 CFR 24.23	Customs COBRA user fee/limitation	New fee/limitation adjusted in accordance with the FAST Act
(b)(9)(A)(ii)	(b)(1)(i)(A)	Fee: Express Consignment Carrier/Centralized Hub Facility Fee, Per Individual Waybill/Bill of Lading Fee.	\$1.31
(b)(9)(B)(i)	(b)(4)(ii) ⁵	Limitation: Minimum Express Consignment Carrier/Centralized Hub Facility Fee ⁶ .	0.46
(b)(9)(B)(i)	(b)(4)(ii) ⁷	Limitation: Maximum Express Consignment Carrier/Centralized Hub Facility Fee.	1.31
(a)(9)(B)(i); (b)(8)(A)(i) ..	(b)(1)(i)(B) ⁸	Limitation: Minimum Merchandise Processing Fee ⁹	32.71
(a)(9)(B)(i); (b)(8)(A)(i) ..	(b)(1)(i)(B) ¹⁰	Limitation: Maximum Merchandise Processing Fee ^{11 12}	634.62
(b)(8)(A)(ii)	(b)(1)(ii)	Fee: Surcharge for Manual Entry or Release	3.93
(a)(10)(C)(i)	(b)(2)(i)	Fee: Informal Entry or Release; Automated and Not Prepared by CBP Personnel.	2.62
(a)(10)(C)(ii)	(b)(2)(ii)	Fee: Informal Entry or Release; Manual and Not Prepared by CBP Personnel.	7.85
(a)(10)(C)(iii)	(b)(2)(iii)	Fee: Informal Entry or Release; Manual; Prepared by CBP Personnel	11.78
(b)(9)(A)(ii)	(b)(4)	Fee: Express Consignment Carrier/Centralized Hub Facility Fee, Per Individual Waybill/Bill of Lading Fee.	1.31

² The Commercial Truck Arrival Fee is the CBP fee only; it does not include the fiscal year 2025 United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Agricultural and Quarantine Inspection (AQI) User Fee (\$12.40) that is collected by CBP on behalf of USDA to make a total Single Crossing Fee of \$19.60. See 7 CFR 354.3(c) and 19 CFR 24.22(c)(1). Once eighteen Single Crossing Fees have been paid and used for a vehicle identification number (VIN)/vehicle in a Decal and Transponder Online Procurement System (DTOPS) account within a calendar year, the payment required for the nineteenth (and subsequent) single-crossing is only the \$12.40 AQI fee and no longer includes CBP's \$7.20 Commercial Truck Arrival fee (for the remainder of that calendar year). For APHIS AQI User Fee information, see: <https://www.aphis.usda.gov/aqi/fees>.

³ The Commercial Truck Arrival fee, as adjusted by the terms of 19 CFR 24.22(k), is evenly divided

by 0.05, so no further adjustment is made. See 19 CFR 24.22(c)(1).

⁴ The Commercial Truck Calendar Year Prepayment Fee is the CBP fee only; it does not include the fiscal year 2025 AQI Commercial Truck with Transponder Fee (\$622.00) that is collected by CBP on behalf of APHIS to make the total Commercial Vehicle Transponder Annual User Fee of \$752.85.

⁵ Appendix B of part 24 inadvertently included a reference to paragraph (b)(1)(i)(B)(2) of section 24.23. However, the reference should have been to paragraph (b)(4)(ii). CBP intends to publish a future document in the **Federal Register** to make several technical corrections to part 24 of title 19 of the CFR, including corrections to Appendix B of part 24. The technical corrections will also address the inadvertent errors specified in footnotes 7, 8, and 10 below.

⁶ Although the minimum limitation is published, the fee charged is the fee required by 19 U.S.C. 58c(b)(9)(A)(ii).

⁷ Appendix B of part 24 inadvertently included a reference to paragraph (b)(1)(i)(B)(2) of section 24.23. However, the reference should have been to paragraph (b)(4)(ii).

⁸ Appendix B of part 24 inadvertently included a reference to paragraph (b)(1)(i)(B)(1) of section 24.23. However, the reference should have been to paragraph (b)(1)(i)(B).

⁹ Only the limitation is increasing; the *ad valorem* rate of 0.3464 percent remains the same. See 82 FR 50523 (November 1, 2017).

¹⁰ Appendix B of part 24 inadvertently included a reference to paragraph (b)(1)(i)(B)(1) of section 24.23. However, the reference should have been to paragraph (b)(1)(i)(B).

¹¹ Only the limitation is increasing; the *ad valorem* rate of 0.3464 percent remains the same. See 82 FR 50523 (November 1, 2017).

¹² For monthly pipeline entries, see <https://www.cbp.gov/trade/entry-summary/pipeline-monthly-entry-processing/pipeline-line-qa>.

Tables 1 and 2, setting forth the adjusted fees and limitations for Fiscal Year 2025, will also be maintained for the public's convenience on the CBP website at www.cbp.gov.

Troy A. Miller, Senior Official Performing the Duties of the Commissioner, having reviewed and approved this document, has delegated the authority to electronically sign this document to the Director (or Acting Director, if applicable) of the Regulations and Disclosure Law Division of CBP, for purposes of publication in the **Federal Register**.

Robert F. Altneu,

Director, Regulations & Disclosure Law Division, Regulations & Rulings, Office of Trade, U.S. Customs and Border Protection.

[FR Doc. 2024-15990 Filed 7-19-24; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA-2024-0020; OMB No. 1660-0039]

Agency Information Collection Activities: Proposed Collection, Comment Request; National Fire Academy Long-Term Evaluation Form for Supervisors and National Fire Academy Long-Term Evaluation Form for Students/Trainees

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 60-Day notice of extension and request for comments.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on an extension, without change, of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the long-term evaluation forms used to evaluate all National Fire Academy training.

DATES: Comments must be submitted on or before September 20, 2024.

ADDRESSES: To avoid duplicate submissions to the docket, please submit comments at www.regulations.gov under Docket ID FEMA-2024-0020. Follow the instructions for submitting comments.

All submissions received must include the Agency name and Docket

ID. Regardless of the method used to submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at <http://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy and Security Notice that is available via a link on the homepage of www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Dawn Long, Statistician, Federal Emergency Management Agency, United State Fire Administration, National Fire Academy, at (301) 447-1488 or dawn.long@fema.dhs.gov. You may contact the Information Management Division for copies of the proposed collection of information at email address: FEMA-Information-Collections-Management@fema.dhs.gov.

SUPPLEMENTARY INFORMATION: The National Fire Academy is mandated under the Fire Prevention and Control Act of 1974 (Pub. L. 93-498) to provide training and education to the Nation's fire service and emergency service personnel. The state-of-the-art programs offered by the National Fire Academy serve as models of excellence and State and local fire service agencies rely heavily on the curriculum to train their personnel. To maintain the quality of these training programs, it is critical that courses be evaluated after students have had the opportunity to apply the knowledge and skills gained from their training. Information collected from the evaluation forms enables the U.S. Fire Administration and National Fire Academy staff to monitor and recommend changes in course materials, individual subject selection criteria, and to make curriculum-wide reviews and assessments.

Collection of Information

Title: National Fire Academy Long-Term Evaluation Form for Supervisors and National Fire Academy Long-Term Evaluation Form for Students/Trainees.

Type of Information Collection: Extension, without change, of a currently approved information collection.

OMB Number: 1660-0039.

FEMA Forms: FEMA Form FF-USFA-FY-22-118 (formerly 078-0-2), National Fire Academy Long-Term Evaluation Form for Supervisors; FF-USFA-FY-22-119 (formerly 078-0-2A), National Fire Academy Long-Term Evaluation Form for Students/Trainees.

Abstract: The National Fire Academy Long-Term Evaluation Forms will be used to evaluate all National Fire

Academy on-campus resident training courses. Course graduates and their supervisors will be asked to evaluate the impact of the training on both individual job performance and the performance of the fire and emergency response department where the student works. The data provided by students and supervisors is used to update existing National Fire Academy course materials and to develop new courses that reflect the emerging issues and needs of the Nation's fire service.

Affected Public: State, Local or Tribal Government.

Estimated Number of Respondents: 3,000.

Estimated Number of Responses: 3,000.

Estimated Total Annual Burden Hours: 405 hours.

Estimated Total Annual Respondent Cost: \$21,962.

Estimated Respondents' Operation and Maintenance Costs: \$0.

Estimated Respondents' Capital and Start-Up Costs: \$0.

Estimated Total Annual Cost to the Federal Government: \$66,609.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the Agency, including whether the information shall have practical utility; evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Millicent Brown Wilson,

Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

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DEPARTMENT OF HOMELAND SECURITY**U.S. Immigration and Customs Enforcement**

[Docket No. ICEB–2024–0008]

RIN 1653–ZA52

Employment Authorization for Somali F–1 Nonimmigrant Students Experiencing Severe Economic Hardship as a Direct Result of the Current Crisis in Somalia**AGENCY:** U.S. Immigration and Customs Enforcement; Department of Homeland Security.**ACTION:** Notice.

SUMMARY: The Department of Homeland Security (DHS) is suspending certain regulatory requirements for F–1 nonimmigrant students from Somalia who are experiencing severe economic hardship as a direct result of the current crisis in Somalia. The Secretary is providing relief to these students who are in lawful F–1 nonimmigrant status, so the students may request employment authorization, work an increased number of hours while school is in session, and reduce their course load while continuing to maintain their F–1 nonimmigrant status.

DATES: This action covers eligible Somali F–1 nonimmigrant students beginning on September 18, 2024, and ending on March 17, 2026.

FOR FURTHER INFORMATION CONTACT: Sharon Snyder, Unit Chief, Policy and Response Unit, Student and Exchange Visitor Program, MS 5600, U.S. Immigration and Customs Enforcement, 500 12th Street SW, Washington, DC 20536–5600; email: sevp@ice.dhs.gov, telephone: (703) 603–3400. This is not a toll-free number. Program information can be found at <https://www.ice.gov/sevis/>.

SUPPLEMENTARY INFORMATION:**What action is DHS taking under this notice?**

The Secretary is exercising authority under 8 CFR 214.2(f)(9) to temporarily suspend the applicability of certain requirements governing on-campus and off-campus employment for F–1 nonimmigrant students whose country of citizenship is Somalia regardless of country of birth (or individuals having no nationality who last habitually resided in Somalia), who are present in the United States in lawful F–1 nonimmigrant student status on the date of publication of this notice, and who are experiencing severe economic hardship as a direct result of the current

crisis in Somalia. The original notice, which applied to F–1 nonimmigrant students who met certain criteria, including having been lawfully present in the United States in F–1 nonimmigrant status on September 18, 2021, was effective from September 18, 2021, through March 17, 2023. *See* 86 FR 38739 (July 22, 2021). Most recently, DHS issued a notice which applied to F–1 nonimmigrant students who met certain criteria, including having been lawfully present in the United States in F–1 nonimmigrant status on March 13, 2023, was effective from March 18, 2023, through September 17, 2024. *See* 88 FR 15427 (Mar. 13, 2023). Effective with this publication, suspension of the employment limitations is available through March 17, 2026, for those who are in lawful F–1 nonimmigrant status on the date of publication of this notice. DHS will deem an F–1 nonimmigrant student granted employment authorization through this Notice to be engaged in a “full course of study” for the duration of the employment authorization, if the student satisfies the minimum course load set forth in this notice.¹ *See* 8 CFR 214.2(f)(6)(i)(F).

Who is covered by this notice?

This notice applies exclusively to F–1 nonimmigrant students who meet all of the following conditions:

- (1) Are a citizen of Somalia regardless of country of birth (or an individual having no nationality who last habitually resided in Somalia);
- (2) Were lawfully present in the United States on the date of publication of this notice in F–1 nonimmigrant status under section 101(a)(15)(F)(i) of the Immigration and Nationality Act (INA), 8 U.S.C. 1101(a)(15)(F)(i);
- (3) Are enrolled in an academic institution that is Student and Exchange Visitor Program (SEVP)-certified for enrollment for F–1 nonimmigrant students;
- (4) Are currently maintaining F–1 nonimmigrant status; and
- (5) Are experiencing severe economic hardship as a direct result of the current crisis in Somalia.

This notice applies to F–1 nonimmigrant students in an approved private school in kindergarten through

grade 12, public school grades 9 through 12, and undergraduate and graduate education. An F–1 nonimmigrant student covered by this notice who transfers to another SEVP-certified academic institution remains eligible for the relief provided by means of this notice.

Why is DHS taking this action?

DHS is taking action to provide relief to Somali F–1 nonimmigrant students experiencing severe economic hardship due to the current crisis in Somalia. Based on its review of country conditions in Somalia and input received from the U.S. Department of State (DOS), DHS is taking action to allow eligible F–1 nonimmigrant students from Somalia to request employment authorization, work an increased number of hours while school is in session, and reduce their course load while continuing to maintain F–1 nonimmigrant student status.

Somalia faces multiple and competing security threats, including political instability, frequent attacks from international terrorist organizations, like Al-Shabaab, and inter-clan violence.² Additionally, the already bleak and widespread humanitarian situation has been exacerbated by droughts, disease, and general lack of access to essential goods like food, clean water, and medical supplies.³

Security Concerns

Somali President, Hassan Sheikh Mohamud, announced “total war” against Al-Shabaab in 2022 after the group attacked a popular hotel in Somalia’s capital, Mogadishu, in August of that year, killing 21 people.⁴ The Somali government launched a series of counter-insurgency operations against Al-Shabaab, beginning in central Somalia and expanding to southern Somalia.⁵ These operations resulted in

² Humanitarian Action for Children 2024—Somalia, UNICEF, Dec. 28, 2023, available at <https://reliefweb.int/report/somalia/humanitarian-action-children-2024-somalia> (last visited on Mar. 12, 2024).

³ *Id.*

⁴ Al Shabab: Are militant attacks on the rise in Somalia, BBC News, Nov. 2, 2022, available at <https://www.bbc.com/news/world-africa-49908716> (last visited on Mar. 8, 2024).

⁵ Somalia: The Government and al-Shabaab Vie for the Support of Clan Militias, ACLED, Sept. 15, 2023, available at <https://acleddata.com/2023/09/15/somalia-situation-update-september-2023-the-government-and-al-shabaab-vie-over-the-support-of-clan-militias/> (last visited on Mar. 8, 2024). Somalia is divided into 18 administrative regions (including Somaliland and Puntland). These regions are: Gedo, Middle Juba and Lower Juba (in Jubbaland state); Bakool, Bay and Lower Shabelle (in South-West state); Benadir (Banaadir)/Mogadishu (BNA); Hiraaan and Middle Shabelle (in

¹ Because the suspension of requirements under this notice applies throughout an academic term during which the suspension is in effect, DHS considers an F–1 nonimmigrant student who engages in a reduced course load or employment (or both) after this notice is effective to be engaging in a “full course of study,” *see* 8 CFR 214.2(f)(6), and eligible for employment authorization, through the end of any academic term for which such student is matriculated as of March 17, 2026, provided the student satisfies the minimum course load requirements in this notice.

an increase of Al-Shabaab-led attacks throughout Somalia, particularly in Mogadishu.⁶ In October 2023, the head of the African Union Transition Mission in Somalia stated that Al-Shabaab remains the main threat to Somalia and the region.⁷ In addition to the Al-Shabaab-led attacks, the Islamic State of Iraq and the Levant (ISIL)⁸ faction in Somalia continues to function and carry out attacks in the Puntland state.⁹ For example, in February 2023, ISIL-Somalia claimed responsibility for an improvised explosive device incident which targeted a convoy of electoral delegates traveling through the Bari Region of Somalia.¹⁰

Additionally, inter-clan violence remains a security concern in Somalia.¹¹ DOS reported in April 2023 that “[c]lan-based political violence involved

revenge killings and attacks on civilian settlements.”¹² In February 2023, the UN Independent Expert on the Situation of Human Rights in Somalia expressed “alarm at the high number of civilian casualties” in the country, and called “upon all parties involved in the clashes to fully respect their obligations under international law, in particular with regard to the protection of civilians.”¹³ Furthermore, in an October 2023 statement to the UN Security Council, the UN Special Representative for Somalia reported that “Conflicts in Somalia continue to take a heavy toll on civilians. Last year [2022], we saw the largest increase in civilian casualties since 2017. Sadly, early data indicate a similar trend in 2023, with 1,289 civilian casualties recorded so far.”¹⁴

Humanitarian Concerns

In 2024, 6.9 million people are estimated to require humanitarian and protection assistance.¹⁵ In January 2024, the UN Office for the Coordination of Humanitarian Affairs (UNOCHA) reported that civilians in Somalia face multiple risks, including “gender-based violence, kidnapping and abduction, discrimination, family separation, abuse, forced eviction and destruction of properties, presence of mines and other explosive ordnance, civilian death or injury, and child recruitment into armed groups, among others.”¹⁶ Per UNOCHA, between January and October 2023, more than 120,000 people were evicted from privately owned sites, “sixty percent of whom were in Mogadishu.”¹⁷

As of February 2024, UNOCHA reported that there were 3.8 million people displaced in Somalia.¹⁸ In addition, more than 80 percent of the

displaced population in Somalia “are women and children who face significant protection risks.”¹⁹ UNOCHA assessed that “lack of food, drought-reduced access to water was the key driver for displacement in the first half of 2023.”²⁰ UNOCHA further noted that “the number of people newly or re-displaced due to conflict and insecurity in 2023–653,000 people—also stood at an all-time high [for Somalia].”²¹

In its annual report covering 2023, Human Rights Watch assessed that “[t]he humanitarian situation in Somalia remain[s] dire.”²² In a December 2023 report, the World Food Programme (WFP) reported that “Poverty is widespread, with seven out of ten Somalis living on less than USD 1.90 a day.”²³ In the same report, the WFP stated that, “malnutrition is driven by chronic food insecurity, poor infant and young child feeding practices, diseases, limited access to clean water, sanitation, and health.”²⁴ The WFP also noted that “1.5 million children under the age of five are estimated to suffer from acute malnutrition in 2023.”²⁵ Additionally, UNOCHA reported that “4.3 million people—almost one fourth of Somalia’s population [of 17 million²⁶—remain acutely food insecure in 2024.”²⁷

Concurrent disease outbreaks have also impacted “the health and the lives of the crisis-affected populations of Somalia.”²⁸ In February 2024, the Somalia Ministry of Health and Human Services further assessed that “the ongoing cholera outbreak can be attributed to a growing number of people, who lack access to safe water and proper sanitation.”²⁹

¹⁹ Somalia 2024 Humanitarian Needs and Response Plan, UNOCHA, Jan. 30, 2024, available at <https://reliefweb.int/report/somalia/somalia-2024-humanitarian-needs-and-response-plan-hnpr> (last visited on Mar. 12, 2024).

²⁰ *Id.*

²¹ *Id.*

²² Somalia, Human Rights Watch, Jan. 11, 2024, available at <https://www.hrw.org/world-report/2024/country-chapters/somalia#fa7e90> (last visited on Mar. 19, 2024).

²³ Somalia Country Brief, WFP, Dec. 2023, available at <https://reliefweb.int/report/somalia/wfp-somalia-country-brief-december-2023> (last visited on Mar. 12, 2024).

²⁴ *Id.*

²⁵ *Id.*

²⁶ Somalia Country Brief, WFP, Dec. 2023, available at <https://reliefweb.int/report/somalia/wfp-somalia-country-brief-december-2023> (last visited on Mar. 14, 2024).

²⁷ Somalia 2024 Humanitarian Needs and Response Plan, UNOCHA, Jan. 30, 2024, available at <https://reliefweb.int/report/somalia/somalia-2024-humanitarian-needs-and-response-plan-hnpr> (last visited on Mar. 12, 2024).

²⁸ *Id.*

²⁹ Acute Water Diarrhea/Cholera Weekly Epidemiological Report, Ministry of Health and

Hirshabelle state); Galgaduud and Mudug (in Galmudug state); Nugal and Bari (in Puntland state); Sool and Sanaag (contested between Puntland and Somaliland); Togdheer, Awdal and Woogoyi Galbeed (in Somaliland state). Somalia Security Situation, Country of Origin Information Report, European Asylum Support Office, Sept. 2021, available at https://euaa.europa.eu/sites/default/files/publications/2021_09_EASO_COI_Report_Somalia_Security_situation_new_AC.pdf (last visited on Mar. 20, 2024).

⁶ Statement by Special Representative of the Secretary-General Catriona Laing to the Security Council on the Situation on Somalia, United Nations Assistance Mission in Somalia (UNSOM), Oct. 19, 2023, available at <https://reliefweb.int/report/somalia/statement-special-representative-secretary-general-catriona-laing-security-council-situation-somalia> (last visited on Mar. 8, 2024).

⁷ As African Union Mission in Somalia Draws Down, Al-Shabaab Remains Threat to Country, Region, Special Representative Tells Security Council, UN News, Oct. 19, 2023, available at <https://press.un.org/en/2023/sc15457.doc.htm> (last visited on Mar. 8, 2024).

⁸ ISIL is also known as DAESH or DA'ISH, an acronym for its name in Arabic. The group was designated as a Foreign Terrorist Organization on December 17, 2004. See 69 FR 75587 (Dec. 17, 2004); see also, Counter Terrorism Guide-Islamic State of Iraq and the Levant, National Counterterrorism Center, available at <https://www.dni.gov/nctc/groups/isil.html> (last visited on June 3, 2024).

⁹ Somalia: Protection Analysis Update (Feb. 2022), Global Protection Cluster/UN High Commissioner for Refugees, Feb. 9, 2022, available at <https://reliefweb.int/report/somalia/somalia-protection-analysis-update-february-2022> (last visited on Mar. 20, 2024). In Puntland State, both the ISIL or DAESH and Al-Shabaab are present in the region. *Id.* The ISIL-Somalia fighters broke away from Al-Shabaab in 2015. See Foreign Terrorist Organizations: ISIS—SOMALIA, DNI, Sept 2022, available at https://www.dni.gov/nctc/ftos/isis-somalia_fto.html (last visited June 3, 2024).

¹⁰ Situation in Somalia—Report of the Secretary-General (covering Feb–June 2023), UN Security Council, June 15, 2023, available at <https://reliefweb.int/report/somalia/situation-somalia-report-secretary-general-s2023443-enarruzh> (last visited on Mar. 8, 2024).

¹¹ 2022 Country Reports on Human Rights Practices: Somalia, U.S. Department of State, Apr. 12, 2023, available at <https://www.state.gov/reports/2022-country-reports-on-human-rights-practices/somalia/> (last visited on Mar. 12, 2024).

¹² *Id.*

¹³ Situation in Somalia—Report of the Secretary-General (covering Feb–June 2023), UN Security Council, June 15, 2023, available at <https://reliefweb.int/report/somalia/situation-somalia-report-secretary-general-s2023443-enarruzh> (last visited on Mar. 8, 2024).

¹⁴ Statement by Special Representative of the Secretary-General Catriona Laing to the Security Council on the situation in Somalia, UNSOM, Oct. 19, 2023, available at https://unsos.unmissions.org/sites/default/files/19102023_srgs_statement_as_delivered.pdf (last visited on Apr. 24, 2024).

¹⁵ Somalia 2024 Humanitarian Needs and Response Plan, UNOCHA, Jan. 30, 2024, available at <https://reliefweb.int/report/somalia/somalia-2024-humanitarian-needs-and-response-plan-hnpr> (last visited on Mar. 12, 2024).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ Somalia Fact Sheet—Key Figures, UNOCHA, Feb. 29, 2024, available at https://reliefweb.int/report/somalia/somalia-factsheet-key-figures-29-feb-2024?_gl=1*1okgrm2*_ga*OT11NTY0MTI2LjE2ZnQ2NzM4NjU.*_ga_E60ZNX2F68*MTcxMDg2Nzg5MC4xMDMuMS4xNzEwODY5MzQzLjYwLjA1MA (last visited on Mar. 20, 2024).

According to UNOCHA's January 2024 report, humanitarian access remains a challenge in Somalia due to ongoing conflict and insecurity, and inter-clan violence.³⁰ Close to 900,000 people live in areas that are inaccessible to humanitarian aid, and an additional two million people live in areas with significant access constraints due to the presence of non-state armed actors.³¹ Continued attacks on humanitarian workers and infrastructure, and restrictions on movement have exacerbated access and operational challenges.³²

Economic Concerns

According to the World Bank, in 2023, Somalia completed the Heavily Indebted Poor Countries Initiative.³³ After completing the initiative, Somalia "achieved debt service savings of \$4.5 billion and got access to critical additional financial resources that will help Somalia strengthen its economy, reduce poverty, and promote job creation."³⁴ As a result of this, Somalia's external debt fell to less than 6 percent of the GDP by the end of 2023.³⁵ Despite these achievements, the trade deficit was 59 percent of the GDP in 2023, and "real GDP growth has been low and volatile, averaging only 2 percent per year in 2019–23 while real GDP per capita averaged –0.8 percent per year."³⁶ Additionally, the purchasing power of many civilians has been eroded, "increasing the risk of more people falling into poverty."³⁷

As of June 28, 2024, approximately 130 F–1 nonimmigrant students from Somalia are enrolled at SEVP-certified

academic institutions in the United States. Given the extent of the current crisis in Somalia, affected students whose primary means of financial support comes from Somalia may need to be exempt from the normal student employment requirements to continue their studies in the United States. The current crisis has made it unfeasible for many students to safely return to Somalia for the foreseeable future. Without employment authorization, these students may lack the means to meet basic living expenses.

What is the minimum course load requirement to maintain valid F–1 nonimmigrant status under this notice?

Undergraduate F–1 nonimmigrant students who receive on-campus or off-campus employment authorization under this notice must remain registered for a minimum of six semester or quarter hours of instruction per academic term. Undergraduate F–1 nonimmigrant students enrolled in a term of different duration must register for at least one half of the credit hours normally required under a "full course of study." See 8 CFR 214.2(f)(6)(i)(B) and (F). A graduate-level F–1 nonimmigrant student who receives on-campus or off-campus employment authorization under this notice must remain registered for a minimum of three semester or quarter hours of instruction per academic term. See 8 CFR 214.2(f)(5)(v). Nothing in this notice affects the applicability of other minimum course load requirements set by the academic institution.

In addition, an F–1 nonimmigrant student (either undergraduate or graduate) granted on-campus or off-campus employment authorization under this notice may count up to the equivalent of one class or three credits per session, term, semester, trimester, or quarter of online or distance education toward satisfying this minimum course load requirement, unless their course of study is in an English language study program. See 8 CFR 214.2(f)(6)(i)(G). An F–1 nonimmigrant student attending an approved private school in kindergarten through grade 12 or public school in grades 9 through 12 must maintain "class attendance for not less than the minimum number of hours a week prescribed by the school for normal progress toward graduation," as required under 8 CFR 214.2(f)(6)(i)(E). Nothing in this notice affects the applicability of federal and state labor laws limiting the employment of minors.

May an eligible F–1 nonimmigrant student who already has on-campus or off-campus employment authorization benefit from the suspension of regulatory requirements under this notice?

Yes. An F–1 nonimmigrant student who is a Somali citizen, regardless of country of birth (or an individual having no nationality who last habitually resided in Somalia), who already has on-campus or off-campus employment authorization and is otherwise eligible may benefit under this notice, which suspends certain regulatory requirements relating to the minimum course load requirement under 8 CFR 214.2(f)(6)(i) and certain employment eligibility requirements under 8 CFR 214.2(f)(9). Such an eligible F–1 nonimmigrant student may benefit without having to apply for a new Form I–766, Employment Authorization Document (EAD). To benefit from this notice, the F–1 nonimmigrant student must request that their designated school official (DSO) enter the following statement in the remarks field of the student's Student and Exchange Visitor Information System (SEVIS) record, which the student's Form I–20, Certificate of Eligibility for Nonimmigrant (F–1) Student Status, will reflect:

Approved for more than 20 hours per week of [DSO must insert "on-campus" or "off-campus," depending upon the type of employment authorization the student already has] employment authorization and reduced course load under the Special Student Relief authorization from [DSO must insert the beginning date of the notice or the beginning date of the student's employment, whichever date is later] until [DSO must insert either the student's program end date, the current EAD expiration date (if the student is currently authorized for off-campus employment), or the end date of this notice, whichever date comes first].³⁸

Must the F–1 nonimmigrant student apply for reinstatement after expiration of this special employment authorization if the student reduces his or her "full course of study"?

No. DHS will deem an F–1 nonimmigrant student who receives and complies with the employment authorization permitted under this

³⁸ Because the suspension of requirements under this notice applies throughout an academic term during which the suspension is in effect, DHS considers an F–1 nonimmigrant student who engages in a reduced course load or employment (or both) after this notice is effective to be engaging in a "full course of study," see 8 CFR 214.2(f)(6), and eligible for employment authorization, through the end of any academic term for which such student is matriculated as of March 17, 2026, provided the student satisfies the minimum course load requirements in this notice.

Human Services, Federal Government of Somalia, Feb. 19–25, 2024, available at https://reliefweb.int/report/somalia/awdcholera-weekly-epidemiological-report-epi-week-8-19-february-25-february-2024?_gl=1*1nmseu4*_ga*OT1NTY0MTI2LjE2NzQ2NzQ4NjU.*_ga_E60ZNX2F68*MTcxMTM3NTY3My4xMTIuMS4xNzExMzc3NjI2LjQ4LjAuMA (last visited on Mar. 22, 2024).

³⁰ Somalia 2024 Humanitarian Needs and Response Plan, UNOCHA, Jan. 30, 2024, available at <https://reliefweb.int/report/somalia/somalia-2024-humanitarian-needs-and-response-plan-hnrrp> (last visited on Mar. 12, 2024).

³¹ Joint Justice and Corrections Programme: 01 June 2023–30 May 2027, UN Somalia Joint Fund, available at https://mptf.undp.org/sites/default/files/documents/2023-09/unsjif_mptf_prodoc_jjcp_redacted.pdf (last visited May 2, 2024).

³² Somalia 2024 Humanitarian Needs and Response Plan, UNOCHA, Jan. 30, 2024, available at <https://reliefweb.int/report/somalia/somalia-2024-humanitarian-needs-and-response-plan-hnrrp> (last visited on Mar. 12, 2024).

³³ The World Bank in Somalia, The World Bank, Feb. 26, 2024, available at <https://www.worldbank.org/en/country/somalia/overview> (last visited Apr. 19, 2024).

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

notice to be engaged in a “full course of study”³⁹ for the duration of the student’s employment authorization, provided that a qualifying undergraduate level F–1 nonimmigrant student remains registered for a minimum of six semester or quarter hours of instruction per academic term, and a qualifying graduate level F–1 nonimmigrant student remains registered for a minimum of three semester or quarter hours of instruction per academic term. *See* 8 CFR 214.2(f)(5)(v) and (f)(6)(i)(F). Undergraduate F–1 nonimmigrant students enrolled in a term of different duration must register for at least one half of the credit hours normally required under a “full course of study.” *See* 8 CFR 214.2(f)(6)(i)(B) and (F). DHS will not require such students to apply for reinstatement under 8 CFR 214.2(f)(16) if they are otherwise maintaining F–1 nonimmigrant status.

Will an F–2 dependent (spouse or minor child) of an F–1 nonimmigrant student covered by this notice be eligible for employment authorization?

No. An F–2 spouse or minor child of an F–1 nonimmigrant student is not authorized to work in the United States and, therefore, may not accept employment while in F–2 nonimmigrant status, consistent with 8 CFR 214.2(f)(15)(i).

Will the suspension of the applicability of the standard student employment requirements apply to an individual who receives an initial F–1 visa and makes an initial entry into the United States after the effective date of this notice in the Federal Register?

No. The suspension of the applicability of the standard regulatory requirements only applies to certain F–1 nonimmigrant students who meet the following conditions:

- (1) Are a citizen of Somalia regardless of country of birth (or an individual having no nationality who last habitually resided in Somalia);
- (2) Were lawfully present in the United States on the date of publication of this notice in F–1 nonimmigrant status, under section 101(a)(15)(F)(i) of the INA, 8 U.S.C. 1101(a)(15)(F)(i);
- (3) Are enrolled in an academic institution that is SEVP-certified for enrollment of F–1 nonimmigrant students;
- (4) Are maintaining F–1 nonimmigrant status; and
- (5) Are experiencing severe economic hardship as a direct result of the current crisis in Somalia.

An F–1 nonimmigrant student who does not meet all these requirements is ineligible for the suspension of the applicability of the standard regulatory requirements (even if experiencing severe economic hardship as a direct result of the current crisis in Somalia).

Does this notice apply to a continuing F–1 nonimmigrant student who departs the United States after the effective date of this notice in the Federal Register and who needs to obtain a new F–1 visa before returning to the United States to continue an educational program?

Yes. This notice applies to such an F–1 nonimmigrant student, but only if the DSO has properly notated the student’s SEVIS record, which will then appear on the student’s Form I–20. The normal rules for visa issuance remain applicable to a nonimmigrant who needs to apply for a new F–1 visa to continue an educational program in the United States.

Does this notice apply to elementary school, middle school, and high school students in F–1 status?

Yes. However, this notice does not by itself reduce the required course load for F–1 nonimmigrant students from Somalia enrolled in kindergarten through grade 12 at a private school, or grades 9 through 12 at a public high school. Such students must maintain the minimum number of hours of class attendance per week prescribed by the academic institution for normal progress toward graduation, as required under 8 CFR 214.2(f)(6)(i)(E). The suspension of certain regulatory requirements related to employment through this notice is applicable to all eligible F–1 nonimmigrant students regardless of educational level. Eligible F–1 nonimmigrant students from Somalia enrolled in an elementary school, middle school, or high school may benefit from the suspension of the requirement in 8 CFR 214.2(f)(9)(i) that limits on-campus employment to 20 hours per week while school is in session.

On-Campus Employment Authorization

Will an F–1 nonimmigrant student who receives on-campus employment authorization under this notice be authorized to work more than 20 hours per week while school is in session?

Yes. For an F–1 nonimmigrant student covered in this notice, the Secretary is suspending the applicability of the requirement in 8 CFR 214.2(f)(9)(i) that limits an F–1 nonimmigrant student’s on-campus employment to 20 hours per week while school is in session. An eligible F–1

nonimmigrant student has authorization to work more than 20 hours per week while school is in session if the DSO has entered the following statement in the remarks field of the student’s SEVIS record, which will be reflected on the student’s Form I–20:

Approved for more than 20 hours per week of on-campus employment and reduced course load, under the Special Student Relief authorization from [DSO must insert the beginning date of this notice or the beginning date of the student’s employment, whichever date is later] until [DSO must insert the student’s program end date or the end date of this notice, whichever date comes first].⁴⁰

To obtain on-campus employment authorization, the F–1 nonimmigrant student must demonstrate to the DSO that the employment is necessary to avoid severe economic hardship directly resulting from the current crisis in Somalia. An F–1 nonimmigrant student authorized by the DSO to engage in on-campus employment by means of this notice does not need to file any applications with U.S. Citizenship and Immigration Services (USCIS). The standard rules permitting full-time on-campus employment when school is not in session or during school vacations apply, as described in 8 CFR 214.2(f)(9)(i).

Will an F–1 nonimmigrant student who receives on-campus employment authorization under this notice have authorization to reduce the normal course load and still maintain his or her F–1 nonimmigrant student status?

Yes. DHS will deem an F–1 nonimmigrant student who receives on-campus employment authorization under this notice to be engaged in a “full course of study”⁴¹ for the purpose of maintaining their F–1 nonimmigrant student status for the duration of the on-campus employment, if the student satisfies the minimum course load requirement described in this notice, consistent with 8 CFR 214.2(f)(6)(i)(F). However, the authorization to reduce the normal course load is solely for DHS purposes of determining valid F–1 nonimmigrant student status. Nothing in this notice mandates that school officials allow an F–1 nonimmigrant

⁴⁰ Because the suspension of requirements under this notice applies throughout an academic term during which the suspension is in effect, DHS considers an F–1 nonimmigrant student who engages in a reduced course load or employment (or both) after this notice is effective to be engaging in a “full course of study,” *see* 8 CFR 214.2(f)(6), and eligible for employment authorization, through the end of any academic term for which such student is matriculated as of March 17, 2026, provided the student satisfies the minimum course load requirements in this notice.

⁴¹ *See* 8 CFR 214.2(f)(6).

³⁹ *See* 8 CFR 214.2(f)(6).

student to take a reduced course load if the reduction would not meet the academic institution's minimum course load requirement for continued enrollment.⁴²

Off-Campus Employment Authorization
What regulatory requirements does this notice temporarily suspend relating to off-campus employment?

For an F–1 nonimmigrant student covered by this notice, as provided under 8 CFR 214.2(f)(9)(ii)(A), the Secretary is suspending the following regulatory requirements relating to off-campus employment:

(a) The requirement that a student must have been in F–1 nonimmigrant student status for one full academic year to be eligible for off-campus employment;

(b) The requirement that an F–1 nonimmigrant student must demonstrate that acceptance of employment will not interfere with the student's carrying a full course of study;

(c) The requirement that limits an F–1 nonimmigrant student's employment authorization to no more than 20 hours per week of off-campus employment while the school is in session; and

(d) The requirement that the student demonstrate that employment under 8 CFR 214.2(f)(9)(i) is unavailable or otherwise insufficient to meet the needs that have arisen as a result of the unforeseen circumstances.

Will an F–1 nonimmigrant student who receives off-campus employment authorization under this notice have authorization to reduce the normal course load and still maintain F–1 nonimmigrant status?

Yes. DHS will deem an F–1 nonimmigrant student who receives off-campus employment authorization by means of this notice to be engaged in a "full course of study"⁴³ for the purpose of maintaining F–1 nonimmigrant student status for the duration of the student's employment authorization if the student satisfies the minimum course load requirement described in this notice, consistent with 8 CFR 214.2(f)(6)(i)(F). The authorization for a reduced course load is solely for DHS purposes of determining valid F–1 nonimmigrant student status. Nothing in this notice mandates that school officials allow an F–1 nonimmigrant student to take a reduced course load if

such reduced course load would not meet the school's minimum course load requirement.⁴⁴

How may an eligible F–1 nonimmigrant student obtain employment authorization for off-campus employment with a reduced course load under this notice?

An F–1 nonimmigrant student must file a Form I–765, Application for Employment Authorization, with USCIS to apply for off-campus employment authorization based on severe economic hardship directly resulting from the current crisis in Somalia.⁴⁵ Filing instructions are located at <https://www.uscis.gov/i-765>.

Fee considerations. Submission of a Form I–765 currently requires payment of a \$520 fee. An applicant who is unable to pay the fee may submit a completed Form I–912, Request for Fee Waiver, along with the Form I–765, Application for Employment Authorization. See <https://www.uscis.gov/i-912>. The submission must include an explanation about why USCIS should grant the fee waiver and the reason(s) for the inability to pay, and any evidence to support the reason(s). See 8 CFR 106.2 and 106.3.

Supporting documentation. An F–1 nonimmigrant student seeking off-campus employment authorization due to severe economic hardship must demonstrate the following to their DSO:

(1) This employment is necessary to avoid severe economic hardship; and

(2) The hardship is a direct result of the current crisis in Somalia.

If the DSO agrees that the F–1 nonimmigrant student is entitled to receive such employment authorization, the DSO must recommend application approval to USCIS by entering the following statement in the remarks field of the student's SEVIS record, which will then appear on that student's Form I–20:

Recommended for off-campus employment authorization in excess of 20 hours per week and reduced course load under the Special Student Relief authorization from the date of the USCIS authorization noted on Form I–766 until [DSO must insert the program end date or the end date of this notice, whichever date comes first].⁴⁶

⁴⁴ Minimum course load requirement for enrollment in a school must be established in a publicly available document (e.g., catalog, website, or operating procedure), and it must be a standard applicable to all students (U.S. citizens and foreign students) enrolled at the school.

⁴⁵ See 8 CFR 274a.12(c)(3)(iii).

⁴⁶ Because the suspension of requirements under this notice applies throughout an academic term during which the suspension is in effect, DHS considers an F–1 nonimmigrant student who engages in a reduced course load or employment (or

The F–1 nonimmigrant student must then file the properly endorsed Form I–20 and Form I–765 according to the instructions for the Form I–765. The F–1 nonimmigrant student may begin working off campus only upon receipt of the EAD from USCIS.

DSO recommendation. In making a recommendation that an F–1 nonimmigrant student be approved for Special Student Relief, the DSO certifies that:

(a) The F–1 nonimmigrant student is in good academic standing and is carrying a "full course of study"⁴⁷ at the time of the request for employment authorization;

(b) The F–1 nonimmigrant student is a citizen of Somalia, regardless of country of birth (or an individual having no nationality who last habitually resided in Somalia), and is experiencing severe economic hardship as a direct result of the current crisis in Somalia, as documented on the Form I–20;

(c) The F–1 nonimmigrant student has confirmed that the student will comply with the reduced course load requirements of this notice and register for the duration of the authorized employment for a minimum of six semester or quarter hours of instruction per academic term if at the undergraduate level, or for a minimum of three semester or quarter hours of instruction per academic term if the student is at the graduate level;⁴⁸ and

(d) The off-campus employment is necessary to alleviate severe economic hardship to the individual as a direct result of the current crisis in Somalia.

Processing. To facilitate prompt adjudication of the student's application for off-campus employment authorization under 8 CFR 214.2(f)(9)(ii)(C), the F–1 nonimmigrant student should do both of the following:

(a) Ensure that the application package includes the following documents:

(1) A completed Form I–765 with all applicable supporting evidence;

(2) The required fee or properly documented fee waiver request as defined in 8 CFR 106.2 and 106.3; and

(3) A signed and dated copy of the student's Form I–20 with the appropriate DSO recommendation, as previously described in this notice; and

(b) Send the application in an envelope which is clearly marked on the

both) after this notice is effective to be engaging in a "full course of study," see 8 CFR 214.2(f)(6), and eligible for employment authorization, through the end of any academic term for which such student is matriculated as of March 17, 2026, provided the student satisfies the minimum course load requirements in this notice.

⁴⁷ See 8 CFR 214.2(f)(6).

⁴⁸ 8 CFR 214.2(f)(5)(v).

⁴² Minimum course load requirement for enrollment in a school must be established in a publicly available document (e.g., catalog, website, or operating procedure), and it must be a standard applicable to all students (U.S. citizens and foreign students) enrolled at the school.

⁴³ See 8 CFR 214.2(f)(6).

front of the envelope, bottom right-hand side, with the phrase “SPECIAL STUDENT RELIEF.”⁴⁹ Failure to include this notation may result in significant processing delays.

If USCIS approves the student’s Form I-765, USCIS will send the student a Form I-766 EAD as evidence of employment authorization. The EAD will contain an expiration date that does not exceed the end of the granted temporary relief.

Temporary Protected Status (TPS) Considerations

Can an F-1 nonimmigrant student apply for TPS and for benefits under this notice at the same time?

Yes. An F-1 nonimmigrant student who has not yet applied for TPS or for other relief that reduces the student’s course load per term and permits an increased number of work hours per week, such as Special Student Relief,⁵⁰ under this notice has two options.

Under the first option, the F-1 nonimmigrant student may apply for TPS according to the instructions in the USCIS notice designating Somalia for TPS elsewhere in this issue of the **Federal Register**. All TPS applicants must file a Form I-821, Application for Temporary Protected Status, with the appropriate fee (or request a fee waiver). Although not required to do so, if F-1 nonimmigrant students want to obtain a new TPS-related EAD that is valid through March 17, 2026, and to be eligible for automatic EAD extensions that may be available to certain EADs with an A-12 or C-19 category code, they must file Form I-765 and pay the Form I-765 fee (or request a fee waiver). After receiving the TPS-related EAD, an F-1 nonimmigrant student may request that their DSO make the required entry in SEVIS and issue an updated Form I-20, which notates that the nonimmigrant student has been authorized to carry a reduced course load, as described in this notice. As long as the F-1 nonimmigrant student maintains the minimum course load described in this notice, does not otherwise violate their nonimmigrant status, including as provided under 8 CFR 214.1(g), and maintains TPS, then the student maintains F-1 status and TPS concurrently.

Under the second option, the F-1 nonimmigrant student may apply for an EAD under Special Student Relief by

filing Form I-765 with the location specified in the filing instructions. At the same time, the F-1 nonimmigrant student may file a separate TPS application but must submit the Form I-821 according to the instructions provided in the **Federal Register** notice designating Somalia for TPS. If the F-1 nonimmigrant student has already applied for employment authorization under Special Student Relief, they are not required to submit the Form I-765 as part of the TPS application. However, some nonimmigrant students may wish to obtain a TPS-related EAD in light of certain extensions that may be available to EADs with an A-12 or C-19 category code that are not available to the C-3 category under which Special Student Relief falls. The F-1 nonimmigrant student should check the appropriate box when filling out Form I-821 to indicate whether a TPS-related EAD is being requested. Again, as long as the F-1 nonimmigrant student maintains the minimum course load described in this notice and does not otherwise violate the student’s nonimmigrant status, included as provided under 8 CFR 214.1(g), the nonimmigrant will be able to maintain compliance requirements for F-1 nonimmigrant student status while having TPS.

When a student applies simultaneously for TPS and benefits under this notice, what is the minimum course load requirement while an application for employment authorization is pending?

The F-1 nonimmigrant student must maintain normal course load requirements for a “full course of study”⁵¹ unless or until the nonimmigrant student receives employment authorization under this notice. TPS-related employment authorization, by itself, does not authorize a nonimmigrant student to drop below twelve credit hours, or otherwise applicable minimum requirements (e.g., clock hours for non-traditional academic programs). Once approved for a TPS-related EAD and Special Student Relief employment authorization, as indicated by the DSO’s required entry in SEVIS and issuance of an updated Form I-20, the F-1 nonimmigrant student may drop below twelve credit hours, or otherwise applicable minimum requirements (with a minimum of six semester or quarter hours of instruction per academic term if at the undergraduate level, or for a minimum of three semester or quarter hours of instruction per academic term

if at the graduate level). See 8 CFR 214.2(f)(5)(v), (f)(6), and (f)(9)(i) and (ii).

How does a student who has received a TPS-related EAD then apply for authorization to take a reduced course load under this notice?

There is no further application process with USCIS if a student has been approved for a TPS-related EAD. The F-1 nonimmigrant student must demonstrate and provide documentation to the DSO of the direct economic hardship resulting from the current crisis in Somalia. The DSO will then verify and update the student’s record in SEVIS to enable the F-1 nonimmigrant student with TPS to reduce the course load without any further action or application. No other EAD needs to be issued for the F-1 nonimmigrant student to have employment authorization.

Can a noncitizen who has been granted TPS apply for reinstatement of F-1 nonimmigrant student status after the noncitizen’s F-1 nonimmigrant student status has lapsed?

Yes. Regulations permit certain students who fall out of F-1 nonimmigrant student status to apply for reinstatement. See 8 CFR 214.2(f)(16). This provision may apply to students who worked on a TPS-related EAD or dropped their course load before publication of this notice, and therefore fell out of student status. These students must satisfy the criteria set forth in the F-1 nonimmigrant student status reinstatement regulations.

How long will this notice remain in effect?

This notice grants temporary relief until March 17, 2026,⁵² to eligible F-1 nonimmigrant students. DHS will continue to monitor the situation in Somalia. Should the special provisions authorized by this notice need modification or extension, DHS will announce such changes in the **Federal Register**.

Paperwork Reduction Act (PRA)

An F-1 nonimmigrant student seeking off-campus employment authorization due to severe economic hardship

⁴⁹ Guidance for direct filing addresses can be found here: <https://www.uscis.gov/i-765-addresses> (last visited Apr. 29, 2024).

⁵⁰ See DHS Study in the States, Special Student Relief, available at <https://studyinthestates.dhs.gov/students/special-student-relief> (last visited Feb. 28, 2024).

⁵¹ See 8 CFR 214.2(f)(6).

⁵² Because the suspension of requirements under this notice applies throughout an academic term during which the suspension is in effect, DHS considers an F-1 nonimmigrant student who engages in a reduced course load or employment (or both) after this notice is effective to be engaging in a “full course of study,” see 8 CFR 214.2(f)(6), and eligible for employment authorization, through the end of any academic term for which such student is matriculated as of March 17, 2026, provided the student satisfies the minimum course load requirements in this notice.

resulting from the current crisis in Somalia must demonstrate to the DSO that this employment is necessary to avoid severe economic hardship. A DSO who agrees that a nonimmigrant student should receive such employment authorization must recommend an application approval to USCIS by entering information in the remarks field of the student's SEVIS record. The authority to collect this information is in the SEVIS collection of information currently approved by the Office of Management and Budget (OMB) under OMB Control Number 1653-0038.

This notice also allows an eligible F-1 nonimmigrant student to request employment authorization, work an increased number of hours while the academic institution is in session, and reduce their course load while continuing to maintain F-1 nonimmigrant student status.

To apply for employment authorization, certain F-1 nonimmigrant students must complete and submit a currently approved Form I-765 according to the instructions on the form. OMB has previously approved the collection of information contained on the current Form I-765, consistent with the PRA (OMB Control Number 1615-0040). Although there will be a slight increase in the number of Form I-765 filings because of this notice, the number of filings currently contained in the OMB annual inventory for Form I-765 is sufficient to cover the additional filings. Accordingly, there is no further action required under the PRA.

Alejandro Mayorkas,

Secretary, U.S. Department of Homeland Security.

[FR Doc. 2024-15788 Filed 7-19-24; 8:45 am]

BILLING CODE 9111-CB-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2773-24; DHS Docket No. USCIS-2013-0006]

RIN 1615-ZB77

Extension and Redesignation of Somalia for Temporary Protected Status

AGENCY: U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security (DHS).

ACTION: Notice of Temporary Protected Status (TPS) extension and redesignation.

SUMMARY: Through this notice, the Department of Homeland Security (DHS) announces that the Secretary of Homeland Security (Secretary) is extending the designation of Somalia for Temporary Protected Status (TPS) and redesignating Somalia for TPS for 18 months, beginning on September 18, 2024, and ending on March 17, 2026. This extension and redesignation allows Somali nationals (and individuals having no nationality who last habitually resided in Somalia) who have been continuously residing in the United States since July 12, 2024, and who have been continuously physically present in the United States since September 18, 2024, to apply or re-register for TPS.

DATES: *Extension and Redesignation of Designation of Somalia for TPS* begins on September 18, 2024, and will remain in effect for 18 months. For registration instructions, see the Registration Information section below.

FOR FURTHER INFORMATION CONTACT:

- You may contact Rená Cutlip-Mason, Chief, Humanitarian Affairs Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, by mail at 5900 Capital Gateway Drive, Camp Springs, MD 20746, or by phone at 240-721-3000.
- For more information on TPS, including guidance on the registration process and additional information on eligibility, please visit the USCIS TPS web page at <https://www.uscis.gov/tps>. You can find specific information about Somalia's TPS designation by selecting "Somalia" from the menu on the left side of the TPS web page.
- If you have additional questions about TPS, please visit <https://uscis.gov/tools>. Our online virtual assistant, Emma, can answer many of your questions and point you to additional information on our website. If you cannot find your answers there, you may also call our USCIS Contact Center at 800-375-5283 (TTY 800-767-1833).
- Applicants seeking information about the status of their individual cases may check Case Status Online, available on the USCIS website at uscis.gov, or visit the USCIS Contact Center at <https://www.uscis.gov/contactcenter>.
- You can also find more information at local USCIS offices after this notice is published.

SUPPLEMENTARY INFORMATION:

Table of Abbreviations

BIA—Board of Immigration Appeals
CFR—Code of Federal Regulations
DHS—U.S. Department of Homeland Security

DoS—U.S. Department of State
EAD—Employment Authorization Document
FNC—Final Nonconfirmation
Form I-131—Application for Travel Document
Form I-765—Application for Employment Authorization
Form I-797—Notice of Action
Form I-821—Application for Temporary Protected Status
Form I-9—Employment Eligibility Verification
Form I-912—Request for Fee Waiver
Form I-94—Arrival/Departure Record
FR—Federal Register
Government—U.S. Government
IER—U.S. Department of Justice, Civil Rights Division, Immigrant and Employee Rights Section
IJ—Immigration Judge
INA—Immigration and Nationality Act
SAVE—USCIS Systematic Alien Verification for Entitlements Program
Secretary—Secretary of Homeland Security
TPS—Temporary Protected Status
TTY—Text Telephone
USCIS—U.S. Citizenship and Immigration Services
U.S.C.—United States Code

Registration Information

Extension of Designation of Somalia for TPS: The 18-month extension of the designation of Somalia for TPS begins on September 18, 2024, and will remain in effect for 18 months, ending on March 17, 2026. The extension allows existing TPS beneficiaries to retain TPS through March 17, 2026, if they otherwise continue to meet the eligibility requirements for TPS. Existing TPS beneficiaries who wish to extend their status through March 17, 2026, must re-register during the 60-day re-registration period described in this notice.

Re-registration: The 60-day re-registration period for existing beneficiaries runs from July 22, 2024, through September 20, 2024. (*Note:* It is important for re-registrants to timely re-register and apply for new Employment Authorization Documents (EADs) during the re-registration period and not to wait until their EADs expire, as delaying re-registration and the filing of EAD renewal applications could result in gaps in their employment authorization documentation.)

Redesignation of Somalia for TPS: The 18-month redesignation of Somalia for TPS begins on September 18, 2024, and will remain in effect for 18 months, ending on March 17, 2026. The redesignation allows individuals who do not currently have TPS to apply for TPS during the initial registration period described under the first-time registration information in this notice. In addition to demonstrating continuous residence in the United States since July 12, 2024, and meeting other eligibility

criteria, initial applicants for TPS under this designation must demonstrate that they have been continuously physically present in the United States since September 18, 2024, the effective date of this redesignation of Somalia for TPS.

First-time Registration: The initial registration period for new applicants under the Somalia TPS redesignation begins on July 22, 2024, and will remain in effect through March 17, 2026.

Purpose of This Action (TPS)

Through this notice, DHS sets forth procedures necessary for nationals of Somalia (or individuals having no nationality who last habitually resided in Somalia) to (1) re-register for TPS and apply to renew their EAD with USCIS or (2) submit an initial registration application under the redesignation and apply for an EAD.

Re-registration is limited to individuals who have previously registered for TPS under the prior designation of Somalia and whose applications have been granted. If you do not re-register properly within the 60-day re-registration period, USCIS may withdraw your TPS following appropriate procedures. *See* 8 CFR 244.14.

For individuals who have already been granted TPS under Somalia's designation, the 60-day re-registration period runs from July 22, 2024, through September 20, 2024. USCIS will issue new EADs with a March 17, 2026, expiration date to eligible Somali TPS beneficiaries who timely re-register and apply for EADs. Given the time frames involved with processing TPS re-registration applications, DHS recognizes that not all re-registrants may receive a new EAD before their current EAD expires. Accordingly, through this **Federal Register** notice, DHS automatically extends through September 17, 2025, the validity of certain EADs previously issued under the TPS designation of Somalia. As proof of continued employment authorization through September 17, 2025, TPS beneficiaries can show their EAD with the notation A-12 or C-19 under Category and a "Card Expires" date of September 17, 2024, or March 17, 2023. This notice explains how TPS beneficiaries and their employers may determine if an EAD is automatically extended and how this affects the Form I-9, Employment Eligibility Verification, E-Verify, and USCIS Systematic Alien Verification for Entitlements (SAVE) processes.

Individuals who have an Application for Temporary Protected Status (Form I-821) for Somalia or Application for Employment Authorization (Form I-

765) that was still pending as of July 22, 2024, do not need to file either application again. If USCIS approves an individual's pending Form I-821, USCIS will grant the individual TPS through March 17, 2026. Similarly, if USCIS approves a pending TPS-related Form I-765, USCIS will issue the individual a new EAD that will be valid through the same date.

Under the redesignation, individuals who currently do not have TPS may submit an initial application during the initial registration period that runs from July 22, 2024, through the full length of the redesignation period ending March 17, 2026. In addition to demonstrating continuous residence in the United States since July 12, 2024, and meeting other eligibility criteria, initial applicants for TPS under this redesignation must demonstrate that they have been continuously physically present in the United States since September 18, 2024,¹ the effective date of this redesignation of Somalia, before USCIS may grant them TPS. DHS estimates that approximately 4,300 individuals may become newly eligible for TPS under the redesignation of Somalia.

What is Temporary Protected Status (TPS)?

- TPS is a temporary immigration status granted to eligible nationals of a foreign state designated for TPS under the INA, or to eligible individuals without nationality who last habitually resided in the designated foreign state, regardless of their country of birth.

- During the TPS designation period, TPS beneficiaries are eligible to remain in the United States, may not be removed, and are authorized to obtain EADs if they continue to meet the requirements of TPS.

- TPS beneficiaries may also apply for and be granted travel authorization as a matter of DHS discretion.

- To qualify for TPS, beneficiaries must meet the eligibility standards at INA section 244(c)(1)–(2), 8 U.S.C. 1254a(c)(1)–(2).

- When the Secretary terminates a foreign state's TPS designation, beneficiaries return to one of the following:

¹ The "continuous physical presence" date is the effective date of the most recent TPS designation of the country, which is either the publication date of the designation announcement in the **Federal Register** or a later date established by the Secretary. The "continuous residence" date is any date established by the Secretary when a country is designated (or sometimes redesignated) for TPS. *See* INA sec. 244(b)(2)(A) (effective date of designation); 244(c)(1)(A)(i–ii) (continuous residence and continuous physical presence date requirements); 8 U.S.C. 1254a(b)(2)(A); 1254a(c)(1)(A)(i–ii).

- The same immigration status or category that they maintained before TPS, if any (unless that status or category has since expired or terminated); or

- Any other lawfully obtained immigration status or category they received while registered for TPS, if it is still valid beyond the date their TPS terminates.

When was Somalia designated for TPS?

Somalia was initially designated on September 16, 1991, on the basis of extraordinary and temporary conditions that prevented Somalis from returning in safety.² Somalia's designation for TPS has been consecutively extended since its initial designation. Additionally, Somalia was redesignated for TPS in 2001, again based on extraordinary and temporary conditions.³ In 2012, Somalia was again redesignated for TPS on the basis of extraordinary and temporary conditions and on the additional basis of ongoing armed conflict.⁴ Somalia was redesignated on these same bases in 2021.⁵ Most recently, DHS extended and redesignated Somalia for 18 months, from March 18, 2023, through September 17, 2024, again on the basis of ongoing armed conflict and extraordinary and temporary conditions.⁶

What authority does the Secretary have to extend the designation of Somalia for TPS?

Section 244(b)(1) of the INA, 8 U.S.C. 1254a(b)(1), authorizes the Secretary, after consultation with appropriate agencies of the U.S. Government, to designate a foreign state (or part thereof) for TPS if the Secretary determines that certain country conditions exist.⁷ The

² *See Designation of Nationals of Somalia for Temporary Protected Status*, 56 FR 46804 (Sept. 16, 1991).

³ *See Extension and Redesignation of Somalia under Temporary Protected Status Program*, 66 FR 46288 (Sept. 4, 2001).

⁴ *See Extension and Redesignation of Somalia for Temporary Protected Status*, 77 FR 25723 (May 1, 2012).

⁵ *See Extension and Redesignation of Somalia for Temporary Protected Status*, 86 FR 38744 (July 22, 2021).

⁶ *See Extension and Redesignation of Somalia for Temporary Protected Status*, 88 FR 15434 (March 13, 2023).

⁷ INA section 244(b)(1) ascribes this power to the Attorney General. Congress transferred this authority from the Attorney General to the Secretary of Homeland Security. *See* Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135 (2002). The Secretary may designate a country (or part of a country) for TPS on the basis of ongoing armed conflict such that returning would pose a serious threat to the personal safety of the country's nationals and habitual residents, environmental disaster (including an epidemic), or extraordinary and temporary conditions in the country that prevent the safe return of the country's nationals.

decision to designate any foreign state (or part thereof) is a discretionary decision, and there is no judicial review of any determination with respect to the designation, termination, or extension of a designation. *See* INA sec. 244(b)(5)(A), 8 U.S.C. 1254a(b)(5)(A). The Secretary, in their discretion, may then grant TPS to eligible nationals of that foreign state (or individuals having no nationality who last habitually resided in the designated foreign state). *See* INA sec. 244(a)(1)(A), 8 U.S.C. 1254a(a)(1)(A).

At least 60 days before the expiration of a foreign state's TPS designation or extension, the Secretary, after consultation with appropriate U.S. Government agencies, must review the conditions in the foreign state designated for TPS to determine whether they continue to meet the conditions for the TPS designation. *See* INA sec. 244(b)(3)(A), 8 U.S.C. 1254a(b)(3)(A). If the Secretary determines that the foreign state continues to meet the conditions for TPS designation, the designation will be extended for an additional period of 6 months or, in the Secretary's discretion, 12 or 18 months. *See* INA sec. 244(b)(3)(A), (C), 8 U.S.C. 1254a(b)(3)(A), (C). If the Secretary determines that the foreign state no longer meets the conditions for TPS designation, the Secretary must terminate the designation. *See* INA sec. 244(b)(3)(B), 8 U.S.C. 1254a(b)(3)(B).

What is the Secretary's authority to redesignate Somalia for TPS?

In addition to extending an existing TPS designation, the Secretary, after consultation with appropriate Government agencies, may redesignate a country (or part thereof) for TPS. *See* INA sec. 244(b)(1), 8 U.S.C. 1254a(b)(1); *see also* INA sec. 244(c)(1)(A)(i), 8 U.S.C. 1254a(c)(1)(A)(i) (requiring that "the alien has been continuously physically present in the United States since the effective date of the most recent designation of that state") (emphasis added).⁸

For environmental disaster-based designations, certain other statutory requirements must be met, including that the foreign government must request TPS. A designation based on extraordinary and temporary conditions cannot be made if the Secretary finds that allowing the country's nationals to remain temporarily in the United States is contrary to the U.S. national interest. INA sec. 244(b)(1); 8 U.S.C. 1254a(b)(1).

⁸ The extension and redesignation of TPS for Somalia is one of several instances in which the Secretary and, before the establishment of DHS, the Attorney General, have simultaneously extended a country's TPS designation and redesignated the country for TPS. *See, e.g., Extension and Redesignation of Haiti for Temporary Protected Status*, 76 FR 29000 (May 19, 2011); *Extension and Re-designation of Temporary Protected Status for*

When the Secretary designates or redesignates a country for TPS, the Secretary also has the discretion to establish the date from which TPS applicants must demonstrate that they have been "continuously resid[ing]" in the United States. *See* INA sec. 244(c)(1)(A)(ii), 8 U.S.C.

1254a(c)(1)(A)(ii). The Secretary has determined that the "continuous residence" date for applicants for TPS under the redesignation of Somalia will be July 12, 2024. Initial applicants for TPS under this redesignation must also show they have been "continuously physically present" in the United States since September 18, 2024, which is the effective date of the Secretary's redesignation of Somalia. *See* INA sec. 244(c)(1)(A)(i), 8 U.S.C. 1254a(c)(1)(A)(i). For each initial TPS application filed under the redesignation, USCIS cannot make the final determination of whether the applicant has met the "continuous physical presence" requirement until September 18, 2024, the effective date of this redesignation for Somalia.

USCIS, however, will issue employment authorization documentation, as appropriate, during the registration period in accordance with 8 CFR 244.5(b).

Why is the Secretary extending the TPS designation for Somalia and simultaneously redesignating Somalia for TPS through March 17, 2026?

DHS has reviewed country conditions in Somalia. Based on the review, including input received from the Department of State (DoS) and other U.S. Government agencies, the Secretary has determined that an 18-month TPS extension is warranted because the ongoing armed conflict and extraordinary and temporary conditions supporting Somalia's TPS designation remain. The Secretary has further determined that redesignating Somalia for TPS under INA sec. 244(b)(3)(C), 8 U.S.C. 1254a(b)(3)(C) is warranted and is changing the "continuous residence" and "continuous physical presence" dates that applicants must meet to be eligible for TPS.

Overview

Somalia continues to experience widespread insecurity due to armed conflict involving state and non-state actors. The ongoing conflict, as well as other violence, has exposed civilian populations to ill-treatment, abuse, and displacement. Additionally, Somalia

Sudan, 69 FR 60168 (Oct. 7, 2004); *Extension of Designation and Redesignation of Liberia Under Temporary Protected Status Program*, 62 FR 16608 (Apr. 7, 1997).

recently experienced intense flooding that damaged land and infrastructure, impeded efforts to address food insecurity, and exacerbated disease outbreaks. Significant barriers to the delivery of humanitarian aid persist.

Armed Conflict and Violence

The terrorist group Al-Shabaab continues to pose a significant threat to Somalia's security,⁹ frequently conducting attacks using improvised explosive devices¹⁰ and 107mm rockets.¹¹ Since Somalia's last TPS redesignation in March 2023, the government has launched a series of counter-insurgency operations against the group¹² with support from local clan militias.¹³ While the counter-insurgency has had some success,¹⁴ efforts have been hampered by heavy rains and flooding, and Al-Shabaab activities have increased.¹⁵ The Islamic State in Iraq and the Levant faction in Somalia, a separate terrorist group, carries out attacks primarily in Puntland state.¹⁶ The group has clashed with Al-Shabaab over territory and control of smuggling routes.¹⁷

Violence, including armed conflict, has harshly impacted civilians, with nearly 1,300 civilian casualties recorded

⁹ As African Union Mission in Somalia Draws Down, Al-Shabaab Remains Threat to Country, Region, Special Representative Tells Security Council, UN News, Oct. 19, 2023, available at <https://press.un.org/en/2023/sc15457.doc.htm> (last visited May 24, 2024).

¹⁰ Situation in Somalia—Report of the Secretary-General (S/2024/129), UN Security Council, February 2, 2024, pg. 3, Available at <https://reliefweb.int/report/somalia/situation-somalia-report-secretary-general-s2024129-enarruzh> (last visited June 5, 2024).

¹¹ Situation in Somalia, UN Security Council, Oct. 13, 2023, pg. 3, available at <https://www.ecoi.net/en/file/local/2101912/N2328915.pdf>.

¹² Somalia: The Government and al-Shabaab Vie for the Support of Clan Militias, Armed Conflict Location & Event Data Project (ACLED), Sept. 15, 2023, available at <https://acleddata.com/2023/09/15/somalia-situation-update-september-2023-the-government-and-al-shabaab-vie-over-the-support-of-clan-militias/> (last visited May 24, 2024).

¹³ Somalia: Al Shabaab Strikes Back at Local Administrators, ACLED, Oct. 20, 2023, <https://acleddata.com/2023/10/20/somalia-situation-update-october-2023-al-shabaab-strikes-back-at-local-administrators/> (last visited May 24, 2024).

¹⁴ *Id.*

¹⁵ Situation in Somalia—Report of the Secretary-General, UN Security Council (S/2024/129), February 2, 2024, pg. 3, Available at <https://reliefweb.int/report/somalia/situation-somalia-report-secretary-general-s2024129-enarruzh> (last visited June 5, 2024).

¹⁶ Letter dated 29 September 2023 from the Chair of the Security Council Committee pursuant to resolution 751 (1992) concerning Al-Shabaab addressed to the President of the Security Council (S/2023/724), UN Security Council, Oct. 2, 2023, pg. 3, available at <https://www.ecoi.net/en/file/local/2100037/N2325555.pdf>.

¹⁷ *Id.* at 17.

between January and September 2023.¹⁸ Al-Shabaab subjects civilians to numerous human rights abuses, including summary executions, religiously and politically motivated killings, disappearances, physical abuse, and other inhuman treatment.¹⁹ More than 3.8 million people have been displaced due to a combination of conflict, natural disasters, and other factors.²⁰ The number of people displaced due to security issues in 2023 is estimated to be 653,000, the highest figure on record for Somalia.²¹

Women and children face particular risks. Somalia has one of the world's highest rates of violence against women and girls, and such violence is more prevalent among women and girls in internally displaced persons camps.²² Al-Shabaab has raided schools, madrassas, and mosques, and has harassed and coerced clan elders and family members to recruit and train children to carry out violence.²³ They have used children in direct hostilities, including as suicide bombers and as human shields.²⁴ In late 2023, the UN reported a 67 percent increase in the number of grave violations against children compared to earlier in the year, with Al-Shabaab responsible for the majority of the violations.²⁵

In addition to the threat posed by terrorist groups, clan-related violence remains a security concern.²⁶ Clan

militias, including some affiliated with the Somali government, reportedly have engaged in physical abuse and other ill-treatment, and the government has limited capacity and will to hold them accountable.²⁷ Clan militias have also “carried out indiscriminate deadly attacks and, in some cases, targeted killings of civilians.”²⁸

Humanitarian Assistance and Access

As of 2024, an estimated 6.9 million people—around half of Somalia's population²⁹—require humanitarian assistance.³⁰ Humanitarian access remains a challenge due to ongoing conflict, insecurity, and violence.³¹ Close to 900,000 people live in areas that are inaccessible, and an additional two million people live in areas with significant access constraints due to the presence of non-state armed actors.³² Continued attacks on humanitarian workers and infrastructure, as well as restrictions on movement, have exacerbated access and operational challenges.³³ Many impediments stem from Al-Shabaab's targeted disruption efforts, which include attacks against state security forces along main supply routes, seizure of certain routes, limitations on the movement of goods, and deliberate limitation of access by humanitarian organizations.³⁴

Environmental Impacts, Health, and Food Security

Climate change impacts from droughts and floods pose severe hazards

to the country.³⁵ In 2023, Somalia faced “the worst drought in decades followed by the most extensive floods in generations within the span of just a few months.”³⁶ The flooding has affected more than 2.5 million people, and has caused significant damage to agriculture, livestock, and critical infrastructure.³⁷ Floods damaged at least 1.5 million hectares (3.7 million acres) of farmland and led to an increase in waterborne diseases, including acute watery diarrhea and cholera.³⁸

Disease outbreaks are attributed to lack of access to clean water, sanitation, and hygiene; low vaccination rates; and lack of healthcare infrastructure.³⁹ The flooding has further hampered access to health services.⁴⁰ Somalia has faced “uninterrupted” cholera transmission since 2022, and reported more than 18,300 suspected cases and 46 deaths in 2023, with the majority being among children under the age of five.⁴¹

Food insecurity in Somalia persists due to residual drought-like conditions, flooding, protracted conflict and insecurity, and high food prices.⁴² An estimated 4.3 million people are “acutely food insecure.”⁴³ Malnutrition due to food insecurity is compounded by disease, limited access to clean water, and limited sanitation and health resources.⁴⁴ An estimated 1.5 million

³⁵ Somalia, Climate Change Knowledge Portal, available at <https://climateknowledgeportal.worldbank.org/country/somalia#:~:text=Climate%20plays%20a%20key%20role,severe%20hazards%20to%20the%20country> (last visited May 1, 2024).

³⁶ Humanitarian Needs and Response Plan, UNOCHA, Jan. 30, 2024, pg. 8, available at <https://reliefweb.int/report/somalia/somalia-2024-humanitarian-needs-and-response-plan-hnrrp> (last visited May 28, 2024).

³⁷ *Id.*

³⁸ Situation in Somalia—Report of the Secretary General, UN Security Council, Feb. 12, 2024, pg. 6, available at <https://reliefweb.int/report/somalia/situation-somalia-report-secretary-general-s2024129-enarruzh> (last visited May 28, 2024).

³⁹ Humanitarian Needs and Response Plan Somalia, UNOCHA, Jan. 30, 2024, pg. 13, available at <https://reliefweb.int/report/somalia/somalia-2024-humanitarian-needs-and-response-plan-hnrrp> (last visited May 28, 2024).

⁴⁰ *Id.* at 47.

⁴¹ Country analysis—Somalia, ACAPS, available at <https://www.acaps.org/en/countries/somalia#> (last visited June 5, 2024).

⁴² WFP Somalia Country Brief, January 2024, World Food Programme (WFP), Mar. 1, 2024, available at <https://reliefweb.int/report/somalia/wfp-somalia-country-brief-january-2024> (last visited May 28, 2024).

⁴³ Humanitarian Needs and Response Plan Somalia, UNOCHA, Jan. 30, 2024, pg. 12, available at <https://reliefweb.int/report/somalia/somalia-2024-humanitarian-needs-and-response-plan-hnrrp> (last visited May 28, 2024).

⁴⁴ WFP Somalia Country Brief, December 2023, WFP, Jan. 28, 2024, pg. 1, available at <https://reliefweb.int/report/somalia/wfp-somalia-country-brief-december-2023> (last visited May 28, 2024).

¹⁸ Humanitarian Needs and Response Plan Somalia, UNOCHA, Jan. 30, 2024, pg. 8, available at <https://reliefweb.int/report/somalia/somalia-2024-humanitarian-needs-and-response-plan-hnrrp> (last visited May 28, 2024).

¹⁹ 2023 Country Reports on Human Rights Practices: Somalia, U.S. Dep't of State, p. 2, Apr. 22, 2024, available at https://www.state.gov/wp-content/uploads/2024/02/528267_SOMALIA-2023-HUMAN-RIGHTS-REPORT.pdf.

²⁰ Over 1 million people internally displaced in record time, UNHCR, May 24, 2023, available at <https://www.unhcr.org/news/press-releases/over-1-million-people-internally-displaced-somalia-record-time> (last visited June 5, 2024).

²¹ Somalia, UNICEF, Jan. 2024, pg. 2, available at <https://www.unicef.org/media/154536/file/2024-HAC-Somalia-revised-January.pdf>.

²² Hassan Abdullahi Dahie, Mohamed Maalim Dakane, and Bashir Said Hassan, Prevalence, patterns, and determinants of gender-based violence among women and girls in IDP camps, Mogadishu-Somalia, *Journal of Migration and Health*, June 23, 2023, available at <https://pubmed.ncbi.nlm.nih.gov/37637858/> (last visited Apr. 5, 2024).

²³ 2023 Country Reports on Human Rights Practices: Somalia, U.S. Dep't of State, p. 16, Apr. 22, 2024, available at https://www.state.gov/wp-content/uploads/2024/02/528267_SOMALIA-2023-HUMAN-RIGHTS-REPORT.pdf.

²⁴ *Id.*

²⁵ Situation in Somalia, UN Security Council, Oct. 13, 2023, pg. 10, available at <https://reliefweb.int/report/somalia/situation-somalia-report-secretary-general-s2023758-enarruzh> (last visited May 24, 2024).

²⁶ 2023 Country Reports on Human Rights Practices: Somalia, U.S. Dep't of State, p. 3, Apr. 22,

2024, available at https://www.state.gov/wp-content/uploads/2024/02/528267_SOMALIA-2023-HUMAN-RIGHTS-REPORT.pdf.

²⁷ *Id.* at 4–5.

²⁸ *Id.* at 3.

²⁹ Somalia, CIA World Factbook, available at <https://www.cia.gov/the-world-factbook/countries/somalia/#people-and-society> (last visited Apr. 4, 2024). The Factbook estimates Somalia's 2023 population to be around 12.7 million. Other estimates place Somalia's population at around 17 or 18 million.

³⁰ Humanitarian Needs and Response Plan Somalia, UNOCHA, Jan. 30, 2024, pg. 9, available at <https://reliefweb.int/report/somalia/somalia-2024-humanitarian-needs-and-response-plan-hnrrp> (last visited May 28, 2024).

³¹ *Id.* at 30.

³² Joint Justice and Corrections Programme: 01 June 2023–30 May 2027, UN Somalia Joint Fund, pg. 5, available at https://mptf.undp.org/sites/default/files/documents/2023-09/unsjif_mptf_prodod_jjcp_redacted.pdf.

³³ Humanitarian Needs and Response Plan Somalia, UNOCHA, Jan. 30, 2024, pg. 30, available at <https://reliefweb.int/report/somalia/somalia-2024-humanitarian-needs-and-response-plan-hnrrp> (last visited May 28, 2024).

³⁴ 2023 Country Reports on Human Rights Practices: Somalia, U.S. Dep't of State, pp. 17–18 Apr. 22, 2024, available at https://www.state.gov/wp-content/uploads/2024/02/528267_SOMALIA-2023-HUMAN-RIGHTS-REPORT.pdf.

children under the age of five suffered from acute malnutrition in 2023.⁴⁵

Based on this review and after consultation with appropriate U.S. Government agencies, the Secretary has determined that:

- The conditions supporting Somalia's designation for TPS continue to be met. *See* INA sec. 244(b)(3)(A) and (C), 8 U.S.C. 1254a(b)(3)(A) and (C).
- There continues to be an ongoing armed conflict in Somalia and, due to such conflict, requiring the return to Somalia of Somali nationals (or individuals having no nationality who last habitually resided in Somalia) would pose a serious threat to their personal safety. *See* INA sec. 244(b)(1)(A), 8 U.S.C. 1254a(b)(1)(A).
- There continue to be extraordinary and temporary conditions in Somalia that prevent Somali nationals (or individuals having no nationality who last habitually resided in Somalia) from returning to Somalia in safety, and it is not contrary to the national interest of the United States to permit Somali TPS beneficiaries to remain in the United States temporarily. *See* INA sec. 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C).
- The designation of Somalia for TPS should be extended for an 18-month period, beginning on September 18, 2024, and ending on March 17, 2026. *See* INA sec. 244(b)(3)(C), 8 U.S.C. 1254a(b)(3)(C).
- Due to the conditions described above, Somalia should be simultaneously extended and redesignated for TPS beginning on September 18, 2024, and ending on March 17, 2026. *See* INA sec. 244(b)(1)(A) and (C) and (b)(2), 8 U.S.C. 1254a(b)(1)(A) and (C) and (b)(2).
- For the redesignation, the Secretary has determined that TPS applicants must demonstrate that they have continuously resided in the United States since July 12, 2024.
- Initial TPS applicants under the redesignation must demonstrate that they have been continuously physically present in the United States since September 18, 2024, the effective date of the redesignation of Somalia for TPS.
- There are approximately 600 current Somalia TPS beneficiaries who are eligible to re-register for TPS under the extension.
- It is estimated that approximately 4,300 additional individuals may be eligible for TPS under the redesignation of Somalia. This population includes Somali nationals in the United States in

nonimmigrant status or without immigration status.

Notice of the Designation of Somalia for TPS

By the authority vested in me as Secretary under INA section 244, 8 U.S.C. 1254a, I have determined, after consultation with the appropriate U.S. Government agencies, the statutory conditions supporting Somalia's designation for TPS on the basis on ongoing armed conflict and extraordinary and temporary conditions are met, and it is not contrary to the national interest of the United States to allow Somali TPS beneficiaries to remain in the United States temporarily. *See* INA sec. 244(b)(1)(A), 8 U.S.C. 1254a(b)(1)(A) and INA sec. 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C). On the basis of this determination, I am simultaneously extending the existing designation of Somalia for TPS for 18 months, beginning on September 18, 2024, and ending on March 17, 2026, and redesignating Somalia for TPS for the same 18-month period. *See* INA sec. 244(b)(1) and (b)(2); 8 U.S.C. 1254a(b)(1), and (b)(2).

Alejandro N. Mayorkas,
Secretary, U.S. Department of Homeland Security.

Eligibility and Employment Authorization for TPS

Required Application Forms and Application Fees To Register or Re-Register for TPS

To register or re-register for TPS based on the designation of Somalia, you must submit a Form I-821. If you are submitting an initial TPS application, you must pay the application fee for Form I-821 (or request a fee waiver, which you may submit on Form I-912, Request for Fee Waiver). If you are filing an application to re-register for TPS, you do not need to pay the application fee. Whether you are registering as an initial applicant or re-registering, you are required to pay the biometric services fee. If you cannot pay the biometric services fee, you may ask USCIS to waive the fee. Please see additional information under the "Biometric Services Fee" section of this notice.

TPS beneficiaries are eligible for an Employment Authorization Document (EAD), which proves their authorization to work in the United States. You are not required to submit Form I-765 or have an EAD to be granted TPS, but see below for more information if you want an EAD to use as proof that you can work in the United States.

Individuals who have a Somalia TPS application (Form I-821) that was still

pending as of July 22, 2024, do not need to file the application again. If USCIS approves an individual's Form I-821, USCIS will grant the individual TPS through March 17, 2026.

For more information on the application forms and fees for TPS, please visit the USCIS TPS web page at <https://www.uscis.gov/tps>. Fees for the Form I-821, the Form I-765, and biometric services are also described in 8 CFR 106.2 and the fee waiver-related regulations in 8 CFR 106.3. In addition, USCIS Form G-1055, Fee Schedule, provides the current fees required for the Form I-821 and Form I-765 for both initial TPS applicants and existing TPS beneficiaries who are re-registering.

How can TPS beneficiaries obtain an Employment Authorization Document (EAD)?

Everyone must provide their employer with documentation showing that they have the legal right to work in the United States. TPS beneficiaries are eligible to obtain an EAD, which proves their legal right to work. If you want to obtain an EAD, you must file Form I-765 and pay the Form I-765 fee (or request a fee waiver, which you may submit on Form I-912). TPS applicants may file this form with their TPS application, or separately later, if their TPS application is still pending or has been approved.

Beneficiaries with a Somalia TPS-related Form I-765 that was still pending as of July 22, 2024, do not need to file the application again. If USCIS approves a pending TPS-related Form I-765, USCIS will issue the individual a new EAD that will be valid through March 17, 2026.

Refiling an Initial TPS Registration Application After Receiving a Denial of a Fee Waiver Request

If USCIS denies your fee waiver request, you can resubmit your TPS application. The fee waiver denial notice will contain specific instructions about resubmitting your application.

Filing Information

USCIS offers the option to applicants for TPS under Somalia's designation to file Form I-821 and related requests for EADs online or by mail. However, if you request a fee waiver, you must submit your application by mail. When filing a TPS application, you can also request an EAD by submitting a completed Form I-765 with your Form I-821.

Online filing: Form I-821 and Form I-765 are available for concurrent filing

⁴⁵ Somalia Country Brief, WFP, Dec. 2023, pg. 1, available at <https://reliefweb.int/report/somalia/wfp-somalia-country-brief-december-2023> (last visited May 28, 2024).

online.⁴⁶ To file these forms online, you must first create a USCIS online account.⁴⁷

Mail filing: Mail your completed Form I-821; Form I-765, if applicable; Form I-912, if applicable; and supporting

documentation to the proper address in Table 1—Mailing Addresses.

TABLE 1—MAILING ADDRESSES

If you send your paper application via:	Then mail your application to:
U.S. Postal Service (USPS)	USCIS, Attn: TPS Somalia, P.O. Box 6943, Chicago, IL 60680-6943.
FedEx, UPS, or DHL deliveries	USCIS, Attn: TPS Somalia (Box 6943), 131 South Dearborn Street, 3rd Floor, Chicago, IL 60603-5517.

If you were granted TPS by an immigration judge (IJ) or the Board of Immigration Appeals (BIA) and you wish to request an EAD, please file online or mail your Form I-765 to the appropriate address in Table 1. If you file online, please include the fee. If you file by mail, please include the fee or fee waiver request. When you request an EAD based on an IJ or BIA grant of TPS, please include with your application a copy of the order from the IJ or BIA granting you TPS. This will help us verify your grant of TPS and process your application.

Supporting Documents

The filing instructions for Form I-821 list all the documents you need to

establish eligibility for TPS. You may also find information on the acceptable documentation and other requirements for applying (also called registering) for TPS on the USCIS website at <https://www.uscis.gov/tps> under “Somalia.”

Travel

TPS beneficiaries may also apply for and be granted travel authorization as a matter of discretion. You must file for travel authorization if you wish to travel outside of the United States. If USCIS grants travel authorization, it gives you permission to leave the United States and return during a specific period. To request travel authorization, you must file Form I-131, available at <https://www.uscis.gov/i-131>. You may file Form

I-131 together with your Form I-821 or separately. When you file Form I-131, you must:

- Select Item Number 1.d. in Part 2 on the Form I-131; and
- Submit the fee for Form I-131, or request a fee waiver, which you may submit on Form I-912.

If you are filing Form I-131 together with Form I-821, send your forms to the address listed in Table 1. If you are filing Form I-131 separately based on a pending or approved Form I-821, send your form to the address listed in Table 2 and include a copy of Form I-797 for your approved or pending Form I-821.

TABLE 2—MAILING ADDRESSES

If you are . . .	Mail to . . .
Filing Form I-131 together with Form I-821	The address provided in Table 1.
Filing Form I-131 based on a pending or approved Form I-821, and you are using the U.S. Postal Service (USPS):	USCIS, Attn: I-131 TPS, P.O. Box 660167, Dallas, TX 75266-0867.
You must include a copy of the Notice of Action (Form I-797C or I-797) showing USCIS accepted or approved your Form I-821	
Filing Form I-131 based on a pending or approved Form I-821, and you are using FedEx, UPS, or DHL:	USCIS, Attn: I-131 TPS, 2501 S State Hwy. 121, Business, Ste. 400, Lewisville, TX 75067.
You must include a copy of the Notice of Action (Form I-797C or I-797) showing USCIS accepted or approved your Form I-821	

Biometric Services Fee for TPS

Biometrics (such as fingerprints) are required for all applicants, in addition to a biometric services fee. As previously stated, if you cannot pay the biometric services fee, you may request a fee waiver, which you may submit on Form I-912. For more information on the application forms and fees for TPS, please visit the USCIS TPS web page at <https://www.uscis.gov/tps>. USCIS may require you to visit an Application Support Center to have your biometrics collected. For additional information on the USCIS biometric screening process, please see the USCIS Customer Profile Management Service Privacy Impact Assessment, available at <https://www.uscis.gov/privacy>.

www.dhs.gov/publication/dhsuscispia-060-customer-profile-management-service-cpms.

General Employment-Related Information for TPS Applicants and Their Employers

How can I obtain information on the status of my TPS application and EAD request?

To get case status information about your TPS application, as well as the status of your TPS-based EAD request, you can check Case Status Online at <https://uscis.gov> or visit the USCIS Contact Center at <https://www.uscis.gov/contactcenter>. If you still need assistance, you may ask a question

about your case online at <https://egov.uscis.gov/e-request/Intro.do> or call the USCIS Contact Center at 800-375-5283 (TTY 800-767-1833).

Am I eligible to receive an automatic extension of my current EAD through September 17, 2025, through this Federal Register notice?

Yes. Regardless of your country of birth, if you currently have a Somalia TPS-based EAD with the notation A-12 or C-19 under Category and a “Card Expires” date of September 17, 2024, or March 17, 2023, this **Federal Register** notice automatically extends your EAD through September 17, 2025. Although this **Federal Register** notice

⁴⁶ Find information about online filing at “Forms Available to File Online,” <https://www.uscis.gov/file-online/forms-available-to-file-online>.

⁴⁷ https://myaccount.uscis.gov/users/sign_up.

automatically extends your EAD through September 17, 2025, you must timely re-register for TPS in accordance with the procedures described in this **Federal Register** notice to maintain your TPS and avoid possible gaps in your employment authorization documentation.

When hired, what documentation may I show to my employer as evidence of identity and employment authorization when completing Form I-9?

You can find the Lists of Acceptable Documents on Form I-9, Employment Eligibility Verification, as well as the Acceptable Documents web page at <https://www.uscis.gov/i-9-central/acceptable-documents>. Employers must complete Form I-9 to verify the identity and employment authorization of all new employees. Within three business days of hire, employees must present acceptable documents to their employers as evidence of identity and employment authorization to satisfy Form I-9 requirements.

You may present any document from List A (which provides evidence of both identity and employment authorization) or one document from List B (which provides evidence of your identity) together with one document from List C (which provides evidence of employment authorization), or you may present an acceptable receipt as described in these lists. Employers may not reject a document based on a future expiration date. You can find additional information about Form I-9 on the I-9 Central web page at <https://www.uscis.gov/I-9Central>. An EAD is an acceptable document under List A. See the section “How do my employer and I complete Form I-9 using my automatically extended EAD for a new job?” of this **Federal Register** notice for more information. If your EAD states A-12 or C-19 under Category and has a “Card Expires” date of September 17, 2024, or March 17, 2023, this **Federal Register** notice extends it automatically, and you may choose to present your EAD to your employer as proof of identity and employment eligibility for Form I-9 through September 17, 2025, unless your TPS has been withdrawn or your request for TPS has been denied. Your country of birth noted on the EAD does not have to reflect the TPS-designated country of Somalia for you to be eligible for this extension.

What documentation may I present to my employer for Form I-9 if I am already employed but my current TPS-related EAD is set to expire?

Even though we have automatically extended your EAD, your employer is

required by law to ask you about your continued employment authorization. Your employer may need to reexamine your automatically extended EAD to check the “Card Expires” date and Category code if your employer did not keep a copy of your EAD when you initially presented it. Once your employer has reviewed the “Card Expires” date and Category code, they should update the EAD expiration date in Section 2 of Form I-9. See the section “What updates should my current employer make to Form I-9 if my EAD has been automatically extended?” of this **Federal Register** notice for more information. You may show this **Federal Register** notice to your employer to explain what to do for Form I-9 and to show that USCIS has automatically extended your EAD through September 17, 2025, but you are not required to do so. The last day of the automatic EAD extension is September 17, 2025. Before you start work on September 18, 2025, your employer is required by law to reverify your employment authorization on Form I-9. By that time, you must present any document from List A or any document from List C on Form I-9 Lists of Acceptable Documents, or an acceptable List A or List C receipt described in these lists to reverify employment authorization.

Your employer may not specify which List A or List C document you must present and cannot reject an acceptable receipt.

If I have an EAD based on another immigration status, can I obtain a new TPS-based EAD?

Yes, if you are eligible for TPS, you can obtain a new TPS-based EAD, even if you already have an EAD or work authorization based on another immigration status. If you want to obtain a new TPS-based EAD valid through March 17, 2026, you must file Form I-765 and pay the associated fee (unless USCIS grants your fee waiver request).

Can my employer require that I provide any other documentation to complete Form I-9, such as evidence of my status, proof of my Somali citizenship, or a Form I-797C showing that I registered for TPS?

No. When completing Form I-9, employers must accept any documentation you choose to present from the Form I-9 Lists of Acceptable Documents that reasonably appears to be genuine and that relates to you, or an acceptable List A, List B, or List C receipt. Employers may not request other documentation, such as proof of Somali citizenship or proof of

registration for TPS, when completing Form I-9 for new hires or reverifying the employment authorization of current employees. If you present an EAD that USCIS has automatically extended, employers should accept it as a valid List A document if the EAD reasonably appears to be genuine and to relate to you. Refer to the “Note to Employees” section of this **Federal Register** notice for important information about your rights if your employer rejects lawful documentation, requires additional documentation, or otherwise discriminates against you based on your citizenship or immigration status or your national origin.

How do my employer and I complete Form I-9 using my automatically extended EAD for a new job?

When using an automatically extended EAD to complete Form I-9 for a new job before September 18, 2025:

1. For Section 1, you should:
 - a. Check “A noncitizen authorized to work until” and enter September 17, 2025, as the “expiration date”; and
 - b. Enter your USCIS number or A-Number where indicated. (Your EAD or other document from DHS will have your USCIS number or A-Number printed on it; the USCIS number is the same as your A-Number without the A prefix.)
2. For Section 2, employers should:
 - a. Determine whether the EAD is auto-extended by ensuring it is in category A-12 or C-19 and has a “Card Expires” date of September 17, 2024, or March 17, 2023;
 - b. Write in the document title;
 - c. Enter the issuing authority;
 - d. Provide the document number; and
 - e. Write September 17, 2025, as the expiration date.

Before the start of work on September 18, 2025, employers must reverify the employee’s employment authorization on Form I-9.

What updates should my current employer make to Form I-9 if my EAD has been automatically extended?

If you presented a TPS-related EAD that was valid when you first started your job and USCIS has now automatically extended your EAD, your employer may need to re-examine your current EAD if they do not have a copy of the EAD on file. Your employer should determine whether your EAD is automatically extended by ensuring that it contains Category A-12 or C-19 and has a “Card Expires” date of September 17, 2024, or March 17, 2023. Your employer may not rely on the country of birth listed on the card to determine

whether you are eligible for this extension.

If your employer determines that USCIS has automatically extended your EAD, they should update Section 2 of your previously completed Form I-9 as follows:

1. Write EAD EXT and September 17, 2025, as the last day of the automatic extension in the Additional Information field; and
2. Initial and date the correction.

Note: This is not considered a reverification. Employers do not reverify the employee until either the automatic extension has ended, or the employee presents a new document to show continued employment authorization, whichever is sooner. By September 18, 2025, when the employee's automatically extended EAD has expired, employers are required by law to reverify the employee's employment authorization on Form I-9.

If I am an employer enrolled in E-Verify, how do I verify a new employee whose EAD has been automatically extended?

Employers may create a case in E-Verify for a new employee by entering the number from the Document Number field on Form I-9 into the document number field in E-Verify. Employers should enter September 17, 2025, as the expiration date for an EAD that has been extended under this **Federal Register** notice.

If I am an employer enrolled in E-Verify, what do I do when I receive a "Work Authorization Documents Expiring" alert for an automatically extended EAD?

E-Verify automated the verification process for TPS-related EADs that are automatically extended. If you have an employee who provided a TPS-related EAD when they first started working for you, you will receive a "Work Authorization Documents Expiring" case alert when the auto-extension period for this EAD is about to expire. Before this employee starts work on September 18, 2025, you must reverify their employment authorization on Form I-9. Employers may not use E-Verify for reverification.

Note to All Employers

Employers are reminded that the laws requiring proper employment eligibility verification and prohibiting unfair immigration-related employment practices remain in full force. This **Federal Register** notice does not supersede or in any way limit applicable employment verification rules and policy guidance, including those rules setting forth reverification

requirements. For general questions about the employment eligibility verification process, employers may call USCIS at 888-464-4218 (TTY 877-875-6028) or email USCIS at I-9Central@uscis.dhs.gov. USCIS accepts calls and emails in English and many other languages. For questions about avoiding discrimination during the employment eligibility verification process (Form I-9 and E-Verify), employers may call the U.S. Department of Justice, Civil Rights Division, Immigrant and Employee Rights Section (IER) Employer Hotline at 800-255-8155 (TTY 800-237-2515). IER offers language interpretation in many languages. Employers may also email IER at IER@usdoj.gov or get more information online at <https://www.justice.gov/ier>.

Note to Employees

For general questions about the employment eligibility verification process, employees may call USCIS at 888-897-7781 (TTY 877-875-6028) or email USCIS at I-9Central@uscis.dhs.gov. USCIS accepts calls and emails in English, Spanish and many other languages. Employees or job applicants may also call the U.S. Department of Justice, Civil Rights Division, Immigrant and Employee Rights Section (IER) Worker Hotline at 800-255-7688 (TTY 800-237-2515) for information regarding employment discrimination based on citizenship, immigration status, or national origin, including discrimination related to Form I-9 and E-Verify. The IER Worker Hotline provides language interpretation in many languages.

To comply with the law, employers must accept any document or combination of documents from the Lists of Acceptable Documents if the documentation reasonably appears to be genuine and to relate to the employee, or an acceptable List A, List B, or List C receipt as described in these lists. Employers may not require extra or additional documentation other than what is required to complete Form I-9. Further, employers participating in E-Verify who receive an E-Verify case result of "Tentative Nonconfirmation" (mismatch) must promptly inform employees of the mismatch and give these employees an opportunity to resolve the mismatch. A mismatch means that the information entered into E-Verify from Form I-9 differs from records available to DHS.

Employers may not terminate, suspend, delay training, withhold or lower pay, or take any adverse action against an employee because of a mismatch while the case is still pending with E-Verify. A Final Nonconfirmation

(FNC) case result occurs if E-Verify cannot confirm an employee's employment eligibility. An employer may terminate employment based on a case result of FNC. Work-authorized employees who receive an FNC may call USCIS for assistance at 888-897-7781 (TTY 877-875-6028). For more information about E-Verify-related discrimination or to report an employer for discrimination in the E-Verify process based on citizenship, immigration status, or national origin, contact IER's Worker Hotline at 800-255-7688 (TTY 800-237-2515). Additional information about proper nondiscriminatory Form I-9 and E-Verify procedures is available on the IER website at <https://www.justice.gov/ier> and the USCIS and E-Verify websites at <https://www.uscis.gov/i-9-central> and <https://www.e-verify.gov>.

Note Regarding Federal, State, and Local Government Agencies (Such as Departments of Motor Vehicles)

For Federal purposes, if you present an automatically extended EAD referenced in this **Federal Register** notice, you do not need to show any other document, such as a Form I-797C, Notice of Action, reflecting receipt of a Form I-765 EAD renewal application or this **Federal Register** notice, to prove that you qualify for this extension. While Federal Government agencies must follow the guidelines laid out by the Federal Government, State and local government agencies establish their own rules and guidelines when granting certain benefits. Each state may have different laws, requirements, and determinations about what documents you need to provide to prove eligibility for certain benefits. Whether you are applying for a Federal, State, or local government benefit, you may need to provide the government agency with documents that show you are a TPS beneficiary or applicant, show you are authorized to work based on TPS or other status, or that may be used by DHS to determine if you have TPS or another immigration status. Examples of such documents are:

- Your current EAD with a TPS category code of A-12 or C-19, even if your country of birth noted on the EAD does not reflect the TPS-designated country of Somalia;
- Your Form I-94, Arrival/Departure Record;
- Your Form I-797, Notice of Action, reflecting approval of your Form I-765; or
- Form I-797 or Form I-797C, Notice of Action, reflecting approval or receipt of a past or current Form I-821, if you received one from USCIS.

Check with the government agency requesting documentation about which document(s) the agency will accept.

Some state and local government agencies use SAVE to confirm the current immigration status of applicants for public benefits. While SAVE can verify that an individual has TPS or a pending TPS application, each agency's procedures govern whether they will accept an unexpired EAD, Form I-797, Form I-797C, or Form I-94. If an agency accepts the type of TPS-related document you present, such as an EAD, the agency should accept your automatically extended EAD, regardless of the country of birth listed on the EAD. It may assist the agency if you:

a. Give the agency a copy of the relevant **Federal Register** notice showing the extension of TPS-related documentation in addition to your recent TPS-related document with your A-Number, USCIS number, or Form I-94 number;

b. Explain that SAVE will be able to verify the continuation of your TPS using this information; and

c. Ask the agency to initiate a SAVE query with your information and follow through with additional verification steps, if necessary, to get a final SAVE response verifying your TPS.

You can also ask the agency to look for SAVE notices or contact SAVE if they have any questions about your immigration status or automatic extension of TPS-related documentation. In most cases, SAVE provides an automated electronic response to benefit-granting agencies within seconds, but occasionally verification can be delayed.

You can check the status of your SAVE verification by using CaseCheck at <https://www.uscis.gov/save/save-casecheck>. CaseCheck is a free service that lets you follow the progress of your SAVE verification case using your date of birth and one immigration identifier number (such as your A-Number, USCIS number, or Form I-94 number) or Verification Case Number. If an agency has denied your application based solely or in part on a SAVE response, the agency must allow you to appeal the decision in accordance with the agency's procedures. If the agency has received and acted on or will act on a SAVE verification and you do not believe the SAVE response is correct, the SAVE website, <https://www.uscis.gov/save>, has detailed information on how to correct or update your immigration record, make an appointment, or submit a written request to correct records.

[FR Doc. 2024-15829 Filed 7-19-24; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-7080-N-32]

30-Day Notice of Proposed Information Collection: License for the Use of Personally Identifiable Information Protected Under the Privacy Act of 1974, OMB Control No.: 2528-0297

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* August 21, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. Interested persons are also invited to submit comments regarding this proposal and comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Anna Guido, Clearance Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410-5000; email PaperworkReductionActOffice@hud.gov.

FOR FURTHER INFORMATION CONTACT:

Anna P. Guido, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410; email: PaperworkReductionActOffice@hud.gov, telephone (202) 402-5535. This is not a toll-free number, HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit: <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on March 12, 2024 at 89 FR 17864.

A. Overview of Information Collection

Title of Information Collection: License for the Use of Personally Identifiable Information Protected Under the Privacy Act of 1974.

OMB Approval Number: 2528-0297.

Type of Request: Reinstatement with change of a previously approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: The United States Department of Housing and Urban Development (HUD) collects and maintains personally identifiable information on tenants in public and assisted housing, the confidentiality of which is protected by the Privacy Act of 1974 (5 U.S.C. 552a). On occasion, HUD shares this information with contractors and grantees, subject to stringent requirements to protect these households from unauthorized disclosure of information. The purpose for sharing is to further policy-relevant research on the effectiveness of HUD programs.

HUD may, under the terms of the Routine Uses published in its various System of Records Notices, share these data with parties whom HUD has awarded contracts, grants, service agreements, or other agreements. HUD has shared data with contractors and grantees, but it has not until now shared data under service agreements because it has not until now proposed a legal form for effectuating such an agreement. HUD does not wish to limit access to the information to parties that have received specific funding to carry out a study through a grant or contract. Instead, HUD proposes to share the data with legitimate research organizations that have conceived policy-relevant analyses and that are able and willing to protect the data from unauthorized disclosure. The legal form for the proposed service agreement is herein called a "license."

HUD wishes to continue making the data available for statistical, research, or evaluation purposes to organizations and qualified and capable of research and analysis consistent with the statistical, research, or evaluation

purposes for which the data were provided or are maintained, but only if the data are used and protected in

accordance with the terms and condition stated in the license, upon receipt of such assurance of

qualification and capability, and it is agreed by the organization requesting such information and HUD.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hours per response	Annual burden hours	Hourly cost per response	Annual cost
Application for Data License	15	1	15	1	15	\$47.31	\$709.65
Data License Agreement	15	1	15	1	15	57.63	864.45
Affidavit of Nondisclosure	45	1	45	0.25	11.25	23.41	263.36
Data Destruction Certification Form	6	1	6	0.25	1.5	48.85	73.28
Total Burden Hours	81				42.75		1,910.74

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

(5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Anna P. Guido,

*Department Reports Management Office,
Office of Policy Development and Research,
Chief Data Officer.*

[FR Doc. 2024-16055 Filed 7-19-24; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-6191-N-06]

Section 8 Housing Choice Vouchers: Additional Implementation Guidance of the Housing Choice Voucher Mobility Demonstration for Awarded PHAs

AGENCY: Office of the Assistant Secretary for Public and Indian Housing (PIH), Department of Housing and Urban Development (HUD).

ACTION: Notice.

SUMMARY: On July 15, 2020, HUD published a notice (Implementation Notice) implementing the Housing Choice Voucher (HCV) mobility demonstration (demonstration) authorized by the Consolidated Appropriations Act, 2019. The demonstration was later renamed the Community Choice Demonstration (CCD). Through the Implementation Notice, HUD made available up to \$50,000,000 to participating Public Housing Agencies (PHAs) to implement housing mobility programs. On April 30, 2021, HUD announced its selection of PHAs that would participate in the demonstration. Those PHAs received \$45.7 million in total funding under that award. On April 4, 2022, HUD issued "Section 8 Housing Choice Vouchers: Implementation of the Housing Choice Voucher Mobility Demonstration for Awarded PHAs, Supplementary Notice for Demonstration Participants" (Supplementary Notice) which supplemented the Implementation Notice and described additional policies and flexibilities for PHAs selected to participate in the demonstration. Building on the implementation experience since the Supplementary Notice, HUD has identified further policies and flexibilities necessary to ensure effective PHA participation in the demonstration. Additionally, this

notice provides requirements related to recapture and reallocation of funds.

FOR FURTHER INFORMATION CONTACT: Ryan Jones, Director, Housing Voucher Management and Operations Division, Department of Housing and Urban Development, 451 Seventh Street SW, Room 4214, Washington, DC 20410, telephone number (202) 402-2677. (This is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>. HUD encourages submission of questions about the demonstration to be sent to: HCVmobilitydemonstration@hud.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On July 15, 2020, HUD published the Implementation Notice for the demonstration authorized by the Consolidated Appropriations Act, 2019. (85 FR 42890) Through that Implementation Notice, HUD made available up to \$50,000,000 to participating PHAs throughout the country to implement housing mobility programs by offering housing mobility-related services to increase the number of voucher families with children living in opportunity areas. On April 30, 2021, HUD announced that nine lead PHAs would participate in the demonstration and those PHAs were awarded new housing choice vouchers, referred to as Mobility Demonstration Vouchers (MDVs) and housing mobility-related services funding. HUD also announced that an additional four PHAs that applied in partnership with a lead PHA were awarded new housing choice vouchers. Those PHAs were to receive \$45.73 million in total funding under

that award. Through the demonstration, the awarded PHAs will provide approximately 9,000 families with children with better access to low-poverty neighborhoods, high-performing schools, and other strong community resources.

The Implementation Notice described broad parameters for selected PHAs, including the set of housing mobility-related services that they would likely be required to provide to families participating in the program, the likely research design, and an estimated cost of services per family offered participation in the program. The Implementation Notice also described a required evaluation that would be conducted at the selected PHAs and explained that some aspects of the program and research design would be determined jointly by HUD (including its evaluation contractor and technical assistance provider) in collaboration with the selected PHAs.

On April 4, 2022, HUD supplemented the Implementation Notice with a Supplementary Notice describing policies and flexibilities for PHAs selected to participate in the demonstration. (87 FR 19522) After publication of the Supplementary Notice, one PHA demonstration site (both the lead PHA and its partner PHA), and one partnering PHA, withdrew their participation from the demonstration. As a result of those withdrawals, combined with funding not initially awarded, HUD now has \$1,814,262 in MDV assistance and \$7,346,290 in funding for housing mobility-related services to be awarded to PHAs previously competitively selected under the Implementation Notice. Additionally, as the demonstration implementation has advanced, HUD and the PHAs have clarified additional policies necessary to promote the goals of the demonstration and have identified policies necessary to execute the evaluation. Finally, HUD has determined it necessary to adjust the anticipated timelines for implementation of the selected mobility-related services (SMRS) treatment arm. This notice describes HUD's determination to delay the SMRS implementation timeline, additional policies necessary to implement the demonstration, and a funding award process.

II. Changes to SMRS Implementation Timeline

The Implementation Notice estimated that HUD would implement a second treatment arm that would receive a subset of the services offered under comprehensive mobility-related services

(CMRS) in years three through six of the demonstration. HUD has since determined that it will delay the implementation of the SMRS in order to perform additional analysis of the preliminary data being used to develop the SMRS interventions. HUD will publish an additional **Federal Register** document describing any revisions to the timelines and research design for the introduction of the SMRS.

III. Regional PBV Plan

The Implementation Notice described that PHAs that received funding for the development of a Regional Project-based Voucher Plan (RPBVP) would develop the plan throughout the first three years of the demonstration. The plan would then be submitted to HUD at the beginning of the fourth year of the demonstration, which is May 1, 2025. Given the demands of the initial planning period for the demonstration and implementation, HUD recognizes that PHAs may not have had adequate time to develop their RPBVP. Therefore, HUD is extending the deadline of the RPBVP to the start of the seventh year of the demonstration, which is May 1, 2027.

In addition, the RPBVP was an optional component of the Implementation Notice and is not being studied as part of the evaluation. HUD recognizes that PHAs may wish to reconsider their participation in this optional component. Therefore, HUD is allowing those PHAs awarded funding for this component to withdraw from their obligations to develop a RPBVP. PHAs wishing to withdraw from the RPBVP component must submit a written letter to HUD requesting withdrawal. Written requests can be submitted via email to HCVmobilitydemonstration@hud.gov. HUD will only allow withdrawal from the RPBVP component for PHAs that have not already incurred substantial expenses (*i.e.*, more than 60 percent of awarded RPBVP funds) under the RPBVP for which they are requesting reimbursement by HUD. PHAs must submit their withdrawal request prior to the May 1, 2027 deadline for plan submission. All awarded and unexpended funds from any site that withdraws from the RPBVP component will be reallocated in accordance with Section VIII of this notice.

At this point in the demonstration, HUD also recognizes that sites that initially did not apply for RPBVP funding may have identified a new need to develop a RPBVP. Therefore, HUD is also allowing PHAs that were not initially awarded RPBVP funds to request funding for this component.

Lead PHAs wishing to request RPBVP funds for a demonstration site must submit a written letter to HUD requesting funding. In the request, the PHA must demonstrate that it will be able to expend the requested funds and submit a final RPBVP by the May 1, 2027, deadline. Written requests can be submitted via email to HCVmobilitydemonstration@hud.gov.

IV. Extension of the Demonstration Participant Enrollment Period

As described in the Implementation Notice, PHAs would enroll families through year six of the demonstration, which would conclude on April 30, 2027. However, the Consolidated Appropriations Act, 2019 authorized the demonstration through October 1, 2028. In order to provide PHAs more time to enroll families and meet their commitments, HUD is extending the participation period for PHAs through the statutorily authorized date of October 1, 2028. This participation period extension is optional, and PHAs must inform HUD in writing if they want to extend their participation period. PHAs may elect to enroll families through April 30, 2028, or may extend for a lesser period of time by enrolling families through December 31, 2027.

V. Mobility Demonstration Vouchers

Families with children receiving voucher assistance through an MDV that agree to participate in the demonstration are randomly assigned to a treatment group that receives housing mobility-related services or a control group that receives HCV program services already offered by the PHA to all HCV applicants and participants. Although most participants in the demonstration are existing voucher holders, each PHA has received an allocation of MDVs. Families that receive an MDV are required by statute to participate in the demonstration. A family is considered to be participating in the demonstration if they initially enrolled in the study and were randomly assigned to either the treatment or control group. A family that was participating in the demonstration and subsequently withdraws from the study, or no longer has children in the household, may continue to use their MDV. PHAs are encouraged, however, to provide a regular turnover voucher to such families in order to provide the MDV to a family with children actively enrolled in the study.

As provided in the Implementation Notice, after October 1, 2028, MDVs will no longer be restricted to the purposes of the demonstration. The MDVs will

then become part of a PHA's regular HCV program and continue to be available to the PHA upon turnover. However, due to the statutory language authorizing them, these vouchers will continue to be restricted to families with children (age 17 or younger).

VI. Eligible Uses of Funds

Throughout the implementation of the demonstration, PHAs and HUD have identified additional uses of housing mobility-related services funding that will increase effective program implementation, especially the SMRS. These uses of housing mobility-related services funds were not directly addressed by the Implementation Notice or the Supplementary Notice. For the purposes of transparency and clarity, HUD has included a discussion of these uses of funds in this notice.

PHAs participating in the demonstration must recruit and enroll families into the study. In the Supplementary Notice, HUD provided that each PHA site (*i.e.*, an individual PHA or the lead PHA and its partner) may use up to \$40,000 each year for staff time and expenses related to recruitment and enrollment. After working closely with PHAs to understand their current time commitment for these activities, HUD is increasing the eligible amount up to \$80,000 each year.

Under the Implementation Notice, HUD provided that PHAs may use up to \$250,000 of their funding award for start-up costs. Many participating PHAs used their funds for start-up costs related to the CMRS. Based on the level of effort required for CMRS planning, HUD recognizes PHAs may need additional start-up funds to assist in planning for the SMRS. PHAs may use up to an additional \$100,000 for SMRS start-up expenditures, upon written approval from HUD.

PHAs may use their existing housing mobility-related services funding award to pay for these activities. PHAs must update their annual expenditure plans to reflect the amount of funds they intend to use for these purposes and begin immediately reporting these expenditures on their invoices and in HUD's Voucher Management System (VMS).

VII. Demonstration Withdrawal and Recapture of Funds

In 2023, one PHA site (both the lead PHA and its partner PHA), and one partnering PHA, voluntarily withdrew from the demonstration prior to enrollment of any families. These PHAs remitted their funding award to HUD, and HUD has recaptured the funds. This

recapture included \$3,218,700 in housing mobility-related services funding and \$1,814,262 in remaining funding for MDVs.

HUD now establishes criteria for withdrawal—whether voluntary withdrawal on behalf of the PHA or termination of PHA participation by HUD—to help ensure impacts to families and landlords are effectively mitigated since all participating PHAs are well into enrollment. Participating PHAs that wish to request to voluntarily withdraw from the demonstration must submit a letter in writing, with an associated board resolution, recommending withdrawal to HUD. The letter must state the key reasons for withdrawal from the demonstration and a proposed plan for mitigating the impact on participating families and landlords. Upon receipt of the letter, HUD will review the PHA's request. In determining whether voluntary withdrawal will be approved, HUD will consider the PHA's rationale, the impact on participating families and landlords, including any evidence that the PHA's withdrawal from the demonstration would have an unlawful discriminatory effect on participating families or otherwise violate civil rights requirements, and the research evaluation. HUD will make its best efforts to honor the PHA's request.

Adherence to the Implementation Notice, Supplemental Notice, this Notice and the Statement of Responsibilities is critical to ensuring the success of the demonstration. PHAs that have been materially non-compliant with demonstration requirements may be terminated from the demonstration and have their funding recaptured. HUD will issue a notice of corrective action to PHAs found to be in material non-compliance with demonstration requirements, as defined in the Statement of Responsibilities. PHAs will have no fewer than six months to cure any material non-compliance. If after six months, the PHA is found to continue to be in material non-compliance, HUD may issue a notice of intent to terminate the PHA's participation in the demonstration. The PHA may respond to that notice and ask HUD to reconsider its determination.

If HUD accepts a PHA's request to voluntarily withdraw or determines that the termination of participation is necessary, HUD will work closely with the PHA and the evaluator to develop a process by which the PHA will carefully end their participation and implement their plan for mitigating the impact on participating families and landlords. The plan must include consultation from any enrolled families to ensure

that they are successfully transitioned out of the program. After that date, the PHA will submit final invoices to PIH CCD staff and complete final reporting in VMS, the PIH Information Center (PIC)/Housing Information Portal (HIP) and the demonstration's Service Delivery Tool. HUD's Financial Management Center (FMC) will reconcile and process any final invoices and determine the amount of the remaining grant funds. HUD FMC will then recapture the remaining funds from the PHA.

VIII. Additional Allocation and Reallocation of Funds

As mentioned in the Supplemental Notice, after the funding awards made on April 30, 2021, HUD had \$4,127,590 in remaining housing mobility-related services funding. After the withdrawal of one PHA site, and one partner PHA, HUD has a total of \$7,346,290 in housing mobility-related services funding and \$1,814,262 remaining in funding for MDVs.

In any cases where a PHA that is part of a partnership site withdraws from the demonstration, but HUD allows the remaining PHA to continue their participation, HUD will reallocate the site's remaining housing mobility-related services funding, any awarded RPBVP funds and voucher assistance to the remaining PHA to support their continued participation in the demonstration, as they will assume the responsibilities of the withdrawn PHA.

In all other cases, for housing mobility-related services funding, HUD will reallocate funding in two ways: (1) HUD will equally distribute a portion of the remaining funding to all participating demonstration sites; and/or (2) HUD may reserve a reasonable amount of remaining funding to be distributed to sites based on need or for new RPBVP funding, by request. HUD will review requests for need-based funding from sites in accordance with the process described below. HUD may reallocate funding, as needed, throughout the remainder of the demonstration to ensure that sites have the necessary support and to maximize utilization of available funding.

In reallocating voucher assistance for MDVs, HUD will only reallocate recaptured voucher amounts based on need. Selected demonstration sites were required to demonstrate their need for MDVs in their initial applications for demonstration funding. In cases where one PHA withdraws from a partner site, HUD will reallocate recaptured voucher assistance from the withdrawn PHA to the remaining PHA, based on the entire site's determination of need presented

in its initial application. For all other recaptured voucher assistance, HUD will reallocate to other demonstration PHAs based on their jurisdictional need and, when necessary, will prioritize the awards to sites with the highest number of enrolled families.

Any recaptured RPBVP funds due to a site withdrawing from their participation in the RPBVP component, voluntarily withdrawing from the demonstration, or having their participation in the demonstration terminated, will be recaptured and reallocated. Any unexpended RPBVP funds remaining after a site completes its plan will also be recaptured and reallocated.

PHAs wishing to request additional housing mobility-related services funding or voucher assistance under the demonstration must submit a request in writing to HUD. The request must include a narrative describing the need for additional funding, as well as a projected budget for the remainder of the demonstration showing the full expenditure of the requested funds or utilization of the voucher assistance. If applicable, the request should also include an amendment of the program budget for the current year.

IX. Continued Housing Mobility-Related Services at Demonstration End

Upon the October 1, 2028 statutory end date of the demonstration, HUD will work with sites to process final invoices and complete final reporting in VMS, PIC/HIP and the demonstration's Service Delivery Tool. After the demonstration ends, sites will be allowed to use remaining housing mobility-related services funds to continue providing any CMRS services, as described in the Implementation Notice and subsequent notices, to any family participating in a housing mobility program at the site. HUD will provide guidance to sites on invoicing procedures for these funds.

Any waivers and/or alternative requirements implemented by HUD, specific to the demonstration, will terminate upon the October 1, 2028 end date. In addition, any special uses of HCV funding or program flexibilities expressly allowed under the demonstration (e.g., the use of non-MDV housing assistance payments for security deposits) will also terminate upon the October 1, 2028 end date. After the end of the demonstration, PHAs may continue to use their awarded housing mobility-related services funds, but the provision of

services must be in accordance with normal HCV program rules.

Dominique Blom,

General Deputy Assistant Secretary, Office of the Assistant Secretary for Public and Indian Housing.

[FR Doc. 2024-16039 Filed 7-19-24; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-6418-N-03]

Announcement of Funding Awards

AGENCY: Office of Chief Financial Officer, HUD.

ACTION: Notice.

SUMMARY: In accordance with the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding decisions made by the Department in competitions for funding under the Notices of Funding Opportunity (NOFOs) and Notices for the following program(s): Section 4 Capacity Building for Community Development and Affordable Housing, Lead Hazard Reduction Grant Program, Lead Hazard Reduction Capacity Building Grant Program, Lead Risk Assessment Demonstration Grant Program, Choice Neighborhoods Implementation Grants, FY21 Foster Youth to Independence Initiative Notice, FY22 HUD-Veterans Affairs Supportive Housing (HUD-VASH) Notice, and FY 22 PIH Notice 2022-19: Mainstream Vouchers.

FOR FURTHER INFORMATION CONTACT: Dorthera Yorkshire, Director, Grants Management and Oversight, Office of the Chief Financial Officer (Systems), telephone (202) 402-4336 (this is not a toll-free number), email AskGMO@hud.gov, or the contact person listed in each appendix. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

SUPPLEMENTARY INFORMATION:

HUD posted the FY2021 Section 4 Capacity Building for Community Development and Affordable Housing NOFO on [grants.gov](https://www.grants.gov) April 05, 2022, (FR-6500-N-07). The competition closed on June 06, 2022. HUD rated and selected for funding based on selection criteria contained in the notice. This competition awarded \$41,000,000 to 3

recipients to carry out affordable housing and community development activities that benefit low- and moderate-income families and persons. For FY 2021 there is \$41,000,000 available to carry out eligible activities related to community development and affordable housing projects and programs for the Section 4, of which at least \$5,000,000 shall be made available for rural capacity building activities.

HUD posted FY 2022 Lead Hazard Reduction Grant Program on [grants.gov](https://www.grants.gov) June 17, 2022 (FR-6600-N-13). The competition's closing date was extended and it closed on June 27, 2023. HUD rated and selected applications for funding based on selection criteria contained in the NOFO. This competition awarded \$123,106,482 (Lead \$112,224,362 and Healthy Homes Supplement \$10,882,120) to 28 recipients to maximize the number of children under the age of 6 protected from lead poisoning and other housing-related health and safety hazards.

HUD posted FY 2022 Lead Hazard Reduction Capacity Building Grant Program on [grants.gov](https://www.grants.gov) April 27, 2023 (FR-6600-N-31). The competition closed on June 27, 2023. HUD rated and selected applications for funding based on selection criteria contained in the NOFO. This competition awarded \$16,363,920 to 8 recipients to develop the infrastructure to identify and control lead-based paint hazards in privately-owned rentals or owner-occupied housing. The capacity building program focus areas include training staff and contractors, building partnerships and local coalitions, identifying, and assessing potential target areas, develop and implement outreach and marketing, and develop program data sharing and referrals.

HUD posted FY 2022 Lead Risk Assessment Demonstration Grant Program on [grants.gov](https://www.grants.gov) April 27, 2023 (FR-6600-N-86). The competition closed on June 20, 2023. HUD rated and selected applications for funding based on selection criteria contained in the NOFO. This competition awarded \$600,000 to 2 recipients that are Public Housing Authorities to demonstrate the feasibility of conducting lead-based paint risk assessments or lead hazard screens in pre-1978 Housing Choice Voucher assistance (HCV) units (as described at 42 U.S.C. 1437f(o)) occupied or to be occupied by children under the age of 6.

HUD posted the FY 2022 Choice Neighborhoods Implementation Grants on [grants.gov](https://www.grants.gov) September 30, 2022, (FR-6600-N-34). The competition closed on January 11, 2023. HUD rated and selected for funding based on selection

criteria contained in the notice. This competition awarded \$370,000,000 to 8 recipients to redevelop severely distressed public and HUD-assisted housing. Grantees leverage significant public and private dollars to support locally driven strategies that address struggling neighborhoods with distressed public or HUD-assisted housing through a comprehensive approach to neighborhood transformation. Local leaders, residents, and stakeholders, such as public housing authorities, cities, schools, police, business owners, nonprofits, and private developers, come together to create and implement a plan that revitalizes distressed HUD housing and addresses the challenges in the surrounding neighborhood.

HUD posted the FY21 Foster Youth to Independence Initiative Notice on *grants.gov* June 06, 2022 (PIH 2021–26). HUD rated and selected for funding based on selection criteria contained in the Notice. This competition awarded

\$7,215,489 to 97 recipients to Housing Choice Voucher (HCV) assistance available to Public Housing Agencies (PHAs) in partnership with Public Child Welfare Agencies (PCWAs). This funding opportunity is provided on a non-competitive rolling basis.

HUD posted the FY22 HUD-Veterans Affairs Supportive Housing (HUD–VASH) Notice on *grants.gov* August 16, 2022 (PIH 2022–26). The competition closed September 16, 2022. HUD rated and selected for funding based on selection criteria contained in the Notice. This competition awarded \$25,373,842 to 101 recipients to enable homeless veterans to access affordable housing along with an array of supportive services from the Department of Veterans Affairs.

HUD posted the FY 22 PIH Notice 2022–19: Mainstream Vouchers Notice on *grants.gov* June 13, 2022. The competition closed on July 14, 2022. HUD rated and selected for funding based on selection criteria contained in

the Notice. This competition awarded \$29,753,638 (\$24,726,138 for new vouchers and \$5,027,500 for extraordinary administrative fees) to 150 recipients to serve a special population of households. Mainstream Vouchers serve households that include one or more non-elderly persons with disabilities, defined as any family that includes a person with disabilities who is at least 18 years old and not yet 62 years old.

In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat. 1987, 42 U.S.C. 3545(a)(4)(C)), the Department is publishing the awards and the amounts of the awards in Appendices A–H of this document.

Dorthera Yorkshire,

*Director, Grants Management and Oversight,
Office of the Chief Financial Officer.*

Appendix A

SECTION 4 CAPACITY BUILDING FOR COMMUNITY DEVELOPMENT AND AFFORDABLE HOUSING FISCAL YEAR 2021 (FR–6500–N–07)

[Contact: La Ticia Wilson (202) 402–5890]

Organization name	Street address	City	ST	Zip code	Award
Enterprise Community Partners	70 Corporate Center, 11000 Broken Land Parkway, Suite 700.	Columbia	MD	21044	\$15,000,000
Local Initiatives Support Corporation	501 Seventh Avenue, 7th Floor	New York	NY	10018	17,000,000
Habitat for Humanity International ...	121 Habitat Street	Americus	GA	31709	9,000,000
Total Awards					41,000,000

Appendix B

FY2022 LEAD HAZARD REDUCTION GRANT PROGRAM (FR–6600–N–13)

[Contact: Yolanda Brown (202) 402–7596]

Organization name	Street address	City	ST	Zip code	Award
City of Florence	110 W College Street	Florence	AL	35630–0001	\$1,500,000.00
City of Selma	222 Broad Street	Selma	AL	36701–4540	2,215,500.00
Alameda County Healthy Homes	2000 Embarcadero, Ste. 300	Oakland	CA	94606	5,700,000.00
City of Fontana	8353 Sierra Ave	Fontana	CA	92335	4,400,000.00
City of New Haven	54 Meadow Street, 9th Floor	New Haven	CT	06519	7,765,930.22
City of Council Bluffs	209 Pearl Street	Council Bluffs	IA	51503–4270	1,654,303.47
City of Marshalltown	24 North Center Street	Marshalltown	IA	50158	5,026,330.00
City of Muscatine	215 Sycamore St	Muscatine	IA	52761–3839	2,956,932.31
City of Sioux City	405 6th Street	Sioux City	IA	51102	5,187,989.00
County of Cerro Gordo	2570 4th Street SW	Mason City	IA	50401–3435	2,193,665.93
County of McHenry	2200 North Seminary Avenue	Woodstock	IL	600982637	2,032,420.00
City of Monroe	3901 Jackson St	Monroe	LA	71202–5715	4,496,699.00
Jefferson Parish	1221 Elmwood Park Boulevard, Suite 605.	Jefferson	LA	70123–2337	5,700,000.00
Maine State Housing Authority	26 Edison Drive	Augusta	ME	04330	5,700,000.00
City of Worcester	455 Main Street, Suite 405	Worcester	MA	01608	4,100,000.00
City of Grand Rapids	300 Monroe Ave. NW	Grand Rapids	MI	49503	6,600,000.00
Michigan Department of Health & Human Services.	235 S Grand Ave., Suite 800	Lansing	MI	48933–1805	7,997,798.16
Minnesota Department of Health	625 Robert Street North	St. Paul	MN	55164–0975	3,846,869.00
Two Rivers Public Health Depart- ment.	516 W 11th Street	Kearney	NE	68845–7310	1,345,195.00
City of East Orange	44 City Hall Plaza	East Orange	NJ	07018–4502	4,801,958.60
Broome County	225 Front St	Binghamton	NY	13905	6,300,000.00

FY2022 LEAD HAZARD REDUCTION GRANT PROGRAM (FR-6600-N-13)—Continued

[Contact: Yolanda Brown (202) 402-7596]

Organization name	Street address	City	ST	Zip code	Award
City of Utica	1 Kennedy Plaza	Utica	NY	13502	3,974,989.00
County of Niagara	5467 Upper Mountain Road	Lockport	NY	14094-1894	3,300,000.00
City of Charlotte	600 East Trade St	Charlotte	NC	28202	3,573,037.97
Puerto Rico Public Housing Administration.	606 Barbosa Ave	San Juan	PR	00923	3,520,080.00
City of Memphis	170 N. Main Street, 3rd Fl	Memphis	TN	38103-1877	5,700,000.00
Salt Lake County	2001 South State Street	Salt Lake City	UT	84190-2770	5,816,785.00
City of Milwaukee	841 N Broadway	Milwaukee	WI	53202	5,700,000.00
Total					123,106,482.66

Appendix C

FY2022 LEAD HAZARD REDUCTION CAPACITY BUILDING GRANT PROGRAM (FR-6600-N-31)

[Contact: Yolanda Brown (202) 402-7596]

Organization name	Street address	City	ST	Zip code	Award
Triangle J Council of Governments	4307 Emperor Boulevard, Suite 110	Durham	NC	27703-8088	654,507.00
County of Ventura	2240 E Gonzales Rd, Ste. 270	Oxnard	CA	93036	2,500,000.00
City of Montgomery	103 North Perry Street	Montgomery	AL	36104	716,650.00
City of Saint Petersburg	175 5th St. N	St Petersburg	FL	33701	2,500,000.00
Massachusetts Department of Public Health.	250 Washington Street	Boston	MA	02108	2,500,000.00
County of Kent	300 Monroe Ave. NW	Grand Rapids	MI	49503	2,493,629.00
Town of Fort Deposit	260 Old Fort Rd	Fort Deposit	AL	36032	2,499,134.00
Cattaraugus County Health Department.	1 Leo Moss Drive	Olean	NY	14760	2,500,000.00
Total					16,363,920.00

Appendix D

FY2022 LEAD RISK ASSESSMENT DEMONSTRATION GRANT PROGRAM (FR-6600-N-86)

[Contact: Bruce Haber 202-402-7699]

Organization name	Street address	City	ST	Zip code	Award
Eastern Iowa Regional Housing Authority.	7600 Commerce Park	Dubuque	IA	52002-9673	\$300,000.00
Lucas Metropolitan Housing Authority.	424 Jackson Street	Toledo	OH	43604-1410	300,000.00
Total					600,000.00

Appendix E

FY2022 CHOICE NEIGHBORHOODS IMPLEMENTATION GRANTS (FR-6600-N-34)

[Contact: Luci Blackburn (202) 402-4190]

Organization	Address	City	ST	ZIP	Award amount
Atlanta Housing Authority	230 John Wesley Dobbs Ave. NE ...	Atlanta	GA	30303	\$40,000,000.00
City of Tucson	255 W Alameda Street	Tucson	AZ	85701	50,000,000.00
Housing Authority of the Birmingham District.	1826 3rd Avenue South	Birmingham	AL	35233	50,000,000.00
Housing Authority of the City of Pittsburgh.	200 Ross Street, 9th Floor	Pittsburgh	PA	15219	50,000,000.00
Lake Charles Housing Authority	800 Bilbo St., Suite C	Lake Charles	LA	70601	40,000,000.00
Miami-Dade County	MDC Public Housing and Community Development, 701 NW 1st Court, 16th Floor.	Miami	FL	33128	40,000,000.00
Philadelphia Housing Authority	2013 Ridge Avenue	Philadelphia	PA	19121	50,000,000.00

FY2022 CHOICE NEIGHBORHOODS IMPLEMENTATION GRANTS (FR-6600-N-34)—Continued

[Contact: Luci Blackburn (202) 402-4190]

Organization	Address	City	ST	ZIP	Award amount
Wilmington Housing Authority	400 North Walnut Street	Wilmington	DE	19801	50,000,000.00
Total					370,000,000.00

Appendix F

FY22 FOSTER YOUTH TO INDEPENDENCE INITIATIVE (PIH-2023-4)

[Contact: Michelle Daniels, (202) 402-6051 and Ryan Jones (202) 402-2677]

Organization name	Street address or P.O. Box	City	State	Zip code	Award amount
Housing Authority Tuscaloosa	2117 Jack Warner Parkway	Tuscaloosa	AL	35401	\$6,372.00
Housing Authority of Northport	3500 West Circle	Northport	AL	35476	6,724.00
Housing Authority of Alexander City	2110 County Road	Alexander City	AL	35010	4,263.00
Housing Authority of Little Rock	100 South Arch Street	Little Rock	AR	72201	24,162.00
City of Flagstaff Housing Authority ..	3481 Fanning Drive	Flagstaff	AZ	86004	51,591.00
County of San Mateo Housing Authority.	264 Harbor Boulevard	Belmont	CA	94002	340,677.00
City of San Luis Obispo Housing Authority.	487 Leff Street	San Luis Obispo	CA	93401	96,255.00
City of Santa Ana Housing Authority	20 Civic Center Plaza, 2nd Floor	Santa Ana	CA	92701	376,512.00
Jefferson County Housing Authority	11941 W 48th Ave	Wheat Ridge	CO	80033	12,455.00
Norwalk Housing Authority	24½ Monroe Street	Norwalk	CT	06856	17,251.00
Connecticut Dept of Housing	505 Hudson Street	Hartford	CT	06106	307,684.00
Miami Dade Housing Authority	701 NW 1st Court	Miami	FL	33136	348,096.00
Housing Authority of Brevard County.	1401 Guava Ave	Melbourne	FL	32935	70,001.00
Hialeah Housing Authority	75 E 6th Street	Hialeah	FL	33010	250,226.00
Housing Authority of Palm Beach County.	3333 Forest Hill Blvd	West Palm Beach	FL	33406	107,230.00
Housing Authority of Deerfield Beach.	533 South Dixie Hwy., Suite 201	Deerfield Beach ..	FL	33441	218,841.00
Housing Authority of the City of Brunswick.	P.O. Box 1118	Brunswick	GA	31521	16,312.00
Council Bluffs Municipal Housing Agency.	505 S Sixth St	Council Bluffs	IA	51501	12,886.00
City of Davenport, Iowa	226 W 4th St	Davenport	IA	52801	40,103.00
Upper Explorerland Regional	325 Washington Street	Decorah	IA	52101	3,680.00
Housing Authority of Champaign County.	2008 N Market St	Champaign	IL	61822	72,896.00
Indianapolis Housing Agency	1919 North Meridian Street	Indianapolis	IN	46202	184,224.00
Housing Authority City of Jeffersonville.	206 Eastern Boulevard	Jeffersonville	IN	47130	62,844.00
Housing Authority City of Elkhart	1396 Benham Avenue	Elkhart	IN	46516	42,216.00
East Chicago Housing Authority	4444 Railroad Ave	East Chicago	IN	46312	161,367.00
Noblesville Housing Authority	320 Kings Lane	Noblesville	IN	46060	35,830.00
Boston Housing Authority	52 Chauncy Street	Boston	MA	02111	430,904.00
Springfield Housing Authority	60 Congress Street	Springfield	MA	01101	138,724.00
Fitchburg Housing Authority	50 Day Street	Fitchburg	MA	01420	33,882.00
Hagerstown Housing Authority	35 W Baltimore Street	Hagerstown	MD	21740	40,952.00
Housing Authority of the City of Rockville.	1300 Piccard Drive Suite #203	Rockville	MD	20850	58,760.00
Wicomico County Housing Authority	911 Booth Street	Salisbury	MD	21801	8,510.00
Housing Authority Prince George's County.	9200 Basil Court	Largo	MD	20774	379,842.00
Howard County Housing Commission.	9770 Patuxent Woods Drive	Columbia	MD	21046	27,025.00
Queen Anne's County Housing Authority.	P.O. Box 280	Centreville	MD	21617	9,869.00
Portland Housing Authority	14 Baxter Boulevard	Portland	ME	04101	82,583.00
Minneapolis PHA	1001 Washington Avenue N	Minneapolis	MN	55401	67,630.00
Olmsted County HRA	2117 Campus Drive SE	Rochester	MN	55904	55,652.00
Bloomington HRA	1800 W Old Shakopee Road	Bloomington	MN	55431	18,573.00
Itasca County HRA	1115 NW 4th Street	Grand Rapids	MN	55744	17,026.00
Metropolitan Council HRA	390 North Robert Street	St. Paul	MN	55101	117,660.00
Rice County HRA	320 NW 3rd Street	Faribault	MN	55021	14,426.00
Housing Authority of the City of Saint Joseph.	2902 South 36th Street	St Joseph	MO	64503	5,343.00
Boone County PHA	800 N Providence Road	Columbia	MO	65203	31,356.00

FY22 FOSTER YOUTH TO INDEPENDENCE INITIATIVE (PIH-2023-4)—Continued

[Contact: Michelle Daniels, (202) 402-6051 and Ryan Jones (202) 402-2677]

Organization name	Street address or P.O. Box	City	State	Zip code	Award amount
Lincoln County Public Housing Agency.	815 N Bus Hwy. 61	Bowling Green	MO	63334	18,202.00
Howell County Housing Authority	710 E Main St	West Plains	MO	65775	18,455.00
Housing Authority Tennessee Valley	1210 Proper Street	Corinth	MS	38834	25,871.00
Jackson Housing Authority	2747 Livingston Road	Jackson	MS	39213	34,621.00
Butte Housing Authority	220 Curtis Street	Butte	MT	59701	20,960.00
Housing Authority of Durham	330 E Main Street	Durham	NC	27701	9,035.00
Orange County	300 W Tryon Street	Hillsborough	NC	27278	39,053.00
Dover Housing Authority	62 Whittier Street	Dover	NH	03820	27,658.00
Concord Housing Authority	23 Green Street	Concord	NH	03301	7,749.00
Rochester Housing Authority	77 Olde Farm Lane	Rochester	NH	03857	19,434.00
Keene Housing	831 Court Street	Keene	NH	03431	52,318.00
Newark Housing Authority	500 Broad Street	Newark	NJ	07102	297,048.00
Housing Authority of the City of Camden.	2021 Watson Street	Camden	NJ	08105	189,854.00
San Juan County Housing Authority	7450 East Main	Farmington	NM	87402	9,564.00
El Camino Real Housing Authority ..	P.O. Box 00	Socorro	NM	87801	26,972.00
Northern Regional Ha	525 Ranchitos Road, Unit 962	Taos	NM	87571	17,586.00
Town of Brookhaven Dept of Housing Comm Development.	One Independence Hill	Farmingville	NY	11738	17,718.00
City of Buffalo	470 Franklin St	Buffalo	NY	14202	25,044.00
NYS Housing Trust Fund Corporation.	Nys Hcr Statewide Section 8 Program.	New York	NY	10004	35,283.00
Erie MHA	322 Warren Street	Sandusky	OH	44870	20,049.00
Portage MHA	2832 State Route 59	Ravenna	OH	44266	7,314.00
Housing Authority of Lincoln County	1039 Nw Nye Street	Newport	OR	97365	6,812.00
Homes For Good Housing Agency	100 W 13th Ave	Eugene	OR	97401	26,761.00
Housing Authority of Washington County.	161 Nw Adams Ave., Suite 2000, Ms63.	Hillsboro	OR	97124	112,927.00
Beaver County Housing Authority ...	300 State Street	Beaver	PA	15009	16,136.00
Lycoming County Housing Authority	1941 Lincoln Drive	Williamsport	PA	17701	6,008.00
Carbondale Housing Authority	2 John Street	Carbondale	PA	18407	17,328.00
Housing Authority of Mifflin County	141 S Pine Road	Lewistown	PA	17044	4,609.00
East Providence Housing Authority	99 Goldsmith Avenue	East Providence	RI	02914	237,990.00
Laredo Housing Authority	2000 San Francisco Avenue	Laredo	TX	78040	19,036.00
Galveston Housing Authority	4700 Broadway Street	Galveston	TX	77551	42,946.00
San Benito Housing Authority	1400 N Reagan Street	San Benito	TX	78586	5,881.00
Housing Authority of Port Arthur	920 Dequeen Boulevard	Port Arthur	TX	77640	8,152.00
Pharr Housing Authority	104 W Polk	Pharr	TX	78577	30,254.00
Housing Authority of Abilene	1149 E South 11th Street	Abilene	TX	79602	58,968.00
Housing Authority of El Paso County.	650 East G. Street	Fabens	TX	79838	154,431.00
Bexar County Housing Authority	1954 E Houston Street, Suite 104 ..	San Antonio	TX	78202	209,592.00
Longview Housing & Comm. Development.	1202 North Sixth Street	Longview	TX	75601	72,492.00
Rosenberg Housing Authority	117 Lane Drive, Suite 18	Rosenberg	TX	77471	58,775.00
Deep East Tx Council of Govts	1405 Kurth Dr	Lufkin	TX	75904	77,295.00
Midland County Housing Authority ..	1710 Edwards Street	Midland	TX	79701	9,858.00
City of Virginia Beach	2424 Courthouse Dr	Virginia Beach ...	VA	23456	45,403.00
Burlington Housing Authority	65 Main Street	Burlington	VT	05401	71,716.00
Seattle Housing Authority	190 Queen Anne Ave N	Seattle	WA	98109	251,346.00
Housing Authority of the City of Bremerton.	600 Park Avenue	Bremerton	WA	98337	151,748.00
Bellingham Housing Authority	208 Unity Street	Bellingham	WA	98225	36,814.00
Housing Authority of Snohomish County.	12711 4th Avenue West	Everett	WA	98204	29,359.00
Housing Authority City of Superior ..	1219 North 8th Street	Superior	WI	54880	4,700.00
Housing Authority of the City of Milwaukee.	809 North Broadway	Milwaukee	WI	53202	68,284.00
Janesville CDA	18 North Jackson Street	Janesville	WI	53547	36,370.00
Sawyer County Housing Authority ...	15918 West 5th Street	Hayward	WI	54843	3,981.00
Beloit CDA	210 Portland Ave	Beloit	WI	53511	6,074.00
Point Pleasant Housing Authority	404 Second Street	Point Pleasant	WV	25550	4,240.00
Total					7,215,489.00

Appendix G

FY22 HUD-VETERANS AFFAIRS SUPPORTIVE HOUSING (HUD-VASH) (PIH NOTICE 2022-26)

[Contact: Jerriane Anthony (202) 402-2677]

Organization name	Street address	City	State	Zip code	Award Amount
City of Hartford Housing Authority ...	250 Constitution Plaza, 4th Floor ...	Hartford	CT	06103	293,976.00
Boston Housing Authority	52 Chauncy Street	Boston	MA	02111	112,135.00
Cambridge Housing Authority	362 Green Street 3rd Floor	Cambridge	MA	02139	181,858.00
Quincy Housing Authority	80 Clay Street	Quincy	MA	02170	77,168.00
Milton Housing Authority	65 Miller Avenue	Milton	MA	02186	173,306.00
Department of Housing & Commu- nity Development.	100 Cambridge Street, Suite 300 ...	Boston	MA	02114	135,926.00
Department of Housing & Commu- nity Development.	100 Cambridge Street, Suite 300 ...	Boston	MA	02114	1,062,692.00
Lewiston Housing Authority	1 College Street	Lewiston	ME	04240	64,016.00
State of NJ Dept. of Comm. Affairs	101 South Broad Street P.O. Box 051.	Trenton	NJ	08625	201,543.00
Long Branch Housing Authority	Garfield Court	Long Branch	NJ	07740	162,458.00
Housing Authority of the County of Cumberland.	114 N Hanover Street	Carlisle	PA	17013	84,265.00
Adams County Housing Authority ...	40 E High Street	Gettysburg	PA	17325	56,226.00
Fairfax County Redevelopment & Hsg Authority.	3700 Pender, Drive Suite 300	Fairfax	VA	22030	415,494.00
Housing Authority of the City of Par- kersburg.	1901 Cameron Avenue	Parkersburg	WV	26101	26,769.00
Housing Authority of the City of Asheville.	165 S French Broad Ave	Asheville	NC	28801	210,456.00
Western Carolina Community Ac- tion, Inc..	220 King Creek Blvd	Hendersonville ...	NC	28792	30,006.00
Western Piedmont Council of Gov- ernments.	1880 2nd Avenue NW	Hickory	NC	28601	23,476.00
Isothermal Planning & Development Commission.	Post Office Box 841	Rutherfordton	NC	28139	23,360.00
Richmond Redevelopment & Hous- ing Authority.	901 Chamberlayne Parkway	Richmond	VA	23220	40,680.00
Virginia Housing Development Au- thority.	601 South Belvidere Street	Richmond	VA	23220	315,641.00
Roanoke Redevelopment & Hous- ing Authority.	2624 Salem Turnpike NW	Roanoke	VA	24017	36,622.00
Staunton Redevelopment & Hous- ing Authority.	900 Elizabeth Miller Gardens	Staunton	VA	24401	33,703.00
Housing Authority of Rock Hill	467 S Wilson St	Rock Hill	SC	29730	68,852.00
Jacksonville Housing Authority	1300 N Broad Street	Jacksonville	FL	32202	31,178.00
Housing Authority of the City of St. Petersburg.	2001 Gandy Boulevard North	St. Petersburg	FL	33702	445,356.00
Housing Authority of the City of Lakeland.	430 Hartsell Avenue	Lakeland	FL	33815	70,071.00
Winter Haven Housing Authority	2670 Avenue C SW	Winter Haven	FL	33880	134,903.00
Citrus County Housing Services	2804 W Marc Knighton Ct. Key #12	Lecanto	FL	34461	58,102.00
Seminole County Housing Authority	662 Academy Place	Oviedo	FL	32765	253,641.00
Lake County Housing Agency	2008 Classique Lane	Tavares	FL	32778	356,143.00
Osceola County Housing Agency ...	330 N Beamont Avenue	Kissimmee	FL	34741	64,151.00
Brown Metropolitan Housing Author- ity.	406 West Plum Street	Georgetown	OH	45121	20,600.00
Kentucky Housing Corporation- State Agency.	1050 US 127 South	Frankfort	KY	40601	58,620.00
Akron Metropolitan Housing Author- ity.	100 W Cedar Street	Akron	OH	44307	155,474.00
Peoria Housing Authority	100 S Richard Pryor Place	Peoria	IL	61605	25,161.00
Indiana Housing and Community Development Authority.	30 S Meridian St. Suite 900	Indianapolis	IN	46204	93,984.00
Hot Springs Housing Authority	1004 Illinois Street	Hot Springs	AR	71901	35,970.00
Panama City Housing Authority	2315 Ruth Hentz Avenue	Panama City	FL	32405	78,836.00
Ark-Tex Council of Governments Housing Authority.	4808 Elizabeth Street	Texarkana	TX	75501	21,324.00
San Angelo Housing Authority	420 East 28th Street	San Angelo	TX	76903	42,448.00
Housing Authority of Fort Worth	1201 E 13th Street	Fort Worth	TX	76102	192,900.00
Housing Authority of the City of Dal- las, Texas.	3939 N Hampton Road	Dallas	TX	75212	95,555.00
Denton Housing Authority	1225 Wilson	Denton	TX	76205	109,526.00
Tarrant County Housing Assistance Office.	2100 Circle Drive, #200	Fort Worth	TX	76119	184,113.00
City of Mesquite Housing Office	1616 N Galloway Avenue	Mesquite	TX	75149	51,683.00

FY22 HUD-VETERANS AFFAIRS SUPPORTIVE HOUSING (HUD-VASH) (PIH NOTICE 2022-26)—Continued

[Contact: Jerrianne Anthony (202) 402-2677]

Organization name	Street address	City	State	Zip code	Award Amount
San Marcos Housing Authority	1201 Thorpe Lane	San Marcos	TX	78666	66,570.00
Brazos Valley Council of Govern- ments.	3991 E 29th Street	Bryan	TX	77802	172,920.00
Corpus Christi Housing Authority	3701 Ayers Street	Corpus Christi	TX	78415	37,404.00
Garfield County Housing Authority ..	1430-F Railroad Avenue	Rifle	CO	81650	50,598.00
Housing Authority of the County of Salt Lake.	3595 S Main Street	Salt Lake City	UT	84115	41,914.00
Weber Housing Authority	237 26th Street, Suite 224	Ogden	UT	84401	122,914.00
Housing Authority of the City of Salem.	360 Church Street SE	Salem	OR	97301	183,924.00
Linn-Benton Housing Authority	1250 SE Queen Ave	Albany	OR	97322	142,923.00
Housing Authority City of Longview	820 11th Avenue	Longview	WA	98632	77,192.00
Housing Authority & Comm Svcs of Lane Co.	100 W 13th Ave	Eugene	OR	97401	366,216.00
Seattle Housing Authority	190 Queen Anne Ave N P.O. Box 19028.	Seattle	WA	98109	1,158,996.00
Housing Authority of King County ...	600 Andover Park West	Seattle	WA	98188	1,237,812.00
Housing Authority of Thurston County.	1206 12th Avenue SE	Olympia	WA	98501	217,038.00
Housing Authority of Skagit County	1650 Port Drive	Burlington	WA	98233	213,939.00
Housing Authority of the City of Kennewick.	1915 W 4th Place	Kennewick	WA	99336	136,690.00
County of Sacramento Housing Au- thority.	801 12th Street	Sacramento	CA	95814	99,113.00
Housing Authority of the County Contra Costa.	3133 Estudillo Street	Martinez	CA	94553	779,885.00
Housing Authority of the County of Stanislaus.	1701 Robertson Rd	Modesto	CA	95351	72,784.00
Housing Authority of the County of Yolo.	147 West Main Street	Woodland	CA	95695	146,454.00
Regional Housing Authority	1455 Butte House Rd	Yuba City	CA	95993	57,524.00
Housing Authority of the City of Redding.	777 Cypress Avenue	Redding	CA	96001	26,618.00
City of Vacaville	40 Eldridge Avenue #2	Vacaville	CA	95688	282,334.00
City of Roseville	316 Vernon Street, Suite 150	Roseville	CA	95678	91,586.00
Housing Authority of the County of San Mateo.	264 Harbor Boulevard Building A ...	Belmont	CA	94002	107,927.00
Housing Authority of County of Marin.	4020 Civic Center Drive	San Rafael	CA	94903	105,149.00
County of Sonoma	1440 Guerneville Road	Santa Rosa	CA	95403	66,622.00
City of Santa Rosa	90 Santa Rosa Ave	Santa Rosa	CA	95402	127,752.00
Housing Authority of the County of San Mateo.	264 Harbor Boulevard Building A ...	Belmont	CA	94002	107,927.00
Housing Auth. of the County of San Joaquin.	2575 Grand Canal Blvd	Stockton	CA	95203	108,531.00
Santa Clara County Housing Au- thority.	505 W Julian St	San Jose	CA	95110	717,062.00
Housing Authority of the County of Alameda.	22941 Atherton St	Hayward	CA	94541	330,017.00
Santa Cruz County Housing Author- ity.	2160 41st Avenue	Santa Cruz	CA	95060	885,246.00
Housing Authority of the City of Livermore.	3203 Leahy Way	Livermore	CA	94550	94,116.00
Guam Housing & Urban Renewal Authority.	117 Bien Venida Ave	Sinajana	GU	96910	116,081.00
City and County of Honolulu	842 Bethel St. 1st Flr	Honolulu	HI	96813	126,172.00
Kauai County Housing Agency	4444 Rice Street, Suite 330	Lihue	HI	96766	94,728.00
Hawaii Public Housing Authority	1002 North School Street	Honolulu	HI	96817	110,243.00
Housing Authority of the City of Los Angeles.	2600 Wilshire Blvd	Los Angeles	CA	90057	3,252,780.00
Housing Authority of the County of Los Angeles.	700 W Main St	Alhambra	CA	91801	3,360,030.00
City of Long Beach Housing Author- ity.	521 East 4th Street	Long Beach	CA	90802	1,200,615.00
Orange County Housing Authority ...	1770 North Broadway	Santa Ana	CA	92706	155,460.00
City of Glendale Housing Authority	6842 N 61ST Avenue	Glendale	AZ	85301	208,975.00
Chandler Housing & Redevelop- ment Division.	235 S. Arizona Avenue	Chandler	AZ	85225	140,651.00
Tempe Housing Authority	3500 S Rural Road Second Floor ...	Tempe	AZ	85282	96,227.00
Mohave County Housing Authority ..	700 W Beale Street	Kingman	AZ	86401	32,300.00

FY22 HUD-VETERANS AFFAIRS SUPPORTIVE HOUSING (HUD-VASH) (PIH NOTICE 2022-26)—Continued

[Contact: Jerriane Anthony (202) 402-2677]

Organization name	Street address	City	State	Zip code	Award Amount
Arizona Department of Housing	1110 West Washington Street Suite 310.	Phoenix	AZ	85007	562,918.00
San Diego Housing Commission	1122 Broadway, Suite 300	San Diego	CA	92101	352,320.00
Imperial Valley Housing Authority ...	1402 D Street	Brawley	CA	92227	53,854.00
City of Sioux City Housing Authority	405 6th St.—#107	Sioux City	IA	51101	21,139.00
Public Housing Agency of the City of St Paul.	555 N Wabasha Street Suite 400 ...	Saint Paul	MN	55102	150,972.00
Housing Authority of St. Louis Park, Minnesota.	5005 Minnetonka Boulevard	Saint Louis Park	MN	55416	100,625.00
Olmsted County HRA	2117 Campus Drive SE Suite 300 ..	Rochester	MN	55904	27,665.00
Metropolitan Council	390 North Robert Street	St. Paul	MN	55101	252,436.00
Washington County CDA	7645 Currell Boulevard	Woodbury	MN	55125	42,593.00
Housing Authority of the City of Superior.	1219 North 8th Street	Superior	WI	54880	24,468.00
Moline Housing Authority	11th Avenue A	Moline	IL	61265	46,526.00
Total					25,373,842.00

Appendix H

FY22 PIH NOTICE 2022-19: MAINSTREAM VOUCHERS

[Contact: Emily Warren, 202-402-7515]

Organization name	Street address	City	State	Zip	Award amount
Alaska Housing Finance Corporation.	P.O. Box 101020	Anchorage	AK	99510	\$282,850
Johnson County Public Housing Agency.	P.O. Box 353	Clarksville	AR	72830	20,000
Oakland Housing Authority	1619 Harrison St	Oakland	CA	94612	1,088,456
Housing Authority of the City of Los Angeles.	2600 Wilshire Blvd., 3rd Floor	Los Angeles	CA	90057	145,500
County of Contra Costa Housing Authority.	3133 Estudillo St., P.O. Box 2759 ...	Martinez	CA	94553	1,226,436
Housing Authority of the City of San Buenaventura.	995 Riverside Street	Ventura	CA	93001	437,659
Housing Authority of County of Marin.	4020 Civic Center Drive	San Rafael	CA	94903	825,440
City of Berkeley Housing Authority ..	1947 Center Street, 5th Floor	Berkeley	CA	94704	684,103
Housing Authority of the County Santa Clara.	505 West Julian St	San Jose	CA	95110	1,183,788
Housing Authority of the City of San Luis Obispo.	P.O. Box 1289, 487 Leffe Street	San Luis Obispo	CA	93406	462,005
Carlsbad Housing & Neighborhood Services.	1200 Carlsbad Village Drive	Carlsbad	CA	92008	216,276
County of Sonoma	1440 Guerneville Road	Santa Rosa	CA	95403	500,413
Orange County Housing Authority ...	1501 E St. Andrew Place	Santa Ana	CA	92705	1,060,750
County of Shasta Housing Authority	1670 Market Street, Suite 300	Redding	CA	96001	16,500
Imperial Valley Housing Authority ...	1401 D Street	Brawley	CA	92227	142,358
Boulder Housing Partners	4800 Broadway	Boulder	CO	80304	127,466
Fort Collins Housing Authority	1715 W Mountain Ave	Fort Collins	CO	80521	430,776
Grand Junction Housing Authority ...	1011 North Tenth Street	Grand Junction ...	CO	81501	215,791
Jefferson County Housing Authority	7490 West 45th Avenue	Wheatridge	CO	80033	75,000
Housing Authority of the City of Norwalk.	24 1/2 Monroe Street	Norwalk	CT	06856	50,000
Stamford Housing Authority	22 Clinton Ave	Stamford	CT	06901	714,258
Wallingford Housing Authority	45 Tremper Drive	Wallingford Town	CT	64920	10,000
Connecticut Department of Social Services.	505 Hudson Street	Hartford	CT	06106	543,948
Community Connections	801 Pennsylvania Ave., SE 201	Washington	DC	20003	135,571
Tampa Housing Authority	5301 West Cypress St	Tampa	FL	33607	477,816
Orlando Housing Authority	390 North Bumby Avenue	Orlando	FL	32803	288,648
Miami-Dade Housing Agency	701 NW 1st Court, 16th Floor	Miami	FL	33136	986,098
Housing Authority of the City of Lakeland.	P.O. Box 1009, 430 S Hartsell Avenue.	Lakeland	FL	33815	22,500
Housing Authority of New Smyrna Beach.	P.O. Box 688	New Smyrna Beach.	FL	32170	69,000
Seminole County Housing Authority	662 Academy Place	Oviedo	FL	32765	103,955

FY22 PIH NOTICE 2022–19: MAINSTREAM VOUCHERS—Continued

[Contact: Emily Warren, 202–402–7515]

Organization name	Street address	City	State	Zip	Award amount
Pinellas County Housing Authority ..	11479 Ulmerton Road	Largo	FL	33778	37,500
Deland Housing Authority	1450 South Woodland Boulevard, Suite 200A.	De Land	FL	32720	89,903
HA Lee County	14170 Warner Circle NW	North Fort Myers	FL	33903	95,676
Housing Authority of the City of At- lanta Georgia.	230 John Wesley Dobbs Ave. NE ...	Atlanta	GA	30303	705,462
Guam Housing & Urban Renewal Authority.	117 Bien Venida Avenue	Sinajana	GU	96926	221,201
Municipal Housing Agency of Coun- cil Bluffs.	505 South Sixth Street	Council Bluffs	IA	51503	60,114
Eastern Iowa Regional Housing Au- thority.	7600 Commerce Park	Dubuque	IA	52002	39,500
Housing Authority of the City of Po- catello.	P.O. Box 4161	Pocatello	ID	83205	62,525
Chicago Housing Authority	60 East Van Buren St., 11th Floor ..	Chicago	IL	60605	725,312
Housing Authority of the County of Cook.	175 West Jackson Boulevard, Suite 350.	Chicago	IL	60604	530,802
Winnebago County Housing Author- ity.	3617 Delaware Street	Rockford	IL	61102	71,686
Kokomo Housing Authority	219 E Taylor St., P.O. Box 1207	Kokomo	IN	46903	12,500
Thibodaux City	P.O. Box 5418	Thibodaux	LA	70302	57,404
Louisiana Housing Authority	150 N Third Street	Baton Rouge	LA	70801	95,000
Boston Housing Authority	52 Chauncy Street	Boston	MA	21110	205,000
Chelsea Housing Authority	54 Locke Street	Chelsea	MA	21500	229,434
Taunton Housing Authority	30 Olney Street-Suite B	Taunton	MA	27804	481,443
Dedham Housing Authority	163 Dedham Blvd	Dedham	MA	20262	171,049
Yarmouth Housing Authority	Long Pond Plaza	South Yarmouth ..	MA	02664	118,266
Milton Housing Authority	65 Miller Ave	Milton	MA	21864	19,500
Sandwich Housing Authority	20 Tom's Way	Sandwich Town ..	MA	25631	75,500
Community Teamwork, Inc	155 Merrimack Street	Lowell	MA	01852	173,456
Housing Authority of Baltimore City	417 East Fayette Street	Baltimore	MD	21201	58,000
Frederick Housing Authority	209 Madison Street	Frederick	MD	21701	113,788
Housing Authority of Calvert County	480 Main Street	Prince Frederick	MD	20678	105,840
Carroll County Housing and Com- munity Dev.	10 Distillery Drive, Suite 101	Westminster	MD	21157	89,389
Baltimore County, MD	Drumcastle Govt. Center, 6401 York Road, 1st Floor.	Baltimore	MD	21212	648,762
Fort Fairfield Housing Authority	18 Fields Lane	Fort Fairfield	ME	04742	29,639
Portland Housing Authority	14 Baxter Boulevard	Portland	ME	04101	267,012
Lewiston Housing Authority	1 College Street	Lewiston	ME	04240	69,500
Brunswick Housing Authority	P.O. Box A	Brunswick	ME	04011	75,492
The Housing Authority of the City of Westbrook.	30 Liza Harmon Drive	Westbrook	ME	40924	109,967
Biddeford Housing Authority	P.O. Box 2287	Biddeford	ME	40050	102,280
Augusta Housing Authority	33 Union Street, Suite 3	Augusta	ME	43300	\$96,314
Michigan State Housing Develop- ment Authority.	P.O. Box 30044	Lansing	MI	48909	89,500
Itasca County HRA	1115 NW 4th St	Grand Rapids	MN	55744	54,703
Plymouth Housing & Redevelop- ment Authority.	3400 Plymouth Boulevard	Plymouth	MN	55447	95,740
Washington County HRA	7645 Currell Boulevard	Woodbury	MN	55125	94,346
St. Louis Housing Authority	3520 Page Boulevard	St. Louis	MO	63106	386,574
Housing Authority of Kansas City, Missouri.	3822 Summit	Kansas City	MO	64111	50,000
St. Joseph Housing Authority	502 S 10th St., Box 1153	St Joseph	MO	64502	79,876
Housing Authority of the City of Co- lumbia, MO.	201 Switzler Street	Columbia	MO	65203	40,618
Springfield Housing Authority	421 West Madison St	Springfield	MO	65806	41,317
Boone County Public Housing Agency.	807 B North Providence Road	Columbia	MO	65203	66,540
Mississippi Regional Housing Au- thority No. IV.	P.O. Box 1051	Columbus	MS	39703	128,070
The Housing Authority of the City of Jackson.	2747 Livingston Road, P.O. Box 11327.	Jackson	MS	39283	19,500
Housing Authority of Billings	2415 1st Ave., North	Billings	MT	59101	20,000
Housing Authority of the County of Wake.	100 Shannon Street, P.O. Box 399	Zebulon	NC	27597	122,225
Housing Authority of the City of Greenville.	1103 Broad Street, P.O. Box 1426	Greenville	NC	27834	102,360
Sandhills Community Action Pro- gram, Inc.	103 Saunders Street, P.O. Box 937	Carthage	NC	28327	50,789

FY22 PIH NOTICE 2022–19: MAINSTREAM VOUCHERS—Continued

[Contact: Emily Warren, 202–402–7515]

Organization name	Street address	City	State	Zip	Award amount
Western Piedmont Council of Governments.	P.O. Box 9026	Hickory	NC	28603	123,000
Northwestern Regional Housing Authority.	Addison Exe. Office Bldg., 869 Hwy., 105 Ext or P.O. Box 2510.	Boone	NC	28607	219,807
Housing Authority of Cass County ..	230 8th Ave. West	West Fargo	ND	58078	20,000
Stark County Housing Authority	1149 West Villard, P.O. Box 107 ...	Dickinson	ND	58602	10,000
Lincoln Housing Authority	5700 "R" St., P.O. Box 5327	Lincoln	NE	68505	73,500
New Hampshire Housing Finance Agency.	P.O. Box 5087	Manchester	NH	31085	296,572
North Bergen Housing Authority	6121 Grand Avenue	North Bergen	NJ	70475	172,363
Bayonne Housing Authority	50 East 21st Street	Bayonne	NJ	70023	137,376
Hunterdon County Division of Housing.	Administration Building, 8 Gauntt Place, P.O. Box 2900.	Flemington	NJ	88221	139,337
Union County Housing Authority	Administration Building, One Elizabethtown Plaza.	Elizabeth	NJ	72079	20,000
Community Enterprises Corporation	11 Spring Street	Freehold	NJ	07728	45,000
Housing Authority of the County of Santa Fe.	52 Camino De Jacobo	Santa Fe	NM	87507	14,500
Buffalo Municipal Housing Authority	300 Perry Street	Buffalo	NY	14204	79,751
Village of Kaser	15 Elyon Rd	Monsey	NY	10952	187,625
NYS Housing Trust Fund Corporation.	38–40 State Street	Albany	NY	12207	525,660
Cuyahoga Metropolitan Housing Authority.	8120 Kinsman Road	Cleveland	OH	44104	72,500
Akron Metropolitan Housing Authority.	100 W Cedar Street	Akron	OH	44307	286,494
Lake Metropolitan Housing Authority	189 First Street	Painesville	OH	44077	63,920
Medina Metropolitan Housing Authority.	850 Walter Road	Medina	OH	44256	89,730
City of Marietta	304 Putnam Street	Marietta	OH	45750	40,825
Housing Authority of the City of Oklahoma City.	1700 NE Fourth Street	Oklahoma City	OK	73117	307,050
Housing Authority of Clackamas County.	P.O. Box 1510	Oregon City	OR	97045	361,166
Housing Authority of Lincoln County	P.O. Box 1470	Newport	OR	97365	64,068
Housing Authority & Comm Svcs of Lane Co.	177 Day Island Rd	Eugene	OR	97401	237,654
Housing Authority of Yamhill County	135 NE Dunn Place, P.O. Box 865	McMinnville	OR	97128	108,000
Klamath Housing Authority	P.O. Box 5110	Klamath Falls	OR	97601	44,089
Housing Authority of Washington County.	111 NE Lincoln St., Suite 200–L, Ms63.	Hillsboro	OR	97124	89,000
Philadelphia Housing Authority	12 South 23rd Street	Philadelphia	PA	19103	426,486
Allegheny County Housing Authority	625 Stanwix St., 12th Floor	Pittsburgh	PA	15222	62,000
Housing Authority of the County of Huntingdon.	100 Federal Drive	Mount Union	PA	17066	46,106
Housing Authority of the County of Dauphin.	501 Mohn Street, P.O. Box 7598	Steelton	PA	17113	47,000
Housing Authority of the County of Jefferson.	201 N Jefferson Street	Punxsutawney	PA	15767	46,900
Housing Authority of the County of Union.	1610 Industrial Blvd., Suite 400	Lewisburg	PA	17837	93,469
Housing Authority of the City of Pawtucket.	214 Roosevelt Ave., P.O. Box 1303	Pawtucket	RI	28620	50,500
Municipality of Vega Baja	P.O. Box 4555	Vega Baja	PR	69445	62,000
Housing Authority of Myrtle Beach ..	P.O. Box 2468	Myrtle Beach	SC	29578	158,923
Housing Authority of Newberry	P.O. Drawer 737	Newberry	SC	29108	20,000
SC State Housing Authority	300–C Outlet Pointe Blvd	Columbia	SC	29210	37,500
Aberdeen Housing and Redevelopment Commission.	2324 3rd Ave. SE	Aberdeen	SD	57401	20,000
Knoxville's Community Development Corp.	P.O. Box 3550	Knoxville	TN	37927	120,000
Chattanooga Housing Authority	P.O. Box 1486	Chattanooga	TN	37402	63,500
East Tennessee Human Resource Agency.	9111 Cross Park Drive, Suite D100	Knoxville	TN	37923	48,703
Tennessee Housing Development Agency.	502 Deaderick Street, 3rd Floor	Nashville	TN	37243	89,500
Austin Housing Authority	P.O. Box 41119	Austin	TX	78704	563,736
Housing Authority of Fort Worth	P.O. Box 430, 1201 E 13th St	Fort Worth	TX	76101	462,378
San Antonio Housing Authority	818 S Flores Street, P.O. Box 1300	San Antonio	TX	78295	350,298
Brownsville Housing Authority	P.O. Box 4420	Brownsville	TX	78523	8,500

FY22 PIH NOTICE 2022–19: MAINSTREAM VOUCHERS—Continued

[Contact: Emily Warren, 202–402–7515]

Organization name	Street address	City	State	Zip	Award amount
Housing Authority of the City of Dallas, Texas.	3939 N Hampton Rd	Dallas	TX	75212	148,500
City of Mesquite Housing Office	1515 N Galloway P.O. Box 850137	Mesquite	TX	75185	12,500
Bexar County Housing Authority	1017 N Main Ave., Suite 201	San Antonio	TX	78212	39,000
Bear River Regional Housing Authority.	170 North Main	Logan	UT	84321	40,351
Richmond Redevelopment & Housing Authority.	901 Chamberlayne Parkway, P.O. Box 26887.	Richmond	VA	23261	76,500
Danville Redevelopment & Housing Authority.	P.O. Box 1476	Danville	VA	24543	92,000
Roanoke Redevelopment & Housing Authority.	P.O. Box 6359, 2624 Salem Turnpike NW.	Roanoke	VA	24017	174,521
Chesapeake Redevelopment & Housing Authority.	1468 S Military Highway	Chesapeake	VA	23327	63,500
Lynchburg Redevelopment & Housing Authority.	P.O. Box 1298, 918 Commerce Street.	Lynchburg	VA	24505	228,485
Fairfax County Redevelopment & Housing Authority.	3700 Pender Drive, Suite 300	Fairfax	VA	22030	62,500
County of Albemarle/Office of Housing.	1600 5th Street, Suite B	Charlottesville	VA	22902	47,500
People Inc. of Southwest Virginia ...	1173 West Main St	Abingdon	VA	24210	35,586
Virginia Housing Development Authority.	601 South Belvidere Street	Richmond	VA	23220	502,140
Virgin Islands Housing Authority	P.O. Box 7668	St. Thomas	VI	80176	37,500
Rutland Housing Authority	5 Tremont Street	Rutland	VT	05701	110,731
Housing Authority City of Longview	1207 Commerce Avenue	Longview	WA	98632	225,013
Housing Authority of the City of Vancouver.	2500 Main Street, Suite 200	Vancouver	WA	98660	343,501
HA City of Kennewick	1915 West 4th Place	Kennewick	WA	99336	28,000
Housing Authority City of Bellingham.	208 Unity St., Lower Level, P.O. Box 9701.	Bellingham	WA	98225	75,000
Housing Authority of Snohomish County.	12711 4th Ave. W	Everett	WA	98204	496,028
Eau Claire County Housing Authority.	227 1st Street West	Altoona	WI	54720	98,410
Housing Authority of the City of Parkersburg.	1901 Cameron Avenue	Parkersburg	WV	26101	124,155
Housing Authority of Randolph County.	P.O. Box 1579, 1404 N Randolph Ave.	Elkins	WV	26241	55,996
Total					29,753,638

[FR Doc. 2024–16042 Filed 7–19–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7082–N–05]

60-Day Notice of Proposed Information Collection: Application for Displacement/Relocation/Temporary Relocation Assistance for Persons; OMB Control No.: 2506–0016

AGENCY: Office of Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested

parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* September 20, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 60-day Review—Open for Public Comments” or by using the search function. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department

of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000; telephone (202) 402–3400 (this is not a toll-free number) or email: PaperworkReductionActOffice@hud.gov.

FOR FURTHER INFORMATION CONTACT: Lori Martin, Relocation Specialist, Relocation and Real Estate Division, CGHR, Department of Housing and Urban Development, 909 First Avenue, Seattle, WA 98104; email Lori.Martin@hud.gov, telephone (206) 220–5373. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications->

relay-service-trs. Copies of available documents submitted to OMB may be obtained from Ms. Martin.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Application for Displacement/Relocation/TemporaryRelocation Assistance for Persons.

OMB Approval Number: 2506–0016.

Type of Request: Extension of currently approved collection.
Form Number: HUD–40030, HUD–40054, HUD–40055, HUD–40056, HUD–40057, HUD–40058, HUD–40061, and HUD–40072.
Description of the need for the information and proposed use: Application for displacement/relocation assistance for persons (families, individuals, businesses, nonprofit organizations and farms) displaced by, or temporarily relocated for, certain HUD programs. No changes are being made for Forms HUD–40030, HUD–

40054, 40055, HUD–40056, HUD–40057, HUD–40058, HUD–40061, and HUD–40072.
Respondents: Individuals, households, businesses, farms, non-profits, state, local and tribal governments.
Estimated Number of Respondents: 37,800.
Estimated Number of Responses: 61,800.
Frequency of Response: 3.
Average Hours per Response: 8.
Total Estimated Burdens: 56,000 (no change).

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
HUD 40054	12,000.00	1.00	12,000.00	0.5	6,000.00	\$29.68	\$178,080.00
HUD 40055	400.00	1.00	400.00	1.5	600.00	29.68	17,808.00
HUD 40056	400.00	1.00	400.00	1.0	400.00	29.68	11,872.00
HUD 40030	25,000.00	1.00	25,000.00	1.0	25,000.00	29.68	742,000.00
HUD 40057	1,250.00	1.00	1,250.00	1.0	1,250.00	29.68	37,100.00
HUD 40058	8,750.00	1.00	8,750.00	1.0	8,750.00	29.68	259,700.00
HUD 40072	2,000.00	1.00	2,000.00	1.0	2,000.00	29.68	59,360.00
HUD 40061	12,000.00	1.00	12,000.00	1.0	12,000.00	29.68	356,160.00
Total	61,800.00	1.00	61,800.00		56,000.00	29.68	1,662,080.00

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

- (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (2) The accuracy of the agency’s estimate of the burden of the proposed collection of information;
- (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and
- (4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Marion M. McFadden,
Principal Deputy Assistant Secretary for Community Planning and Development.
[FR Doc. 2024–16034 Filed 7–19–24; 8:45 am]
BILLING CODE 4210–67–P

INTERNATIONAL TRADE COMMISSION

[Investigation. No. 337–TA–1410]

Certain Disposable Vaporizer Devices; Notice of Institution of Investigation

AGENCY: U.S. International Trade Commission.
ACTION: Notice.
SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on June 11, 2024, under section 337 of the Tariff Act of 1930, as amended, on behalf of RAI Strategic Holdings, Inc. of Winston-Salem, North Carolina; R.J. Reynolds Vapor Company of Winston-Salem, North Carolina; R.J. Reynolds Tobacco Company of Winston-Salem of North Carolina; and RAI Services Company of Winston-Salem, North Carolina. Supplements were filed on June 12, 2024 and July 1, 2024. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain disposable vaporizer devices and components thereof by reason of the infringement of certain claims of U.S. Patent No. 11,925,202 (“the ‘202 patent”). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute. The complainant requests that the Commission institute

an investigation and, after the investigation, issue a general exclusion order, or in the alternative a limited exclusion order, and cease and desist orders. A motion for temporary relief filed concurrently with the complaint, requests that the Commission issue a temporary exclusion order and temporary cease and desist orders prohibiting the importation into and the sale within the United States after importation of certain disposable vaporizer devices and components thereof during the course of the Commission’s investigation.
ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>.
FOR FURTHER INFORMATION CONTACT: Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2024).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on July 16, 2024, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1, 3, 4, 8–13, and 15 of the '202 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is “disposable electronic vapor device[s] designed to hold and heat a liquid during use to generate an aerosol”;

(3) Pursuant to section 210.58 of the Commission's Rules of Practice and Procedure, 19 CFR 210.58, the motion for temporary relief under subsection (e) of section 337 of the Tariff Act of 1930, which was filed with the complaint, is provisionally accepted and referred to the presiding administrative law judge for investigation;

(4) Pursuant to Commission Rule 210.50(b)(1), 19 CFR 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and hear arguments from the parties or other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. 1337(d)(1), (f)(1), (g)(1);

(5) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

RAI Strategic Holdings, Inc., 401 North Main Street, Winston-Salem, NC 27101

R.J. Reynolds Vapor Company, 401 North Main Street, Winston-Salem, NC 27101

R.J. Reynolds Tobacco Company, 401 North Main Street, Winston-Salem, NC 27101

RAI Services Company, 401 North Main Street, Winston-Salem, NC 27101

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Breeze Smoke, LLC, 4654 Lilly Court, West Bloomfield, MI 48323

Dongguan (Shenzhen) Shikai Technology Co., Ltd., Room 501–510, Building 16, Nan'an Plaza, Exhibition Bay, Zhancheng Community, Fuhai Street, Bao'an District, Shenzhen, Guangdong Province, China 518103

Vapeonly Technology Co. Ltd., 19H Maxgrand Plaza, No. 3 Tai Yau Street, San Po Kong, Kowloon, Hong Kong
iMiracle (Shenzhen) Technology Co., Ltd., Unit 3510–37, Luohu Business Center, No. 2028 Shennan East Road, Chengdong Community, Dongmen Street, Luohu District, Shenzhen, China 518001

Guangdong Qisitech Co., Ltd., Room 201, Building 3, No. 36, Fuxing Road, Chang'an Town, Dongguan, Guangdong Province, China 523873

Fewo Intelligent Manufacturing Ltd., Room 101, Building 9, No. 243 Huiade Road, Humen Town, Dongguan City, Guangdong Province, China 523926

Nevera (HK) Ltd., 19H, Maxgrand Plaza, No.3 Tai Yau Street, San Po Kong, Kowloon, Hong Kong

Guangdong Cellular Workshop Electronics, Technology Co., Ltd., Room 201, Building 3, No. 216, Chang'an Bubugao Road, Chang'an Town, Dongguan City, Guangdong Province, China 523850

Wonder Ladies Ltd., Sea Meadow House, P.O. Box 116, Road Town, Tortola, British Virgin Islands VG1110

Sailing South Ltd., Sea Meadow House, P.O. Box 116, Road Town, Tortola, British Virgin Islands VG1110

Marea Morada Ltd., Sea Meadow House, P.O. Box 116, Road Town, Tortola, British Virgin Islands VG1110

Social Brands, LLC, Beshoy Saad (registered agent), Suite 385, 9696 Skillman Street, Dallas, TX 75243

Zhuhai Qisitech Co., Ltd., Room 201, Building 5, No. 16, Jinxing Road, Tangjiwan Town, High-Tech Zone, Zhuhai, Guangdong Province, China 519085

Shenzhen Han Technology Co., Ltd., Room 401 and Floors 4–6, Building D, Shenzhen Qianwan Hard Technology Industrial Park, Nanchang

Community, Xixiang Street, Bao'an District, Shenzhen, Guangdong Province, China 518102

Palma Terra Ltd., Sea Meadow House, P.O. Box 116, Road Town, Tortola, British Virgin Islands VG1110

Shenzhen IVPs Technology Co., Ltd., Room 101, Building B8, No. 2,

Cengyao Industrial Area, Yulu Community, Yutang Street, Guangming District, Shenzhen, Guangdong Province, China 518132

Heaven Gifts International Ltd., 19H, Maxgrand Plaza, No. 3 Tai Yau Street, San Po Kong, Kowloon, Hong Kong
Maduro Distributors d/b/a The Loon, 3021 82nd Lane NE, Minneapolis, MN 55449

Bidi Vapor, LLC, 200 South Orange Avenue, Suite 2300, Orlando, FL 32801

Kimsun Technology (HuiZhou) Co., Ltd., 18th Floor, Building A, Boton Technology Park, Chaguang Road, Nanshan District, Shenzhen, Guangdong Province, China 518057
Shenzhen Yanyang Technology Co., Ltd., Room 901, Building B, Guanghao Int'l Center, Intersection of Meilong Rd and Zhongmei Rd, Daling Community, Minzhi Street, Longhua District, Shenzhen, Guangdong Province, China 518131

Pastel Cartel, LLC, 5900 Balcones Dr., Ste. 100, Austin, TX 78731

American Vape Company, LLC, 13326 Immanuel Road, Ste. 3, Pflugerville, TX 78660

Affiliated Imports, LLC, 5900 Balcones Dr., Ste. 100, Austin, TX 78731

Shenzhen LC Technology Co., Ltd., Room 301, 3rd Floor, Building 3, Changyi Industrial Factory, No. 1 Lirong Road, Xinshi Community, Dalang Street, Longhua District, Shenzhen, Guangdong Province, China 518109

LCF Labs, Inc., 895 S Rockefeller Avenue, Unit 103, Ontario, CA 91761

Shenzhen Kangvape Technology Co., Ltd., Floors 5 and 2, Building 3, Chuangxin Port, Hanyu Bay District, Liyuan Road, Tangwei Community, Fuhai Street, Bao'an District, Shenzhen, Guangdong Province, China 518104

Flumgio Technology Ltd., Room 21, Unit A, Tin Wui Industrial Building, No. 3 Hing Wong Street, Tuen Mun, N.T., Hong Kong

Shenzhen Pingray Technology, Floors 2, 3 and 4, Building G, Wanfeng Western Entrepreneurship Park, Heyi Community, Shajing Street, Bao'an District, Shenzhen, Guangdong Province, China 518125

SV3, LLC d/b/a Mi-One Brands, 2303 N 44th Street, Unit 2, Phoenix, AZ 85008

Price Point Distributors Inc. d/b/a Price Point NY, 500 Smith Street, Farmingdale, NY 11735

Flawless Vape Shop Inc., 5589 E Santa Ana Canyon Rd., Anaheim, CA 92807

Flawless Vape Wholesale & Distribution Inc., 5589 E Santa Ana Canyon Rd., Anaheim, CA 92807

TheSy, LLC d/b/a Element Vape, Unit 23, 300 W Valley Blvd., Alhambra, CA 91803

VICA Trading Inc. d/b/a Vapesourcing, 3045 Edinger Avenue, Tustin, CA 92780

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW, Suite 401, Washington, DC 20436; and

(6) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainants of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: July 17, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024-16050 Filed 7-19-24; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701-TA-365-366 and 731-TA-734-735 (Fifth Review)]

Certain Pasta From Italy and Turkey; Scheduling of Expedited Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 ("the Act") to determine whether revocation of the antidumping duty orders and countervailing duty orders on certain pasta from Italy and Turkey would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: June 4, 2024.

FOR FURTHER INFORMATION CONTACT: Alec Resch (202-708-1448), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION:

Background.—On June 4, 2024, the Commission determined that the domestic interested party group response to its notice of institution (89 FR 15217, March 1, 2024) of the subject five-year reviews was adequate and that the respondent interested party group responses were inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews.¹ Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Act (19 U.S.C. 1675(c)(3)).²

For further information concerning the conduct of these reviews and rules

of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Staff report.—A staff report containing information concerning the subject matter of the reviews has been placed in the nonpublic record, and will be made available to persons on the Administrative Protective Order service list for these reviews on August 14, 2024. A public version will be issued thereafter, pursuant to § 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in § 207.62(d) of the Commission's rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,³ and any party other than an interested party to the reviews may file written comments with the Secretary on what determination the Commission should reach in the reviews. Comments are due on or before 5:15 p.m. on August 22, 2024, and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by August 22, 2024. However, should the Department of Commerce ("Commerce") extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures*, available on the Commission's website at https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf, elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service

³ The Commission has found the responses submitted on behalf of 8th Avenue Food and Provisions, Inc., Philadelphia Macaroni Company, Winland Foods, Inc., Barilla America, Inc., American Italian Past Company (Subsidiary of Winland Foods, Inc.), Barilla America, Inc., La Molisana, S.p.A., and Industria Alimentare Colavita S.p.A. to be individually adequate. Comments from other interested parties will not be accepted (see 19 CFR 207.62(d)(2)).

¹ A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's website.

² Commissioner David S. Johanson voted to conduct full reviews.

must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determinations.—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Act; this notice is published pursuant to § 207.62 of the Commission's rules.

By order of the Commission.

Issued: July 17, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–16064 Filed 7–19–24; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

[Exemption Application No. L–12006]

Proposed Exemption for Associated General Contractors of America, San Diego Chapter, Inc. Apprenticeship and Training Fund, Located in San Diego, CA

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Notice of proposed exemption.

SUMMARY: This document provides notice of the pendency before the Department of Labor (the Department) of a proposed individual exemption from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974, as amended (ERISA or the Act). This proposed exemption would permit the leasing of certain improved real property located in San Diego, California by the Associated General Contractors of America, San Diego Chapter, Inc. Apprenticeship and Training Fund (the Plan or the Applicant), from the Associated General Contractors of America, San Diego Chapter, Inc. (the Chapter).

DATES:

Comments due: Written comments and requests for a public hearing on the proposed exemption should be submitted to the Department by September 5, 2024.

Exemption date: If granted, this exemption will be in effect beginning on October 1, 2020.

ADDRESSES: All written comments and requests for a hearing should be

submitted to the Employee Benefits Security Administration (EBSA), Office of Exemption Determinations, Attention: Application No. L–12006 via email to e-OED@dol.gov or online through <https://www.regulations.gov>. Any such comments or requests should be sent by the end of the scheduled comment period. The application for exemption and the comments received will be available for public inspection in the Public Disclosure Room of the Employee Benefits Security Administration, U.S. Department of Labor, Room N–1515, 200 Constitution Avenue NW, Washington, DC 20210. See **SUPPLEMENTARY INFORMATION** below for additional information regarding comments.

FOR FURTHER INFORMATION CONTACT: Mr. Frank Gonzalez of the Department at (202) 693–8553 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

Comments

Persons are encouraged to submit all comments electronically and not to follow with paper copies. Comments should state the nature of the person's interest in the proposed exemption and how the person would be adversely affected by the exemption, if granted. Any person who may be adversely affected by an exemption can request a hearing on the exemption. A request for a hearing must state: (1) the name, address, telephone number, and email address of the person making the request; (2) the nature of the person's interest in the exemption, and the manner in which the person would be adversely affected by the exemption; and (3) a statement of the issues to be addressed and a general description of the evidence to be presented at the hearing. The Department will grant a request for a hearing made in accordance with the requirements above where a hearing is necessary to fully explore material factual issues identified by the person requesting the hearing. A hearing notice will be published by the Department in the **Federal Register**. The Department may decline to hold a hearing if: (1) the request for the hearing does not meet the requirements above; (2) the only issues identified for exploration at the hearing are matters of law; or (3) the factual issues identified can be fully explored through the submission of evidence in written (including electronic) form.

Warning: All comments received will be included in the public record without change and may be made available online at <https://www.regulations.gov>, including any

personal information provided, unless the comment includes information claimed to be confidential or other information whose disclosure is restricted by statute.

If you submit a comment, EBSA recommends that you include your name and other contact information in the body of your comment, but DO NOT submit information that you consider to be confidential, or otherwise protected (such as a Social Security number or an unlisted phone number) or confidential business information that you do not want publicly disclosed. However, if EBSA cannot read your comment due to technical difficulties and cannot contact you for clarification, EBSA might not be able to consider your comment. Additionally, the <https://www.regulations.gov> website is an “anonymous access” system, which means EBSA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email directly to EBSA without going through <https://www.regulations.gov>, your email address will be automatically captured and included as part of the comment that is placed in the public record and made available on the internet.

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of ERISA, and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (76 FR 66637, 66644, October 27, 2011).¹ If granted, this proposed exemption would permit, effective October 1, 2020, the leasing of certain improved real property located in San Diego, California by the Associated General Contractors of America, San Diego Chapter, Inc. Apprenticeship and Training Fund (the Plan or the Applicant), from the Associated General Contractors of America, San Diego Chapter, Inc. (the Chapter), provided that the conditions described below are met.

Summary of Facts and Representations²

The Plan

1. The Plan provides apprenticeship training for construction trade

¹ This proposed exemption would not provide relief from the requirements of, or specific sections of, any law not noted herein. Accordingly, the applicant is responsible for ensuring compliance with any other laws applicable to this transaction.

² The Summary of Facts and Representations is based on the Applicant's representations and does not reflect factual findings or opinions of the

employees within five Southern California counties. The Plan is funded by participating employers (contributing approximately 90% of the Plan's annual funding) and the State of California (contributing approximately 10% of the Plan's annual funding). Apprentices do not contribute to the Plan. The Plan's most recent audited financial statements reflect that the Plan's total assets were \$13,725,754 as of March 31, 2023.

2. The Plan's Board of Trustees (the Board) is comprised of six individual members (the Trustees) of participating construction trade employers. The Trustees make all the Plan's administrative and investment decisions including decisions about the lease that is the subject of this proposed exemption.

The Plan Sponsor: The Chapter

3. The Plan is sponsored by the Chapter, which is a trade organization founded in 1927 to promote the interests of employers in the construction industry located in San Diego, California. A Board of Directors comprised of construction trade employers manages the Chapter.

The Plan's Facilities Before October 1, 2020

4. The Applicant represents that before October 1, 2020, the Plan leased three different properties from unrelated parties comprising 11,293 square feet that were used for administrative, educational, and training purposes. According to the Applicant, the facilities on these properties lacked adequate square footage and had outdated training technology, which resulted in increased costs and wasted resources for the Plan. In addition, one of the properties was located more than three miles from the other two properties.

The Chapter's Property

5. On January 18, 2018, the Chapter and the Plan entered into a Memorandum of Understanding (MOU) documenting their shared interest in providing a "world class apprenticeship program" in a "modernized facility." Following execution of the MOU, the Chapter acquired unimproved real

property located at 10140 Riverford Road, Lakeside, California (the Parcel) from Lakeside Land Co., a California limited liability corporation (the LLC). The LLC is not a member of the Chapter, there are no common directors between the LLC and the Chapter, and no LLC directors are Plan Trustees. The LLC has neither contributed nor participated in the Plan, nor does the LLC participate in the Plan's apprenticeship training programs.

6. In 2020, the Chapter utilized the Parcel to construct a high-ceiling training space comprising approximately 43,600 square feet (the Building). The Chapter's acquisition of the Parcel, and subsequent construction of the Building, was based on the Plan's intent expressed in the MOU to sign a 10-year lease to use both the Building once constructed and an unimproved exterior lot (the Property).

The Lease

7. On April 25, 2019, the Plan Trustees, acting on behalf of the Plan, caused the Plan to enter into an agreement with the Chapter to lease both a portion of the Building (once constructed) and an unimproved exterior lot located in the Parcel (the Lease), subject to the review and approval of both a qualified independent fiduciary (described below, the Independent Fiduciary) and the Department.

8. The Lease's term is for 10 years, under which the Plan holds a leasehold interest to occupy and use 90 percent of the Building's rentable space (39,115 square feet of the Building's total space of 43,600 square feet) and an unimproved exterior lot along with rights to use the Property's common areas. The Chapter utilizes the remaining 10 percent, and it has no present plans to change its Building's space allocation.

9. The Plan's initial base rent under the Lease is \$40,000 per month or approximately \$1.02 per square foot (the Base Rent). This expense during a twelve (12) month period is about 3.5 percent of the Plan's total assets as reflected in the Plan's audited financial statements for accounting year ending March 31, 2023. The Base Rent is subject to annual increases that are discussed further below.

The Independent Appraiser

10. On May 17, 2019, the Plan engaged Cushman & Wakefield Western Inc. as the Independent Appraiser to determine the Property's fair market rental value. Trevor G. Chapman, a California licensed Certified General Real Estate Appraiser, who is an

employee of the Independent Appraiser, performed the appraisal.

11. Mr. Chapman represents that the Independent Appraiser has no present or prospective interest in the Property that is subject to the Lease, and no personal interest with respect to the Plan and the Chapter. In addition, Mr. Chapman represents that the Independent Appraiser's annual gross revenues derived from parties in interest with respect to the Plan represented 0.37% of its gross revenues for the 2020 tax year. Furthermore, the Independent Appraiser's agreement with the Plan does not contain any provisions that provide for the direct or indirect indemnification or reimbursement of the Independent Appraiser by the Plan or any other party for any failure to adhere to its contractual obligations or to state or Federal laws applicable to the Independent Appraiser's work, or that waive any rights, claims or remedies of the Plan or its participants and beneficiaries under ERISA, the Code, or other Federal and state laws against the Independent Appraiser with respect to the transaction(s) that are the subject of the exemption.

12. Mr. Chapman inspected the Property on July 1, 2019, to collect primary and secondary data related to the Property, investigate the general trends in the regional economy and local area, analyzed rental data where appropriate, and reviewed (i) the cost estimates based upon submitted architects' plans, and (ii) the proposed Lease using generally accepted market-derived appropriate methods and procedures. In a written report (the Independent Appraisal Report) dated October 23, 2019, Mr. Chapman determined that the Property's fair market rental rate was \$44,443 per month, which represented \$1.14 per square foot of the Plan's rentable space.

13. According to the Independent Appraiser, the Lease is a triple net lease.³ Notwithstanding the types of commercial leases that may exist in any given marketplace, the Independent Appraiser informed the Department that the Property subject to the Lease is located in a market area in which commercial leases are typically written on a triple-net basis with tenants

Department, unless indicated otherwise. The Department notes that the availability of this exemption, if granted, is subject to the express condition that the material facts and representations contained in application L-12006 (the Application) are true and complete and accurately describe all material terms of the transactions covered by the exemption. If there is any material change in the transaction covered by this proposed exemption or in a material fact or representation described in the Application, the exemption will cease to apply as of the date of the change.

³ The Independent Appraiser notes that a triple net lease is a type of commercial lease wherein the lessee is responsible for their pro rata share of expenses for common area maintenance, taxes, and insurance. Also, in addition to a base rent, tenants subject to triple net leases are often required to reimburse the landlord for certain expenses; recovery clauses for expenses range from absolutely net (whereby the tenant pays all property expenses) to fully gross (in which tenant pays no expenses), which provisions can vary by property type, locale, and can fall anywhere within the net to gross range.

responsible for all operating expenses, including common area maintenance, taxes, and insurance. Lease terms within the Property's market are generally between 3 and 7 years for industrial tenants and contain annual escalations of 3.0 percent.

The Independent Fiduciary

14. On October 27, 2019, the Plan Trustees retained the services of Prudent Fiduciary Services, LLC (PFS) of Los Angeles, California, to serve as the Plan's Independent Fiduciary with respect to the Lease. Specifically, Mr. Miguel Paredes, a principal with PFS, was appointed to undertake the duties and responsibilities on behalf of PFS in its role as the Plan's Independent Fiduciary to ensure that the Lease arrangement complied with ERISA.

15. The Independent Fiduciary represents that neither Mr. Paredes nor PFS had a pre-existing relationship with the Plan or the Chapter. The Independent Fiduciary also represents that Mr. Paredes and PFS expect to derive approximately 0.55 percent of their combined annual gross revenues from the Plan and parties in interest with respect to the Plan. The Independent Fiduciary's agreement with the Plan did not contain any provisions that violated ERISA Section 410 or the Department's Regulations codified at § 2509.75-4;⁴ and did not contain any provision providing for the direct or indirect indemnification or reimbursement of the Independent Fiduciary by the Plan or other party for any failure to adhere to its contractual obligations or to state or Federal laws applicable the Independent Fiduciary's work, or waiving any rights, claims, or remedies of the Plan under ERISA, state, or Federal law against the Independent Fiduciary with respect to the transaction(s) that are the subject of the exemption.

16. The Independent Fiduciary examined whether the Lease would be reasonable, prudent, in the interest of, and protective of the Plan and of the Plan's participants. To perform this examination, the Independent Fiduciary: (a) reviewed various documents provided by the Plan, such as trust agreements, IRS Forms 990, financial statements, written policies, guidelines, and procedures, lease agreements, and the Plan Trustees'

meeting minutes; (b) interviewed and/or held discussions with representatives of the Plan; (c) reviewed the Independent Appraisal Report; (d) conducted an in-person visit of the Property site; (e) reviewed applicable laws and guidance; and (f) considered the Plan Trustees' decision-making process with respect to entering into the Lease.⁵

17. In a report dated October 28, 2019 (the Independent Fiduciary Report), the Independent Fiduciary noted that the Property allows for onsite heavy equipment operator training, which was not an option in the Plan's former location due to space constraints. Plus, the new location represents an upgrade in size and quality, which should translate into better training programs. The Independent Fiduciary stated that having the classrooms and apprenticeship/training offices in the same location as the Chapter offices potentially improves the operation and efficiency of the training programs because the Chapter's oversight and resources are nearby. The Independent Fiduciary also noted that the Plan and Chapter share an interest in providing high quality apprenticeship and continuing training education programs because the Plan would be able to provide excellent benefits to its participants and the Chapter would be able to use the training programs to promote Chapter membership.

18. The Independent Fiduciary reviewed the Independent Appraiser's specific qualifications, including his education, prior experience, and professional licenses, memberships, and affiliations. Based upon its review, the Independent Fiduciary determined that the Independent Appraiser possessed the appropriate training, experience, and facilities to provide a qualified appraisal report on behalf of the Trust Fund regarding the subject property.

19. The Independent Fiduciary next examined the Independent Appraiser's independence. The Independent Fiduciary represents that it did not find any relationship between Chapman or Cushman, or any affiliates, to the parties that would be engaging in the transaction contemplated by the Lease Agreement. The Independent Fiduciary's review also did not reveal

any other information that would call into question the Independent Appraiser's independence.

20. The Independent Fiduciary next determined whether the payments from the Plan to the Chapter under the Lease would be reasonable. To do this, the Independent Fiduciary reviewed the methodology provided by the Independent Appraiser to calculate the fair market rent, which included comparing comparable rental properties, having discussions with local brokers, and testing the Independent Appraiser's conclusions through a return on cost analysis. The Independent Fiduciary adjusted the Lease's base rent of \$1.02 per square foot upwards by \$0.07 per square foot, to account for the Plan's additional \$2,579 monthly payments to the Reserve Fund, and determined that even with the adjusted rate, the Lease's adjusted monthly rent of \$1.09 per square foot is less than its appraised fair market value of \$1.14 per square foot. Additionally, the Independent Fiduciary noted in the Independent Fiduciary Report that leases in the Property's subject market are typically written on a triple net basis, which is consistent with the structure of the Lease. The Independent Fiduciary stated that it also reviewed the properties and key lease information used in the Independent Appraisal Report analysis of rental activity for comparable space in similar properties in the Property's subject market and found that the selected comparable properties were appropriate and reasonably similar. The Independent Fiduciary noted how other lease terms, such as rent escalation clauses, duration, and tenant improvement allowances, contained in the comparable leases that the Independent Appraiser identified compared to those in the Lease. For the reasons set forth above, the Independent Fiduciary determined that the arrangements provided under the Lease are necessary for the operation of the Plan and that the compensation to be paid by the Plan to the Chapter is reasonable. It also determined that entering into the Lease was reasonable, prudent, and in the Plan's interest.

21. On July 28, 2020, the Independent Fiduciary issued an addendum and supplement to the Independent Fiduciary Report. In the addendum, the Independent Fiduciary agreed to perform the following additional duties on behalf of the Plan: (a) monitor the terms of this exemption, if granted, on an ongoing basis and take all actions that are necessary and proper to enforce the Plan's rights under the Lease to protect the Plan's participants and

⁴ ERISA section 410 provides, in part, that "except as provided in ERISA Sections 405(b)(1) and 405(d), any provision in an agreement or instrument which purports to relieve a fiduciary from responsibility or liability for any responsibility, obligation, or duty under this part [meaning Part 4 of Title I of ERISA] shall be void as against public policy."

⁵ The Independent Fiduciary represents that the Trustees appeared to have undertaken a reasonable and thorough process before making this decision. The Independent Fiduciary represents that the Trustees had explored other alternatives and real estate properties in the area. Specifically, starting in year 2015 the Trustees began searching for new facilities. The Trustees evaluated 12 real properties, comprised of six existing buildings, three parcels of open land for building, two properties for operating engineer usage, and the additional annex near the then current facility.

beneficiaries; (b) review and approve the material terms and conditions of the Lease and make any adjustments thereto; (c) engage the Independent Appraiser and/or other service providers as they reasonably determine to be necessary; (d) monitor the Lease, including during any subsequent renewal period; and (e) ensure that all conditions of this exemption, if granted, are met. The obligations in the addendum have been subsumed into the Independent Fiduciary's duties below.

22. The proposed exemption requires the Independent Fiduciary to engage a qualified independent appraiser to perform an independent appraisal of the Property following the beginning date of the Lease, on a periodic basis as prudence requires, to ensure the Plan does not pay more than fair market value under the Lease. The Independent Fiduciary must regularly evaluate the prudence of the Plan's continued participation in the Lease and ensure that participation in the Lease remains in the interest of and protective of the interests of the Plan's participants. The Plan's ongoing participation in the Lease requires the ongoing approval and consent of the Independent Fiduciary. The Independent Fiduciary is responsible for the selection of the independent appraiser, the frequency of appraisals, and the assessment of the reliability of the appraisals in determining fair market value. The Plan may continue to participate in the Lease during any period only to the extent the Independent Fiduciary has affirmatively determined that participation in the Lease remains in the interest of and protective of the Plan and its participants and beneficiaries. The amounts that the Plan has paid or will continue to pay under the Lease may not exceed fair market value.

23. In the July 28, 2020, supplement to the Independent Fiduciary Report, the Independent Fiduciary stated that the Plan needed more space to comply with social distancing requirements and guidelines in the COVID-19 environment and to enable the Plan to offer sufficient classes in a manner compliant with State Division of Apprenticeship Standards Guidelines. In the supplement, the Independent Fiduciary confirmed that the Plan's entering into the Lease was reasonable, prudent, and in the interest of the Plan.

24. On October 1, 2020, the Independent Appraiser conducted another appraisal of the Property and determined that the Property's fair market rental value under the Lease was

\$48,890 per month as of that date.⁶ The Plan moved into the Building on the same day, stating that it urgently needed larger space due to the COVID-19 health pandemic. On January 14, 2022, the Independent Fiduciary represented to the Department that for the period beginning on October 1, 2020, the terms of the Lease, including the base monthly rent of \$40,000 per month, are in the interest of, and protective of, the Plan and its participants and beneficiaries, and reflect a below fair market rent for the subject premises.

Other Duties of the Independent Fiduciary

25. The Independent Fiduciary must ensure that the Lease is in the interest and protective of the Plan and its participants and beneficiaries, including with respect to any amendment or renewal of the Lease. Further, the Independent Fiduciary must take all necessary and proper steps to ensure that the Plan and its participants and beneficiaries are protected in connection with the Lease, including by approving any amendment or renewal thereof, and beginning on the day that the notice of exemption is published in the **Federal Register**, the Independent Fiduciary must ensure that the Plan's total payments under the Lease during a twelve (12) month period do not exceed ten (10) percent of the Plan's total assets as reflected in the most recently issued report from the independent accounting firm responsible for auditing the Plan's financial statements.

In order to ensure that the Lease and its terms continue to be in the interest of participants and beneficiaries of the Plan, this proposal requires the Independent Fiduciary to give prior written notice to the Department's Office of Exemption Determinations at least 60 days before the Lease is amended, modified, or extended, unless such delay would cause imminent harm to the Plan in which case the notice must be provided immediately. The notification must include a complete description of the amendment, modification, or extension, including all material terms.⁷ Additionally, the Independent Fiduciary must notify the Chapter of the Plan's intention to extend

the Lease beyond the initial 10-year term, and any subsequent renewal must not exceed five-years.

The Independent Fiduciary, while acting on the Plan's behalf with respect to the Lease, must not be directly or indirectly controlled by or through one or more intermediaries, or under common control with either the Chapter, the Plan, or any related employers' members.

26. The Independent Fiduciary has not entered into and must not enter into any agreement or instrument that violates either ERISA Section 410 or the Department's Regulations codified at § 2509.75-4;⁸ and has not entered and must not enter into any agreement, arrangement, or understanding that includes any provision that provides for the direct or indirect indemnification or reimbursement of the Independent Fiduciary by the Plan or other party for any failure to adhere to its contractual obligations or to state or Federal laws applicable to the Independent Fiduciary's work, or that waives any rights, claims, or remedies of the Plan under ERISA, state, or Federal law against the Independent Fiduciary with respect to the transaction(s) that are the subject of the exemption.

Other Lease Terms

27. The Lease defines the formula to be used in determining the Base Rent annual increases as follows:

"Beginning on the date that is one (1) year after the Commencement Date [Lease's start date], and on each successive one-year anniversary thereof (each an 'Adjustment Date') throughout the [term, the Base Rent shall be increased by the amount of increase in the CPI . . . [s]uch increase shall be calculated by multiplying the then-current Base Rent by a fraction, the numerator of which shall be the CPI for the Adjustment Date and the denominator of which shall be the CPI for the previous Adjustment Date (or the CPI for the Commencement Date in case of the adjustment for the first Adjustment Date). If there is no increase in CPI, or a decrease in CPI, the Base Rent shall remain unchanged."⁹

⁸ ERISA section 410 provides, in part, that "except as provided in ERISA Sections 405(b)(1) and 405(d), any provision in an agreement or instrument which purports to relieve a fiduciary from responsibility or liability for any responsibility, obligation, or duty under this part [meaning Part 4 of Title I of ERISA] shall be void as against public policy."

⁹ CPI means the Consumer Price Index; the Department's Bureau of Labor Statistics publishes the CPI. The Lease also provides that ". . . [t]he CPI for any Adjustment Date shall be the CPI for the most recent month for which it is published before the Adjustment Date (or before the Commencement Date, as the case may be)." The Department understands such Base Rent increase calculation to mean that the Base Rent may increase annually based on the published CPI for the applicable period.

⁶ This determination is set forth in the Independent Appraiser's written report, dated December 16, 2021.

⁷ Because the proposed exemption provides retroactive exemptive relief, within 60 days of the date of publication of the notice of exemption in the **Federal Register** (the Publication Date), the Independent Fiduciary will provide a summary of all amendments, modifications, or extensions of the Lease made between October 1, 2020, and the Publication Date.

28. Notwithstanding the Lease's CPI Base Rent annual increases provision discussed above, and as further described below, the Independent Fiduciary must ensure that the total amount paid by the Plan in connection with the Lease does not exceed the fair market rental value.

29. In addition to the Base Rent, the Lease requires the Plan to pay certain operating expenses (the Operating Expenses).¹⁰ The Operating Expenses are subject to both an annual reconciliation process (the Annual Reconciliation) and to the Plan's exercise of audit rights, because of the Building's 90/10 allocation ratio between the Plan and the Chapter, respectively. The computation of the Operating Expenses must be made in accordance with fair and reasonable accounting principles customarily applied by owners of similar properties located in San Diego, California.¹¹

30. The Lease requires both the Plan and the Chapter to make monthly payments into a Capital Replacement Reserve Fund (the Reserve Fund); both the Plan and the Chapter must pay their pro rata monthly amount to the Reserve Fund based on their space utilization under the Lease—the Chapter must pay \$136 per month for occupying 4,485 square feet while the Plan must pay \$2,579 per month for occupying 39,115 square feet.¹² The Reserve Fund's

monthly amounts will remain the same throughout the Lease's duration, including extensions.

31. The Reserve Fund is intended to segregate payments for future replacement needs and its calculations are based on reasonable life expectancy¹³ and anticipated replacement costs of the Reserve Fund Items; as such, the Reserve Fund is not subject to the Annual Reconciliation provision.

32. The Reserve Fund may only be used for the replacement of certain items (such as roofing, doors, frames and hardware, flooring, asphalt and concrete paving and resealing, fencing and gates, etc.) that are listed in the Lease's addendum, and the Reserve Fund may not be used for any other purpose unless agreed to by both the Chapter and the Plan, subject to the Independent Fiduciary's approval.¹⁴

33. Further, the Lease requires the Chapter to keep the Property, including interior and exterior walls, roof, and common areas, in good condition and repair except that the Plan is responsible for day-to-day maintenance and repairs to the interior of its allocated rented space to the extent such cost is attributable to causes beyond normal wear and tear. The Lease requires the Chapter to keep the moneys in the Reserve Fund in a restricted account that may not be used for any purpose other than to fund the replacement of the items described above. Amounts paid by the Plan into the Reserve Fund constitute a portion of the Plan's overall consideration paid to the landlord, and once the amounts are paid into the Reserve Fund, the Plan has no legal right to such amounts beyond what is described in the Lease. The Lease's termination ends the Plan's right under the Lease.¹⁵

¹³ The Lease provides a life cycle costs analysis for the Reserve Fund Items, which considers all costs of acquiring, operating, maintaining, and disposing of a building component or system.

¹⁴ The Reserve Fund includes the following additional items: backflow preventers on site utilities; casework and countertops; sheet metal, caulking, joint sealants; roofing maintenance and re-roofing; doors, frames, and hardware; operable walls in classroom; coiling service doors; glass and glazing storefront system; ceramic tile; flooring carpet replacement and base; paint and coatings; elevator; plumbing; HVAC equipment; electrical and site lighting; and fire alarm and security system.

¹⁵ As described in more detail above, the Independent Fiduciary determined that the aforementioned Lease terms, including the Reserve Fund provision, were prudent, and in the interest of the Plan. Moreover, this proposed exemption prohibits the Plan's participants from paying any Plan operating expenses, including amounts paid into the Reserve Fund.

Exemptive Relief Requested and Analysis

34. Absent an administrative exemption, the Lease would violate ERISA Sections 406(a)(1)(A) and (D) and 406(b)(2). ERISA Section 406(a)(1)(A) prohibits the sale, exchange, or lease, of any property between a plan and a party in interest. The Chapter is a party in interest with respect to the Plan under ERISA Section 3(14)(D) because it is an employee organization whose members are covered by the Plan. Therefore, the Lease would violate ERISA section 406(a)(1)(A).

35. Additionally, ERISA section 406(a)(1)(D) prohibits the transfer to or use of any plan assets by or for the benefit of a party in interest of a plan. Because the Lease requires monthly cash payments from the Plan's assets to the Chapter, the payments would be considered a transfer of Plan assets to a party in interest in violation of ERISA section 406(a)(1)(D).

36. Finally, the Lease would violate ERISA section 406(b)(2), which prohibits a plan fiduciary acting in their individual capacity or in any other capacity in a transaction involving the plan on behalf of a party (or representing a party) whose interests are adverse to the interests of the plan or its participants or beneficiaries. Because both the Trustees and the Board are comprised of individuals representing participating employers who are the Chapter's members, these individuals are involved on both sides of the Lease in violation of ERISA Section 406(b)(2).

Conditions for Exemptive Relief¹⁶

37. In addition to the protections described above, the Plan's participants must not pay any of the Plan's operating expenses. The terms and conditions of the Lease must be at least as favorable to the Plan as those that the Plan could obtain in a comparable lease from an unrelated party in an arm's-length transaction. If granted, this exemption will not cover any type of service that is otherwise covered under an administrative class exemption or a statutory exemption of ERISA, such as ERISA section 408(b)(2).

38. In the event that the Independent Fiduciary retains an Independent Appraiser in connection with the Lease, such Independent Appraiser must not have entered into, and must not enter into, any agreement, arrangement, or understanding that includes any

¹⁶ The Department notes that this is a summary of the conditions intended for the convenience of a reader; however, the governing conditions for the Proposed Transaction are those reflected in section II of the proposed exemption.

¹⁰ The Lease defines Operating Expenses as additional rent for costs that the Chapter incurs, which include the following: (1) operation, repair, maintenance, and replacement of the common areas; (2) trash disposal, janitorial and security services; (3) any service provided by the Chapter that is an operating expense under the Lease; (4) the cost of the premiums for the liability and property insurance policies required to be maintained by the Chapter under the Lease; (5) the cost of water, sewer, gas, electricity, solar panels, and other publicly mandated services; (6) labor, salaries and applicable fringe benefits and costs, materials, supplies and tools, used in maintaining and/or cleaning the premises, and accounting and management fees attributable to the operation of the premises; (7) replacing and/or adding improvements mandated by any governmental agency and any repairs or removals necessitated thereby; (8) replacements of equipment or improvements, as amortized over such equipment or improvements' useful life for depreciation purposes according to federal income tax guidelines; (9) reserves set aside for maintenance, repair and/or replacement of common area improvements and equipment as set forth in the Lease's Addendum; (10) environmental damages and earthquake coverage to the extent not recovered by Chapter directly from any tenants; and (11) all taxes, assessments and charges levied on or with respect to the facility, or any personal property of the Chapter used in the operation thereof and payable by the Chapter.

¹¹ The Independent Fiduciary's duties include reviewing and approving the Lease's Operating Expenses provisions.

¹² As noted above, the Independent Fiduciary determined that these payments had the effect of adjusting the Lease's base rent of \$1.02 per square foot upward by \$0.07 per square foot.

provision that provides for the direct or indirect indemnification or reimbursement of the Independent Appraiser by the Plan or any other party for any failure to adhere to its contractual obligations or to state or Federal laws applicable to the Independent Appraiser's work, or that waives any rights, claims or remedies of the Plan or its participants and beneficiaries under ERISA, the Code, or other Federal and state laws against the Independent Appraiser with respect to the transaction(s) that are the subject of the exemption.

39. Finally, this proposed exemption would require the Plan to adhere to the material facts and representations described in the proposed exemption and set forth in the exemption application, including the Plan's representations made pursuant to the Department's Regulations codified in 29 CFR 2570.34–35.

Statutory Findings

40. ERISA Section 408(a) provides, in part, that the Department may not grant an exemption unless the Department finds that the exemption is administratively feasible, in the interest of affected plans and of their participants and beneficiaries, and protective of the rights of such plan and its participants and beneficiaries, which criteria are discussed below.

a. *The Proposed Exemption Is "Administratively Feasible."* The Department has tentatively determined that the proposed exemption is administratively feasible because, among other things, the Independent Fiduciary must represent the Plan for all purposes relating to the proposed transaction. This representation includes: reviewing and approving the Lease terms and conditions; and ensuring that the Plan's entering into the Lease and continuation of the Lease, including any amendment to or renewal thereof, is reasonable, prudent, and in the interests of, the Plan and its participants and beneficiaries.

b. *The Proposed Exemption Is "In the Interests of the Plan."* The Department has tentatively determined that the proposed exemption is in the Plan's interest because the Lease permits the Plan to rent a modern facility located in a central location with updated equipment that can accommodate a large group of apprentices for an amount not exceeding fair market value.

c. *The Proposed Exemption Is "Protective of the Plan."* The Department has tentatively determined that the proposed exemption is protective of the rights of the Plan and its participants, and beneficiaries,

because the Independent Fiduciary must represent the Plan's interests for all purposes with respect to the Lease in accordance with ERISA's fiduciary duties of prudence and loyalty, including prudently monitoring the terms of the Lease on an ongoing basis and ensuring that the protective conditions of the exemption are fully met.

Notice to Interested Persons

Notice of the proposed exemption will be given to all Interested Persons within 15 days of the publication of the notice of proposed exemption in the **Federal Register**, by first class U.S. mail, to the last known address of all such individuals. The notice will contain a copy of the notice of proposed exemption, as published in the **Federal Register**, and a supplemental statement, as required pursuant to 29 CFR 2570.43(a)(2). The supplemental statement will inform interested persons of their right to comment on the pending exemption. Written comments are due within 45 days of the publication of the notice of proposed exemption in the **Federal Register**. All comments will be made available to the public.

Warning: If you submit a comment, the Department recommends that you include your name and other contact information in the body of your comment, but DO NOT submit information that you consider to be confidential, or otherwise protected (such as a Social Security number or an unlisted phone number) or confidential business information that you do not want publicly disclosed. All comments may be posted on the internet and can be retrieved by most internet search engines.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under ERISA section 408(a) does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of ERISA and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of ERISA section 404, which, among other things, require a fiduciary to discharge their duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with ERISA section 404(a)(1)(b); nor does it affect the requirement of Code section 401(a) that the plan must operate for the

exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under ERISA section 408(a) and/or Code section 4975(c)(2), the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries, and protective of the rights of participants and beneficiaries of the plan;

(3) The proposed exemption, if granted, will be supplemental to, and not in derogation of, any other provisions of ERISA and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(4) The proposed exemption, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete at all times, and that each application accurately describes all material terms of the transaction which is the subject of the exemption.

Proposed Exemption

Section I. Covered Transaction

If the proposed exemption is granted, the restrictions of ERISA sections 406(a)(1)(A), (D), and 406(b)(2) shall not apply, effective October 1, 2020, to the leasing of office, classroom, and training facilities (the Lease) located on an improved parcel of real property (the Property) by the Associated General Contractors of America, San Diego Chapter, Inc. Apprenticeship and Training Fund (the Plan) from the Associated General Contractors of America, San Diego Chapter, Inc. (the Chapter), to provide construction trade apprenticeship training to Plan participants, as long as the conditions set forth in section II are met.

Section II. General Conditions

(a) The Plan has paid, and will continue to pay, no more than the fair market rental value in connection with the Lease;

(b) The Plan's participants do not contribute to the Plan;

(c) A qualified independent fiduciary (the Independent Fiduciary) represents the Plan's interests in all respects to the Lease, including by approving the Lease and, if warranted, any amendment to or renewal of the Lease. Additionally, the Independent Fiduciary, acting on the Plan's behalf with respect to the Lease:

(1) Must not be directly or indirectly controlled by or through one or more intermediaries, or under common control with either the Chapter, the Plan, or any related employers' members;

(2) Reviewed the Lease, including the terms and conditions, and determined that the Lease was reasonable and in the interest of and protective of the Plan and its participants and beneficiaries in accordance with ERISA's fiduciary duties of prudence and loyalty;

(3) Confirmed that the initial base rent did not exceed the current fair market rental value of the Property by reviewing an appraisal performed by a qualified independent appraiser (the Independent Appraiser) both when the Plan entered into the Lease, and when the Plan began occupying the Property;

(4) Determined in advance of the Plan's entering into the lease for the Property, that the Lease is reasonable, prudent, in the interest of, and protective of the Plan and its participants and beneficiaries in accordance with ERISA's fiduciary duties of prudence and loyalty;

(5) Must engage a qualified independent appraiser to perform an independent appraisal of the Property following the beginning date of the Lease, on a periodic basis as prudence requires, to ensure the Plan does not pay more than fair market value under the Lease. The Independent Fiduciary is responsible for the selection of the Independent Appraiser, the frequency of appraisals, and the assessment of the reliability of the appraisals in determining fair market value;

(6) Must regularly evaluate the prudence of the Plan's continued participation in the Lease and ensure that participation in the Lease remains in the interest of and protective of the interests of the Plan's participants;

(7) Must monitor the parties' compliance with the terms and conditions of the exemption, if granted, and take all necessary and proper steps to ensure that the Plan and its participants and beneficiaries are completely protected throughout the Lease's term and any related transactions (including any renewal thereof);

(8) Must review and approve the Lease's operating expenses on an ongoing basis, including but not limited to ensuring that the Plan undergoes both an annual reconciliation for such accrued expenses and it exercises its audit rights when prudently needed.

(9) Must give prior written notice to the Chapter of the Plan's intention to extend the Lease beyond the initial 10-year term;

(10) Has not entered into and must not enter into any agreement or instrument that violates either ERISA section 410, or the Department's Regulations codified at 29 CFR 2509.75-4;¹⁷ and

(11) Has not entered into and must not enter into any agreement, arrangement, or understanding that includes any provision that provides for the direct or indirect indemnification or reimbursement of the Independent Fiduciary by the Plan or other party for any failure to adhere to its contractual obligations or to state or Federal laws applicable to the Independent Fiduciary's work, or that waives any rights, claims, or remedies of the Plan under ERISA, state, or Federal law against the Independent Fiduciary with respect to the transaction(s) that are the subject of the exemption;

(d) The Plan's ongoing participation in the Lease requires the continuing approval and consent of the Independent Fiduciary and the Plan may continue to participate in the Lease during any period only to the extent the Independent Fiduciary has affirmatively determined that participation in the Lease remains in the interest of and protective of the Plan and its participants and beneficiaries;

(e) Any adjustments to the base rent under the Lease must be linked to the Consumer Price Index for All Urban Consumers for the San Diego, California area, as published by the Department's Bureau of Labor Statistics;

(f) Any renewal of the Lease's initial 10-year term must be made solely at the Plan's discretion subject to approval by the Independent Fiduciary and if the Lease is renewed, the Lease term must not exceed five-years;

(g) The Independent Appraiser must not have entered into, and must not enter into, any agreement, arrangement, or understanding that includes any provision that provides for the direct or indirect indemnification or reimbursement of the Independent Appraiser by the Plan or any other party for any failure to adhere to its contractual obligations or to state or Federal laws applicable to the Independent Appraiser's work, or that waives any rights, claims or remedies of the Plan or its participants and beneficiaries under ERISA, the Code, or other Federal and state laws against the

¹⁷ ERISA section 410 provides, in part, that "except as provided in ERISA Sections 405(b)(1) and 405(d), any provision in an agreement or instrument which purports to relieve a fiduciary from responsibility or liability for any responsibility, obligation, or duty under this part [meaning Part 4 of ERISA] shall be void as against public policy."

Independent Appraiser with respect to the transaction(s) that are the subject of the exemption;

(h) The exemption does not cover any type of service that is otherwise covered under an administrative class exemption or a statutory exemption from ERISA's prohibited transaction provisions;

(i) Beginning on the day that the notice of exemption is published in the **Federal Register**, the Plan's total payments under the Lease during any given twelve (12) month period must not exceed ten (10) percent of the Plan's total assets as reflected in the most recently issued report from the independent accounting firm that audited the Plan's financial statements;

(j) The terms and conditions of the Lease are at least as favorable to the Plan as those which the Plan could obtain in a comparable lease from an unrelated party in an arm's-length transaction;

(k) All of the material facts and representations set forth in the Summary of Facts and Representations are true and accurate; and

(l) Within 60 days of the date of publication of the notice of exemption in the **Federal Register** (the Publication Date), the Independent Fiduciary will provide a summary of all amendments, modifications, or extensions of the Lease made between October 1, 2020, and the Publication Date. After the Publication Date, on an ongoing basis, the Independent Fiduciary must inform the Department's Office of Exemption determinations if the Lease is amended, modified, or extended at least 60 days before the amendment, modification, or extension unless such delay would cause imminent harm to the Plan in which case the notice must be provided immediately. The notification must include a complete description of the amendment, modification, or extension, including all material terms thereof.

Exemption Date: The proposed exemption would be effective October 1, 2020.

Signed at Washington, DC, this 16th day of July 2024.

George Christopher Cosby,

Director, Office of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. 2024-16035 Filed 7-19-24; 8:45 am]

BILLING CODE 4510-29-P

DEPARTMENT OF LABOR**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Application for a Farm Labor Contractor or Farm Labor Contractor Employee Certificate of Registration**

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Wage and Hour Division (WHD)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before August 21, 2024.

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

FOR FURTHER INFORMATION CONTACT: Michelle Neary by telephone at 202–693–6312, or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: The Migrant and Seasonal Agricultural Worker Protection Act provides that no individual may perform farm labor contracting activities without a certificate of registration. Form WH–530 is the application form that provides the Department of Labor with the information necessary to issue certificates specifying the farm labor contracting activities authorized. In addition, certain vehicle and safety standards are required of farm labor contractor applicants and such data is collected via Forms WH–514, WH–514a, WH–515, WH–530, WH–535, and WH–540. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on February 14, 2024 (89 FR 11319).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and

cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–WHD.

Title of Collection: Application for a Farm Labor Contractor or Farm Labor Contractor Employee Certificate of Registration.

OMB Control Number: 1235–0016.

Affected Public: Businesses or other for-profits, Farms.

Total Estimated Number of Respondents: 35,224.

Total Estimated Number of Responses: 58,570.

Total Estimated Annual Time Burden: 18,329 hours.

Total Estimated Annual Other Costs Burden: \$1,524,890.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Michelle Neary,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2024–15997 Filed 7–19–24; 8:45 am]

BILLING CODE 4510–27–P

DEPARTMENT OF LABOR**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Work-Study Program of the Child Labor Regulations**

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Wage and Hour

Division (WHD)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before August 21, 2024.

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

FOR FURTHER INFORMATION CONTACT: Michelle Neary by telephone at 202–693–6312, or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: This information collection contains the paperwork requirements for a school-supervised and school-administered Work-Study Program of the Child Labor Regulations. This program allows for the employment of 14- and 15-year-olds under conditions Child Labor Regulation 3 otherwise prohibit. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March 18, 2024 (89 FR 19362).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not

display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–WHD.

Title of Collection: Work-Study Program of the Child Labor Regulations. OMB Control Number: 1235–0024.

Affected Public: Business or other for-profit, Not-for-profit institutions, Farms, Federal, State, Local, or Tribal Government.

Total Estimated Number of Respondents: 1,010.

Total Estimated Number of Responses: 1,010.

Total Estimated Annual Time Burden: 528 hours.

Total Estimated Annual Other Costs Burden: \$0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Michelle Neary,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2024–15996 Filed 7–19–24; 8:45 am]

BILLING CODE 4510–27–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–24–0016; NARA–2024–046]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice of certain Federal agency requests for records disposition authority (records schedules). We publish notice in the **Federal Register** and on [regulations.gov](https://www.regulations.gov) for records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on such records schedules.

DATES: We must receive responses on the schedules listed in this notice by September 6, 2024.

ADDRESSES: To view a records schedule in this notice, or submit a comment on one, use the following address: <https://www.regulations.gov/docket/NARA-24-0016/document>. This is a direct link to

the schedules posted in the docket for this notice on [regulations.gov](https://www.regulations.gov). You may submit comments by the following method:

Federal eRulemaking Portal: <https://www.regulations.gov>. On the website, enter either of the numbers cited at the top of this notice into the search field. This will bring you to the docket for this notice, in which we have posted the records schedules open for comment. Each schedule has a ‘comment’ button so you can comment on that specific schedule. For more information on [regulations.gov](https://www.regulations.gov) and on submitting comments, see their FAQs at <https://www.regulations.gov/faq>.

If you are unable to comment via [regulations.gov](https://www.regulations.gov), you may email us at request.schedule@nara.gov for instructions on submitting your comment. You must cite the control number of the schedule you wish to comment on. You can find the control number for each schedule in parentheses at the end of each schedule’s entry in the list at the end of this notice.

FOR FURTHER INFORMATION CONTACT:

Kimberly Richardson, Strategy and Performance Division, by email at regulation_comments@nara.gov or at 301–837–2902. For information about records schedules, contact Records Management Operations by email at request.schedule@nara.gov or by phone at 301–837–1799.

SUPPLEMENTARY INFORMATION:

Public Comment Procedures

We are publishing notice of records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on these records schedules, as required by 44 U.S.C. 3303a(a), and list the schedules at the end of this notice by agency and subdivision requesting disposition authority.

In addition, this notice lists the organizational unit(s) accumulating the records or states that the schedule has agency-wide applicability. It also provides the control number assigned to each schedule, which you will need if you submit comments on that schedule.

We have uploaded the records schedules and accompanying appraisal memoranda to the [regulations.gov](https://www.regulations.gov) docket for this notice as “other” documents. Each records schedule contains a full description of the records at the file unit level as well as their proposed disposition. The appraisal memorandum for the schedule includes information about the records.

We will post comments, including any personal information and

attachments, to the public docket unchanged. Because comments are public, you are responsible for ensuring that you do not include any confidential or other information that you or a third party may not wish to be publicly posted. If you want to submit a comment with confidential information or cannot otherwise use the [regulations.gov](https://www.regulations.gov) portal, you may contact request.schedule@nara.gov for instructions on submitting your comment.

We will consider all comments submitted by the posted deadline and consult as needed with the Federal agency seeking the disposition authority. After considering comments, we may or may not make changes to the proposed records schedule. The schedule is then sent for final approval by the Archivist of the United States. After the schedule is approved, we will post on [regulations.gov](https://www.regulations.gov) a “Consolidated Reply” summarizing the comments, responding to them, and noting any changes we made to the proposed schedule. You may elect at [regulations.gov](https://www.regulations.gov) to receive updates on the docket, including an alert when we post the Consolidated Reply, whether or not you submit a comment. If you have a question, you can submit it as a comment, and can also submit any concerns or comments you would have to a possible response to the question. We will address these items in consolidated replies along with any other comments submitted on that schedule.

We will post schedules on our website in the Records Control Schedule (RCS) Repository, at <https://www.archives.gov/records-mgmt/rcs>, after the Archivist approves them. The RCS contains all schedules approved since 1973.

Background

Each year, Federal agencies create billions of records. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA’s approval. Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. The records schedules authorize agencies to preserve records of continuing value in the National Archives or to destroy, after a specified period, records lacking continuing administrative, legal, research, or other value. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however,

cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

Agencies may not destroy Federal records without the approval of the Archivist of the United States. The Archivist grants this approval only after thorough consideration of the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the Government's activities, and whether or not the records have historical or other value. Public review and comment on these records schedules is part of the Archivist's consideration process.

Schedules Pending

1. Department of Defense, Missile Defense Agency, Counterintelligence Records (DAA-0565-2020-0001).
2. Department of Health and Human Services, Administration for Strategic Preparedness and Response, National Disaster Medical System Records (DAA-0611-2023-0009).
3. Department of Health and Human Services, Health Resources and Services Administration, J-1 Visa Waiver Documents (DAA-0512-2024-0005).
4. Department of Health and Human Services, Health Resources and Services Administration, Provider Relief Fund Case Management System (DAA-0512-2023-0003).
5. Department of the Navy, Agency-wide, Operations and Readiness (DAA-NU-2021-0002).
6. Department of Transportation, Federal Railroad Administration, Drug and Alcohol Management Information System (DAMIS) Annual Reports (DAA-0399-2024-0002).
7. American Battle Monuments Commission, Agency-wide, Public Affairs (DAA-0117-2023-0009).
8. Farm Credit Administration, Office of Inspector General, Records of the Office of Inspector General (DAA-0103-2023-0001).

William P. Fischer,
Acting Chief Records Officer for the U.S. Government.

[FR Doc. 2024-16045 Filed 7-19-24; 8:45 am]

BILLING CODE 7515-01-P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board hereby gives notice of the scheduling of a meeting of the National Science Board/National Science Foundation Commission on Merit Review (MRX) for

the transaction of National Science Board business pursuant to the NSF Act and the Government in the Sunshine Act.

TIME AND DATE: The MRX meeting is scheduled for Tuesday, July 23, 2024, from 9:00 a.m.–12:00 p.m. EDT.

PLACE: This meeting will be at the National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314, and by videoconference.

STATUS: Closed.

MATTERS TO BE CONSIDERED: The agenda for the MRX meeting is: Commission Chair's remarks about the agenda; Discussion with NSF Executive Leadership Team; Discussion of Preliminary Accountability Suggestions; Discussion of Revised Implementation Suggestions; Discussion of Next Steps for Report Preparation; Commission Chair's closing remarks.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Chris Blair, cblair@nsf.gov, 703/292-7000. Meeting information and updates may be found at www.nsf.gov/nsb.

Ann E. Bushmiller,

Senior Counsel to the National Science Board.

[FR Doc. 2024-16098 Filed 7-18-24; 8:45 am]

BILLING CODE 7555-01-P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board (NSB) and, the NSB Committee on Strategy (CS) hereby give notice of the scheduling of meetings for the transaction of National Science Board business pursuant to the National Science Foundation Act and the Government in the Sunshine Act.

TIME AND DATE: Wednesday, July 24, 2024, from 8:45 a.m.–5:25 p.m. and Thursday, July 25, 2024, from 8:00 a.m.–10:00 a.m. Eastern.

PLACE: These meetings will be held at NSF headquarters, 2415 Eisenhower Avenue, Alexandria, VA 22314, and by videoconference. If the COVID status for Alexandria, Virginia goes to "high," please fill out and bring OMB's certification of vaccination form with you. All open sessions of the meeting will be webcast live on the NSB YouTube channel.

July 24, 2024: <https://youtube.com/live/DVtbQLYJBY0?feature=share>.

July 25, 2024: All sessions on day 2 are closed.

STATUS: Parts of these meetings will be open to the public. The rest of the meetings will be closed to the public. See full description below.

MATTERS TO BE CONSIDERED:

Wednesday, July 24, 2024

Plenary Board Meeting

Open Session: 8:45 a.m.–3:00 p.m.

- NSB Chair's Opening Remarks
 - Welcome
 - Agenda Preview
 - Opening Address
- NSF Director's Opening Remarks
 - Highlights of NSF Thematic Priorities
 - Engagements
 - Senior Staff introductions
- NSB External Panel—*Changed S&E Landscape-Seizing the Opportunities*
- NSF Update on Sexual Assault & Harassment Prevention Response
- Approval of May 2024 Open Meeting Minutes
- 2024 NSB Meeting Dates and Vote
- NSB Committee Reports
 - Committee on External Engagement
 - Highlights of engagement initiatives
 - Committee on Science and Engineering Policy
 - Indicators 2026
 - Committee on Awards and Facilities
 - Antarctic Science and Engineering Support Contract Update
 - NSB-NSF Commission on Merit Review
 - Overview of Commission Work

Plenary Board Meeting

Closed session: 3:05 p.m.–4:10 p.m.

- NSB Chair's remarks
- NSF Director's Remarks
 - Agency Operating Status
- Approval of May 2024 closed meeting minutes
- Committee Reports
 - Committee on Awards and Facilities
 - Antarctic Infrastructure Update
 - Committee on Strategy
 - Long-term planning and FY 2026 Budget Development

Committee on Strategy

Closed session: 4:10 p.m.–5:25 p.m.

- Budget Update FY 2025
- Initial Discussion of the Budget Submission FY 2026

Thursday, July 25, 2024

Plenary Board Meeting

Closed session: 8:00a.m.–9:00 a.m.

- NSB Chair's Welcome
- Commission Report
 - NSB-NSF Commission on Merit Review
 - Discussion of preliminary implementation and accountability

suggestions

- Vote to enter Executive Plenary Closed Session

Executive closed session: 9:00 a.m.–10:00 a.m.

- NSB Chair's Remarks
- Approval of May 2024 Executive Plenary Closed Minutes
- Director's Remarks
 - Organizational updates
- Board Elections
 - Executive Committee seat
- NSB Chair's closing remarks

Plenary Meeting Adjourns: 10:00 a.m.

Committee on Strategy

Closed session: 1:55 p.m.–2:30 p.m.

- Presentation and discussion of updated FY 2026 performance measures

Portions Open to the Public:

Wednesday, July 24, 2024

8:45 a.m.–3:00 p.m. Plenary NSB

Portions Closed to the Public:

Wednesday, July 24, 2024

3:05 p.m.–3:55 p.m. Plenary NSB

4:10 p.m.–5:25 p.m. Committee on Strategy

Thursday, July 25, 2024

8:00 a.m.–9:00 a.m. Plenary NSB

9:00 a.m.–10:00 a.m. Executive Plenary closed

1:55 p.m.–2:30 p.m. Committee on Strategy

Members of the public are advised that the *NSB provides some flexibility around start and end times*. A session may be allowed to run over by as much as 15 minutes if the Chair decides the extra time is warranted. The next session will start no later than 15 minutes after the noticed start time. If a session ends early, the next meeting may start up to 15 minutes earlier than the noticed start time. Sessions will not vary from noticed times by more than 15 minutes.

CONTACT PERSON FOR MORE INFORMATION:

The NSB Office contact is Christopher Blair, cblair@nsf.gov, 703–292–7000. The NSB Public Affairs contact is Nadine Lymn, nlymn@nsf.gov, 703–292–2490. Please refer to the NSB website for additional information: <https://www.nsf.gov/nsb>.

Ann E. Bushmiller,

Senior Legal Counsel to the National Science Board.

[FR Doc. 2024–16099 Filed 7–18–24; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Membership of National Science Foundation's Senior Executive Service Performance Review Board

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation is announcing the members of the Senior Executive Service Performance Review Board.

ADDRESSES: Comments should be addressed to Branch Chief, Executive Services, Division of Human Resource Management, National Science Foundation, Room W15219, 2415 Eisenhower Avenue, Alexandria, VA 22314.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer Munz at the above address or (703) 292–2478.

SUPPLEMENTARY INFORMATION: The membership of the National Science Foundation's Senior Executive Service Performance Review Board is as follows:

Karen Marrongelle, Chief Science Officer, Chairperson

Wonzie Gardner, Jr., Chief Human Capital Officer and Office Head, Office of Information and Resource Management

Simon Malcomber, Deputy Assistant Director, Directorate for Biological Sciences

Evan Heit, Division Director, Division of Research on Learning in Formal and Informal Settings, Directorate for STEM Education

Janis Coughlin-Piester, Deputy Office Head, Office of Budget, Finance and Award Management

Angel Williams, General Counsel, Office of General Counsel

Irina Dolinskaya, Deputy Division Director, Division of Computing and Communication Foundations, Directorate for Computer and Information Science and Engineering

William Malyszka, Division Director, Division of Human Resource Management and PRB Executive Secretary

This announcement of the membership of the National Science Foundation's Senior Executive Service Performance Review Board is made in compliance with 5 U.S.C. 4314(c)(4).

Dated: July 16, 2024.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2024–16070 Filed 7–19–24; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2024–0033]

Information Collection: Voluntary Reporting of Planned New Reactor Applications

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, “Voluntary Reporting of Planned New Reactor Applications.”

DATES: Submit comments by September 20, 2024. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2024–0033. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2024–0033 when contacting the NRC about

the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website*: Go to <https://www.regulations.gov> and search for Docket ID NRC–2024–0033. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2024–0033 on this website.

- *NRC's Agencywide Documents Access and Management System (ADAMS)*: You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to PDR.Resource@nrc.gov. A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML24102A160. The supporting statement is available in ADAMS under Accession No. ML24030A841.

- *NRC's PDR*: The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

- *NRC's Clearance Officer*: A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: Infocollects.Resource@nrc.gov.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC–2024–0033, in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <https://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized as follows.

1. *The title of the information collection*: Voluntary Reporting of Planned New Reactor Applications.
2. *OMB approval number*: 3150–0228.
3. *Type of submission*: Revision.
4. *The form number, if applicable*: Not applicable.
5. *How often the collection is required or requested*: Annually.
6. *Who will be required or asked to respond*: Applicants, licensees, and potential applicants report this information on a strictly voluntary basis.
7. *The estimated number of annual responses*: 20.
8. *The estimated number of annual respondents*: 20.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request*: 1,405.

10. *Abstract*: This voluntary information collection assists the NRC in determining resource and budget needs with respect to future construction-related activities, anticipated licensing and design certification rulemaking actions under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), "Domestic Licensing of Production and Utilization Facilities" and/or 10 CFR part 52 "Licenses, Certifications, and Approvals for Nuclear Power Plants" and other regulatory and preapplication activities for large light water reactors (LWRs), light water cooled small modular reactors, non-LWRs, and nonpower production and utilization facilities. In addition, information provided to the NRC staff is intended to promote early communications between the NRC and potential applicants about planned licensing and construction activities under 10 CFR part 50 and/or 10 CFR part 52. The overarching goal of this

information collection is to assist the NRC staff more effectively and efficiently plan, schedule, and implement activities and reviews in a timely manner.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your answer.
2. Is the estimate of the burden of the information collection accurate? Please explain your answer.
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: July 16, 2024.

For the Nuclear Regulatory Commission.

David Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2024–16008 Filed 7–19–24; 8:45 am]

BILLING CODE 7590–01–P

PENSION BENEFIT GUARANTY CORPORATION

Proposed Submission of Information Collection for OMB Review; Comment Request; Historical Pension Plan Tracing Service Intake Information

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of intent to request OMB approval of information collection.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) intends to request that the Office of Management and Budget (OMB) approve, under the Paperwork Reduction Act, a new collection of information. The purpose of the information collection is to obtain information that the Office of the PBGC Participant and Plan Sponsor Advocate requires from the public to conduct its pension plan tracing service. This notice informs the public of PBGC's intent and solicits public comment on the collection of information.

DATES: Comments must be submitted on or before September 20, 2024.

ADDRESSES: Comments may be submitted by any of the following methods:

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

- *Email: paperwork.comments@pbgc.gov*. Refer to Pension Plan Tracing Service in the subject line.

- *Mail or Hand Delivery:* Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024–2101.

Commenters are strongly encouraged to submit comments electronically. Commenters who submit comments on paper by mail should allow sufficient time for mailed comments to be received before the close of the comment period.

All submissions received must include the agency's name (Pension Benefit Guaranty Corporation, or PBGC) and refer to the Pension Plan Tracing Service. All comments received will be posted without change to PBGC's website, www.pbgc.gov, including any personal information provided. Do not submit comments that include any personally identifiable information or confidential business information.

Copies of the collection of information may be obtained without charge by writing to the Disclosure Division, (disclosure@pbgc.gov), Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024–2101; or, calling 202–229–4040 during normal business hours. If you are deaf or hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

FOR FURTHER INFORMATION CONTACT:

Monica O'Donnell (odonnell.monica@pbgc.gov), Attorney, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024–2101; 202–229–8706. If you are deaf or hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: The Office of the PBGC Participant and Plan Sponsor Advocate (OPPSA) acts as a liaison between PBGC, sponsors of defined benefit pension plans insured by PBGC, and participants in pension plans insured by PBGC. OPPSA assists participants with searching for historical pension plan information as part of its pension plan tracing service. To conduct the tracing research, OPPSA uses an internal pension plan tracing research dashboard, which displays select data elements from various PBGC systems, including annual premium filing records and case information. The information found through OPPSA's tracing research can help participants locate historical plan information. To perform the search, OPPSA will request

participant contact information and specific plan information. This information includes the participant's name, phone number, and email address; the employer's name and location; the pension plan name; the employer identification number (EIN); the plan number (PN); the years that the participant worked for the employer; whether the person was an hourly, salaried, or part-time employee; any information or relevant documentation regarding the pension plan and the inquirer's benefit; and any other information about the employer or pension plan, such as historical or corporate research. The collection of information is voluntary and minimally burdensome. It will enable OPPSA to more effectively run its pension plan tracing service and to assist participants in locating historical plan information.

PBGC estimates that it will receive intake information from approximately 200 participants annually and that it will take participants 0.5 hours to complete and submit the information. The time needed to provide the information will vary among participants depending on what information they have readily available to them. The total amount of burden associated with this collection of information is estimated to be 100 hours and an estimated \$0.

PBGC intends to request that OMB approve PBGC's use of this form for 3 years. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

PBGC is soliciting public comments to—

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodologies and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Issued in Washington, DC.

Hilary Duke,

Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2024–16001 Filed 7–19–24; 8:45 am]

BILLING CODE 7709–02–P

PENSION BENEFIT GUARANTY CORPORATION

Proposed Submission of Information Collection for OMB Review; Comment Request; Partitions of Eligible Multiemployer Plans

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of intent to request extension of OMB approval of information collection.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) intends to request that the Office of Management and Budget (OMB) extend approval, under the Paperwork Reduction Act, of a collection of information contained in its regulation on Partitions of Eligible Multiemployer Plans. This notice informs the public of PBGC's intent and solicits public comment on the collection of information.

DATES: Comments must be submitted on or before September 20, 2024.

ADDRESSES: Comments may be submitted by any of the following methods:

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

- *Email:* paperwork.comments@pbgc.gov. Refer to OMB control number 1212–0068 in the subject line.

- *Mail or Hand Delivery:* Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024–2101.

Commenters are strongly encouraged to submit comments electronically. Commenters who submit comments on paper by mail should allow sufficient time for mailed comments to be received before the close of the comment period.

All submissions received must include the agency's name (Pension Benefit Guaranty Corporation, or PBGC) and refer to OMB control number 1212–0068. All comments received will be posted without change to PBGC's website, www.pbgc.gov, including any personal information provided. Do not submit comments that include any personally identifiable information or confidential business information.

Copies of the collection of information may be obtained without

charge by writing to the Disclosure Division, (*disclosure@pbgc.gov*), Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024–2101; or, calling 202–229–4040 during normal business hours. If you are deaf or hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

FOR FURTHER INFORMATION CONTACT:

Monica O'Donnell (*odonnell.monica@pbgc.gov*), Attorney, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024–2101; 202–229–8706. If you are deaf or hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Sections 4233(a) and (b) of the Employee Retirement Income Security Act of 1974 (ERISA) allow a plan sponsor of a multiemployer plan to apply to PBGC for a partition of the plan and state the criteria that PBGC uses to determine a plan's eligibility for a partition.

PBGC's regulation on Partitions of Eligible Multiemployer Plans (29 CFR part 4233) sets forth the procedures for applying for a partition, the information required to be included in a partition application, and notices to interested parties of the application.

PBGC needs the information to determine whether a plan is eligible for partition and whether a proposed partition would comply with the statutory conditions required before PBGC may order a partition.

The collection of information under the regulation has been approved by OMB under control number 1212–0068 (expires January 31, 2025). PBGC intends to request that OMB extend its approval for another 3 years. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

PBGC estimates that each year there will be one application for a partition submitted by a plan sponsor under this regulation. The total estimated annual burden of the collection of information is 13 hours and \$45,600.

PBGC is soliciting public comments to—

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the

proposed collection of information, including the validity of the methodologies and assumptions used;

- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Issued in Washington, DC, by
Hilary Duke,
Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2024–15992 Filed 7–19–24; 8:45 am]

BILLING CODE 7709–02–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100542; File No. SR–BX–2024–023]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Options 2, Sections 6 and 10

July 16, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on July 2, 2024, Nasdaq BX, Inc. (“BX” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Options 2, Sections 6 and 10.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rules>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

BX proposes to amend Options 2, Section 6, Market Maker Orders, to add an exception to the rule. Additionally, the Exchange proposes to amend Options 2, Section 10, Directed Market Makers, to amend the current quoting obligations for Directed Market Makers.³

Options 2, Section 6

Options 2, Section 6(a) currently states that Market Makers may enter all order types defined in Options 3, Section 7 in the options classes to which they are appointed and non-appointed. Today, Market Makers are unable to enter a Customer Cross Order pursuant to Options 3, Section 7(a)(10). Customer Cross Orders are a Public Customer-to-Public Customer Cross Order by definition⁴ and therefore cannot be entered by a Market Maker. The Exchange believes noting this exception, which is clear from Options 3, Section 12(a), will bring greater transparency to Options 2, Section 6.

Options 2, Section 10

In 2021, the Exchange filed to amend the expiration timeframe of Long-Term Options Series or “LEAPs” in Options 4A, Section 12(b) and amended the bid/ask differentials in Options 2, Sections 4 and 5⁵ to reflect the change to Options 4A, Section 12(b) regarding LEAPs.⁶

³ A Directed Market Maker is a Market Maker that may be entitled to an allocation in accordance with Options 3, Section 10 provided the Directed Market Maker was quoting at the better of the internal BBO or the NBBO at the time of receipt of the Directed Order. See Options 2, Section 10.

⁴ See Options 3, Section 12(a).

⁵ Options 2, Sections 4 and 5 describe quoting obligations for Market Makers and Lead Market Makers.

⁶ See Securities Exchange Act Release No. 92664 (August 13, 2021), 86 FR 46724 (August 19, 2021) (SR–BX–2021–034) (Notice of Filing and Immediate

Specifically, in 2021, the Exchange amended the expiration timeframe of LEAPs to lengthen the expiration term on index options from nine to sixty months to twelve to sixty months.⁷ The Exchange amended BX Options 2, Sections 4(j) and 5(d)(1), applicable to Market Makers and Lead Market Makers, respectively, to note the timeframes for index options that are considered LEAPs to carve out those quoting requirements as an exception. A similar timeframe is currently carved out for options on equities and exchange-traded funds (“ETFs”). Today, Market Makers and Lead Market Makers are currently not required to make two-sided markets in Quarterly Option Series, any Adjusted Option Series, and any option series with an expiration of nine months or greater in equities, and ETFs.⁸ Also, today, with respect to indexes, Market Makers and Lead Market Makers are not required to make two-sided markets in Quarterly Option Series, any Adjusted Option Series, and any option series with an expiration of twelve months or greater, although the rule text does not reflect the timeframe associated with LEAPs on index options. The Exchange notes that these same obligations would apply to a Market Maker or Lead Market Maker that received a Directed Order.

At this time, the Exchange proposes to make a conforming amendment to Options 2, Section 10(a)(3)(A) and (B), similar to the current rule text applicable to Market Makers and Lead Market Makers in Options 2, Sections 4(j) and 5(d)(1), to reflect that Directed Market Makers are not required to make two-sided markets in any Quarterly Option Series, any Adjusted Option Series, and any option series with an expiration of twelve months or greater for index options. Options 2, Section 10(a)(3)(A) and (B) currently provides that an Options Participant shall not be required to make two-sided markets in any Quarterly Option Series, any Adjusted Option Series, and any option series with an expiration of nine months or greater. The addition of this language concerning the current quoting requirement for Market Makers and Lead Market Makers who receive Directed Orders with respect to LEAPs in index options brings greater clarity to the Rule and conforms the requirements applicable to Market Makers and Lead Market Makers to those requirements

noted in current Options 2, Sections 4(j)(1) and 5(d)(1)(A).

Additionally, the Exchange proposes to amend Options 2, Section 10(a)(3)(A) related to the quoting obligations applicable to a Directed Market Maker. The current rule text states that Directed Market Makers, associated with the same Options Participant, are collectively required to provide two-sided quotations in 90% of the cumulative number of seconds, or such higher percentage as BX may announce in advance, for which that Options Participant’s assigned options series are open for trading. With respect to a Directed Market Maker, BX currently requires that the Directed Market Maker provide two-sided quotations in 90% of the cumulative number of seconds, or such higher percentage as BX may announce in advance, among all options series in which the Directed Market Maker has executed a Directed Order on a daily basis. BX requires the Market Maker to fulfill this requirement in addition to its requirement to quote as a Market Maker or a Lead Market Maker.

Below the Exchange presents examples of how the new rule text would operate.

Example 1

- Assume a Market Maker was assigned in options overlying AAPL, SPY, NFLX, ORCL and ADBE.
- Assume this Market Maker had previously executed a Directed Order and executes a Directed Order in NFLX and ADBE on February 27, 2024.
- The Directed Market Maker obligation is a daily obligation once triggered and continues until the Directed Market Maker notifies the Exchange that it no longer desires to be a part of the Directed Order program.
- Moreover, on February 28, 2024 and each day thereafter the Directed Market Maker is required to provide two-sided quotations in 90% of the cumulative number of seconds among all options series in which the Directed Market Maker has executed a Directed Order on a daily basis until a Directed Market Maker notifies the Exchange that it is no longer directed. Therefore, the Directed Market Maker would be required to quote at 90% of the cumulative number of seconds among all options series in which the Directed Market Maker has executed a Directed Order each day, regardless of whether the Directed Market Maker executed a Directed Order that day.

Obligations

This Market Maker is required to provide two-sided quotations in 60% of the cumulative number of seconds, or

such higher percentage as BX may announce in advance, for which that Options Participant’s assigned options series are open for trading among AAPL, SPY, and ORCL to fulfill its Market Maker obligation.

Separately, this Market Maker would be obligated, separate and apart from its Market Maker obligations described in this example, to provide two-sided quotations in 90% of the cumulative number of seconds, or such higher percentage as BX may announce in advance, among NFLX and ADBE to fulfill its Directed Market Maker Obligation.

This Market Maker would not be required to make two-sided markets in any Quarterly Option Series, any Adjusted Option Series, and any option series with an expiration of nine months or greater for options on equities and ETFs or with an expiration of twelve months or greater for index options in AAPL, SPY, NFLX, ORCL and ADBE when meeting its Market Maker or Directed Market Maker requirements.

Example 2

- Assume a Lead Market Maker was assigned in options overlying AAPL, SPY, NFLX, ORCL and ADBE.
- Assume this Lead Market Maker had previously executed a Directed Order and executes a Directed Order in NFLX and ADBE on February 27, 2024. The Directed Market Maker obligation is a daily obligation once triggered and continues until the Directed Market Maker notifies the Exchange that it no longer desires to be a part of the Directed Order program.
- The Directed Market Maker obligation is a daily obligation once triggered and continues until the Directed Market Maker notifies the Exchange that it no longer desires to be a part of the Directed Order program.
- Moreover, on February 28, 2024 and each day thereafter the Directed Market Maker is required to provide two-sided quotations in 90% of the cumulative number of seconds among all options series in which the Directed Market Maker has executed a Directed Order on a daily basis until a Directed Market Maker notifies the Exchange that it is no longer directed. Therefore, the Directed Market Maker would be required to quote at 90% of the cumulative number of seconds among all options series in which the Directed Market Maker has executed a Directed Order each day, regardless of whether the Directed Market Maker executed a Directed Order that day.

Effectiveness of Proposed Rule Change To Amend the Expiration Timeframe of Long-Term Index Options Series).

⁷ *Id.*

⁸ See BX Options 2, Sections 4(j) and 5(d)(1).

Obligations

This Lead Market Maker, associated with the same Options Participant, is collectively required to provide two-sided quotations in 90% of the cumulative number of seconds, or such higher percentage as BX may announce in advance, among AAPL, SPY, and ORCL to fulfill its Lead Market Maker obligation.⁹

Separately, this Lead Market Maker would be obligated, separate and apart from its Lead Market Maker obligations described in this example, to provide two-sided quotations in 90% of the cumulative number of seconds, or such higher percentage as BX may announce in advance, among NFLX and ADBE to fulfill its Directed Market Maker obligation.

This Market Maker would not be required to make two-sided markets in any Quarterly Option Series, any Adjusted Option Series, and any option series with an expiration of nine months or greater for options on equities and ETFs or with an expiration of twelve months or greater for index options in AAPL, SPY, NFLX, ORCL and ADBE when meeting its Lead Market Maker or Directed Market Maker requirements.

The Exchange proposes to amend the rule text in Options 2, Section 10(a)(3)(A) to require Directed Market Makers, collectively, to provide two-sided quotations in 90% of the cumulative number of seconds, or such higher percentage as BX may announce in advance, among all options series in which the Directed Market Maker has executed a Directed Order on a daily basis, except that a Directed Market Maker shall not be required to make two-sided markets in any Quarterly Option Series, any Adjusted Option Series, and any options series with an expiration of nine months or greater for options on equities and exchange-traded funds (“ETFs”) or with an expiration of twelve months or greater for index options. The Exchange notes that the proposed requirements are similar to requirements imposed by other options exchanges. NYSE Arca, Inc. (“NYSE Arca”) and NYSE American LLC (“NYSE American”) require that their lead market makers and market makers provide continuous two-sided quotations throughout the trading day in issues for which it receives Directed Orders for 90% of the time the Exchange is open for trading in each issue.¹⁰

The Exchange also proposes to relocate certain rule text within Options 2, Section 10(a)(3)(A) to make clear the requirements applicable to a Directed Market Maker and make other amendments as well. The Exchange proposes to amend the timeframe in which a Directed Market Maker is obligated to commence complying with the quoting obligations of Options 2, Section 10(a)(3)(A).¹¹ Today, a Directed Market Maker must commence complying with the quoting obligations specified in Options 2, Section 10(a)(3)(A) when a Directed Market Maker receives a Directed Order in any option in which they are assigned until such time as the Directed Market Maker notifies the Exchange that they are no longer directed. Pursuant to Options 2, Section 10(a)(1), “[w]hen the Exchange’s disseminated price is the NBBO at the time of receipt of the Directed Order, and the Directed Market Maker is quoting at the better of the internal BBO or the NBBO, the Directed Order shall be automatically executed and allocated in accordance with Options 3, Section 10 such that the Directed Market Maker shall receive a Directed Market Maker participation entitlement provided for therein.” The Exchange proposes to amend Options 2, Section 10(a)(3)(A) to instead begin requiring a Directed Market Maker to comply with the Directed Market Maker quoting obligations in Options 2, Section 10(a)(3)(A) when the Directed Market Maker executes its first Directed Order in any option in which they are assigned. A Directed Market Maker has the ongoing quoting obligation from the time a Directed Market Maker executes its first Directed Order in the options in which the Directed Market Maker is assigned until a Directed Market Maker notifies the Exchange that the Directed Market Maker is no longer directed. Because Directed Market Makers are unaware if an order is directed to them until such time as they execute the Directed Order and receive an allocation pursuant to Options 3, Section 10, the Exchange believes that starting the quoting obligation once a Directed Order is executed is a practical approach to ensuring that Directed Market Makers comply with their quoting obligations.

Directed Orders, rather than on an issue-by-issue basis.

¹¹ Currently, Options 2, Section 10(a)(3)(A) provides that an Options Participant shall be considered directed in all assigned options once the Options Participant receives a Directed Order in any option in which they are assigned and shall be considered a Directed Market Maker until such time as an Options Participant notifies the Exchange that they are no longer directed.

The proposed rule text would provide,

Directed Market Makers, associated with the same Options Participant, are collectively required to provide two-sided quotations in 90% of the cumulative number of seconds, or such higher percentage as BX may announce in advance, among all options series in which the Directed Market Maker has executed a Directed Order on a daily basis, except that a Directed Market Maker shall not be required to make two-sided markets in any Quarterly Options Series, any Adjusted Options Series, and any options series with an expiration of nine months or greater for options on equities and ETFs or with an expiration of twelve months or greater for index options. A Directed Market Maker has the ongoing quoting obligation from the time a Directed Market Maker executes its first Directed Order in the options in which the Directed Market Maker is assigned until a Directed Market Maker notifies the Exchange that the Directed Market Maker is no longer directed.

A Directed Market Maker shall not be required to make two-sided markets in any Quarterly Options Series, any Adjusted Options Series, and any options series with an expiration of nine months or greater for options on equities and ETFs or with an expiration of twelve months or greater for index options and would receive a participation entitlement in the Quarterly Options Series, the Adjusted Options Series, and an options series with an expiration of nine months or greater for options on equities and ETFs or with an expiration of twelve months or greater for index options for the Directed Order, only if it complies with the heightened 90% quoting requirement.

As is the case today, a Directed Market Maker must be quoting at the better of the internal BBO or the NBBO at the time of receipt of the Directed Order to be entitled to the allocation in accordance with Options 3, Section 10.

Finally, the Exchange proposes to amend Options 2, Section 10 to adopt a new Supplementary Material .01 to Options 2, Section 10. Specifically, the Exchange proposes to adopt definitions related to Directed Order. The Exchange proposes to define a “Directed Order” as any order to buy or sell which has been directed to a particular Market Maker by an Order Flow Provider. The Exchange proposes to define an “Order Flow Provider” as any Participant that submits, as agent, orders to the Exchange. Finally, the Exchange proposes to adopt a new Supplementary Material .02 to Options 2, Section 10 which would provide that “A Directed Market Maker may be the Lead Market Maker appointed to the options class or any Market Maker appointed to the options class.” The Exchange believes that the definitions and clarity about who can be a Directed Market Maker will provide additional background to Options Participants regarding Directed

⁹ See Options 2, Section 4(j)(1).

¹⁰ See NYSE Arca Rule 6.88–O and NYSE American Rule 964.1NY. NYSE Arca Rule 6.88–O(iv) states that these obligations will apply collectively to all series in all of the issues for which the Directed Order Market Maker receives

Orders. The definitions and description of who can be a Directed Market Maker are consistent with the Exchange's current practice and harmonize BX's definitions to those of Phlx Options 2, Section 10.

The Exchange notes that its Directed Order functionality is currently not offered on BX. The Exchange proposes to add rule text at the beginning of Options 2, Section 10 that states, "The Directed Order functionality is not operative on BX at this time. If the Exchange proposes to commence offering this functionality, it will file a rule change with the Commission specifying the implementation date." The Exchange would file a rule change with the Commission when it determines to commence offering the Directed Order functionality to Participants and will specify the implementation date in that rule change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,¹² in general, and furthers the objectives of Section 6(b)(5) of the Act,¹³ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

Options 2, Section 6

The Exchange's proposal to amend Options 2, Section 6(a) to note that Market Makers may not enter a Customer Cross Order, which are a Public Customer-to-Public Customer Cross Order by definition,¹⁴ is consistent with the Act and the protection of investors and the general public. It is clear from Options 3, Section 12(a) that Market Makers cannot enter this order type. The Exchange believes noting this exception will bring greater transparency to Options 2, Section 6.

Options 2, Section 10

The Exchange's proposal to amend Options 2, Section 10(a)(3)(A) and (B) to reflect the current quoting requirements for Directed Market Makers with respect to LEAPs in index options is consistent with the Act because, today, Market Makers and Lead Market Makers are not required to make two-sided markets in any Quarterly Option Series, any

Adjusted Option Series, and any option series with an expiration of twelve months or greater for index options, pursuant to Options 2, Sections 4(j) and 5(d)(1). The addition of this language concerning the current quoting requirement for Market Makers and Lead Market Makers who receive Directed Orders with respect to LEAPs in index options brings greater clarity to the Rule and conforms the requirements applicable to Market Makers and Lead Market Makers to those requirements noted in current Options 2, Sections 4(j)(1) and 5(d)(1)(A).

The Exchange's proposal to amend the Directed Market Maker quoting obligations in Options 2, Section 10(a)(3)(A) is consistent with the Act. Other options exchanges today require Directed Market Makers, collectively, to provide two-sided quotations in 90% of the cumulative number of seconds among all options series in which the Directed Market Maker has received a Directed Order on a daily basis. The proposed Directed Market Maker quoting obligations would require Directed Market Makers, collectively, to provide two-sided quotations in 90% of the cumulative number of seconds or such higher percentage as BX may announce in advance, among all options series in which the Directed Market Maker has executed a Directed Order on a daily basis in addition to their quoting requirements as Market Makers and Lead Market Makers.

The Exchange believes that these quoting requirements create a direct nexus between the allocation that would be received by a Directed Market Maker pursuant to Options 3, Section 10 and the liquidity that the Directed Market Maker would be required to provide to the market in that particular options series. The Exchange notes that any Directed Market Maker quoting at the NBBO would need to provide two-sided quotations in 90% of the cumulative number of seconds among all options series in which the Directed Market Maker has executed a Directed Order for the entire day in which the Directed Market Maker received the Directed Order and each day thereafter, on a daily basis, until a Directed Market Maker notifies the Exchange that it is no longer directed. The Exchange believes that this quoting obligation is designed to promote just and equitable principles of trade by ensuring that Directed Market Makers quote competitively in as many series as possible to attract Directed Orders so that they may receive an enhanced allocation as a Directed Market Maker.

The proposed rule text would harmonize the Directed Market Maker's

quoting obligations with other options exchanges, such as NYSE Arca and NYSE American which require that their lead market makers and market makers provide continuous two-sided quotations throughout the trading day in issues for which it receives Directed Orders for 90% of the time the Exchange is open for trading in each issue.¹⁵

The Exchange's proposal to amend Options 2, Section 10(a)(3)(A) to require a Directed Market Maker to commence complying with the Options 2, Section 10(a)(3)(A) quoting obligations when the Directed Market Maker executes its first Directed Order in any option in which they are assigned is a practical approach to ensuring that Directed Market Makers comply with their quoting obligations. Directed Market Makers are unaware if an order is directed to them until such time as they execute the Directed Order and receive an allocation pursuant to Options 3, Section 10. Further, the Exchange notes that a Directed Market Maker must be quoting at the better of the internal BBO or the NBBO at the time of receipt of the Directed Order to be entitled to the allocation in accordance with Options 3, Section 10.

The Exchange's proposal to amend Options 2, Section 10 to adopt a new Supplementary Material .01 to Options 2, Section 10 is consistent with the Act as the proposed definitions and clarity about who can be a Directed Market Maker will provide additional background to Options Participants regarding Directed Orders. The definitions and description of who can be a Directed Market Maker are consistent with the Exchange's current practice and harmonize BX's definitions to those of Phlx Options 2, Section 10.

The Exchange's proposal to note that its Directed Order functionality is currently not offered on BX and to commit to file a rule change with the Commission when it determines to commence offering the Directed Order functionality to Participants with the implementation date, will bring greater transparency to the availability of this functionality.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Options 2, Section 6

The Exchange's proposal to amend Options 2, Section 6(a) to note that Market Makers may not enter a

¹² 15 U.S.C. 78f(b).

¹³ 15 U.S.C. 78f(b)(5).

¹⁴ See Options 3, Section 12(a).

¹⁵ See *supra* note 10.

Customer Cross Order, which are a Public Customer-to-Public Customer Cross Order by definition,¹⁶ does not impose an undue burden on competition. No Market Maker may enter a Customer Cross Order; only Public Customers may enter a Customer Cross Order by definition. The proposal does not impose a burden on inter-market competition as other options markets may similarly copy BX's order types and impose similar restrictions.

Options 2, Section 10

The Exchange's proposal to amend Options 2, Section 10(a)(3)(A) and (B) to reflect the current quoting requirements for Directed Market Makers with respect to LEAPs in index options does not impose an undue burden on competition because all Market Makers, Lead Market Makers and Directed Market Makers are subject to the same quoting requirements with respect to LEAPs in index options in that they are not required to make two-sided markets in any Quarterly Option Series, any Adjusted Option Series, and any option series with an expiration of twelve months or greater for index options. The proposed rule text would conform the requirements applicable to Market Makers and Lead Market Makers to those requirements noted in current Options 2, Sections 4(j)(1) and 5(d)(1)(A). The proposal does not impose a burden on inter-market competition as other options markets may impose similar quoting obligations.

The Exchange's proposal to amend the Directed Market Maker quoting obligations in Options 2, Section 10(a)(3)(A) does not impose an undue burden on competition as every Directed Market Maker would be required, collectively, to provide two-sided quotations in 90% of the cumulative number of seconds or such higher percentage as BX may announce in advance, among all options series in which the Directed Market Maker has executed a Directed Order for the entire day in which the Directed Market Maker received the Directed Order, on a daily basis, until a Directed Market Maker notifies the Exchange that it is no longer directed. The proposal does not impose a burden on inter-market competition as other options markets today impose similar quoting obligations.

The Exchange's proposal to amend Options 2, Section 10(a)(3)(A) to require a Directed Market Maker to commence complying with the Options 2, Section 10(a)(3)(A) quoting obligations when the Directed Market Maker executes its first Directed Order in any option in which

they are assigned does not impose an undue burden on competition because all Directed Market Makers will be required to commence complying with Options 2, Section 10(a)(3)(A) when the Directed Market Maker executes its first Directed Order in any option in which they are assigned. The proposal does not impose a burden on inter-market competition as other options markets today impose similar quoting obligations and may amend their rules to mirror those of BX.

The Exchange's proposal to amend Options 2, Section 10 to adopt a new Supplementary Material .01 to Options 2, Section 10 does not impose an undue burden on competition as the proposed definitions and clarity about who can be a Directed Market Maker will be uniformly applied to all Options Participants. The definitions and description of who can be a Directed Market Maker are consistent with the Exchange's current practice and harmonize BX's definitions to those of Phlx Options 2, Section 10. The proposal does not impose a burden on inter-market competition as other options markets today offer similar functionality and apply it similar BX.

The Exchange's proposal to note that its Directed Order functionality is currently not offered on BX and commit to filing a rule change with the Commission when it determines to commence offering the Directed Order functionality to Participants and will specify the implementation date in that rule change does not impose an undue burden competition as no Participant would be able to utilize this functionality at this time. The proposal does not impose a burden on inter-market competition as other options markets today offer similar functionality.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁷ and subparagraph (f)(6) of Rule 19b-4 thereunder.¹⁸

¹⁷ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁸ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule

change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-BX-2024-023 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.
- All submissions should refer to file number SR-BX-2024-023. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the

change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹⁶ See Options 3, Section 12(a).

Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–BX–2024–023 and should be submitted on or before August 12, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁹

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–15999 Filed 7–19–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, July 25, 2024.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at <https://www.sec.gov>.

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topics:

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the

scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION:

For further information, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Authority: 5 U.S.C. 552b.

Dated: July 18, 2024.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–16144 Filed 7–18–24; 11:15 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Opportunity for Public Comment on Release of Federally Obligated Land at the Myrtle Beach International Airport (MYR), Myrtle Beach, SC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The FAA proposes to rule and invites public comment on the release of land at the Myrtle Beach International Airport (MYR), Myrtle Beach, South Carolina.

DATES: Comments must be received on or before August 21, 2024.

ADDRESSES: Documents are available for review by prior appointment at the following location:

Atlanta Airports District Office, Attn: Joseph Robinson, Planner, 1701 Columbia Ave., Suite 220, College Park, Georgia 30337–2747, Telephone: (404) 305–6749.

Comments on this notice may be mailed or delivered in triplicate to the FAA at the following address: Atlanta Airports District Office, Attn: Joseph Robinson, Planner, 1701 Columbia Ave., Suite 220, College Park, Georgia 30337–2747.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Breck Dunne, Director of Airport Development, Myrtle Beach International Airport at the following address: 1100 Jetport Rd., Myrtle Beach, South Carolina 29577.

FOR FURTHER INFORMATION CONTACT:

Joseph Robinson, Airport Planner, Atlanta Airports District Office, 1701 Columbia Ave., Suite 220, College Park, Georgia 30337–2747, (404)305–6749.

The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request

to release and sell one tract of land consisting of approximately 20 acres of airport property at the Myrtle Beach International Airport (MYR) under the provisions of 49 U.S.C. 47107(h)(2). On July 17, 2024, the FAA determined the request to release property at the Myrtle Beach International Airport (MYR) submitted by the Sponsor meets the procedural requirements of the Federal Aviation Administration and the release of the property does not and will not impact future aviation needs at the airport. The FAA may approve the request, in whole or in part, no sooner than thirty days after the publication of this notice.

The following is a brief overview of the request:

The Myrtle Beach International Airport (MYR) is proposing the release of airport property containing 20 acres, more or less. The release of land is necessary to comply with Federal Aviation Administration Grant Assurances that do not allow federally acquired airport property to be used for non-aviation purposes. The sale of the subject property will result in the land at the Myrtle Beach International Airport (MYR) being changed from aeronautical to non-aeronautical use and release the lands from the conditions of the Airport Improvement Program Grant Agreement Grant Assurances in order to dispose of the land. In accordance with 49 U.S.C. 47107(c)(2)(B)(i) and (iii), the airport will receive fair market value for the property, which will be subsequently reinvested in another eligible airport improvement project for aviation use.

Any person may inspect, by appointment, the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**.

Issued in Atlanta, Georgia on July 17, 2024.

Joseph Parks Preston,

Manager, Atlanta Airports District Office, Southern Region.

[FR Doc. 2024–16060 Filed 7–19–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Dallas and Kaufman Counties, Texas

AGENCY: Texas Department of Transportation (TxDOT), Federal Highway Administration (FHWA), Department of Transportation.

¹⁹ 17 CFR 200.30–3(a)(12).

ACTION: Federal notice of intent to prepare an Environmental Impact Statement (EIS).

SUMMARY: FHWA, on behalf of TxDOT, is issuing this notice to advise the public that an EIS will be prepared for a proposed transportation project to construct the East Branch extension of the President George Bush Turnpike (PGBT), connecting Interstate Highway 30 (I-30) to I-20 in eastern Dallas County, Texas. The project sponsor is the North Texas Tollway Authority (NTTA).

FOR FURTHER INFORMATION CONTACT: Mr. Craig Hancock, NTTA Senior Program Manager of Planning/Environment, 5900 W Plano Pkwy., Plano, Texas 75093; Phone (214) 224-2434 or email at chancock@ntta.org. NTTA's normal business hours are 8:00 a.m.–6:00 p.m. (central standard time), Monday through Friday.

SUPPLEMENTARY INFORMATION: The environmental review, consultation, and other actions required by applicable Federal environmental laws for this project are being, or have been, carried-out by TxDOT pursuant to 23 U.S.C. 327 and a Memorandum of Understanding dated December 9, 2019, and executed by FHWA and TxDOT.

The purpose of the proposed project is to reduce congestion and improve mobility between I-30 and I-20 in eastern Dallas County while contributing to improved system linkage within the Metropolitan Planning Area. The proposed project is needed because local roadways are insufficient for local and regional traffic movement (traffic congestion/capacity issues); increases in corporate, industrial, and retail development, population growth, and residential developments create a higher demand for roadways (increasing transportation demand); and incomplete roadway networks increase deficiencies and decrease mobility (deficient system linkage).

The proposed project would construct the East Branch extension of the PGBT, a six-lane, limited-access toll road on new location, connecting I-30 to I-20 in eastern Dallas County, Texas. Each alternative is approximately 11 miles long.

The EIS will evaluate a range of build alternatives and a no-build alternative. Project build alternatives are located in Dallas and Kaufman Counties and would pass through the municipalities of Garland, Dallas, Sunnyvale and Mesquite. The proposed project would provide a limited-access toll road, with discontinuous one-way frontage roads on each side within an anticipated right-

of-way width of 400 feet. The typical section would consist of three 12-foot (ft.) wide travel lanes in each direction and 10-ft. wide inside and outside shoulders. Grade-separated interchanges would include 14-ft. wide ramps with 4-ft. wide inside shoulders and 8-ft. wide outside shoulders. Bridges and overpasses along the main lanes would have a minimum vertical clearance of 16.5 feet with minimum vertical clearance over railroads at 23.5 feet. Sections of the new roadway may be elevated or not include frontage roads to lessen impacts.

Both build alternatives would result in potential impacts to wetlands and waters of the US, floodplain/floodway encroachment and need for compensatory storage, conversion of farmland to transportation use, cultural resources, wildlife/habitat, air quality, traffic noise, the visual environment, induced growth, and cumulative effects.

The proposed action may require issuance of an Individual or Nationwide Permit under section 404 of the Clean Water Act, section 401 Water Quality Certification, section 402/Texas Pollution Discharge Elimination System Permit; conformance with Executive Orders on Environmental Justice (12898 and 14096), Limited English Proficiency (13166), Wetlands (11990), Floodplain Management (11988), Invasive Species (13112); and compliance with section 106 of the National Historic Preservation Act, section 7 of the Endangered Species Act, the Migratory Bird Treaty Act, section 4(f) of the US Department of Transportation Act (49 U.S.C. 303), section 6(f) of the Land and Water Conservation Act (54 U.S.C. 200305(f)(3)), title VI of the Civil Rights Act, and other applicable Federal and State regulations.

The NTTA and TxDOT anticipate issuing the Draft EIS for public and agency review in November 2025 and completing the study process with a combined Final EIS and Record of Decision by July 2026.

TxDOT will issue a single Final Environmental Impact Statement and Record of Decision document pursuant to 23 U.S.C. 139(n)(2), unless TxDOT determines statutory criteria or practicability considerations preclude issuance of a combined document.

In accordance with 23 U.S.C. 139, cooperating agencies, participating agencies, and the public will be given an opportunity for continued input on project development. A public scoping meeting is planned for August 20, 2024, 5:30 p.m. (central standard time), at the Mesquite Convention Center located at 1750 Rodeo Drive, Mesquite, TX 75149. The public scoping meeting will

provide an opportunity for the public to review and comment on the draft coordination plan and schedule, the project purpose and need, the range of alternatives, and methodologies and level of detail for analyzing alternatives. It will also allow the public an opportunity to provide input on any expected environmental impacts, anticipated permits or other authorizations, and any significant issues that should be analyzed in depth in the EIS. In addition to the public scoping meeting, a public hearing will be held after the draft EIS is prepared. Public notice will be given of the time and place of the meeting and hearing.

The public meeting will be conducted in English. If you need an interpreter or document translator because English is not your primary language or you have difficulty communicating effectively in English, one will be provided to you. If you have a disability and need assistance, special arrangements can be made to accommodate most needs. If you need interpretation or translation services or you are a person with a disability who requires an accommodation to attend and participate in the public meeting, please contact Mr. Brian Sanfilippo, NTTA Project Communications Manager, at (214) 224-2481 no later than 4 p.m. CT, August 15, 2024. Please be aware that advance notice is required as some services and accommodations may require time to arrange.

The public is requested to provide public comment on alternatives or impacts and on relevant information, studies, or analyses with respect to this proposed project. Comments may be provided in writing by mail to Craig Hancock at the NTTA, located at 5900 W Plano Pkwy., Plano, Texas 75093 or by email to chancock@ntta.org. Comments must be received by September 19, 2024.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction.)

Authority: 23 CFR 771.123(a).

Michael T. Leary,

Director, Planning and Program Development, Federal Highway Administration.

[FR Doc. 2024–16026 Filed 7–19–24; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION**Federal Highway Administration****[Docket No. FHWA–2024–0049]****Proposed Second Renewal of Memorandum of Understanding (MOU) Assigning Certain Federal Environmental Responsibilities to the State of Nebraska, Including National Environmental Policy Act (NEPA) Authority for Certain Categorical Exclusions (CEs)****AGENCY:** Federal Highway Administration (FHWA).**ACTION:** Notice of proposed second renewal of MOU; request for comments.

SUMMARY: The FHWA and the State of Nebraska, acting by and through its Department of Transportation (State), propose renewing the MOU providing participation of the State in the Categorical Exclusion Assignment program. This program allows FHWA to assign its authority and responsibility for determining whether certain designated activities within the geographic boundaries of the State, as specified in the proposed MOU, are categorically excluded from preparation of an environmental assessment or an environmental impact statement under the National Environmental Policy Act.

DATES: Comments must be received on or before August 21, 2024.**ADDRESSES:** You may submit comments, identified by Docket Number FHWA–2024–0049, by any of the methods described below. To ensure that you do not duplicate your submissions, please submit them by only one of the following means:

- **Federal eRulemaking Portal:** Go to www.regulations.gov and follow the online instructions for submitting comments.
- **Mail:** U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, Room W12–140, Washington, DC 20590–0001.
- **Hand Delivery or Courier:** U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9:00 a.m. and 5:00 p.m. ET, except Federal holidays.

Instructions: You must include the agency name and docket number FHWA–2024–0049 at the beginning of your comments. All comments received will be posted without change to www.regulations.gov, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: For FHWA: Luke Pitts; by email at

Luke.Pitts@dot.gov or by telephone at 402–742–8466. The Nebraska Division Office's normal business hours are 8 a.m. to 5 p.m. (Central Standard Time), Monday through Friday, except Federal holidays. For the State of Nebraska: Kyle Keller: by email at Kyle.Keller@nebraska.gov or by telephone at 402–479–4795. The Nebraska Department of Transportation's business hours are 8 a.m. to 5 p.m. (Central Standard Time), Monday through Friday, except State and Federal holidays.

SUPPLEMENTARY INFORMATION:**Electronic Access and Filing**

This document, a complete copy of the proposed second renewal MOU, background documents, and comments received may be viewed online through the Federal eRulemaking portal at www.regulations.gov. The website is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's website at www.federalregister.gov and the Government Publishing Office's website at www.govinfo.gov. This document is also available on the Nebraska Department of Transportation (NDOT) website at <https://dot.nebraska.gov/projects/environment/pepa-assignment/>.

Background

Section 326 of title 23, United States Code (U.S.C.), creates a program that allows the Secretary of the U.S. Department of Transportation (Secretary), to assign, and a State to assume, responsibility for determining whether certain highway projects are included within classes of action that are categorically excluded (CE) from requirements for environmental assessments or environmental impact statements pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321 *et seq.* (NEPA). In addition, this program allows the assignment of other environmental review requirements applicable to Federal highway projects. The FHWA is authorized to act on behalf of the Secretary with respect to these matters.

The FHWA would execute the second renewal of Nebraska's participation in this program through an MOU. Statewide decision making responsibility would be assigned for all activities identified in the MOU within the categories listed in 23 CFR 771.117(c) and those listed as examples in 23 CFR 771.111(d), and any activities added through FHWA rulemaking to those listed in 23 CFR 771.117(c) or example activities listed in 23 CFR

771.117(d) after the date of the execution of this MOU. In addition to the NEPA CE determination responsibilities, the MOU would assign to the State the responsibility for conducting Federal environmental review, consultation, and other related activities for projects that are subject to the MOU with respect to the following Federal laws and Executive Orders:

- Clean Air Act (CAA), 42 U.S.C. 7401–7671q. *Including determinations for project-level conformity if required for the project, except as specified in Stipulation II.B.2 of the MOU*
- Noise Control Act of 1972, 42 U.S.C. 4901–4918
- Compliance with the noise regulations in 23 CFR part 772 (except approval of the State noise policy in accordance with 23 CFR 772.7)
- Section 7 of the Endangered Species Act of 1973, 16 U.S.C. 1531–1544, and 1536
- Fish and Wildlife Coordination Act, 16 U.S.C. 661–667d
- Migratory Bird Treaty Act, 16 U.S.C. 703–712
- Bald and Golden Eagle Treaty Act, as amended, 16 U.S.C. 668–668c
- Section 106 of the National Historic Preservation Act of 1966, as amended, 54 U.S.C. 306108
- Archeological Resources Protection Act of 1979, 16 U.S.C. 470aa–mm
- Title 54, Chapter 3125—Preservation of Historical and Archeological Data, 54 U.S.C. 312501–312508
- Native American Grave Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3001–3013; 18 U.S.C. 1170
- Section 4(f) of the Department of Transportation Act of 1966, 23 U.S.C. 138 and 49 U.S.C. 303; 23 CFR part 774, *except as specified in Stipulation II.B.2 of the MOU*
- American Indian Religious Freedom Act, 42 U.S.C. 1996
- Farmland Protection Policy Act (FPPA), 7 U.S.C. 4201–4209
- Clean Water Act, 33 U.S.C. 1251–1377, Sections 401, 404, and 319
- Rivers and Harbors Act of 1899, 33 U.S.C. 403
- Wild and Scenic Rivers Act, 16 U.S.C. 1271–1287
- Emergency Wetlands Resources Act, 16 U.S.C. 3921, 3931
- Wetlands Mitigation, 23 U.S.C. 103(b)(6)(m), 133(b)(3)
- FHWA wetland and natural habitat mitigation regulations, 23 CFR part 777
- Flood Disaster Protection Act, 42 U.S.C. 4001–4128
- Safe Drinking Water Act (SDWA), 42 U.S.C. 300f–300j–6
- Land and Water Conservation Fund (LWCF), Public Law 88–578, 78 Stat. 897 (known as Section 6(f))

- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9601–9675
- Superfund Amendments and Reauthorization Act of 1986 (SARA), 42 U.S.C. 9671–9675
- Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6901–6992k
- Landscaping and Scenic Enhancement (Wildflowers), 23 U.S.C. 319
- E.O. 11990, Protection of Wetlands
- E.O. 11988, Floodplain Management (except approving design standards and determinations that a significant encroachment is the only practicable alternative under 23 CFR 650.113 and 650.115)
- E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations
- E.O. 11593, Protection and Enhancement of Cultural Resources
- E.O. 13007, Indian Sacred Sites
- E.O. 13175, Consultation and Coordination with Indian Tribal Governments
- E.O. 13122 and E.O. 13751, Invasive Species
- E.O. 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government
- Planning and Environmental Linkages, 23 U.S.C. 168, except for those FHWA responsibilities associated with 23 U.S.C. 134 and 135
- Programmatic Mitigation Plans, 23 U.S.C. 169, except for those FHWA responsibilities associated with 23 U.S.C. 134 and 135.

The MOU allows the State to act in the place of FHWA in carrying out the functions described above, except with respect to government-to-government consultations with federally recognized Indian Tribes. The FHWA will retain responsibility for conducting formal government-to-government consultation with federally recognized Indian Tribes, which is required under some of the above-listed laws and Executive Orders. The State may also assist FHWA with formal consultations, with consent of a Tribe, but FHWA remains responsible for the consultation.

This assignment includes transfer to the State of Nebraska the obligation to fulfill the assigned environmental responsibilities on any proposed projects meeting the criteria in Stipulation 1(B) of the MOU that were determined to be CEs prior to the effective date of the proposed MOU but that have not been completed as of the effective date of the MOU.

The FHWA will consider the comments submitted on the proposed second renewal MOU when making its decision on whether to execute this MOU. The FHWA will make the final, executed MOU publicly available.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 326; 42 U.S.C. 4331, 4332; 23 CFR 771.117; 40 CFR 1507.3, 1508.4.

Richard Wayne Fedora,
Nebraska Division Administrator, Federal Highway Administration.

[FR Doc. 2024–16024 Filed 7–19–24; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Department of the Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury’s Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC’s Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC’s determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them. Additionally, OFAC is publishing updates to the identifying information of one person currently included on the SDN List.

DATES: This action takes effect on the date listed in **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC’s website (<https://ofac.treasury.gov>).

Notice of OFAC Actions

A. On July 16, 2024, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Individuals

1. ARREDONDO PINZON, Griselda Margarita, Puerto Vallarta, Jalisco, Mexico; DOB 01 Jun 1990; POB Puerto Vallarta, Jalisco, Mexico; nationality Mexico; Gender Female; C.U.R.P. AEPG900601MJCRNR08 (Mexico) (individual) [ILLCIT–DRUGS–EO14059].

Designated pursuant to section 1(b)(iii) of Executive Order 14059 of December 15, 2021, “Imposing Sanctions on Foreign Persons Involved in the Global Illicit Drug Trade,” 86 FR 71549 (December 17, 2021) (E.O. 14059) for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Cartel de Jalisco Nueva Generacion (CJNG), a person sanctioned pursuant to E.O. 14059.

2. FOUBERT CADENA, Keyda Del Refugio, Puerto Vallarta, Jalisco, Mexico; DOB 02 Jul 1980; POB Guadalajara, Jalisco, Mexico; nationality Mexico; Gender Female; C.U.R.P. FOCX800702MJCBDY03 (Mexico) (individual) [ILLCIT–DRUGS–EO14059].

Designated pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, CJNG, a person sanctioned pursuant to E.O. 14059.

3. SANCHEZ MARTINEZ, Emiliano, Puerto Vallarta, Jalisco, Mexico; DOB 23 Nov 1980; POB Tamuin, San Luis Potosi, Mexico; nationality Mexico; Gender Male; C.U.R.P. SAME801123HSPNRM06 (Mexico) (individual) [ILLCIT–DRUGS–EO14059].

Designated pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, CJNG, a person sanctioned pursuant to E.O. 14059.

Entities

1. CONSTRUCTORA SANDGRIS, S. DE R.L. DE C.V., Puerto Vallarta, Jalisco, Mexico; Organization Established Date 12 Mar 2019; Organization Type: Non-specialized wholesale trade [ILLCIT–DRUGS–EO14059] (Linked To: ARREDONDO PINZON, Griselda Margarita).

Designated pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Griselda Margarita Arredondo Pinzon, a person sanctioned pursuant to E.O. 14059.

2. BONA FIDE CONSULTORES FS S.A.S., Libramiento Luis Donaldo Colosio 550, 8, Lazaro Cardenas, Puerto Vallarta, Jalisco C.P. 48280, Mexico; Organization Established Date 16 Jan 2021; Organization Type: Accounting, bookkeeping and auditing activities; tax consultancy [ILLCIT–DRUGS–EO14059] (Linked To: SANCHEZ MARTINEZ, Emiliano).

Designated pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Emiliano Sanchez Martinez, a person sanctioned pursuant to E.O. 14059.

3. PACIFIC AXIS REAL ESTATE, S.A. DE C.V., Puerto Vallarta, Jalisco, Mexico; Organization Established Date 18 Jul 2018; Organization Type: Real estate activities with own or leased property [ILLICIT-DRUGS-EO14059] (Linked To: FOUBERT CADENA, Xeyda Del Refugio).

Designated pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Xeyda Del Refugio Foubert Cadena, a person sanctioned pursuant to E.O. 14059.

4. REALTY & MAINTENANCE BJ, S.A. DE C.V. (a.k.a. REALTY MAINTENANCE BJ), Ave Luis Donaldo Colosio 550 Loc 8, Lazaro Cardenas, Puerto Vallarta, Jalisco C.P. 48330, Mexico; Organization Established Date 18 Jul 2018; Organization Type: Real estate activities with own or leased property [ILLICIT-DRUGS-EO14059] (Linked To: FOUBERT CADENA, Xeyda Del Refugio).

Designated pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Xeyda Del Refugio Foubert Cadena, a person sanctioned pursuant to E.O. 14059.

Additionally, OFAC is updating the SDN List entry for the previously designated person listed below.

From:

GRUPO MINERA BARRA PACIFICO, S.A.P.I. DE C.V., Leon, Guanajuato, Mexico; Organization Established Date 08 Feb 2021; Organization Type: Mining and Quarrying; Folio Mercantil No. N-2021024215 (Mexico) [ILLICIT-DRUGS-EO14059].

To:

GRUPO MINERO BARRA PACIFICO, S.A.P.I. DE C.V., Leon, Guanajuato, Mexico; Organization Established Date 08 Feb 2021; Organization Type: Mining and Quarrying; Folio Mercantil No. N-2021024215 (Mexico) [ILLICIT-DRUGS-EO14059].

Dated: July 16, 2024.

Bradley T. Smith,

*Director, Office of Foreign Assets Control,
U.S. Department of the Treasury.*

[FR Doc. 2024-16000 Filed 7-19-24; 8:45 am]

BILLING CODE P



FEDERAL REGISTER

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Monday,

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July 22, 2024

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 406, 407, 410, et al.

Office of the Secretary

45 CFR Part 180

Medicare and Medicaid Programs; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services**

42 CFR Parts 406, 407, 410, 411, 416, 419, 435, 440, 457, 482 and 485

Office of the Secretary**45 CFR Part 180**

[CMS–1809–P]

RIN 0938–AV35

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital Outpatient Prospective Payment System (OPPS) and the Medicare Ambulatory Surgical Center (ASC) payment system for calendar year 2025 based on our continuing experience with these systems. In this proposed rule, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. Also, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting Program, Rural Emergency Hospital Quality Reporting Program, Ambulatory Surgical Center Quality Reporting Program, and Hospital Inpatient Quality Reporting Program. This proposed rule would request information on options being considered for future changes to the Overall Hospital Quality Star Rating methodology. The proposed rule would narrow the description of “custody” for

purposes of Medicare’s no legal obligation to pay payment exclusion. The proposed rule would revise the eligibility requirements in the special enrollment period (SEP) for formerly incarcerated individuals to tie the eligibility for this SEP to the determination made by the Social Security Administration that they are no longer incarcerated for releases that occur on and after January 1, 2025. This rule also proposes to codify the requirement in the Consolidated Appropriations Act, 2023 (CAA, 2023) to provide 12 months of continuous eligibility to children under the age of 19 in Medicaid and CHIP, with limited exceptions. Further, this proposed rule would provide updates to the Conditions of Participation (CoPs) for hospitals and critical access hospitals (CAHs) in an effort to advance the health and safety of pregnant, birthing, and postpartum patients. This rule proposes to separately pay IHS and tribal hospitals for high-cost drugs furnished in hospital outpatient departments through an add-on payment in addition to the AIR under the authorities used to calculate the AIR starting January 1, 2025. This rule also requests further information related to a Tribal Technical Advisory Group request to apply the Indian Health Service encounter rate to all outpatient tribal clinics. Finally, the proposed rule would provide exceptions to the Medicaid clinic services benefit four walls requirement for Indian Health Service and Tribal clinics, and, at state option, for behavioral health clinics and clinics located in rural areas.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by September 9, 2024.

ADDRESSES: In commenting, please refer to file code CMS–1809–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <https://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1809–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the

following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1809–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Au’Sha Washington or Elise Barringer at OPPS-ASC-Rulemaking@cms.hhs.gov.

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at APCPanel@cms.hhs.gov.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program policies, contact Anita Bhatia via email at Anita.Bhatia@cms.hhs.gov.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program measures, contact Marsha Hertzberg via email at Marsha.Hertzberg@cms.hhs.gov.

All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service (IHS) and Tribal Facilities, contact Nate Vercauteren via email at Nathan.Vercauteren@cms.hhs.gov.

Blood and Blood Products, contact Au’Sha Washington via email at AuShaWashington@cms.hhs.gov or Josh McFeeters via email at Joshua.McFeeters@cms.hhs.gov.

Cancer Hospital Payments, contact Scott Talaga via email at Scott.Talaga@cms.hhs.gov.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email at Chuck.Braver@cms.hhs.gov.

Medicaid Clinic Services Four Walls Flexibilities, contact Sheri Gaskins via email at Sheri.Gaskins@cms.hhs.gov or Ryan Tisdale via email at Ryan.Tisdale@cms.hhs.gov.

Composite APCs (Multiple Imaging and Mental Health) and Comprehensive APCs (C-APCs), via email at Mitali Dayal via email at Mitali.Dayal2@cms.hhs.gov.

Device-Intensive Status and No Cost/Full Credit and Partial Credit Devices, contact Scott Talaga via email at Scott.Talaga@cms.hhs.gov.

Domestic Personal Protection Equipment RFI, contact Jesse Hawkins via email at jesse.hawkins@hhs.gov.

Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals, contact The Clinical Standards Group, HealthandSafetyInquiries@cms.hhs.gov.

Hospital Inpatient Quality Reporting (IQR) Program measures, contact Melissa Hager or Ngozi Uzokwe via email melissa.hager@cms.hhs.gov or ngozi.uzokwe@cms.hhs.gov.

Hospital Outpatient Quality Reporting (OQR) Program policies, contact Kimberly Go via email Kimberly.Go@cms.hhs.gov.

Hospital Outpatient Quality Reporting (OQR) Program measures, contact Janis Grady via email Janis.Grady@cms.hhs.gov.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Abby Cesnik via email at Abigail.Cesnik@cms.hhs.gov or Nate Vercauteren via email at Nathan.Vercauteren@cms.hhs.gov.

IHS Outpatient Encounter Rate available to all American Indian and Alaska Native (AI/AN) Outpatient Programs Request for Information, contact Lisa Parker via email at Lisa.Parker1@cms.hhs.gov.

Inpatient Only (IPO) Procedures List, contact Abigail Cesnik via email at Abigail.Cesnik@cms.hhs.gov.

Medicaid and CHIP Continuous Eligibility Policy, contact Cassie Lagorio via email at Cassandra.Lagorio@cms.hhs.gov.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email at Scott.Talaga@cms.hhs.gov.

No Legal Obligation to Pay Payment Exclusion, contact Frederick Grabau via email at Frederick.Grabau@cms.hhs.gov.

Non-Opioid Policy or Implementation of Section 4135 of the Consolidated Appropriations Act (CAA), 2023, contact Mitali Dayal via email at Mitali.Dayal2@cms.hhs.gov or Cory Duke via email at Cory.Duke@cms.hhs.gov.

OPPS Brachytherapy, contact Cory Duke via email at Cory.Duke@cms.hhs.gov and Scott Talaga via email at Scott.Talaga@cms.hhs.gov.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang via email at Erick.Chuang@cms.hhs.gov, or Scott Talaga via email at Scott.Talaga@cms.hhs.gov, or Josh McFeeters via email at Joshua.McFeeters@cms.hhs.gov.

OPPS Dental Policy, contact Nicole Marcos via email at Nicole.Marcos@cms.hhs.gov.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Josh McFeeters via email at Joshua.McFeeters@cms.hhs.gov, Gil Ngan via email at Gil.Ngan@cms.hhs.gov, Cory Duke via email at Cory.Duke@cms.hhs.gov, or Au'Sha Washington via email at Ausha.Washington@cms.hhs.gov.

OPPS New Technology Procedures/Services, contact the New Technology APC mailbox at NewTechAPCapplications@cms.hhs.gov.

OPPS Packaged Items/Services, contact Mitali Dayal via email at Mitali.Dayal2@cms.hhs.gov or Cory Duke via email at Cory.Duke@cms.hhs.gov.

OPPS Pass-Through Devices, contact the Device Pass-Through mailbox at DevicePTapplications@cms.hhs.gov.
OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova via email at Marina.Kushnirova@cms.hhs.gov.

Outpatient Department Prior Authorization Process, contact Kelly Wojciechowski via email at Kelly.Wojciechowski@cms.hhs.gov.

Overall Hospital Quality Star Rating Request for Information, contact Tyson Nakashima Sr. via email Tyson.Nakashima@cms.hhs.gov.

Partial Hospitalization Program (PHP), Intensive Outpatient (IOP), and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at PHPPaymentPolicy@cms.hhs.gov.

Payment Policy for Devices in Category B Investigational Device Exemption Clinical Trials Policy and Drugs with a Medicare

Coverage with Evidence Development (CED) Designation, contact Cory Duke via email at Cory.Duke@cms.hhs.gov.

Remote Services, contact Emily Yoder via email at Emily.Yoder@cms.hhs.gov or Nate Vercauteren via email at Nathan.Vercauteren@cms.hhs.gov.

Rural Emergency Hospital Quality Reporting (REHQR) Program policies, contact Anita Bhatia via email at Anita.Bhatia@cms.hhs.gov.

Rural Emergency Hospital Quality Reporting (REHQR) Program measures, contact Melissa Hager via email Melissa.Hager@cms.hhs.gov.

Special Enrollment Period for Formerly Incarcerated Individuals, contact Steve Manning via email at Steve.Manning@cms.hhs.gov.

All Other Issues Related to Hospital Outpatient Payments Not Previously Identified, contact the OPSS mailbox at OutpatientPPS@cms.hhs.gov.

All Other Issues Related to the Ambulatory Surgical Center Payments Not Previously Identified, contact the ASC mailbox at ASCPSP@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <https://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at <https://www.regulations.gov/>.

Addenda Available Only Through the Internet on the CMS Website

In the past, a majority of the Addenda referred to in our OPSS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the calendar year (CY) 2012 OPSS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPSS/ASC proposed and final rules to decrease

administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS website. The Addenda relating to the OPSS are available at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-regulations-notice>.

The Addenda relating to the ASC payment system are available at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notice>.

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I. Summary and Background

A. Executive Summary of this Document

1. Purpose

In this proposed rule, we propose to update the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), beginning January 1, 2025. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary) to review certain components of the OPPS not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments that take into account changes in medical practice, changes in technology, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i)(D)(v) of the Act, we annually review and update the ASC payment rates. This proposed rule also includes additional policy changes made in accordance with our experience with the OPPS and the ASC payment system and recent changes in our statutory authority. We describe these and various other statutory authorities in the relevant sections of this proposed rule. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the Rural Emergency Hospital Quality Reporting (REHQR) Program, the Ambulatory Surgical Center Quality Reporting (ASCQR) Program, and the Hospital Inpatient Quality Reporting (IQR) Program. This proposed rule would request information on options being considered for future changes to the Overall Hospital Quality Star Rating methodology. Given that the maternal health crisis in the United States is among the highest in high-income countries and also disproportionately

impacts racial and ethnic minorities, we are proposing updates to the CoPs for hospitals and CAHs in an effort to advance the health and safety of pregnant, birthing, and post-partum women.

The proposed rule would narrow the description of “custody” for the purposes of Medicare’s no legal obligation to pay payment exclusion at § 411.4(b), add a definition of “penal authority,” reorganize the regulation, and make certain technical edits. The proposed rule would revise the eligibility requirements in the special enrollment period (SEP) for formerly incarcerated individuals at §§ 406.27(d) (Premium Part A) and 407.23(d) (Part B) to tie the eligibility for this SEP to the determination made by SSA that they are no longer incarcerated for releases beginning on January 1, 2025 and limit the current eligibility criteria for the SEP, with reference to “custody” associated with § 411.4(b) to releases between January 1, 2023 and December 31, 2024.

Finally, this proposed rule includes a proposal to create exceptions to the Medicaid clinic services benefit four walls requirement, to authorize Medicaid payment for services provided outside the four walls of the clinic for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas. Our current regulation at 42 CFR 440.90(b) includes an exception to the four walls requirement under the Medicaid clinic services benefit only for certain clinic services furnished to individuals who are unhoused. We believe these proposed exceptions would help maintain and improve access for the populations served by IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas.

Please note, some sections of this proposed rule contain a request for information (RFI). In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), these general solicitations are exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency’s full consideration, are not generally considered information collections and therefore not subject to the PRA.

Respondents are encouraged to provide complete but concise responses. These RFIs are issued solely for information and planning purposes; they do not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. These RFIs do not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to these RFIs; all costs associated with responding to these RFIs will be solely at the interested party’s expense. Not responding to these RFIs does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor these RFI announcements for additional information pertaining to these requests.

Please note that CMS will not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of these RFIs may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. These RFIs should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publicly post the comments received, or a summary thereof.

2. Summary of the Major Provisions

- **OPPS Update:** For CY 2025, we propose to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 2.6 percent. This increase factor is based on the proposed inpatient hospital market basket percentage increase of 3.0 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS) reduced by a proposed productivity adjustment of 0.4 percentage point. Based on this update, we estimate that total payments to OPPS providers (including beneficiary cost

sharing and estimated changes in enrollment, utilization, and case mix) for calendar year (CY) 2025 would be approximately \$88.2 billion, a proposed increase of approximately \$5.2 billion compared to estimated CY 2024 OPPS payments.

We are continuing to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9805 to the OPPS payments and copayments for all applicable services.

- *ASC Payment Update:* For CYs 2019 through 2023, we adopted a policy to update the ASC payment system using the hospital market basket update. In light of the impact of the COVID-19 PHE on healthcare utilization, we extended our policy to update the ASC payment system using the hospital market basket update an additional 2 years—through CYs 2024 and 2025. Using the hospital market basket methodology, for CY 2025, we propose to increase payment rates under the ASC payment system by 2.6 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This increase is based on a proposed hospital market basket percentage increase of 3.0 percent reduced by a productivity adjustment of 0.4 percentage point. Based on this proposed update, we estimate that total payments to ASCs (including beneficiary cost sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2025 will be approximately \$7.4 billion, an increase of approximately \$202 million compared to estimated CY 2024 Medicare payments.

- *Data Used in CY 2025 OPPS/ASC Ratesetting:* To set OPPS and ASC payment rates, we normally use the most updated claims and cost report data available. The best available claims data is the most recent set of data which would be from 2 years prior to the calendar year that is the subject of rulemaking. Cost report data usually lags the claims data by a year, and we believe that using the most updated cost report extract available from the Healthcare Cost Report Information System (HCRIS) is appropriate for CY 2025 OPPS ratesetting. Therefore, we are using our typical data process of using the most updated cost reports and claims data available for CY 2025 OPPS ratesetting.

- *Device Pass-Through Payment Applications:* For CY 2025, we received 14 complete applications for device pass-through payments. We solicit public comment on these applications

and will make final determinations on these applications in the CY 2025 OPPS/ASC final rule with comment period.

- *Changes to the List of ASC Covered Surgical Procedures and Ancillary Services Lists:* For CY 2025, we propose to add 20 medical and dental procedures to the ASC CPL and ancillary services lists based upon existing criteria at § 416.166.

- *Changes to the Inpatient Only (IPO) List:* For CY 2025, we propose to add three services for which codes were newly created by the AMA CPT Editorial Panel for CY 2025 to the IPO list: CPT codes 0894T (Cannulation of the liver allograft in preparation for connection to the normothermic perfusion device and decannulation of the liver allograft following normothermic perfusion), 0895T (Connection of liver allograft to normothermic machine perfusion device, hemostasis control; initial 4 hours of monitoring time, including hourly physiological and laboratory assessments (e.g., perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary), and 0896T (Connection of liver allograft to normothermic machine perfusion device, hemostasis control; each additional hour, including physiological and laboratory assessments (e.g., perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment)).

- *Remote Services:* For CY 2025, we are clarifying our policies for remotely furnished outpatient therapy services, Diabetes Self-Management Training and Medical Nutrition Therapy services and mental health services furnished remotely to beneficiaries in their homes by hospital staff to maintain alignment across payment systems.

- *All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities:* In CY 2024 OPPS/ASC rulemaking, due to health equity and beneficiary access concerns, we solicited comment from the public on whether Medicare should pay separately for certain high-cost drugs provided by IHS and tribal facilities and, if so, how we might do so. Based on the responses we received, we are proposing, starting January 1, 2025, to separately pay IHS and tribal hospitals for high-cost drugs furnished in hospital outpatient departments through an add-on payment in addition to the AIR under the authorities used to calculate the AIR.

- *Clinical Trials Coding and Payment:* We propose technical refinements to our Category B clinical trials coding and payment policy for devices and procedures. We are also proposing to extend our coding and payment policy to drugs and devices that meet CAG's coverage and evidence development (CED) requirement for which there is a control arm.

- *Payment for HIV Pre-Exposure Prophylaxis (PrEP) in Hospital Outpatient Departments:* For CY 2025, we are proposing to pay for HIV PrEP drugs covered as an additional preventive service and related services under the OPPS, if covered by CMS through a National Coverage Determination. We propose a site neutral policy where products are generally paid similar rates under the OPPS and Physician Fee Schedule.

- *Diagnostic Radiopharmaceuticals Separate Payment:* We propose to pay separately for diagnostic radiopharmaceuticals with per day costs above a threshold of \$630, which is approximately two times the volume weighted average cost amount currently associated with diagnostic radiopharmaceuticals. We also propose to update the \$630 threshold in CY 2026 and subsequent years by the Producer Price Index (PPI) for Pharmaceutical Preparations. Finally, we propose to pay for separately payable diagnostic radiopharmaceuticals based on their Mean Unit Cost (MUC) derived from OPPS claims and seek comment on the use of Average Sales Price (ASP) for payment in future years.

- *Exclusion of Cell and Gene Therapies from Comprehensive Ambulatory Payment Classification (C-APC) Packaging:* We propose to exclude qualifying cell and gene therapies from C-APC packaging and seek comment on whether there are other changes to the C-APC packaging policy we should consider for future years.

- *Add-on Payment for Radiopharmaceutical Technetium-99m (Tc-99m):* For CY 2025, an add-on payment applies radiopharmaceuticals that use Tc-99m produced without use of highly enriched uranium (HEU). We propose for CY 2026 that we would replace the add-on payment for radiopharmaceuticals produced without the use of Tc-99m derived from non-HEU sources with an add-on payment for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99.

- *Changes to the Review Timeframes for the Hospital Outpatient Department (OPD) Prior Authorization Process:* We are changing the current review timeframe for prior authorization

requests for OPD services from 10-business days to 7-calendar days for standard reviews.

- *Cross-Program Proposals for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs:* We propose to: (1) adopt the Hospital Commitment to Health Equity (HCHE) measure in the Hospital OQR and REHQR Programs and the Facility Commitment to Health Equity (FCHE) measure in the ASCQR Program beginning with the CY 2025 reporting period/CY 2027 payment or program determination; (2) adopt the Screening for Social Drivers of Health (SDOH) measure in all three programs beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination; (3) adopt the Screen Positive Rate for SDOH measure in all three programs beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination; and (4) modify the Immediate Measure Removal policy for adopted Hospital OQR and ASCQR Program measures beginning with CY 2025.

- *Hospital Outpatient Quality Reporting (OQR) Program:* In addition to the cross-program proposals, we propose to: (1) adopt the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM) beginning with voluntary reporting for the CY 2026 reporting period followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination; (2) remove the MRI Lumbar Spine for Low Back Pain measure beginning with the CY 2025 reporting period/CY 2027 payment determination; (3) remove the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure beginning with the CY 2025 reporting period/CY 2027 payment determination; (4) require electronic health record (EHR) technology to be certified to all electronic clinical quality measures (eCQMs) available to report beginning with the CY 2025 reporting period/CY 2027 payment determination; and (5) publicly report the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients measure—Psychiatric/

Mental Health Patients stratification on Care Compare beginning with CY 2025.

- *Rural Emergency Hospital Quality Reporting (REHQR) Program:* In addition to the cross-program proposals, we propose to: (1) extend the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure from one year to two years beginning with the CY 2027 program determination; and (2) establish when, after status conversion, REHs would be required to report data under the REHQR Program.

- *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* In addition to the cross-program proposals, we are requesting public comment on the potential development of frameworks for specialty focused reporting and minimum case number for required reporting under the ASCQR Program.

- *Hospital Inpatient Quality Reporting (IQR) Program:* We propose to continue voluntary reporting of the core clinical data elements (CCDEs) and linking variables for both the Hybrid Hospital-Wide Readmission (HWR) and Hybrid Hospital-Wide Standardized Mortality (HWM) measures, for the performance period of July 1, 2023 through June 30, 2024, impacting the FY 2026 payment determination for the Hospital IQR Program.

- *Overall Hospital Quality Star Rating:* We are requesting information on potential modifications to the Safety of Care measure group in the Overall Hospital Quality Star Rating methodology.

- *Medicare FFS No Legal Obligation to Pay Payment Exclusion and Incarceration:* We propose to narrow the description of “custody” for purposes of Medicare’s no legal obligation to pay payment exclusion at § 411.4(b), add a definition of “penal authority,” reorganize the regulation, and make certain technical edits.

- *Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals:* The proposed rule would revise the eligibility requirements in the special enrollment period (SEP) for formerly incarcerated individuals at §§ 406.27(d) and 407.23(d) to remove the reference to “custody” associated with § 411.4(b) and instead tie the eligibility for this SEP to the determination made by SSA that they are no longer incarcerated.

- *Continuous Eligibility in Medicaid and CHIP:* We propose to revise Medicaid and CHIP regulations to codify the requirement within the CAA, 2023 to require States to provide 12 months of continuous eligibility to

children under the age of 19 in Medicaid and CHIP, with limited exceptions. Specifically, we propose to remove the option to provide continuous eligibility to a subgroup of Medicaid and CHIP enrollees and for a time period of less than 12 months. For CHIP, we propose to remove the option to disenroll children from CHIP during a continuous eligibility period for failure to pay premiums.

- *Medicaid Clinic Services Four Walls Exceptions:* Beginning with the effective date of any final rule implementing this proposal, we propose to add three exceptions to the Medicaid clinic services benefit four walls requirement at 42 CFR 440.90. Our current regulation at 42 CFR 440.90(b) allows for Medicaid payment for clinic services furnished outside of the four walls of the clinic only to individuals who are unhoused. Our proposal would add a mandatory exception to the four walls requirement for IHS/Tribal clinics at 42 CFR 440.90(c) and optional exceptions for behavioral health clinics and clinics located in rural areas at 42 CFR 440.90(d) and (e), respectively.

- *Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals:* CMS is proposing new Conditions of Participation (CoPs) for hospitals and CAHs for obstetrical services, including new requirements for maternal quality assessment and performance improvement (QAPI), maternal health data reporting, baseline standards for the organization, staffing, and delivery of care within obstetrical units, and staff training on evidence-based best practices on an annual basis. CMS is further proposing revisions to the emergency services CoP related to emergency readiness for hospitals and CAHs that provide emergency services. In addition, CMS is proposing revisions to the Discharge Planning CoP for all hospitals and CAHs related to transfer protocols. Lastly, CMS is soliciting comments on whether these proposed requirements should also apply to rural emergency hospitals (REHs).

3. Summary of Costs and Benefits

In section XXVI of this proposed rule, we set forth a detailed analysis of the regulatory and federalism impacts that the proposed changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of All OPPS Changes

Table 131 in section XXVI.C of this proposed rule displays the distributional impact of all the proposed OPPS changes on various groups of hospitals and CMHCs for CY 2025

compared to all estimated OPPS payments in CY 2024. We estimate that the proposed policies in this proposed rule would result in a 2.3 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for CY 2025, including beneficiary cost-sharing, to the approximately 3,500 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would increase by approximately \$1.8 billion compared to CY 2024 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our proposed OPPS policies on CMHCs because CMHCs have historically only been paid for partial hospitalization services under the OPPS. Since CY 2024, they have also been paid for new intensive outpatient program (IOP) services under the OPPS. Continuing the provider-specific structure we adopted beginning in CY 2011, and basing payment fully on the type of provider furnishing the service, we estimate a 7.2 percent increase in CY 2025 payments to CMHCs relative to their CY 2024 payments.

b. Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes based on the fiscal year (FY) 2025 IPPS final rule wage indexes would result in a 0.1 percent increase for urban hospitals under the OPPS and a 1.0 percent increase for rural hospitals. These wage indexes include the implementation of the Office of Management and Budget (OMB) labor market area delineations based on 2020 Decennial Census data, with updates, as discussed in section II.C of this proposed rule.

c. Impacts of the Rural Adjustment and the Cancer Hospital Payment Adjustment

For CY 2025, we are continuing to provide additional payments to cancer hospitals so that a cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. Section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. In light of the COVID-19 PHE impact on claims and cost data used to calculate the target PCR, we had maintained the CY 2021 target PCR of 0.89 through CYs 2022 and 2023. However, in CY 2024, we finalized a policy to reduce the target PCR by 1.0 percentage point each calendar year

until the target PCR equals the PCR of non-cancer hospitals using the most recently submitted or settled cost report data. For CY 2024, we finalized a target PCR of 0.88. For CY 2025, we are proposing a target PCR of 0.87 to determine the CY 2025 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments would be the additional payments needed to result in a PCR equal to 0.87 for each cancer hospital.

d. Impacts of the OPD Fee Schedule Increase Factor

For the CY 2025 OPPS/ASC, we are proposing an OPD fee schedule increase factor of 2.6 percent and proposing to apply that increase factor to the conversion factor for CY 2025. As a result of the proposed OPD fee schedule increase factor and the proposed budget neutrality adjustments, we estimate that urban hospitals would experience an increase in payments of approximately 2.4 percent and that rural hospitals would experience an increase in payments of 2.8 percent. Classifying hospitals by teaching status, we estimate non-teaching hospitals would experience an increase in payments of 2.5 percent, minor teaching hospitals would experience an increase in payments of 2.6 percent, and major teaching hospitals would experience an increase in payments of 2.1 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership would experience an increase of 2.3 percent in payments, while hospitals with government ownership would experience an increase of 2.4 percent in payments. We estimate that hospitals with proprietary ownership would experience an increase of 3.5 percent in payments.

e. Impacts of the Proposed ASC Payment Update

For impact purposes, the surgical procedures on the ASC covered surgical procedure list are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the CY 2025 payment rates, compared to estimated CY 2024 payment rates, generally ranges between an increase of 1 percent and an increase of 4 percent, depending on the service, with some exceptions. We estimate the impact of applying the proposed inpatient hospital market basket update to ASC payment rates will increase payments by \$202 million under the ASC payment system in CY 2025.

f. Impacts of Medicaid Clinic Services Four Walls Exceptions

We estimate that the proposed exceptions to the four walls requirement under the Medicaid clinic services benefit for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas would increase total expenditures by \$1.18 billion from FY 2025 through 2029. Our estimate includes a Federal impact of \$1.15 billion and impact to States of \$30 million. These estimates are discussed in more detail in section XXVI of this proposed rule.

g. Impacts of Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals

We propose maternal health focused revisions to the CoPs for hospitals and critical access hospitals (CAHs), which are estimated to increase burden on hospitals and CAHs by \$446 million annually with total costs estimated at \$4.46 billion over 10 years. We expect an average annual cost of \$70,671 per hospital and CAH. As discussed in detail in section XXVI, we expect the benefits of these proposed policies to include reduced maternal morbidity and mortality, leading to financial benefits for patients, their families, and payors. We also expect that the proposed policies are likely to reduce inequality in maternal health outcomes among pregnant and postpartum women from different groups and lead to overall improvements in patient care.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1833(t) to the Act, authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: the Medicare,

Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112–78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112–96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93), enacted on March 27, 2014; the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114–10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted November 2, 2015; the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015, the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016; the Consolidated Appropriations Act, 2018 (Pub. L. 115–141), enacted on March 23, 2018; the Substance Use Disorder-Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271), enacted on October 24, 2018; the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94), enacted on December 20, 2019; the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136), enacted on March 27, 2020; the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), enacted on December 27, 2020; the Inflation

Reduction Act, 2022 (Pub. L. 117–169), enacted on August 16, 2022; and Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–238), enacted December 29, 2022.

Under the OPSS, we generally pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPSS includes payment for most hospital outpatient services, except those identified in section I.C of this final rule with comment period. Section 1833(t)(1)(B) of the Act provides for payment under the OPSS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPSS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use, as required by section 1833(t)(2)(B) of the Act. In accordance with section 1833(t)(2)(B) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the “2 times rule”). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPSS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as “transitional pass-through payments,” for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through

payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPSS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPSS. While most hospital outpatient services are payable under the OPSS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPSS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. In addition, section 1833(t)(1)(B)(v) of the Act does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider (as defined in subparagraph (B) of paragraph (21)). We set forth the services that are excluded from payment under the OPSS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPSS. These excluded hospitals are:

- Critical access hospitals (CAHs);
- Hospitals located in Maryland and paid under Maryland's All-Payer or Total Cost of Care Model;
- Hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico;
- Indian Health Service (IHS) hospitals; and
- Rural emergency hospitals (REH).

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPTS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPTS, not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practices, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPTS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>.

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 106–113, requires that we consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to annually review (and advise the Secretary concerning) the clinical integrity of the payment groups and their weights under the OPPTS. In CY 2000, based on section 1833(t)(9)(A) of the Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the Public Health Service Act (the PHS Act), which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient

therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel). The HOP Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the Panel, and, at that time, named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) who review clinical data and advise CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that the Panel—

- May advise on the clinical integrity of Ambulatory Payment Classification (APC) groups and their associated weights;
- May advise on the appropriate supervision level for hospital outpatient services;
- May advise on OPPTS APC rates for ASC covered surgical procedures;
- Continues to be technical in nature;
- Is governed by the provisions of the FACA;
- Has a Designated Federal Official (DFO); and
- Is chaired by a Federal Official designated by the Secretary.

The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add critical access hospital (CAH) representation to its membership. The Panel's charter was also amended on November 6, 2014 (80 FR 23009), and the number of members was revised from up to 19 to up to 15 members. The Panel's current charter was approved on November 21, 2022, for a 2-year period.

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS

website at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>.

3. Panel Meetings and Organizational Structure

The Panel has held many meetings, with the last meeting taking place on August 21, 2023. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting, new members, and any other changes of which the public should be aware. Beginning in CY 2017, we have transitioned to one meeting per year (81 FR 31941). In CY 2022, we published a **Federal Register** notice requesting nominations to fill vacancies on the Panel (87 FR 68499). CMS is currently accepting nominations at: <https://mearis.cms.gov>.

In addition, the Panel has established an administrative structure that, in part, currently includes the use of three subcommittee workgroups to provide preparatory meeting and subject support to the larger panel. The three current subcommittees include the following:

- **APC Groups and Status Indicator Assignments Subcommittee**, which advises and provides recommendations to the Panel on the appropriate status indicators to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid, as well as the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made;
- **Data Subcommittee**, which is responsible for studying the data issues confronting the Panel and for recommending options for resolving them; and
- **Visits and Observation Subcommittee**, which reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPTS.

Each of these workgroup subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 21, 2023, meeting that the subcommittees continue. We accepted this recommendation.

For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPTS/ASC proposed and final rules, the CMS website mentioned earlier in this section, and the FACA database at <https://facadatabase.gov>.

F. Public Comments Received on the CY 2024 OPPS/ASC Final Rule With Comment Period

We received approximately 180 timely pieces of correspondence on the CY 2024 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 22, 2023 (88 FR 81540) and the related correction notice. In-scope comments were related to the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes, which are identified with comment indicator “NI” in OPPS Addendum B, ASC Addendum AA, and ASC Addendum BB to that final rule).

II. Proposed Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for Ambulatory Payment Classifications (APCs). In the April 7, 2000, OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000, for each APC group.

For the CY 2025 OPPS, we propose to recalibrate the APC relative payment weights for services furnished on or after January 1, 2025, and before January 1, 2026 (CY 2025), using the same basic methodology that we described in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81549 through 81552), using CY 2023 claims data. That is, we propose to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services to construct a database for calculating APC group weights.

For the purpose of recalibrating the proposed APC relative payment weights for CY 2025, we began with approximately 145 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2023, and before January 1, 2024, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 73 million final action claims to develop the proposed CY 2025 OPPS payment weights. For exact numbers of claims used and additional details on the

claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for this proposed rule on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

Addendum N to this proposed rule (which is available via the internet on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>) includes the proposed list of bypass codes for CY 2025. The proposed list of bypass codes contains codes that are reported on claims for services in CY 2023 and, therefore, includes codes that were in effect in CY 2023 and used for billing. We propose to retain these deleted bypass codes on the proposed CY 2025 bypass list because these codes existed in CY 2023 and were covered OPD services in that period, and CY 2023 claims data were used to calculate proposed CY 2025 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more “pseudo” single procedure claims for ratesetting purposes. “Overlap bypass codes” that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to this proposed rule. HCPCS codes that we propose to add for CY 2025 are identified by asterisks (*) in the fourth column of Addendum N.

b. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2025, we propose to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the proposed CY 2025 APC payment rates are based, we calculated hospital-specific departmental CCRs for each hospital for which we had CY 2023 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2022. For the proposed CY 2025 OPPS payment rates, we used the set of claims processed during CY 2023. We applied the hospital-specific CCR to the hospital’s charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue

codes for CY 2023 (the year of claims data we used to calculate the proposed CY 2025 OPPS payment rates) and updates to the National Uniform Billing Committee (NUBC) 2023 Data specifications Manual. That crosswalk is available for review and continuous comment on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

In accordance with our longstanding policy, similar to our finalized policy for CY 2024 OPPS ratesetting, we propose to calculate CCRs for the standard cost centers—cost centers with a predefined label—and nonstandard cost centers—cost centers defined by a hospital—accepted by the electronic cost report database. In general, the most detailed level at which we calculate CCRs is the hospital-specific departmental level.

While we generally view the use of additional cost data as improving our OPPS ratesetting process, we have historically not included cost report lines for certain nonstandard cost centers in the OPPS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. We believe it is important to further investigate the accuracy of these cost report data before including such data in the ratesetting process. Further, we believe it is appropriate to gather additional information from the public as well before including them in OPPS ratesetting. For CY 2025, we propose not to include the nonstandard cost centers reported in this way in the OPPS ratesetting database construction.

2. Proposed Data Development and Calculation of Costs Used for Ratesetting

In this section of this proposed rule, we discuss the use of claims to calculate the OPPS payment rates for CY 2025. The Hospital OPPS page on the CMS website on which this proposed rule is posted (<https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>) provides an accounting of claims used in the development of the proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, later in this section we discuss the file of claims that comprises the data set that is available upon payment of an administrative fee under a CMS data use agreement. The CMS website, <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>, includes information about obtaining

the “OPPS Limited Data Set,” which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM) diagnosis codes and revenue code payment amounts. This file is derived from the CY 2023 claims that are used to calculate the proposed payment rates for this proposed rule.

Previously, the OPPS established the scaled relative weights on which payments are based using APC median costs, a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost.

We used the methodology described in sections II.A.2.a through II.A.2.c of this proposed rule to calculate the costs we used to establish the proposed relative payment weights used in calculating the OPPS payment rates for CY 2025 shown in Addenda A and B to this proposed rule (which are available via the internet on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices>). We refer readers to section II.A.4 of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

We note that under the OPPS, CY 2019 was the first year in which the claims data used for setting payment rates (CY 2017 data) contained lines with the modifier “PN,” which indicates nonexcepted items and services furnished and billed by off-campus provider-based departments (PBDs) of hospitals. Because nonexcepted items and services are not paid under the OPPS, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58832), we finalized a policy to remove those claim lines reported with modifier “PN” from the claims data used in ratesetting for the CY 2019 OPPS and subsequent years. For the CY 2025 OPPS, we propose to continue to remove claim lines with modifier “PN” from the ratesetting process.

For details of the claims accounting process used in this CY 2025 OPPS/ASC proposed rule, we refer readers to the claims accounting narrative under supporting documentation for this proposed rule on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

a. Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

We propose to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology (88 FR 49562), which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. To address the differences in CCRs and to better reflect hospitals’ costs, our methodology simulates blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals’ overall CCRs for those hospitals that do report costs and charges for blood cost centers and applies this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports. We propose to calculate the costs upon which the proposed payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific, simulated, blood-specific CCR

for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific, simulated, blood-specific CCR methodology takes into account the unique charging and cost accounting structure of each hospital, as it better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. This methodology also yields more accurate estimated costs for these products and results in payment rates for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and for these blood products in general.

We refer readers to Addendum B to this proposed rule (which is available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices>) for the proposed CY 2025 payment rates for blood and blood products (which are generally identified with status indicator “R”).

For a more detailed discussion of payments for blood and blood products through APCs, we refer readers to:

- the CY 2005 OPPS proposed rule (69 FR 50524 and 50525) for a more comprehensive discussion of the blood-specific CCR methodology;
- the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810) for a detailed history of the OPPS payment for blood and blood products; and
- the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795 and 66796) for additional discussion of our policy not to make separate payments for blood and blood products when they appear on the same claims as services assigned to a C-APC.

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy—cancer treatment through solid source radioactive implants—consisting of a seed or seeds (or radioactive source) (“brachytherapy sources”) separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2012 OPPS/ASC final rule with comment period (77 FR 68240 and 68241). As we have stated in prior OPPS updates, we believe that adopting the

general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPPS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to costs. We believe that the OPPS methodology, as opposed to payment based on hospitals' charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPS payment for brachytherapy sources.

For CY 2025, except where otherwise indicated, we propose to continue our policy and use the costs derived from CY 2023 claims data to set the proposed CY 2025 payment rates for brachytherapy sources because CY 2023 is the year of data we propose to use to set the proposed payment rates for most other items and services that would be paid under the CY 2025 OPPS. With the exception of the proposed payment rate for brachytherapy source C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and the proposed payment rates for low-volume brachytherapy APCs discussed in section III.D of this proposed rule, we propose to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we propose for other items and services paid under the OPPS, as discussed in section II.A.2 of this proposed rule. We also propose for CY 2025 and subsequent years to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). For CY 2025 and subsequent years, we propose to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise specified, per source) and C2699 (Brachytherapy source, non-stranded, not otherwise specified, per source), at a rate equal to the lowest

stranded or nonstranded prospective payment rate for such sources, respectively, on a per-source basis (as opposed to, for example, per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). For CY 2025 and subsequent years, we also propose to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010, by section 142 of Pub. L. 110–275). Specifically, this policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals. The proposed CY 2025 payment rates for brachytherapy sources are included on Addendum B to this proposed rule (which is available via the internet on the CMS website) and identified with status indicator “U.”

For CY 2018, we assigned status indicator “U” (Brachytherapy Sources, Paid under OPPS; separate APC payment) to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) in the absence of claims data and established a payment rate using external data (invoice price) at \$4.69 per mm² for the brachytherapy source's APC—APC 2648 (Brachytx planar, p-103). For CY 2019, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at \$4.69 per mm² for APC 2648 (Brachytx planar, p-103). Our CY 2018 claims data available for the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142) included two claims with a geometric mean cost for HCPCS code C2645 of \$1.02 per mm². In response to comments from interested parties, we agreed that, given the limited claims data available and a new outpatient indication for C2645, a payment rate for HCPCS code C2645 based on the geometric mean cost of \$1.02 per mm² may not adequately reflect the cost of HCPCS code C2645. In the CY 2020 OPPS/ASC final rule with comment period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall

establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the CY 2019 payment rate of \$4.69 per mm² for HCPCS code C2645 for CY 2020. Similarly, in the absence of sufficient claims data to establish an APC payment rate, in the CY 2021, CY 2022, CY 2023, and CY 2024 OPPS/ASC final rules with comment period (85 FR 85879 through 85880, 86 FR 63469, 87 FR 71760–71761, and 88 FR 81553), we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of \$4.69 per mm² for HCPCS code C2645 for CYs 2021 through 2024.

There are no CY 2023 claims available that reported HCPCS code C2645 for this CY 2025 OPPS/ASC proposed rule. Therefore, in the absence of claims data, we propose to continue to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2024 payment rate of \$4.69 per mm² for HCPCS code C2645, which is proposed to be assigned to APC 2648 (Brachytx planar, p-103), for CY 2025.

Additionally, for CY 2022 and subsequent calendar years, we adopted a Universal Low Volume APC policy for clinical and brachytherapy APCs. As discussed in further detail in section X.C of the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted this policy to mitigate wide variation in payment rates that occur from year to year for APCs with low utilization. Such volatility in payment rates from year to year can result in even lower utilization and potential barriers to access. Brachytherapy APCs that have fewer than 100 single claims used for ratesetting purposes are designated as Low Volume APCs unless an alternative payment rate is applied, such as the use of our equitable adjustment authority under section 1833(t)(2)(E) of the Act in the case of APC 2648 (Brachytx planar, p-103), for which HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) is the only code assigned as discussed previously in this section.

For CY 2025, we propose to designate six brachytherapy APCs as Low Volume APCs as these APCs meet our criteria to be designated as Low Volume APCs. For more information on the brachytherapy APCs we propose to designate as Low Volume APCs, see section III.D of this proposed rule.

We invite interested parties to submit recommendations for new codes to describe new brachytherapy sources.

Such recommendations should be directed via email to outpatientpps@cms.hhs.gov or by mail to the Division of Outpatient Care, Mail Stop C4-01-26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

b. Comprehensive APCs (C-APCs) for CY 2025

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014, but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C-APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C-APC policy (79 FR 66798 through 66810).

A C-APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C-APCs as a category broadly for OPPS payment and implemented 25 C-APCs beginning in CY 2015 (79 FR 66809 and 66810). We have gradually added new C-APCs since the policy was implemented beginning in CY 2015, with the number of C-APCs now totaling 72 (80 FR 70332; 81 FR 79584 and 79585; 83 FR 58844 through 58846; 84 FR 61158 through 61166; 85 FR 85885; 86 FR 63474; 87 FR 71769; and 88 FR 81562).

Under our C-APC policy, we designate a service described by a HCPCS code assigned to a C-APC as the primary service when the service is identified by OPPS status indicator “J1.” When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as “adjunctive services”) and representing components of a complete

comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level. One example of a primary service would be a partial mastectomy and an example of a secondary service packaged into that primary service would be a radiation therapy procedure.

Services excluded from the C-APC policy under the OPPS include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through payment drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 and 66801). A list of services excluded from the C-APC policy is included in Addendum J to this proposed rule (which is available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>). If a service does not appear on this list of excluded services, payment for it will be packaged into the payment for the primary C-APC service when it appears on an outpatient claim with a primary C-APC service.

The C-APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period and modified and implemented beginning in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPS/ASC final rule with comment period, we define the C-APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator “J1,”¹ excluding services that are not covered

OPD services or that cannot by statute be paid for under the OPPS. Services and procedures described by HCPCS codes assigned to status indicator “J1” are assigned to C-APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC.

In the CY 2016 OPPS/ASC final rule with comment period, we expanded the C-APC payment methodology to qualifying extended assessment and management encounters through the “Comprehensive Observation Services” C-APC (C-APC 8011). Services within this APC are assigned status indicator “J2.”² Specifically, we make a payment through C-APC 8011 for a claim that:

- Does not contain a procedure described by a HCPCS code to which we have assigned status indicator “T;”
- Contains 8 or more units of services described by HCPCS code G0378 (Hospital observation services, per hour);
- Contains services provided on the same date of service or one day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379 (Direct admission of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit

¹ Status indicator “J1” denotes Hospital Part B Services Paid Through a Comprehensive APC. Further information can be found in CY 2025 Addendum D1.

² Status indicator “J2” denotes Hospital Part B Services That May Be Paid Through a Comprehensive APC. Further information can be found in CY 2025 Addendum D1.

for assessment and management of a patient); and

- Does not contain services described by a HCPCS code to which we have assigned status indicator “J1.”

The assignment of status indicator “J2” to a specific set of services performed in combination with each other allows for all other OPPS payable services and items reported on the claim (excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim (80 FR 70333 through 70336).

Services included under the C-APC payment packaging policy, that is, services that are typically adjunctive to the primary service and provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that represent services that are provided during the complete comprehensive service (78 FR 74865 and 79 FR 66800).

In addition, payment for hospital outpatient department services that are similar to therapy services, such as speech language pathology, and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and are deemed not to be therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as hospital outpatient department services. Payment for these nontherapy

outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are hospital outpatient department services and not therapy services. We refer readers to the July 2016 OPPS Change Request 9658 (Transmittal 3523) for further instructions on reporting these services in the context of a C-APC service.

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and SADs, unless they function as packaged supplies (78 FR 74868, 74869, and 74909 and 79 FR 66800). We refer readers to Section 50.2M, Chapter 15, of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.³

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator “J1” as a single “J1” unit procedure claim (78 FR 74871 and 79 FR 66801). Line-item charges for services included on the C-APC claim are converted to line-item costs, which are then summed to develop the estimated APC costs. These claims are then assigned one unit of the service with status indicator “J1” and later used to develop the geometric mean costs for the C-APC relative payment weights. (We note that we use the term “comprehensive” to describe the geometric mean cost of a claim reporting “J1” service(s) or the geometric mean cost of a C-APC, inclusive of all the items and services included in the C-APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We apply our standard data trims, which exclude claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource

similarity and, along with clinical similarity, dictate the assignment of the primary services to the C-APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator “J1” according to its comprehensive geometric mean costs. For the minority of claims reporting more than one primary service assigned to status indicator “J1” or units thereof, we identify one “J1” service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple “J1” procedure claims to the C-APC to which the service designated as the primary service is assigned. If the reported “J1” services on a claim map to different C-APCs, we designate the “J1” service assigned to the C-APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple “J1” services on a claim map to the same C-APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator “J1” to the most appropriate C-APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying paired “J1” service code combinations or paired code combinations of “J1” services and certain add-on codes (as described further below) from the originating C-APC (the C-APC to which the designated primary service is first assigned) to the next higher paying C-APC in the same clinical family of C-APCs. We apply this type of complexity adjustment when the paired code combination represents a complex, costly form or version of the primary service according to the following criteria:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and
- Violation of the 2 times rule, as stated in section 1833(t)(2) of the Act and section III.B.2 of this proposed rule, in the originating C-APC (cost threshold).

These criteria identify paired code combinations that occur commonly and exhibit materially greater resource requirements than the primary service. The CY 2017 OPPS/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment

³ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.

eligibility criteria. Specifically, we finalized a policy to discontinue the requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) also not create a 2 times rule violation in the higher level or receiving APC.

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator “J1” (or certain add-on codes) to determine if there are paired code combinations that meet the complexity adjustment criteria. For a new HCPCS code, we determine initial C-APC assignment and qualification for a complexity adjustment using the best available information, crosswalking the new HCPCS code to a predecessor code(s) when appropriate.

Once we have determined that a particular code combination of “J1” services (or combinations of “J1” services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim including the complex version of the primary service as described by the code combination to the next higher cost C-APC within the clinical family, unless the primary service is already assigned to the highest cost APC within the C-APC clinical family or assigned to the only C-APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C-APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C-APC would be the highest paying C-APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C-APC. However, certain primary service add-on combinations may qualify for a complexity adjustment. As noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70331), all add-on codes that can be appropriately reported in combination with a base code that describes a primary “J1” service are evaluated for a complexity adjustment.

To determine which combinations of primary service codes reported in conjunction with an add-on code may

qualify for a complexity adjustment for CY 2025, we apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator “J1” and any number of units of a single add-on code for the primary “J1” service. If the frequency and cost criteria thresholds for a complexity adjustment are met and reassignment to the next higher cost APC in the clinical family is appropriate (based on meeting the criteria outlined above), we make a complexity adjustment for the code combination; that is, we reassign the primary service code reported in conjunction with the add-on code to the next higher cost C-APC within the same clinical family of C-APCs. As previously stated, we package payment for add-on codes into the C-APC payment rate. If any add-on code reported in conjunction with the “J1” primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and is not reassigned to the next higher cost C-APC. We list the complexity adjustments for “J1” and add-on code combinations for CY 2025, along with all the other proposed complexity adjustments, in Addendum J to this proposed rule (which is available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>).

Addendum J to this proposed rule includes the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to this proposed rule also contains summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and be reassigned to the next higher cost C-APC within the clinical family. The combined statistics for all proposed reassigned complex code combinations are represented by an alphanumeric code with the first four digits of the designated primary service followed by a letter. For example, the proposed geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3320R, which is assigned to C-APC 5224 (Level 4 Pacemaker and Similar Procedures), includes all paired code combinations that will be reassigned to C-APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to this proposed rule

allows interested parties the opportunity to better assess the impact associated with the assignment of claims with each of the paired code combinations eligible for a complexity adjustment.

(2) Exclusion of Procedures Assigned to New Technology APCs From the C-APC Policy

Services that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for them. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected (82 FR 59277).

The C-APC payment policy packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. Prior to CY 2019, when a procedure assigned to a New Technology APC was included on the claim with a primary procedure, identified by OPPS status indicator “J1,” payment for the new technology service was typically packaged into the payment for the primary procedure. Because the new technology service was not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service was reduced. This was contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable us to assign the service to an appropriate clinical APC.

To address this issue and ensure that there are sufficient claims data for services assigned to New Technology APCs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58847), we finalized excluding payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a “J1” service assigned to a C-APC. In the CY 2020 OPPS/ASC final rule with comment period, we finalized that beginning in CY 2020, payment for services assigned to a New Technology APC would be excluded from being packaged into the payment for comprehensive observation

services assigned status indicator “J2” when they are included on a claim with a “J2” service (84 FR 61167).

(3) Exclusion of Drugs and Biologicals Described by HCPCS Code C9399 (Unclassified Drugs or Biologicals) From the C-APC Policy

Section 1833(t)(15) of the Act, as added by section 621(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), provides for payment under the OPPS for new drugs and biologicals until HCPCS codes are assigned. Under this provision, we are required to make payment for a covered outpatient drug or biological that is furnished as part of covered outpatient department services but for which a HCPCS code has not yet been assigned in an amount equal to 95 percent of average wholesale price (AWP) for the drug or biological.

In the CY 2005 OPPS/ASC final rule with comment period (69 FR 65805), we implemented section 1833(t)(15) of the Act by instructing hospitals to bill for a drug or biological that is newly approved by the Food and Drug Administration (FDA) and that does not yet have a HCPCS code by reporting the National Drug Code (NDC) for the product along with the newly created HCPCS code C9399 (Unclassified drugs or biologicals). We explained that when HCPCS code C9399 appears on a claim, the Outpatient Code Editor (OCE) suspends the claim for manual pricing by the Medicare Administrative Contractor (MAC). The MAC prices the claim at 95 percent of the drug or biological's AWP, using Red Book or an equivalent recognized compendium, and processes the claim for payment. We emphasized that this approach enables hospitals to bill and receive payment for a new drug or biological concurrent with its approval by the FDA. The hospital does not have to wait for the next quarterly release or for approval of a product specific HCPCS code to receive payment for a newly approved drug or biological or to resubmit claims for adjustment. We instructed that hospitals would discontinue billing HCPCS code C9399 and the NDC upon implementation of a product specific HCPCS code, status indicator, and appropriate payment amount with the next quarterly update. We also note that HCPCS code C9399 is paid in a similar manner in the ASC setting, as 42 CFR 416.171(b) outlines that certain drugs and biologicals for which separate payment is allowed under the OPPS are considered covered ancillary services for which the OPPS payment rate, which is 95 percent of

AWP for HCPCS code C9399, applies. Since the implementation of the C-APC policy in 2015, payment for drugs and biologicals described by HCPCS code C9399 had been included in the C-APC payment when these products appear on a claim with a primary C-APC service. Packaging payment for these drugs and biologicals that appear on a hospital outpatient claim with a primary C-APC service is consistent with our C-APC packaging policy under which we make payment for all items and services, including all non-pass-through drugs, reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing components of a complete comprehensive service, with certain limited exceptions (78 FR 74869). It was our position that the total payment for the C-APC with which payment for a drug or biological described by HCPCS code C9399 is packaged includes payment for the drug or biological at 95 percent of its AWP.

However, we determined that in certain instances, drugs and biologicals described by HCPCS code C9399 are not being paid at 95 percent of their AWP when payment for them is packaged with payment for a primary C-APC service. In order to ensure payment for new drugs, biologicals, and radiopharmaceuticals described by HCPCS code C9399 at 95 percent of their AWP, for CY 2023 and subsequent years, we finalized our proposal to exclude any drug, biological, or radiopharmaceutical described by HCPCS code C9399 from packaging when the drug, biological, or radiopharmaceutical is included on a claim with a “J1” service, which is the status indicator assigned to a C-APC, and a claim with a “J2” service, which is the status indicator assigned to comprehensive observation services. See Addendum J for the CY 2025 C-APC payment policy exclusions.

In the CY 2023 OPPS/ASC final rule with comment period, we finalized the proposal in section XI. “CY 2023 OPPS Payment Status and Comment Indicators” to add a new definition to status indicator “A” to include unclassified drugs and biologicals that are reportable with HCPCS code C9399 (87 FR 72051). The definition, found in Addendum D1, would ensure the MAC prices claims for drugs, biologicals, or radiopharmaceuticals billed with HCPCS code C9399 at 95 percent of the drug or biological's AWP and pays separately for the drug, biological, or radiopharmaceutical under the OPPS when it appears on the same claim as a primary C-APC service.

(4) Exclusion of Cell and Gene Therapies From the C-APC Policy

As previously discussed in this section, and in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74865), the C-APC policy packages payment for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to the primary service and provided during the delivery of the comprehensive service, including diagnostic procedures, laboratory tests and other diagnostic tests and treatments that assist in the delivery of the primary procedure. In the CY 2014 OPPS/ASC final rule (78 FR 74861), we finalized defining a comprehensive APC as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Because a comprehensive APC treats all individually reported codes as representing components of the comprehensive service, we make a single prospective payment based on the cost of all individually reported codes that represent the provision of a primary service and all adjunctive services provided to support that delivery of the primary service.

We generally treat all items and services reported on a C-APC claim as integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing components of a comprehensive service. Historically, items packaged for payment provided in conjunction with the primary C-APC service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and those drugs that are usually self-administered (SADs), unless they function as supplies (78 FR 74868 through 74869 and 74909).

Our intent has been to make a single prospective payment based on the cost of all individually reported codes that appear on a claim with the primary C-APC service, which we believe represent the provision of a primary service and all adjunctive services provided to support that delivery of the primary service. However, there are rare instances where the cell and gene therapies listed in Table 1, which are usually separately payable under the OPPS, appear on the same claim as a primary C-APC service and therefore, have their payment packaged with payment for the primary C-APC service. The therapies in Table 1 are usually separately paid and priced using the ASP methodology when not on a C-APC claim. Given the unique nature of these therapies, we do not believe they

function as integral, ancillary, supportive, dependent, or adjunctive to any of the current C-APCs primary services. The cell therapies described in Table 1 are primarily for the treatment of specific cancers and are administered through an intravenous infusion. The gene therapies listed in Table 1 are generally for the treatment of certain rare ocular or spinal conditions caused by specific genetic mutations and are also either intravenously infused or administered through a subretinal injection. When these products are administered, they are the primary treatment being administered to a patient and thus, are not integral, ancillary, supportive, dependent, or adjunctive to any primary C-APC services. Additionally, the current primary C-APC services describe common surgical procedures, such as breast/lymphatic surgery and musculoskeletal procedures. The cell and gene therapies listed in Table 1 are intended to treat a specific condition and would not be used to support the outcome of any primary C-APC procedure. For example, HCPCS code J3399 (Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5×10^{15} vector genomes) may be used to describe the gene therapy Zolgensma. This product is FDA-approved as an adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene. The specified mechanism of onasemnogene abeparvovec is a recombinant AAV9-based gene therapy designed to deliver a copy of the gene encoding the human SMN protein.⁴ The function of a product such as Zolgensma, is not intended to be integral, ancillary, supportive, dependent, and adjunctive to any C-APC as the gene therapy itself is an independent treatment.

Yescarta (HCPCS code Q2041) is an example of a cell therapy that functions as an independent treatment. Based on its FDA-approved indication,⁵ this product's intended clinical use would not be integral, ancillary, supportive, dependent, or adjunctive to any current C-APC primary service. Yescarta is indicated as a CD19-directed genetically modified autologous T cell immunotherapy for the treatment of

Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy and adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. Yescarta is the primary treatment being performed when administered for these FDA-approved indications and should not be packaged as supportive of any C-APC primary service even if the two services appear on the same claim. We explained in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74868) that intravenous drugs, for example, are OPPS services that are considered adjunctive to the primary procedure because the correct administration of the drug either promotes a beneficial outcome, such as the use of intravenous pain medications, or prevents possible complications, such as the use of intravenous blood pressure medications to temporarily replace oral blood pressure medications and reduce the risk of a sudden rise in blood pressure when a normal daily medication is stopped. In the case of the cell and gene therapies described in Table 1, however, we do not believe the therapies "promote a beneficial outcome" or "prevent possible complications" of any of the procedures currently designated as primary C-APC services. While the cell and gene therapies in Table 1 may "promote a beneficial outcome" for the patient in general, we do not believe the provision of cell and gene therapies are "promoting a beneficial outcome" for any of the primary C-APC services themselves, as the cell and gene therapies are serving as independent therapies. These are distinguishable from the previous examples of intravenous pain medications that are directly related to the primary C-APC service and promote a beneficial outcome for that procedure. Further, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74865), we stated that we proposed to package into C-APCs all of these integral, ancillary, supportive, dependent, and adjunctive services, hereinafter collectively

referred to as "adjunctive services," provided during the delivery of the comprehensive service. This includes the diagnostic procedures, laboratory tests and other diagnostic tests, and treatments that assist in the delivery of the primary procedure. We do not believe that the cell and gene therapies listed in Table 1 are assisting in the delivery of any primary procedure currently assigned to a C-APC.

Therefore, for CY 2025 only, we propose not to package payment for the cell and gene therapies listed in Table 1 into the payment for the primary C-APC service when they appear on the same claim as primary C-APCs services. We propose this policy for one year only in order to gather more information from interested parties as to whether this proposed policy appropriately captures all of the unique therapies, such as the cell and gene therapies listed in Table 1, that function as primary treatments and do not support C-APC primary services. As discussed later in this section, we welcome comments from readers on this proposal and the potential need for a different, modified, expanded, or supplemental policy for future rulemaking. We will assess whether to continue this policy, or a modified version of this policy, beyond one year in future rulemaking, taking into consideration the comments received.

We are not proposing to include therapies that are on drug pass-through status for all of CY 2025 in Table 1 because pass-through drugs are already excluded from C-APC packaging. We are proposing that products for which pass-through status is expiring in CY 2025 would be excluded from C-APC packaging after their pass-through status expires. For example, the product described by HCPCS code Q2056 has pass-through status expiring June 30, 2025. Until its pass-through status expires, the product will be excluded from C-APC packaging due to the pass-through C-APC exclusion policy, but after its pass-through status expires, we propose that the therapy would continue to be excluded from C-APC packaging under our proposed exclusion for cell and gene therapies. For more information on drug pass-through status, including expiring and continuing pass-through status, please see section V.A. of this proposed rule.

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⁴ Zolgensma, FDA Package Insert, October 2023. <https://www.fda.gov/media/126109/download?attachment>.

⁵ FDA Package Insert, Yescarta, April 2024. <https://www.fda.gov/media/108377/download?attachment>.

TABLE 1: Cell and Gene Therapies Proposed for Exclusion from C-APC Packaging

Trade Name	HCPCS Code	Long Descriptor
Yescarta	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Kymriah	Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Provenge	Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion
Tecartus	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Breyanzi	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Abecma	Q2055	Idecabtagene vicleucel, up to 510 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Carvytki	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Luxturna	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes
Zolgensma	J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5×10^{15} vector genomes

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We propose to exclude the therapies listed in Table 1 from C-APC packaging. We seek comment on this proposal, and we seek comment on whether there are any additional cell and gene therapies that may be appropriate to exclude from C-APC packaging for CY 2025. Commenters should explain why any additional cell and gene therapies that they believe should be excluded from C-APC packaging are not integral,

ancillary, supportive, dependent, or adjunctive to any C-APC primary service. We seek comment on whether this proposal should be extended beyond 1 year or if a different, expanded, or supplemental policy approach may be warranted in future rulemaking. For example, we are interested in comments on whether there are other classes of drugs, biologicals, or other products that are

not clearly integral, ancillary, adjunctive, or supportive of a primary C-APC service but could appear on the same claim as the C-APC for that primary service and for which payment would be packaged into the C-APC payment under our current policy. We would expect clinical evidence supporting commenters' assertion that other identified classes of drugs, biologicals, medical devices, or other

products are not clearly supportive of a primary C-APC service but may nonetheless appear on the same claim as a primary C-APC procedure. Similarly, we seek comment on whether interested parties believe it is appropriate for these other classes of drugs, biologicals, or medical devices to be excluded from packaging with all C-APCs or only specific C-APCs, such as the Comprehensive Observation Services C-APC (SI = "J2").

Finally, we seek comment on the following:

(1) Because the cell and gene therapies listed in Table 1 are not integral, ancillary, supportive, dependent, or adjunctive to any current C-APC procedure, how could CMS structure a new C-APC, or similar packaged payment policy, for the service to administer cell or gene therapies, such by creating as a Chimeric Antigen Receptor (CAR) T-cell therapy administration C-APC, with which the CAR-T or gene therapy would be integral, ancillary, supportive, dependent, or adjunctive to the primary C-APC service?

(2) What integral, ancillary, supportive, dependent, or adjunctive items and services are routinely provided as part of the administration of cell and gene therapies or in conjunction with cell and gene therapies generally?

We recognize that currently, the following HCPCS codes are associated with CAR-T therapy: HCPCS code 0537T (Chimeric antigen receptor t-cell (car-t) therapy; harvesting of blood-derived t lymphocytes for development of genetically modified autologous car-t cells, per day), 0538T (Chimeric antigen receptor t-cell (car-t) therapy; preparation of blood-derived t lymphocytes for transportation (e.g., cryopreservation, storage)), 0539T (Chimeric antigen receptor t-cell (car-t) therapy; receipt and preparation of car-t cells for administration), and 0540T (Chimeric antigen receptor t-cell (car-t)

therapy; car-t cell administration, autologous) as discussed in previous OPPTS rulemaking, including the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63550 through 63552).

Separately, we also seek comment on whether policy revisions to the C-APC policy may be appropriate in future rulemaking, such as a modified outlier payment policy specific to C-APCs to address related situations in the future. We list all proposed C-APC exclusion categories for CY 2025 in Addendum J to this proposed rule (which is available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>).

(5) Exclusion of Non-Opioid Products for Pain Relief Under Section 4135 of the Consolidated Appropriations Act, 2023 From the C-APC Policy

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117-328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA, 2023, titled "Access to Non-Opioid Treatments for Pain Relief," amended section 1833(t)(16) and section 1833(i) of the Social Security Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief (as that term is defined in section 1833(t)(16)(G)(i) of the Act). In particular, section 1833(t)(16)(G) provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount. As stated earlier in this section,

our current policy is to exclude from the packaged C-APC payment those items and services that are required by statute to be separately paid.

Accordingly, we propose to exclude the non-opioid treatments for pain relief identified as satisfying the required criteria for payment under Section 4135 of the CAA, 2023 from the C-APC policy to ensure payment is not packaged into any C-APC and that separate payment is made in accordance with the statute. Please see section XIII.F. of this proposed rule for a list of the products that we propose would qualify for payment under the new payment policy for non-opioid drugs, biologicals, and devices for pain relief.

(6) C-APCs for CY 2025

For CY 2025 and subsequent years, we propose to continue to apply the C-APC payment policy methodology. We refer readers to the CY 2017 OPPTS/ASC final rule with comment period (81 FR 79583) for a discussion of the C-APC payment policy methodology and revisions.

Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPTS. As a result of our annual review of the services and the APC assignments under the OPPTS, we are not proposing to convert any standard APCs to C-APCs in CY 2025; thus, we propose that the number of C-APCs for CY 2025 would be the same as the number for CY 2024, which is 72 C-APCs.

Table 2 lists the proposed C-APCs for CY 2025, all of which were established in past rules. All C-APCs are also displayed in Addendum J to this proposed rule (which is available via the internet on the CMS website). Addendum J to this proposed rule also contains all the data related to the C-APC payment policy methodology, including the list of complexity adjustments and other information.

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TABLE 2: PROPOSED CY 2025 C-APCs

C-APC	CY 2025 APC Group Title	Clinical Family	New C-APC
5072	Level 2 Excision/Biopsy/Incision and Drainage	EBIDX	
5073	Level 3 Excision/Biopsy/Incision and Drainage	EBIDX	
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5093	Level 3 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5094	Level 4 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5112	Level 2 Musculoskeletal Procedures	ORTHO	
5113	Level 3 Musculoskeletal Procedures	ORTHO	
5114	Level 4 Musculoskeletal Procedures	ORTHO	
5115	Level 5 Musculoskeletal Procedures	ORTHO	
5116	Level 6 Musculoskeletal Procedures	ORTHO	
5153	Level 3 Airway Endoscopy	AENDO	
5154	Level 4 Airway Endoscopy	AENDO	
5155	Level 5 Airway Endoscopy	AENDO	
5163	Level 3 ENT Procedures	ENTXX	
5164	Level 4 ENT Procedures	ENTXX	
5165	Level 5 ENT Procedures	ENTXX	
5166	Cochlear Implant Procedure	COCHL	
5182	Level 2 Vascular Procedures	VASCX	
5183	Level 3 Vascular Procedures	VASCX	
5184	Level 4 Vascular Procedures	VASCX	
5191	Level 1 Endovascular Procedures	EVASC	
5192	Level 2 Endovascular Procedures	EVASC	
5193	Level 3 Endovascular Procedures	EVASC	
5194	Level 4 Endovascular Procedures	EVASC	
5200	Implantation Wireless PA Pressure Monitor	WPMXX	
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	
5232	Level 2 ICD and Similar Procedures	AICDP	
5244	Level 4 Blood Product Exchange and Related Services	SCTXX	
5302	Level 2 Upper GI Procedures	GIXXX	

C-APC	CY 2025 APC Group Title	Clinical Family	New C-APC
5303	Level 3 Upper GI Procedures	GIXXX	
5313	Level 3 Lower GI Procedures	GIXXX	
5331	Complex GI Procedures	GIXXX	
5341	Level 1 Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	
5342	Level 2 Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	
5361	Level 1 Laparoscopy and Related Services	LAPXX	
5362	Level 2 Laparoscopy and Related Services	LAPXX	
5372	Level 2 Urology and Related Services	UROXX	
5373	Level 3 Urology and Related Services	UROXX	
5374	Level 4 Urology and Related Services	UROXX	
5375	Level 5 Urology and Related Services	UROXX	
5376	Level 6 Urology and Related Services	UROXX	
5377	Level 7 Urology and Related Services	UROXX	
5378	Level 8 Urology and Related Services	UROXX	
5414	Level 4 Gynecologic Procedures	GYNXX	
5415	Level 5 Gynecologic Procedures	GYNXX	
5416	Level 6 Gynecologic Procedures	GYNXX	
5431	Level 1 Nerve Procedures	NERVE	
5432	Level 2 Nerve Procedures	NERVE	
5461	Level 1 Neurostimulator and Related Procedures	NSTIM	
5462	Level 2 Neurostimulator and Related Procedures	NSTIM	
5463	Level 3 Neurostimulator and Related Procedures	NSTIM	
5464	Level 4 Neurostimulator and Related Procedures	NSTIM	
5465	Level 5 Neurostimulator and Related Procedures	NSTIM	
5471	Implantation of Drug Infusion Device	PUMPS	
5491	Level 1 Intraocular Procedures	INEYE	
5492	Level 2 Intraocular Procedures	INEYE	
5493	Level 3 Intraocular Procedures	INEYE	
5494	Level 4 Intraocular Procedures	INEYE	
5495	Level 5 Intraocular Procedures	INEYE	
5496	Level 6 Intraocular Procedures	INEYE	
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5627	Level 7 Radiation Therapy	RADTX	
5881	Ancillary Outpatient Services When Patient Dies	N/A	
8011	Comprehensive Observation Services	N/A	

C-APC Clinical Family Descriptor Key:

AENDO = Airway Endoscopy
 AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.
 BREAS = Breast Surgery
 COCHL = Cochlear Implant
 EBIDX = Excision/ Biopsy/Incision and Drainage
 ENTXX = ENT Procedures
 EPHYS = Cardiac Electrophysiology/
 EVASC = Endovascular Procedures
 EXEYE = Extraocular Ophthalmic Surgery
 GIXXX = Gastrointestinal Procedures
 GYNXX = Gynecologic Procedures
 INEYE = Intraocular Surgery
 LAPXX = Laparoscopic Procedures
 NERVE = Nerve Procedures
 NSTIM = Neurostimulators
 ORTHO = Orthopedic Surgery
 PUMPS = Implantable Drug Delivery Systems
 RADTX = Radiation Oncology
 SCTXX = Stem Cell Transplant
 UROXX = Urologic Procedures
 VASCX = Vascular Procedures
 WPMXX = Wireless PA Pressure Monitor

BILLING CODE 4120-01-C**c. Calculation of Composite APC Criteria-Based Costs**

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high-quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for mental health services and multiple imaging services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66614 and 66650 through 66652) for a full discussion of the development of the composite APC methodology, and the CY 2012 OPPS/ASC final rule with

comment period (76 FR 74163) and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59241, 59242, and 59246 through 52950) for more recent background.

(1) Mental Health Services Composite APC

For CY 2025, we propose to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services (88 FR 49572). We refer readers to the April 7, 2000, OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33580, 33581, 59246, and 59247), we proposed and finalized the policy for CY 2018 and subsequent years that, when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a

hospital, those specified mental health services will be paid through composite APC 8010 (Mental Health Services Composite). In addition, we set the payment rate for composite APC 8010 for CY 2018 at the same payment rate for APC 5863, which was the maximum partial hospitalization per diem payment rate for a hospital, and finalized a policy that the hospital would continue to be paid the payment rate for composite APC 8010. This policy applied in CYs 2018 through 2023.

In the CY 2024 OPPS/ASC proposed rule, we stated that APC 5863 was no longer the maximum partial hospitalization per diem payment rate for a hospital due to the creation of APC 5864, which is 4 or more hospital-based PHP services per day (88 FR 49572). We solicited comment on whether APC 5864 would be appropriate to use as the daily mental health cap, as we have historically set the daily mental health cap for composite APC 8010 at the maximum partial hospitalization per diem payment rate for a hospital (88 FR 49572). Based on public comments received and our longstanding policy, in CY 2024 OPPS/ASC final rule, we finalized APC 5864, four hospital-based PHP services per day, as the daily mental health cap (88 FR 81566).

We continue to believe that the costs associated with administering a partial hospitalization program at a hospital represent the most resource intensive of all outpatient mental health services.

For CY 2025 and subsequent years, we propose to continue this policy that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the per diem payment rate for 4 partial hospitalization services provided in a day by a hospital (the payment amount for APC 5864), those specified mental health services would be paid through composite APC 8010. In addition, we propose to continue to set the payment rate for composite APC 8010 at the same payment rate that we propose for APC 5864, which is a partial hospitalization per diem payment rate for 4 partial hospitalization services furnished in a day by a hospital.

Under this proposed policy, the Integrated OCE (I/OCE) would continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 5864 for all the specified mental health services furnished by the hospital on that single date of service by paying for the services through composite APC 5863.

(2) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Effective January 1, 2009, we provide a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 3 below.

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the “with contrast” composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment based on the payment rate for APC 8008, the “with contrast” composite APC.

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

For CY 2025, we propose to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy would reflect and promote the

efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

For CY 2025, except where otherwise indicated, we propose to use the costs derived from CY 2023 claims data to set the proposed CY 2025 payment rates. Therefore, for CY 2025, the proposed payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) were based on proposed geometric mean costs calculated from CY 2023 claims available for the CY 2025 OPPS/ASC proposed rule that qualify for composite payment under the current policy (that is, those claims reporting more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we used the same methodology that we used to calculate the geometric mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as “overlap bypass codes” that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this proposed rule (which is available via the internet on the CMS website) and are discussed in more detail in section II.A.1.a of this proposed rule.

For this CY 2025 OPPS/ASC proposed rule, we were able to identify approximately 0.95 million “single session” claims out of an estimated 2.1 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 45.0 percent of all eligible claims, to calculate the proposed CY 2025 geometric mean costs for the multiple imaging composite APCs. Table 3 lists the proposed HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC proposed geometric mean costs for CY 2025.

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TABLE 3: OPPTS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2025 APC 8004 (Ultrasound Composite)	CY 2025 Approximate APC Geometric Mean Cost = \$305.72
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76981	Us parenchyma
76982	Us 1 st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2025 APC 8005 (CT and CTA without Contrast Composite) *	CY 2025 Approximate APC Geometric Mean Cost = \$225.57
0633T	Ct breast w/3d uni c-
0636T	Ct breast w/3d bi c-
70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
74176	Ct angio abd & pelvis
74261	Ct colonography, w/o dye
CY 2025 APC 8006 (CT and CTA with Contrast Composite)	CY 2025 Approximate APC Geometric Mean Cost = \$434.01
0634T	Ct breast w/3d uni c+
0635T	Ct breast w/3d uni c-/c+
0637T	Ct breast w/3d bi c+
0638T	Ct breast w/3d bi c-/c+
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye

70482	Ct orbit/ear/fossa w/o & w/dye
70487	Ct maxillofacial w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o & w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o & w/dye
73206	Ct angio upr extrm w/o & w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o & w/dye
73706	Ct angio lwr extr w/o & w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
* If a “without contrast” CT or CTA procedure is performed during the same session as a “with contrast” CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.	
Family 3 - MRI and MRA with and without Contrast	
CY 2025 APC 8007 (MRI and MRA without Contrast Composite) *	CY 2025 Approximate APC Geometric Mean Cost = \$536.10
0609T	Mrs disc pain acquisj data
70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye
70544	Mr angiography head w/o dye
70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye

70554	Fmri brain by tech
71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
76391	Mr elastography
77046	Mri breast c- unilateral
77047	Mri breast c- bilateral
C8901	MRA w/o cont, abd
C8910	MRA w/o cont, chest
C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis
C8932	MRA, w/o dye, spinal canal
C8935	MRA, w/o dye, upper extr
C9762	Cardiac MRI seg dys strain
C9763	Cardiac MRI seg dys stress
CY 2025 APC 8008 (MRI and MRA with Contrast Composite)	CY 2025 Approximate APC Geometric Mean Cost = \$853.87
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o & w/dye
70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye
70549	Mr angiograph neck w/o & w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye
72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye

72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o & w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o & w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o & w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o & w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o&w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr
* If a “without contrast” MRI or MRA procedure is performed during the same session as a “with contrast” MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.	

BILLING CODE 4120-01-C**3. Proposed Changes to Packaged Items and Services****a. Background and Rationale for Packaging in the OPPS**

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular

beneficiary. The OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and

supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which may occur if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services

or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPSS since its implementation in August 2000. As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPSS packaging policies. Most, but not necessarily all, categories of items and services currently packaged in the OPSS are listed in 42 CFR 419.2(b). Our overarching goal is to make payments for all services under the OPSS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPSS to determine which OPSS services can be packaged to further achieve the objective of advancing the OPSS toward a more prospective payment system.

b. Proposal on Packaged Items and Services

For CY 2025, we examined the items and services currently provided under the OPSS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment for the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and hospital outpatient department billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to existing OPSS packaging policies or a

logical expansion of those existing OPSS packaging policies.

For CY 2025, we do not propose any changes to the overall packaging policy discussed. We propose to continue to conditionally package the costs of selected newly identified ancillary services into payment for a primary service where we believe that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code.

c. Proposed Payment for Diagnostic Radiopharmaceuticals

(1) Background on OPSS Packaging Policy for Diagnostic Radiopharmaceuticals

Under the OPSS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in § 419.2(b), we refer to them as “policy-packaged” drugs, biologicals, and radiopharmaceuticals. In particular, under § 419.2(b)(15), payment for drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure is packaged with the payment for the related procedure or service. Packaging costs into a single aggregate payment for a service, encounter, or episode of care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of supportive items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and enables hospitals to manage their resources with maximum flexibility.

In the CY 2008 OPSS/ASC final rule with comment period we finalized the packaging status of diagnostic radiopharmaceuticals as part of our overall enhanced packaging approach for the CY 2008 OPSS and subsequent years (72 FR 66635 through 66641). Importantly, we believed diagnostic radiopharmaceuticals are always intended to be used with a diagnostic nuclear medicine procedure and function as supplies when used in a diagnostic test or procedure, making it appropriate to package the payment for the diagnostic radiopharmaceutical into the payment for the related nuclear medicine procedure. Diagnostic radiopharmaceuticals are one specific type of product that is policy packaged under the category described by § 419.2(b)(15). Since we implemented

this policy in CY 2008, interested parties have raised concerns regarding policy packaging of diagnostic radiopharmaceuticals. In previous rulemaking (87 FR 71962 and 71963), commenters recommended that CMS always pay separately under the OPSS for diagnostic radiopharmaceuticals, not just when the products have pass-through payment status. Many of these commenters mentioned that pass-through payment status helps the diffusion of new diagnostic radiopharmaceuticals into the market. However, commenters believe the packaged payment rate is often inadequate after pass-through status expires, especially in cases where the diagnostic radiopharmaceutical is high-cost and has low utilization.

We have heard from interested parties regarding alternative payment methodologies, such as subjecting diagnostic radiopharmaceuticals to the drug packaging threshold and creating separate APC payments for diagnostic radiopharmaceuticals with a per-day cost greater than \$500. Interested parties have also recommended that we analyze our nuclear medicine APC structure and consider establishing additional nuclear medicine APCs to reflect the costs of diagnostic radiopharmaceuticals more accurately. Historically, commenters opposed incorporating the cost of diagnostic radiopharmaceuticals into the associated nuclear medicine APC as the nuclear medicine APCs are sometimes paid at a lower rate than the payment rate for the diagnostic radiopharmaceutical itself when it has pass-through payment status (87 FR 71962 and 71963).

Importantly, commenters historically have also been concerned that packaging payment for precision diagnostic radiopharmaceuticals in the outpatient hospital setting creates barriers to beneficiary access for safety net hospitals serving a high proportion of Medicare beneficiaries and hospitals serving underserved communities (87 FR 71962 and 71963). Commenters specified that certain populations, such as those with Alzheimer’s disease, depend on the use of certain high-cost diagnostic radiopharmaceuticals. Commenters discussed difficulties enrolling hospitals in clinical studies due to OPSS packaging policies and suggested that we pay separately under the OPSS specifically for radiopharmaceuticals that are used for Alzheimer’s disease. Additionally, commenters have recommended that CMS continue to apply radiolabeled product edits to the nuclear medicine procedures to ensure that all packaged costs are included on nuclear medicine

claims to establish appropriate payment rates in the future. Beginning January 1, 2008, CMS implemented OPPS edits that require hospitals to include a HCPCS code for a radiolabeled product when a separately payable nuclear medicine procedure is present on a claim. This policy to require hospitals to include a HCPCS code for a radiolabeled product for a separately payable nuclear medicine procedure ended in CY 2014 (78 FR 75033 through 75034).

Many of these comments and our responses have been discussed in rulemaking since the policy to package diagnostic radiopharmaceuticals was adopted, and they prompted us to solicit comment on the payment of diagnostic radiopharmaceuticals in the CY 2024 OPPS/ASC proposed rule (88 FR 49577). In that proposed rule, we stated we continue to believe that diagnostic radiopharmaceuticals are an integral component of many nuclear medicine and imaging procedures and charges associated with them should be reported on hospital claims to the extent they are used. Accordingly, we reiterated our belief that the payment for the diagnostic radiopharmaceutical should be reflected within the payment for the primary procedure with which it is used. We noted that ratesetting uses the geometric mean of reported procedure costs, which in the example of nuclear medicine procedures includes the costs of the reported diagnostic radiopharmaceutical, based on data submitted to CMS from all hospitals paid under the OPPS to set the payment rate for the service. The costs that are calculated by Medicare reflect the average costs of items and services that are packaged into a primary procedure and will not necessarily equal the sum of the cost of the primary procedure and the average sales price of the specific items and services used in the procedure in each case. Furthermore, we explained that the costs are based on the reported costs submitted to Medicare by the hospitals and not the list price established by the manufacturer. Claims data that include the diagnostic radiopharmaceutical packaged with the associated procedure should reflect the combined cost of the procedure and the radiopharmaceutical used in the procedure.

As we have reiterated over the years, we believe packaging policies are inherent principles of the OPPS and are essential to a prospective payment system. At the same time, we have explained that we are committed to ensuring beneficiary access to diagnostic radiopharmaceuticals while also ensuring the availability of new and innovative diagnostic tools for Medicare

beneficiaries. Therefore, we sought public comments on potential modifications to our packaging policy for diagnostic radiopharmaceuticals to ensure equitable payment and continued beneficiary access.

As described in the CY 2024 OPPS/ASC proposed rule (88 FR 49578), we solicited comment on how the OPPS packaging policy for diagnostic radiopharmaceuticals has impacted beneficiary access, including whether there are specific patient populations or clinical disease states for whom this issue is especially critical.

In addition, we solicited comment on the following potential approaches that would enhance beneficiary access, while also maintaining the principles of the outpatient prospective payment system. These approaches included: (1) paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPS drug packaging threshold of \$140; (2) establishing a specific per-day cost threshold that may be greater or less than the OPPS drug packaging threshold; (3) restructuring APCs, including by adding nuclear medicine APCs for services that utilize high-cost diagnostic radiopharmaceuticals; (4) creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials; and (5) adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

Finally, we were interested in hearing from stakeholders how the suggested policy modifications might impact our overarching goal of utilizing packaging policies to better align OPPS policies with those of a prospective payment system rather than a fee schedule. We stated we would also like to know if making any of the suggested policy changes could have negative consequences for beneficiaries, such as unintentionally influencing clinical practice decisions, increasing beneficiary cost-sharing obligations, or inadvertently encouraging the use of higher-cost diagnostic radiopharmaceuticals over lower cost, but equally effective, diagnostic options.

We received a significant number of comments in response to the comment solicitation on potential issues caused by our current payment policy for diagnostic radiopharmaceuticals under the OPPS and on new approaches to payment for these products. Commenters expressed concerns regarding the CMS policy to package diagnostic radiopharmaceuticals and the financial implications this policy has for facilities. Commenters believe that, for

newer, more innovative radiopharmaceuticals, the current OPPS packaging policy has led to a lack of patient access to the technologies after the radiopharmaceutical's pass-through status expires, especially if there is no clinical alternative to the radiopharmaceutical. Most commenters requested that CMS provide separate payment for diagnostic radiopharmaceuticals. Some commenters believed paying separately for all diagnostic radiopharmaceuticals regardless of their per-day cost was the best methodology to avoid encouraging price inflation for diagnostic radiopharmaceuticals to reach a certain threshold. Other commenters thought that applying the existing OPPS per-day cost threshold (\$135 for CY 2024) to the payment of diagnostic radiopharmaceuticals would be an adequate solution. Others supported a \$500 threshold, and many cited the Facilitating Innovative Nuclear Diagnostics Act (FIND Act) of 2023 as their rationale for that number and recognized that the \$500 threshold number may be a more targeted approach relative to the OPPS drug packaging threshold as the higher cost diagnostic radiopharmaceuticals are the most disadvantaged by the OPPS packaging policy in their view. For the full discussion on the comment solicitation summarized here, refer to the CY 2024 OPPS/ASC final rule with comment period (88 FR 81573 through 81577).

(2) Proposed Packaging Threshold for Diagnostic Radiopharmaceuticals

As stated in the CY 2024 OPPS final rule with comment period (88 FR 81577), we agree with commenters that payment for diagnostic radiopharmaceuticals is a complex and important issue. We explained that we intended to further consider these points and take them into consideration for future notice and comment rulemaking. After significant consideration and ongoing engagement from interested parties, we are proposing a change to our current policy that packages diagnostic radiopharmaceuticals regardless of their cost.

We continue to believe diagnostic radiopharmaceuticals are always intended to be used with a diagnostic nuclear medicine procedure and function as supplies when used in a diagnostic test or procedure, generally making it appropriate to package payment for them with payment for the related nuclear medicine procedure. While we continue to believe that this should be the policy for most diagnostic

radiopharmaceuticals, we believe there are certain situations in which the packaged payment amount attributed to the diagnostic radiopharmaceutical used in an imaging procedure assigned to a nuclear medicine APC may not adequately account for the cost of a diagnostic radiopharmaceutical that has a significantly higher cost, but lower utilization relative to the other diagnostic radiopharmaceuticals that may be used with the procedure. In situations where a hospital may have to pay significantly more to purchase a diagnostic radiopharmaceutical than Medicare pays, a hospital may decide not to provide that specific diagnostic radiopharmaceutical imaging agent to Medicare beneficiaries. This could potentially deny access to diagnostic tools for which there is no clinical alternative. To ensure Medicare payment policy is not providing a financial disincentive to using high cost, low utilization diagnostic radiopharmaceuticals, especially when those agents may be the most clinically appropriate, and to ensure appropriate beneficiary access, we believe a subset of diagnostic radiopharmaceuticals with higher per day costs should be paid separately and not packaged into the

diagnostic procedure with which the diagnostic radiopharmaceutical is used.

To address these concerns, we propose to pay separately for any diagnostic radiopharmaceutical with a per day cost greater than \$630. Any diagnostic radiopharmaceutical with a per day cost below that threshold would continue to be policy packaged under the current policy at § 419.2(b)(15). We discuss our methodology for determining the proposed per day cost threshold of \$630 in further detail in this section.

To determine an appropriate threshold, we estimated the approximate payment that would typically be attributable to diagnostic radiopharmaceutical payment within each nuclear medicine APC (APCs 5591, 5592, 5593, and 5594). We did this by assessing the offsets associated with these APCs that were directly attributable to “policy packaged” drugs. The offset amounts used are correlated with the approximate portion of APC payment associated with these “policy packaged” drugs. For nuclear medicine APCs, the primary “policy packaged” drugs are diagnostic radiopharmaceuticals. To calculate this threshold, we calculated a volume weighted average of the offset dollar amount of each nuclear medicine APC.

This involved taking the offset percentage for “policy packaged” drugs, multiplying it by the APC geometric mean to get an offset dollar amount, and then multiplying that offset amount by the number of single claims to get the total offset amount for each nuclear medicine APC level. We then calculated the sum of the total offset amount for all 4 of the nuclear medicine APCs. We divided this number by the total number of single claims for all 4 nuclear medicine APCs, resulting in \$314.28, which represents the volume weighted average policy packaged offset amount for the nuclear medicine APC series. We then took that number and multiplied it by 2, and rounded it to the nearest \$5 increment, which resulted in \$630. See Table 4 for the values used to calculate this threshold amount. We note that the data values in Table 4 were collected without unpackaging the set of diagnostic radiopharmaceuticals listed in Table 5. If we finalize our proposal and those diagnostic radiopharmaceuticals are unpackaged, it would change the APC geometric mean unit costs (MUCs) as well as the offset percentages. This is why the APC geometric mean cost values listed below are not the same as in the addenda to this rule.

TABLE 4: CY 2025 Costs Statistics for Nuclear Medicine APCs

APC	APC Title	Number of Single Claims	APC Geometric mean Cost	Portion of APC Payment Associated with "Policy Packaged" Drugs / Offset Percent for <u>Packaged Drugs that are Always Packaged</u>
5591	Level 1 Nuclear Medicine and Related Services	155,289	\$416.50	0.152
5592	Level 2 Nuclear Medicine and Related Services	60,334	\$556.84	0.2146
5593	Level 3 Nuclear Medicine and Related Services	496,758	\$1,399.48	0.2387
5594	Level 4 Nuclear Medicine and Related Services	402,439	\$1,738.01	0.2393

The offset percentages used have been updated based on the available data for CY 2025 rulemaking and would be updated for the final rule. However, the file and corresponding offset percentages used are similar to the ones that can be found in the CY 2024 NFRM APC Offset File. These files are available

via the internet on the CMS OPPS website.⁶

We propose to multiply by two the volume weighted average amount of the offset to establish the threshold triggering separate payment because this amount would ensure that separate

payment would apply only to diagnostic radiopharmaceuticals whose costs significantly exceed the approximate amount of payment already attributed to the product in the nuclear medicine APC payment. This is consistent with the principles of a prospective payment system where some payments are lower than hospitals' costs while other payments are greater than a hospitals'

⁶ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/annual-policy-files>.

costs. However, diagnostic radiopharmaceuticals with costs more than double the volume weighted average amount of the offset could present a hospital with a significant financial loss. This is why the OPSS has several payment provisions that rely on a multiplier of costs as a threshold for modifying payment.

Our proposed approach to multiply the average offset amount by two is consistent with the two-times rule the OPSS uses to determine Ambulatory Payment Classification (APC) levels, where a significant service that has a cost greater than two times the lowest cost significant service in an APC is generally moved to a higher level APC in the series. The two-times rule requires that the highest calculated cost of an individual procedure categorized to any given APC cannot exceed two times the calculated cost of the lowest cost procedure categorized to that same APC. We note that the two-times rule does not apply to diagnostic radiopharmaceuticals themselves, but only to the procedures in which they are used, which is why we are proposing a diagnostic radiopharmaceutical packaging threshold utilizing a similar two-times methodology.

Our proposed approach to multiply the average offset amount by two is also generally consistent with the OPSS outlier policy applicable to certain high-cost procedures, where costs greater than 1.75 times the APC payment trigger an additional outlier payment. The OPSS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. Outlier payments are provided on a service basis when the cost of a service exceeds the APC payment amount multiplier threshold (1.75) as well as the APC payment amount plus a fixed-dollar amount threshold. The proposed diagnostic radiopharmaceutical packaging threshold would serve a similar purpose as the outlier policy, in that it would provide payments to hospitals to help mitigate the financial risk associated with high-cost diagnostic radiopharmaceuticals, where a very costly diagnostic radiopharmaceutical could present a hospital with significant financial loss.

While we are proposing two, and believe two is the most appropriate number for the multiplier for the volume weighted average amount of the offset, for the reasons articulated for the OPSS outlier policy, we seek comment on the alternatives of using 1.75 times the volume weighted average amount of

the offset as the threshold amount for triggering separate payment, or another appropriate multiplier amount. For example, an interested party could present data that a financial disincentive to use diagnostic radiopharmaceuticals exists when costs are 1.75 times, or three times or five times, the volume weighted average offset amount. Since the hospital outpatient outlier payment policy is a longstanding policy familiar to most hospitals, we seek comment on utilizing elements of that policy for purposes of our proposed diagnostic radiopharmaceutical packaging policy in order to help hospitals mitigate the financial risk that may be associated with furnishing high-cost and complex diagnostic radiopharmaceuticals. As previously mentioned, we seek comment on the use of 1.75 times as the multiplier threshold rather than 2. Although the outlier policy uses both a 1.75 multiplier threshold and a fixed-dollar threshold, we are seeking comment regarding the use of 1.75 as the multiplier to set a fixed dollar threshold for the volume weighted average amount of the offset as the goals of the outlier policy and this proposed diagnostic radiopharmaceutical policy are similar.

We also solicit comment on the alternative of using the standard drug packaging threshold, which is proposed to be \$140 for CY 2025 in this rule, as the threshold for separate payment for diagnostic radiopharmaceuticals. We believe that diagnostic radiopharmaceuticals are functioning as supplies to the nuclear medicine procedure in which they are used. Because diagnostic radiopharmaceuticals function as supplies in the diagnostic procedures in which they are used, they are serving as an item that is integral, ancillary, supportive, dependent, or adjunctive to the primary diagnostic service. This is in contrast to therapeutic drugs, biologicals, and therapeutic radiopharmaceuticals that are typically packaged under the standard drug packaging threshold. These products could be the only therapeutic modality provided to a patient during an encounter and may not serve as an item that is integral, ancillary, supportive, dependent, or adjunctive to the primary service. Due to this clinical difference, we do not believe that using the standard drug packaging threshold is appropriate for diagnostic radiopharmaceuticals, and therefore we are proposing a threshold specific to diagnostic radiopharmaceuticals. We would be interested to hear from

commenters whether they agree or disagree with this assessment.

(3) Calculating the Per Day Cost of Diagnostic Radiopharmaceuticals

We are proposing to calculate the per day costs for diagnostic radiopharmaceuticals using a methodology similar to the one we use for determining the per day costs of drugs and biologicals for comparison to the OPSS drug packaging threshold, proposed to be \$140 for CY 2025.

We propose to calculate the per day cost based on the methodology described in section V.B.1.b. of this proposed rule, which relies on the methodology in the CY 2006 OPSS/ASC proposed rule (70 FR 42723 and 42724) and finalized in the CY 2006 OPSS final rule with comment period (70 FR 68636 through 68638). Though the clinical use of the drugs, biologicals, and therapeutic radiopharmaceuticals differs from diagnostic radiopharmaceuticals, we believe the method of determining how much of that item is used per day should be similar. Therefore, we are proposing to use a similar methodology for determining the per day costs of diagnostic radiopharmaceuticals, as we do drugs, biologicals, and therapeutic radiopharmaceuticals. This methodology consists of nine steps:

Step 1. After application of the CCRs, we aggregated all line-items for a single date of service on a single claim for each product. This resulted in creation of a single line-item with the total number of units and the total cost of a diagnostic radiopharmaceutical given to a patient in a single day.

Step 2. We then created a separate record for each diagnostic radiopharmaceutical by date of service, regardless of the number of lines on which the diagnostic radiopharmaceutical was billed on each claim. For example, “diagnostic radiopharmaceutical X” is billed on a claim with two different dates of service, and for each date of service, the diagnostic radiopharmaceutical is billed on two line-items with a cost of \$10 and 5 units for each line-item. In this case, the computer program would create two records for this diagnostic radiopharmaceutical, and each record would have a total cost of \$20 and 10 units of the product.

Step 3. We trimmed records with unit counts per day greater or less than 3 standard deviations from the geometric mean.

Step 4. For each remaining record for a diagnostic radiopharmaceutical, we calculated the cost per unit of the diagnostic radiopharmaceutical. If the HCPCS descriptor for “diagnostic

radiopharmaceutical X” is “per 1 millicurie” and one record was created for a total of 10 millicurie (as indicated by the total number of units for the diagnostic radiopharmaceutical on the claim for each unique date of service), the computer program divided the total cost for the record by 10 to give a per unit cost. We then weighted this unit cost by the total number of units in the record. We did this by generating a number of line-items equivalent to the number of units in that particular claim. Thus, a claim with 100 units of “diagnostic radiopharmaceutical X” and a total cost of \$200 would be given 100 line-items, each with a cost of \$2, while a claim of 50 units with a cost of \$50 would be given 50 line items, each with a cost of \$1.

Step 5. We trimmed the unit records with cost per unit greater or less than 3 standard deviations from the geometric mean.

Step 6. We aggregated the remaining unit records to determine the mean cost per unit of the diagnostic radiopharmaceutical.

Step 7. Using only the records that remained after records with unit counts per day greater or less than 3 standard deviations from the geometric mean were trimmed (step 3), we determined the total number of units billed for each item and the total number of unique per-day records for each item. We divided the count of the total number of units by the total number of unique per day records for each item to calculate an average number of units per day.

Step 8. We used the payment rate (the mean unit cost (MUC) derived from the CY 2023 hospital claims data) for each diagnostic radiopharmaceutical and multiplied the payment rate by the average number of units per day for each diagnostic radiopharmaceutical to arrive at its per day cost.

Step 9. We packaged the items with per day costs less than or equal to \$630 and designated items with per day costs greater than \$630 as separately payable.

As just described, to determine the proposed CY 2025 packaging status for all nonpass-through diagnostic radiopharmaceuticals, we propose to use the per day cost, calculated on a HCPCS code-specific basis, of each diagnostic radiopharmaceutical that had a HCPCS code in CY 2023 and was paid (via packaged or separate payment) under the OPSS. We used data from CY 2023 claims processed through December 31, 2023, for this calculation.

We propose to continue to package payment for diagnostic radiopharmaceuticals with per day costs less than or equal to \$630 under our existing packaging policy for diagnostic

radiopharmaceuticals that function as surgical supplies under § 419.2(b)(15). Similar to our policy for the drug packaging threshold, we propose to use updated claims data to make final determinations of the packaging status of HCPCS codes for diagnostic radiopharmaceuticals for each OPSS/ASC final rule with comment period. We propose to make an annual packaging determination for each diagnostic radiopharmaceutical HCPCS code only when we develop the OPSS/ASC final rule with comment period for the update year. We propose that only diagnostic radiopharmaceutical HCPCS codes that are identified as separately payable in the final rule with comment period would be subject to quarterly updates.

Consequently, the packaging status of some HCPCS codes for diagnostic radiopharmaceuticals in the OPSS/ASC proposed rule may differ from the same HCPCS codes’ packaging status determined based on the data used for the final rule with comment period. Under these circumstances, we propose to follow the established policies for the OPSS drug packaging threshold, which were initially adopted for the CY 2005 OPSS (69 FR 65780), to more equitably pay for those diagnostic radiopharmaceuticals whose costs fluctuate relative to the proposed CY 2025 OPSS diagnostic radiopharmaceutical packaging threshold in a way that affects the product’s payment status (packaged or separately payable). Our policy for the OPSS drug packaging threshold has not changed for many years and is the same as described in the CY 2016 OPSS/ASC final rule with comment period (80 FR 70434). We believe these same policies should apply to diagnostic radiopharmaceuticals in order to ensure payment consistency for those diagnostic radiopharmaceuticals whose costs fluctuate relative to the proposed CY 2025 OPSS diagnostic radiopharmaceutical packaging threshold. For CY 2025, similar to our historical practice for the drug packaging threshold, we propose to apply the following policies to those HCPCS codes for diagnostic radiopharmaceuticals whose relationship to the diagnostic radiopharmaceutical packaging threshold changes based on the final updated data: HCPCS codes for diagnostic radiopharmaceuticals that are proposed for separate payment in CY 2025, and that then have per day costs equal to or less than the CY 2025 final rule diagnostic radiopharmaceutical packaging threshold, based on the

updated hospital claims data used for the CY 2025 final rule, would remain packaged in CY 2025. HCPCS codes for diagnostic radiopharmaceuticals for which we proposed packaged payment in CY 2025 but that then have per-day costs greater than the CY 2025 final rule drug packaging threshold, based on updated hospital claims data used for the CY 2025 final rule, would receive separate payment in CY 2025.

(4) Proposal To Update the Diagnostic Radiopharmaceutical Packaging Threshold in CY 2026

Starting in CY 2026 and subsequent years, we propose to update the proposed threshold amount of \$630 by the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IHS Global, Inc (IGI). IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the various price indexes including the Producer Price Index (PPI) Pharmaceuticals for Human Use (Prescription). This is the same as the update factor used for the OPSS drug packaging threshold, where we originally used the four-quarter moving average PPI levels for Pharmaceutical Preparations (Prescription) to trend the \$50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of the applicable calendar year. We believe it is appropriate to use the same PPI for Pharmaceuticals for Human Use (Prescription) for the diagnostic radiopharmaceutical packaging threshold, as diagnostic radiopharmaceuticals are also prescription pharmaceuticals for human use. We propose that starting for CY 2026, we would use the most recently available four quarter moving average PPI levels to trend the final CY 2025 threshold forward from the third quarter of CY 2024 to the third quarter of CY 2025 and round the resulting dollar amount to the nearest \$5 increment. This proposal to update the diagnostic radiopharmaceutical packaging threshold maintains consistency with our longstanding methodology for updating the OPSS drug packaging threshold, which is discussed in more detail in section V.B.1.a. of this rule and also in the CY 2007 OPSS/ASC final rule with comment period (71 FR 68085 and 68086).

(5) Amount of Separate Payment for Diagnostic Radiopharmaceuticals Exceeding the Threshold

Once we determine that the per day cost of a nonpass-through diagnostic

radiopharmaceutical exceeds the proposed cost threshold of \$630 per day for CY 2025, we then propose to assign that radiopharmaceutical to an APC, making it a specified covered outpatient drug (SCOD) per section 1833(t)(14)(B) of the Act. Accordingly, we propose to pay for those nonpass-through, separately payable diagnostic radiopharmaceuticals based on our authority under section 1833(t)(14)(A)(iii)(II) of the Act. While under this authority we would ordinarily use the ASP methodology under section 1847A of the Act, we find that the ASP data we have is not usable for payment purposes. As previously mentioned, radiopharmaceuticals are not required to report ASP under 1847A, and as such, there are very few manufacturers reporting ASP for their products currently. Of those few manufacturers reporting ASP, the ASP values that we do have generally do not align with the ASP we would expect based on the cost and MUC data submitted to CMS by hospitals. For example, a frequently used diagnostic radiopharmaceutical has a reported ASP that is over 23,000 percent higher than the MUC derived from claims data. As manufacturers of diagnostic radiopharmaceuticals may be unaware of the correct reporting requirements, we believe it would be inappropriate to propose to pay for separately payable diagnostic radiopharmaceuticals based on their ASPs as currently reported, without giving manufacturers the opportunity to submit, certify, or restate the ASPs of their products. We believe MUC is an appropriate proxy for the average price for a diagnostic radiopharmaceutical for a given year, as it is calculated based on the average costs for a particular year and is directly reflective of the actual cost data that hospitals submit to CMS.

Under our policy for therapeutic radiopharmaceuticals (74 FR 60520), there are several requirements for reporting ASP. For example, ASP data submitted would need to be provided for a patient-specific dose, or patient-ready form, of the radiopharmaceutical in order to properly calculate the ASP amount for a given HCPCS code if that HCPCS code dose descriptor was per study dose or similar. ASP data submitted should align with the code's dose descriptor and billing unit. We stated we would expect that the ASP data reported by a manufacturer would be representative of the item(s) sold by the manufacturer. We used the term "patient-ready" in that rule to ensure that ASP data submitted for OPPTS payment purposes for separately

payable radiopharmaceuticals reflect the costs of all the component materials of the finished radiopharmaceutical product. We expect that the ASP data would represent the sales price of all of the component materials of the finished radiopharmaceutical product sold by the manufacturer in terms that reflect the applicable HCPCS code descriptor such as "per study dose", "per millicurie" and "up to XX millicuries." For the few manufacturers currently reporting ASP data for their diagnostic radiopharmaceuticals, we believe it may be possible that they are not aware of the reporting requirements or are unaware of how to properly report ASP for their product, as CMS has not used ASP as the basis of payment for non-pass-through diagnostic radiopharmaceuticals before. Therefore, we believe a reasonable alternative for separate payment of diagnostic radiopharmaceuticals that exceed the per day cost threshold is the use of their mean unit cost from claims data. This is consistent with our current practice for therapeutic radiopharmaceuticals when ASP data is not available. For diagnostic radiopharmaceuticals, we believe that ASP data is effectively not available for purposes of determining a payment amount and, therefore, payment based on MUC is a reasonable alternative.

We previously acknowledged (74 FR 35335), and continue to acknowledge, the complexities associated with reporting ASP for radiopharmaceuticals. We encourage manufacturers to submit ASP information for diagnostic radiopharmaceuticals, if possible. While CMS is proposing to use MUC to pay for separately payable diagnostic radiopharmaceuticals in CY 2025, manufacturers can begin, or continue, to report ASP data for potential future use in paying for diagnostic radiopharmaceuticals. For CY 2025, ASP reporting is voluntary for diagnostic radiopharmaceuticals paid under the OPPTS. We encourage interested parties to submit comments regarding potential issues that may arise that prevent appropriate ASP reporting for diagnostic radiopharmaceuticals. If manufacturers choose to report ASP data, the data must meet reporting requirements in order to be used for payment under the OPPTS.

Manufacturers that choose to report ASP data for their diagnostic radiopharmaceuticals would need to provide comprehensive data in order for CMS to calculate an ASP amount for a given HCPCS code. In instances where there is more than one manufacturer of a particular diagnostic radiopharmaceutical, we propose that all manufacturers would need to submit

ASP information in order for payment to be made based on ASP. This is because it would be inappropriate for Medicare payment for a HCPCS code to be based on the payment information submitted by one manufacturer, if that payment is used for a product made by different manufacturers. This is because the ASP information reported by one manufacturer might not reflect the ASP of the same product made by other manufacturers.

We note that ASP submissions for radiopharmaceutical payment under the OPPTS would need to meet all of the existing regulatory and subregulatory requirements of the ASP reporting process under sections 1847A and 1927(b)(3) of the Act.

Specifically, we reiterate our ASP reporting requirements outlined in the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60520) for products for which we are encouraging the reporting of ASP, but for which reporting is not statutorily required. The ASP data submitted would need to be provided for a patient-specific dose, or patient-ready form, of the diagnostic radiopharmaceutical in order to properly calculate the ASP amount that aligns with the dose descriptor for a given HCPCS code. When reporting an ASP for a separately payable radiopharmaceutical, we expect that the ASP data reported by a manufacturer would be representative of the item(s) sold by the manufacturer. In the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60520), we used the term "patient-ready" to ensure that ASP data submitted for OPPTS payment purposes for separately payable radiopharmaceuticals reflect the costs of all the component materials of the finished radiopharmaceutical product. We expect that the ASP data would represent the sales price of all of the component materials of the finished radiopharmaceutical product sold by the manufacturer in terms that reflect the applicable HCPCS code descriptor, such as "per study dose" or "millicurie." We defined a "patient-ready" dose for OPPTS purposes as including all component materials of the radiopharmaceutical, at a minimum, and any other processing the manufacturer requires to produce the radiopharmaceutical that it sells that are reflected in the sales price, including radiolabeling, as long as any fees paid for such processing done on behalf of the manufacturer meet the definition of "bona fide service fees" under § 414.802 (74 FR 60525).

We understand that manufacturers of separately payable radiopharmaceuticals produce

radiopharmaceuticals that require a variety of processing steps in order to prepare the product for administration to a beneficiary. To be used for separate OPPS radiopharmaceutical payment, the ASP data reported by a manufacturer must represent sales of all of the component materials associated with the radiopharmaceutical. For our full policy on which factors to incorporate into ASP pricing, please see the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521).

In order to be used for payment under the OPPS, all radiopharmaceutical ASP submissions should meet the existing regulatory and subregulatory requirements of the ASP submission process under sections 1847A and 1927(b)(3) of the Act. In particular, we believe the “bona fide service fee” test in the ASP regulations is instructive here, and we refer readers to the CY 2010 OPPS/ASC final rule with comment period for our discussion on radiopharmaceutical ASP reporting (74 FR 60521).

To summarize our CY 2010 policy for ASP reporting on radiopharmaceuticals for OPPS payment purposes (74 FR 60521), a patient-specific dose or patient-ready form in the context of OPPS ASP submission for radiopharmaceutical payment means that the ASP reflecting manufacturer sales must represent sales of all of the component materials for the radiopharmaceutical, including a minimum of a cold kit and a radioisotope, and be reported in terms that reflect the applicable HCPCS code descriptor, such as “treatment dose” or “millicurie.” The ASP would not necessarily take into account the preparation of the final form of the radiopharmaceutical for patient administration, including radiolabeling, which may be conducted by the manufacturer, freestanding radiopharmacy, hospital pharmacy, or other entity. With respect to the latter, fees paid by the manufacturer for these services would be excluded from the ASP calculation (that is, would not be considered price concessions that reduce the ASP) only if they are “bona fide service fees” as defined in the regulations governing ASP. Thus, if the manufacturer pays a “bona fide service fee” for the services of the freestanding radiopharmacy, hospital pharmacy, or other entity, and reflects that fee in its price for the radiopharmaceutical, the amount of the “bona fide service fee” would be taken into account in the reported ASP data. However, manufacturers are not required to pay for the preparation of a

radiopharmaceutical (including radiolabeling) in a freestanding radiopharmacy, hospital pharmacy, or other entity after sale of all of the component materials, and in that case, the cost of those services would not be reflected in the ASP data submitted to CMS. Manufacturers should submit ASP data for a separately payable radiopharmaceutical that incorporates prices for sales of all of the component materials by the manufacturer. We seek comment on these ASP reporting requirements outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60521) and previous CMS guidance on the guidelines for the Submission of OPPS ASP Data for Nonpass-Through Separately Payable Therapeutic Radiopharmaceuticals and Radiopharmaceuticals with Pass-Through Status.⁷ We continue to believe that these ASP reporting practices should be applicable to radiopharmaceuticals, including both therapeutic and diagnostic radiopharmaceuticals, but seek comment from interested parties in this space to ensure that these reporting guidelines are clear and reflective of clinical practice today.

We still see the potential value in the use of ASP data for payment purposes for diagnostic radiopharmaceuticals when reported correctly and by all manufacturers who manufacture a product that is described by a given HCPCS code. We believe that the use of ASP information for OPPS payment could provide an opportunity to improve payment accuracy for separately payable diagnostic radiopharmaceuticals by applying an established methodology that has already been successfully implemented under the OPPS for other separately payable drugs and biologicals, as well as therapeutic radiopharmaceuticals. Because the per day cost calculations determine whether a diagnostic radiopharmaceutical qualifies for separate payment, using the most accurate pricing information is paramount. The use of ASP information could provide an opportunity to further improve the accuracy of the per day cost calculations and the separate payment amounts for diagnostic radiopharmaceuticals. As previously mentioned, we do not believe that the limited amount of ASP information submitted currently is adequate for the purpose of determining separate payment for those few products that

⁷ https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/opps_asp_radiopharm_guidance10302009.pdf.

currently do report ASP, which is why we are proposing to pay diagnostic radiopharmaceuticals with per day costs above the proposed \$630 threshold at each diagnostic radiopharmaceutical's mean unit cost. However, we are still interested in the potential to use ASP for the purpose of determining a diagnostic radiopharmaceutical's per day cost and payment amount in the future. Therefore, we want to engage with interested parties to learn about the unique aspects and challenges that may be associated with reporting ASP for diagnostic radiopharmaceuticals, and radiopharmaceuticals in general. We specifically seek comment as to whether interested parties believe CMS should require payment for diagnostic radiopharmaceuticals on ASP in the future, such as in CY 2026 rulemaking, if interested parties are confident in their reporting ability.

We do believe that there could be situations in which it is appropriate to use ASP currently. For example, in section V.A.4. of this proposed rule, we propose to utilize ASP in payment for diagnostic radiopharmaceuticals on OPPS transitional pass-through status. In this situation, we believe the use of ASP is appropriate as the manufacturer of that diagnostic radiopharmaceutical is actively involved in the radiopharmaceutical's pass-through application, and CMS can ensure that pricing is reported appropriately for purposes of the drug pass-through cost significance tests and for purposes of payment if the pass-through status is approved. Typically, there is only one manufacturer for a diagnostic radiopharmaceutical applying for pass-through status, so CMS does not have to ensure all manufacturers are reporting ASP for that particular HCPCS code prior to establishing a separate payment amount based on ASP. Additionally, as discussed in section V.B.5. (Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes but Without OPPS Hospital Claims Data) of this rule, we propose to base the initial payment for new diagnostic radiopharmaceuticals with HCPCS codes, but which do not have pass-through status and are without claims data, on ASP, and on the WAC for these products if ASP data for these diagnostic radiopharmaceuticals are not available. If the WAC also is unavailable, we propose to make payment for new diagnostic radiopharmaceuticals at 95 percent of the products' most recent AWP. We believe the volume of products in this category will typically be very low; however, in these rare situations, we

believe it would be appropriate to use ASP until a MUC is available. Similar to drugs applying for pass-through status, there is typically only one manufacturer for a diagnostic radiopharmaceutical that is new and described by a HCPCS code, but without claims data, so CMS does not have to ensure all manufacturers are reporting ASP for that particular HCPCS code prior to establishing a separate payment amount based on ASP. Additionally, although reporting of ASP is not a condition of CMS approving a HCPCS application, CMS has the opportunity to actively engage with the manufacturer, or sponsor of a HCPCS application, during the HCPCS application process. This allows for ongoing dialogue and education regarding the unique ASP reporting requirements that may be associated with a particular product, including how to ensure the reported ASP aligns with the dose descriptor for the newly assigned HCPCS code.

We seek comments on additional unique situations in which it still may be appropriate for CMS to use ASP information to assess per day costs and payment amounts for diagnostic radiopharmaceuticals for CY 2025. For example, one such unique situation could be continuing the use of ASP for a particular HCPCS code once its pass-through status has ended, if the HCPCS code was actively being paid based on ASP while on pass-through status. Under our current proposal, payment for a diagnostic radiopharmaceutical would be based on MUC once its pass-through status ends. We seek comment on this potential unique situation, as well as others of which readers may be aware, and we may finalize utilizing ASP in additional situations that commenters bring to our attention in the final rule as policies for CY 2025 depending on comments received.

As discussed, we propose to base the payment rate for diagnostic radiopharmaceuticals on mean unit cost data derived from hospital claims. We are not proposing to use ASP data for determining payment rates of non-passthrough diagnostic radiopharmaceuticals with claims data but are seeking comment on its use for determining the per day cost and setting the payment rate for diagnostic radiopharmaceuticals in the future. Additionally, we are not proposing to use WAC or AWP as a basis for payment for diagnostic radiopharmaceuticals. Similar to our reasoning for payment of therapeutic radiopharmaceuticals in the CY 2012 OPPTS/ASC final rule with comment period (77 FR 68390), we believe that paying for diagnostic radiopharmaceuticals using mean unit

cost would appropriately pay for the average price of nonpass-through separately payable diagnostic radiopharmaceuticals for the applicable year. We believe MUC is an appropriate proxy for the average price for a diagnostic radiopharmaceutical for a given year, as it is calculated based on the average costs for a particular year and is directly reflective of the actual cost data that hospitals submit to CMS.

As we stated in the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60523), we believe that WAC or AWP is not an appropriate proxy to provide OPPTS payment for average therapeutic radiopharmaceutical acquisition cost and associated handling costs when manufacturers are not required to submit ASP data because payment based on WAC or AWP for separately payable drugs and biologicals is usually temporary for a calendar quarter until a manufacturer is able to submit the required ASP data in accordance with the quarterly ASP submission timeframes for reporting under section 1847A of the Act. However, WAC and AWP reported to compendia may not be reflective of a patient ready dose. We are additionally concerned about the use of WAC and AWP since ASP reporting for OPPTS payment of separately payable diagnostic radiopharmaceuticals would not be required for CY 2025. The absence of appropriate ASP reporting could result in payment for a separately payable diagnostic radiopharmaceutical based on WAC or AWP indefinitely, a result which we believe would be inappropriate, as these pricing metrics do not capture all of the pricing discounts that may be reflected in the ASP.

Given all of the concerns we currently have with other pricing methodologies for diagnostic radiopharmaceuticals, we propose to rely on CY 2023 mean unit cost data derived from hospital claims data for payment rates for diagnostic radiopharmaceuticals for CY 2025.

Our proposed payment methodology for diagnostic radiopharmaceuticals that have costs above a \$630 threshold would be similar, but not the same as the methodology adopted for therapeutic radiopharmaceuticals as described in the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60518). Although therapeutic radiopharmaceuticals are generally targeted at treating a certain disease or condition, and diagnostic radiopharmaceuticals are generally targeted at diagnosing a certain disease or condition, we believe they are clinically very similar products, manufactured in a similar manner, and

should generally be paid using a similar payment methodology when paid separately. As such, we believe the same payment method as is used for therapeutic radiopharmaceuticals should apply to diagnostic radiopharmaceuticals above the cost threshold. However, as previously discussed, given our concerns with current ASP reporting patterns, we are proposing to use MUC as the basis of payment for non-passthrough diagnostic radiopharmaceuticals for CY 2025. Therefore, we believe it is appropriate for the methodology to determine the proposed payment amounts to differ between diagnostic and therapeutic radiopharmaceuticals, at least for CY 2025. We will consider aligning the payment methodologies between therapeutic and diagnostic radiopharmaceuticals, either based on ASP or MUC, in future rulemaking.

We believe mean unit cost data is an appropriate and adequate proxy for the average price for diagnostic radiopharmaceuticals and associated handling costs for these products. Mean unit cost data is reflective of the actual cost data that hospitals submit to CMS. The MUC payment methodology is consistent with our payment policy for therapeutic radiopharmaceuticals as stated in the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60523) and is the basis for payment of many therapeutic radiopharmaceuticals when ASP is unavailable currently.

As previously discussed, we find that the ASP data we have is not usable for the purpose of paying for diagnostic radiopharmaceuticals and, therefore, we are proposing to pay for qualifying non-passthrough diagnostic radiopharmaceuticals with claims data based on MUC. However, we are also seeking comment on how we could potentially use our equitable adjustment authority at section 1833(t)(2)(E) of the Act to make an adjustment to the ASP data that has been reported in order to make it usable for the purpose of paying equitably for these products. For example, we seek comment as to whether CMS could use its equitable adjustment authority to adjust payment for diagnostic radiopharmaceuticals based on an adjusted ASP value when the ASP amounts reported to CMS deviate by a given threshold, such as two times the MUC calculated for the diagnostic radiopharmaceutical using claims data. Alternatively, the adjusted payment rate could be an average of the reported ASP and MUC, or other methodologies suggested by commenters. We broadly seek comment on this potential use of equitable adjustment authority to make the

limited ASP data reported for diagnostic radiopharmaceuticals usable for purposes of setting payment rates for qualifying products.

We note, if readers do not believe it is appropriate for CMS to base the payment amount for diagnostic radiopharmaceuticals on MUC for CY 2025, we would propose in the alternative to maintain our current policy of unconditionally policy packaging all diagnostic radiopharmaceuticals regardless of their cost until an appropriate payment

methodology can be established to determine a separate payment amount for diagnostic radiopharmaceuticals.

HCPCS codes that describe diagnostic radiopharmaceuticals with per day costs that meet or exceed the proposed diagnostic radiopharmaceutical packaging threshold would be assigned to a status indicator of “K”, indicating separate payment. An APC and a payment rate would be assigned as shown in Addendum B to this proposed rule. HCPCS codes that describe diagnostic radiopharmaceuticals with

per day costs that are at or below the proposed diagnostic radiopharmaceutical packaging threshold would continue to be assigned to a status indicator of “N”, indicating packaged payment. We welcome comment on these determinations. The proposed list of diagnostic radiopharmaceuticals that have calculated per day costs that exceed \$630 and their proposed status indicators can be found in table 5.

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TABLE 5: Proposed Qualifying Diagnostic Radiopharmaceuticals with Per Day Costs Exceeding \$630

HCPCS Code	Short Descriptor	Proposed CY 2025 Status Indicator Assignment
A9515	Choline c-11	K
A9521	Tc99m exametazime	K
A9542	In111 ibritumomab, dx	K
A9547	In111 oxyquinoline	K
A9548	In111 pentetate	K
A9557	Tc99m biccisate	K
A9568	Technetium tc99m arcitumomab	K
A9569	Technetium tc-99m auto wbc	K
A9570	Indium in-111 auto wbc	K
A9572	Indium in-111 pentetreotide	K
A9582	Iodine i-123 iobenguane	K
A9584	Iodine i-123 ioflupane	K
A9586	Florbetapir f18	K
A9587	Gallium ga-68	K
A9588	Fluciclovine f-18	K
A9591	Fluoroestradiol f 18	K
A9592	Copper cu 64 dotatate diag	K
A9593	Gallium ga-68 psma-11 ucsf	K
A9594	Gallium ga-68 psma-11, ucla	K
A9595	Piflu f-18, dia 1 millicurie	K
A9596	Gallium illuccix 1 millicure	K*
A9602	Fluorodopa f-18 diag per mci	K**
A9800	Gallium locametz 1 millicuri	K***
C9067	Gallium ga-68 dotatoc	K
Q9982	Flutemetamol f18 diagnostic	K
Q9983	Florbetaben f18 diagnostic	K

*HCPCS code A9596 will be assigned to status indicator “G” until its pass through expiration on 06/30/2025. For the remainder of CY 2025, we would propose to assign it to status indicator “K.”

**HCPCS code A9602 will be assigned to status indicator “G” until its pass through expiration on 09/30/2025. For the remainder of CY 2025, we would propose to assign it to status indicator “K.”

***HCPCS code A9800 will be assigned to status indicator “G” until its pass through expiration on 09/30/2025. For the remainder of CY 2025, we would propose to assign it to status indicator “K.”

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Definitions of status indicators can be found in Addendum D1 to this proposed rule. Addenda to this proposed rule can be found on the CMS OPPS web page.

We propose corresponding regulation text edits at § 419.2(b)(15) to only package diagnostic radiopharmaceuticals when their per day cost is at or below the per day diagnostic radiopharmaceutical packaging threshold for the applicable year. This is achieved by adding the text “at or below the per-day diagnostic radiopharmaceutical packaging threshold for the applicable year” to qualify the packaging of diagnostic radiopharmaceuticals. We also propose corresponding regulation text edits at § 419.41 (Calculation of national beneficiary copayment amounts and national Medicare program payment amounts) to codify our proposed payment policy for diagnostic radiopharmaceuticals and our existing policy for therapeutic radiopharmaceuticals.

4. Proposed Implementation of Section 4135 of the Consolidated Appropriations Act (CAA)

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA, 2023, titled Access to Non-Opioid Treatments for Pain Relief, amended sections 1833(t)(16) and 1833(i) of the Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief (as that term is defined in section 1833(t)(16)(G)(i) of the Act). In particular, section 1833(t)(16)(G) of the Act provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount, respectively.

As the additional payments are required to begin on January 1, 2025, we propose to implement the CAA, 2023 section 4135 amendments in this proposed rule. Our proposal to implement section 4135 of CAA, 2023 can be found in section XIII.E of this proposed rule.

5. Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81577 through 81578), we applied this policy and calculated the relative payment weights for each APC for CY 2024 that were shown in Addenda A and B of the CY 2024 OPPS/ASC final rule with comment period (which were made available via the internet on the CMS website) using the APC costs discussed in sections II.A.1 and II.A.2 of the CY 2024 OPPS/ASC final rule with comment period (88 FR 81549 through 81572). For CY 2025, as we did for CY 2024, we proposed to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2025 using geometric mean-based APC costs.

For CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), representing all clinic visits under the OPPS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT Evaluation or Assessment and Management (E/M) codes for clinic visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For CY 2016, we deleted APC 0634 and reassigned the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70372). For CY 2025, as we did for CY 2024, we propose to continue to standardize all of the relative payment weights to APC 5012. We believe that standardizing relative payment weights to the geometric mean of the APC to which HCPCS code G0463 is assigned maintains consistency in calculating unscaled weights that represent the cost of some of the most frequently provided OPPS services. For

CY 2025, as we did for CY 2024, we propose to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2025 is neither greater than nor less than the estimated aggregate weight that would have been calculated without the changes. To comply with this requirement concerning the APC changes, we proposed to compare the estimated aggregate weight using the CY 2024 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2025 unscaled relative payment weights.

For CY 2024, we multiplied the CY 2024 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2023 claims to calculate the total relative payment weight for each service. We then added together the total relative payment weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2025, we propose to apply the same process using the estimated CY 2025 unscaled relative payment weights rather than scaled relative payment weights. We propose to calculate the weight scalar by dividing the CY 2024 estimated aggregate weight by the unscaled CY 2025 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>. Click on the link labeled “Hospital Outpatient Prospective Payment—Notice of Proposed Rulemaking with Comment Period (NPRM)” for 2025, which can be found under the heading “Hospital Outpatient Regulations and Notices” and open the claims accounting document link, which is labeled “2025 NPRM OPPS Claims Accounting (PDF).”

We propose to compare the estimated unscaled relative payment weights in CY 2025 to the estimated total relative

payment weights in CY 2024 using CY 2023 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we propose to adjust the calculated CY 2025 unscaled relative payment weights for purposes of budget neutrality. We propose to adjust the estimated CY 2025 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4405 to ensure that the proposed CY 2025 relative payment weights are scaled to be budget neutral. The proposed CY 2025 relative payment weights listed in Addenda A and B to this proposed rule (which are available via the internet on the CMS website) are scaled and incorporate the recalibration adjustments discussed in sections II.A.1 and II.A.2 of this proposed rule.

Section 1833(t)(14) of the Act provides the payment rates for certain specified covered outpatient drugs (SCODs). Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9) but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.2 of this proposed rule) is included in the budget neutrality calculations for the CY 2025 OPPS.

B. Proposed Conversion Factor Update

1. OPD Fee Schedule Increase Factor

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2025 IPPS/Long Term Care Hospital (LTCH) PPS proposed rule (89 FR 36204), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2023 forecast, the proposed FY 2025 IPPS market basket percentage increase was 3.0 percent. We note that under our regular process for the CY 2025 OPPS/ASC final rule with comment period, we would use the market basket update for the FY 2025 IPPS/LTCH PPS final rule. If that forecast is different than the IPPS market basket percentage increase used

for this proposed rule, the CY 2025 OPPS/ASC final rule with comment period OPD fee schedule increase factor would reflect that updated forecast of the market basket percentage increase.

For CY 2025, we propose to use the estimate of the hospital inpatient market basket percentage increase of 3.0 percent as one component to calculate the OPD fee schedule increase factor.

2. Productivity Adjustment

Section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the "productivity adjustment"). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the productivity adjustment. The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of private nonfarm business productivity for the U.S. economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term multifactor productivity (MFP) with total factor productivity (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business total factor productivity. However, as mentioned, the data and methods are unchanged. Please see www.bls.gov for the BLS historical published TFP data. A complete description of IHS Global, Inc.'s (IGI) TFP projection methodology is available on the CMS website at <https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information>. In addition, we note that beginning with the FY 2022 IPPS/LTCH PPS final rule, we refer to this adjustment as the productivity

adjustment rather than the MFP adjustment to more closely track the statutory language in section 1886(b)(3)(B)(xi)(II) of the Act. We note that the adjustment continues to rely on the same underlying data and methodology. In the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36204), the proposed productivity adjustment for FY 2025 was 0.4 percentage point.

Therefore, we propose that the productivity adjustment for the CY 2025 OPPS/ASC would be 0.4 percentage point. We also propose that if more recent data subsequently became available after the publication of the CY 2025 OPPS/ASC proposed rule (for example, a more recent estimate of the market basket percentage increase and/or the productivity adjustment), we would use such updated data, if appropriate, to determine the CY 2025 hospital inpatient market basket update and the productivity adjustment, which are components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we propose for CY 2025 an OPD fee schedule increase factor of 2.6 percent for the CY 2025 OPPS/ASC (which is the proposed estimate of the hospital inpatient market basket percentage increase of 3.0 percent, less the proposed 0.4 percentage point productivity adjustment).

3. Other Conversion Factor Adjustments

To set the OPPS conversion factor for 2025, we propose to increase the CY 2024 conversion factor of \$87.382 by 2.6 percent. In accordance with section 1833(t)(9)(B) of the Act, we propose further to adjust the conversion factor for CY 2025 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We propose to calculate an overall budget neutrality factor of 1.0026 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2025 IPPS wage indexes to those payments using the FY 2024 IPPS wage indexes, as adopted on a calendar year basis for the OPPS. We further propose to calculate an additional budget neutrality factor of 0.9982 to account for our proposed policy to cap wage index reductions for

hospitals at 5 percent on an annual basis.

For CY 2025, we propose to maintain the current rural adjustment policy, as discussed in section II.E of this proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment is 1.0000.

We propose to calculate a CY 2025 budget neutrality adjustment factor for the cancer hospital payment adjustment by transitioning from the target PCR of 0.89 we finalized for CYs 2020 through 2023 (which included the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act) and incrementally reducing the target PCR by an additional 1.0 percentage point for each calendar year, beginning with CY 2024, until the target PCR equals the PCR of non-cancer hospitals calculated using the most recent data minus 1.0 percentage point as required by section 16002(b) of the 21st Century Cures Act. Therefore, we propose to apply a budget neutrality adjustment factor of 1.0006 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 1833(t)(18)(C) of the Act, as added by section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255), we reduce the target PCR by 0.01, which brings the proposed target PCR to 0.87. This is 0.02 less than the target PCR of 0.89 from CY 2021 through CY 2023, which was held at the pre-PHE target.

For this proposed rule, we estimated that proposed pass-through spending for drugs, biologicals, and devices for CY 2025 would equal approximately \$625

million, which represents 0.71 percent of total projected CY 2025 OPPS spending. Therefore, we stated that the proposed conversion factor would be adjusted by the difference between the 0.27 percent estimate of pass-through spending for CY 2024 and the 0.71 percent estimate of proposed pass-through spending for CY 2025, resulting in a proposed decrease to the conversion factor for CY 2025 of 0.44 percent.

We propose that estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2025. We estimated for this proposed rule that outlier payments would be approximately 0.85 percent of total OPPS payments in CY 2024; the 1.00 percent for proposed outlier payments in CY 2025 would constitute a 0.15 percent increase in payment in CY 2025 relative to CY 2024.

For 2025, we propose to use a conversion factor of \$87.382 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the proposed OPD fee schedule increase factor of 2.6 percent for CY 2025, the required proposed wage index budget neutrality adjustment of approximately 1.0026, the proposed 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9982, the proposed cancer hospital payment adjustment of 1.0006, and the proposed adjustment of a decrease of 0.44 percentage point of projected OPPS

spending for the difference in pass-through spending, which resulted in a proposed conversion factor for CY 2025 of \$89.379.

For CY 2025, we also propose that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we propose to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of 0.6 percent (that is, the proposed OPD fee schedule increase factor of 2.6 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2025 of \$87.636 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of – 1.743 in the conversion factor relative to hospitals that met the requirements). For further discussion of the Hospital OQR Program, we refer readers to section XV of this proposed rule. For 2025, we propose to use a reduced conversion factor of \$87.636 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of – 1.743 in the conversion factor relative to hospitals that met the requirements).

The calculations we performed to determine the CY 2025 proposed conversion factor are shown in Table 6.

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TABLE 6: CALCULATION OF CY 2025 PROPOSED OPPTS CONVERSION FACTOR

<u>Start:</u> CY 2024 Final OPPTS Conversion Factor = \$87.382
<u>Step 1a:</u> Adjust the conversion factor to temporarily account for additional drug and device pass-through spending and outlier spending in CY 2024. This action causes an increase in the conversion factor. So, the amount of both drug and device pass-through spending (0.0027) and the percentage of outlier spending (0.01), as a share of total OPPTS outpatient hospital spending is subtracted from 1.0000, which represents total OPPTS outpatient hospital spending for CY 2024. ➤ $1.0000 - (0.0027 + 0.01) = 0.9873$
<u>Step 1b:</u> Divide \$87.382 by 0.9873 ➤ $\\$87.382 / 0.9873 = \mathbf{\\$88.506}$
<u>Step 2:</u> Adjust the conversion factor by the required wage index budget neutrality adjustment of approximately 1.0026. This adjustment increases the amount of OPPTS outpatient hospital spending and is multiplied with \$88.506. ➤ $\\$88.506 * 1.0026 = \mathbf{\\$88.736}$
<u>Step 3:</u> Adjust the conversion factor by the 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9982. This adjustment reduces the amount of OPPTS outpatient hospital spending and is multiplied with \$88.736. ➤ $\\$88.736 * 0.9982 = \mathbf{\\$88.576}$
<u>Step 4:</u> Adjust the conversion factor by the cancer hospital payment adjustment of 1.0006. Because the PCR for cancer hospitals is declining between CY 2024 and CY 2025, it increases the amount of OPPTS outpatient hospital spending for providers that are not cancer hospitals and is multiplied with \$88.576. ➤ $\\$88.576 * 1.0006 = \mathbf{\\$88.630}$
<u>Step 5:</u> Adjust the conversion factor by rural SCH adjustment policy of 1.0000. Since we are maintaining our current policy, there is no impact on the conversion by this policy. ➤ $\\$88.630 * 1.0000 = \mathbf{\\$88.630}$
<u>Step 6a:</u> Adjust the conversion factor by the OPD fee schedule increase factor of 0.026 for CY 2025. The OPD fee schedule increase factor increases outpatient hospital spending in CY 2025 over CY 2024 and is added to 1.0000 which represents total outpatient hospital OPPTS spending in CY 2024. ➤ $1.0000 + 0.026 = 1.0260$

Step 6b: Multiply \$88.630 by 1.0260.

➤ $\$88.630 \times 1.0260 = \$90.934$

Step 7a: Adjust the conversion factor to remove additional drug and device pass-through spending and outlier spending for CY 2025. This action causes a decrease in the conversion factor. So, the amount of both drug and device pass-through spending (0.0071) and the percentage of outlier spending (0.01) as a share of total OPPS outpatient hospital spending is subtracted from 1.0000, which represents total OPPS outpatient hospital spending for CY 2025.

➤ $1.0000 - (0.0071 + 0.01) = 0.9829$

Step 7b: Multiply \$90.934 by 0.9829 to get the CY 2025 final OPPS conversion factor.

$\$90.934 \times 0.9829 = \$89.379$

Finish: **CY 2025 OPPS Conversion Factor = \$89.379**

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C. Proposed Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner (codified at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.A.5 of this proposed rule.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). We propose to continue this policy for the CY 2025 OPPS/ASC. We refer readers to section II.C of this proposed rule for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

As discussed in the claims accounting narrative included with the supporting documentation for this proposed rule

(which is available via the internet on the CMS website (<https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>)), for estimating APC costs, we would standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2025 pre-reclassified wage index that we use under the IPPS to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000, final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998, OPPS/ASC proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage

index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (3) of our regulations. For CY 2025 we propose to implement this provision in the same manner as we have since CY 2011. Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, the rural floor, and rural floor budget neutrality) is less than 1.00. Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We refer readers to the FY 2011 through FY 2024 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of “frontier States” as provided for in section 1886(d)(3)(E)(iii)(II) of the Act: for FY 2011, 75 FR 50160 through 50161; for FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 and 53370; for FY 2014, 78 FR 50590 and

50591; for FY 2015, 79 FR 49971; for FY 2016, 80 FR 49498; for FY 2017, 81 FR 56922; for FY 2018, 82 FR 38142; for FY 2019, 83 FR 41380; for FY 2020, 84 FR 42312; for FY 2021, 85 FR 58765; for FY 2022, 86 FR 45178; FY 2023, 87 FR 49006; and for FY 2024, 88 FR 58977.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2025 IPPS wage indexes continue to reflect a number of adjustments implemented in past years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, the imputed floor wage index adjustment in all-urban states, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), and the permanent 5-percent cap on any decrease to a hospital's wage index from its wage index in a prior FY. Beginning with FY 2024, we include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and to exclude "dual reclass" hospitals (hospitals with simultaneous § 412.103 and Medicare Geographic Classification Review Board (MGCRB) reclassifications) implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act (88 FR 58971 through 58973). We also propose to continue the low wage index hospital policy, under which we increase the wage index for hospitals with a wage index value below the 25th percentile wage index value for a fiscal year by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals. We refer readers to the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36181 through 36186) for a detailed discussion of all proposed changes to the FY 2025 IPPS wage indexes.

We note that in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021), we finalized a permanent approach to smooth year-to-year decreases in hospitals' wage indexes. Specifically, for FY 2023 and subsequent years, we apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, a hospital's wage index for FY 2025 would not be less than 95 percent of its final wage index for FY 2024. Except for newly opened hospitals, we apply the cap for a fiscal year using the final wage index applicable to the hospital on the last day of the prior fiscal year. A newly opened

hospital would be paid the wage index for the area in which it is geographically located for its first full or partial fiscal year (subject to any reclassification), and it would not receive a cap for that first year, because it would not have been assigned a wage index in the prior year (in accordance with 42 CFR 419.41(c)(1) and 419.43(c), as noted previously).

We delineate hospital labor market areas based on Core-Based Statistical Areas (CBSAs) established by the Office of Management and Budget (OMB). As discussed in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36139 through 36174), OMB issued revisions to the current labor market area delineations on July 21, 2023, that included a number of significant changes such as new CBSAs, urban counties that become rural, rural counties that become urban, and existing CBSAs that are split apart (OMB Bulletin 23–01). This bulletin can be found at: <https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf>. The proposed changes to the IPPS wage index based on the newest CBSA delineations are available in the FY 2025 IPPS/LTCH PPS proposed rule. We propose that corresponding changes would be adopted in the OPPIs, which uses the IPPS wage index, based on the new OMB delineations in this CY 2025 OPPIs/ASC proposed rule, consistent with any proposals in the FY 2025 IPPS/LTCH PPS proposed rule. We believe that using the revised delineations based on OMB Bulletin No. 23–01 will increase the integrity of the OPPIs wage index system by creating a more accurate representation of current geographic variations in wage levels. We refer readers to proposed changes based on the new OMB delineations in the FY 2025 IPPS/LTCH proposed rule at 89 FR 36139 through 36174, which includes a discussion of the effects of implementation of the proposal to adopt the revised OMB labor market area delineations on reclassified hospitals.

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38130) discussed the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the IPPS and OPPIs wage indexes. However, the SSA county codes are no longer being maintained and updated, although the FIPS codes

continue to be maintained by the U.S. Census Bureau. The Census Bureau's most current statistical area information is derived from ongoing census data from 2020. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: <https://www.census.gov/geo/reference/county-changes.html> (which, as of May 6, 2019, migrated to: <https://www.census.gov/programs-surveys/geography.html>). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), for purposes of cross walking counties to CBSAs for the IPPS wage index, we finalized our proposal to discontinue the use of the SSA county codes and begin using only the FIPS county codes. Similarly, for the purposes of cross walking counties to CBSAs for the OPPIs wage index, in the CY 2018 OPPIs/ASC final rule with comment period (82 FR 59260), we finalized our proposal to discontinue the use of SSA county codes and begin using only the FIPS county codes. For CY 2025, under the OPPIs, we are continuing to use only the FIPS county codes for purposes of cross walking counties to CBSAs.

We propose to use the FY 2025 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPIs to determine the wage adjustments for both the OPPIs payment rate and the copayment rate for CY 2025. We note that the proposed FY 2025 IPPS wage indexes reflect several proposed changes as a result of the revised OMB delineations, including proposed policies to accommodate changes in rural or urban status for existing counties, as well as addition or removal of certain individual CBSAs compared to the previous delineations. Therefore, any policies and adjustments that are finalized for the FY 2025 IPPS post-reclassified wage index would be reflected in the final CY 2025 OPPIs wage index beginning on January 1, 2025, if appropriate. We refer readers to the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36181 through 36186) and the proposed FY 2025 hospital wage index files posted on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2025-ips-proposed-rule-home-page>. Regarding budget neutrality for the CY 2025 OPPIs wage index, we refer readers to section II.C of this proposed rule. We continue to believe that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPPIs is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital was paid under the IPPS, based on its geographic location and any applicable wage index policies and adjustments. We propose to continue this policy for CY 2025. We refer readers to the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36181 through 36186) for a detailed discussion of the proposed changes to the FY 2025 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)) (Pub. L. 108–173). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage index adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that would apply if the hospital were paid under the IPPS. For CY 2025, we propose to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the outmigration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA) (88 FR 49585 and 49586). Furthermore, we propose that the wage index that would apply for CY 2025 to non-IPPS hospitals paid under the OPPS would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index to address wage index disparities. In addition, we propose that the wage index that would apply to non-IPPS hospitals paid under the OPPS would include the 5-percent cap on wage index decreases.

For CMHCs, for CY 2025, we propose to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. Furthermore, we propose that the wage index that would apply to a CMHC for CY 2025 would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index to address wage index disparities. In addition, the wage index that would apply to CMHCs would include the 5-percent cap on wage index decreases.

Also, we propose that the wage index that would apply to CMHCs would not include the outmigration adjustment because that adjustment only applies to hospitals.

Table 4A associated with the FY 2025 IPPS/LTCH PPS proposed rule (available via the internet on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2025-ipp-pps-proposed-rule-home-page>) identifies counties that would be eligible for the out-migration adjustment. Table 2 associated with the FY 2025 IPPS/LTCH PPS proposed rule (available for download via the website noted previously) identifies IPPS hospitals that would receive the out-migration adjustment for FY 2025. We are including the outmigration adjustment information from Table 2 associated with the FY 2025 IPPS/LTCH PPS proposed rule as Addendum L to this proposed rule, with the addition of non-IPPS hospitals that would receive the section 505 outmigration adjustment under this proposed rule Addendum L is available via the internet on the CMS website. We refer readers to the CMS website for the OPPS at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>. At this link, readers will find a link to the proposed FY 2025 IPPS wage index tables and Addendum L.

D. Proposed Statewide Average Default Cost-to-Charge Ratios (CCRs)

In addition to using CCRs to estimate costs from charges on claims for ratesetting, we use overall hospital-specific CCRs calculated from the hospital's most recent cost report (OMB control number: 0938–0050 for Form CMS–2552–10) to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. For certain hospitals, under the regulations at 42 CFR 419.43(d)(5)(iii), we use the statewide average default CCRs to determine the payments mentioned earlier if it is not possible to determine an accurate CCR for a hospital in certain circumstances. This includes hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. We also use the statewide average default CCRs to determine payments for hospitals whose CCR falls outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate

status (Medicare Claims Processing Manual (Pub. L. 100–04), Chapter 4, Section 10.11).

We discussed our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009. For details on our process for calculating the statewide average CCRs, we refer readers to the Claims Accounting Narrative for this CY 2025 OPPS/ASC proposed rule, which is posted on our website. We propose to calculate the default ratios for CY 2025 using the most recent cost report data.

We no longer publish a table in the **Federal Register** containing the statewide average CCRs in the annual OPPS proposed rule and final rule with comment period. These CCRs with the upper limit will be available for download with each OPPS CY proposed rule and final rule on the CMS website. We refer readers to our website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>; click on the link on the left of the page titled “Annual Policy Files” and then select the relevant year to download the statewide CCRs and upper limit in the downloads section of the web page.

E. Proposed Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) Under Section 1833(t)(13)(B) of the Act for CY 2025

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural sole community hospitals (SCHs) of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1833(t)(13) of the Act provides the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS,

we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPSS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPSS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised our regulations at § 419.43(g) to clarify that essential access community hospitals (EACHs) are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPSS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2024.

For CY 2025, we propose to continue the current policy of a 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPSS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, applied in a budget neutral manner.

F. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2025

1. Background

Since the inception of the OPSS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the

OPSS for covered outpatient department services. These cancer hospitals are exempted from payment under the IPSS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), the Congress added section 1833(t)(7), “Transitional Adjustment to Limit Decline in Payment,” to the Act, which requires the Secretary to determine OPSS payments to cancer and children’s hospitals based on their pre-BBA payment amount (these hospitals are often referred to under this policy as “held harmless” and their payments are often referred to as “hold harmless” payments).

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient department services under the OPSS and a “pre-BBA amount.” That is, cancer hospitals are permanently held harmless to their “pre-BBA amount,” and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPSS than the payment amount they would have received before implementation of the OPSS, as set forth in section 1833(t)(7)(F) of the Act. The “pre-BBA amount” is the product of the hospital’s reasonable costs for covered outpatient department services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The “pre-BBA amount” and the determination of the base PCR are defined at § 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10 (OMB NO: 0938–0050), respectively), as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act (Pub. L. 111–148) amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPSS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs

incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals’ costs are higher than those of other hospitals, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPSS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPSS/ASC final rule with comment period (76 FR 74200 and 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs, as discussed in the CY 2012 OPSS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital’s final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the “target PCR”) for other hospitals paid under the OPSS. The target PCR is set in advance of the calendar year and is calculated using the most recently submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. Table 7 displays the target PCR for purposes of the cancer hospital adjustment for CY 2012 through CY 2024.

TABLE 7: CANCER HOSPITAL ADJUSTMENT TARGET PAYMENT-TO-COST RATIOS (PCRS), CY 2012 THROUGH CY 2024

Calendar Year	Target PCR
2012	0.91
2013	0.91
2014	0.90
2015	0.90
2016	0.92
2017	0.91
2018	0.88
2019	0.88
2020	0.89
2021	0.89
2022	0.89
2023	0.89
2024	0.88

2. Proposed Policy for CY 2025

Section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255) amended section 1833(t)(18) of the Act by adding subparagraph (C), which requires that in applying § 419.43(i) (that is, the payment adjustment for certain cancer hospitals) for services furnished on or after January 1, 2018, the target PCR adjustment be reduced by 1.0 percentage point less than what would otherwise apply. Section 16002(b) also provides that, in addition to the percentage reduction, the Secretary may consider making an additional percentage point reduction to the target PCR that takes into account payment rates for applicable items and services described under section 1833(t)(21)(C) of the Act for hospitals that are not cancer hospitals described under section 1886(d)(1)(B)(v) of the Act. Further, in making any budget neutrality adjustment under section 1833(t) of the Act, the Secretary shall not take into account the reduced expenditures that result from application of section 1833(t)(18)(C) of the Act.

We propose to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's proposed PCR is equal to the weighted average PCR (or "target PCR") for the other OPPS hospitals, generally using the most recent submitted or settled cost report data that are available, reduced by 1.0 percentage point, to comply with section 16002(b) of the 21st Century Cures Act, and adjusted by the proposed post-Public Health Emergency (PHE) transition as described later in this

section. We are not proposing an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2025.

To calculate the proposed CY 2025 target PCR, we would use the same extract of cost report data from HCRIS used to estimate costs for the CY 2025 OPPS which, in most cases, would be the most recently available hospital cost reports. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled.

We then limited the dataset to the hospitals with CY 2023 claims data that we used to model the impact of the proposed CY 2025 APC relative payment weights (3,448 hospitals) because it is appropriate to use the same set of hospitals that are being used to calibrate the modeled CY 2025 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2019 to 2023; however, the cost reporting periods were predominantly from fiscal years ending in 2022 and 2023. We then removed the cost report data of the 49 hospitals located in Puerto Rico from our dataset because we did not believe their cost structure reflected the costs of most hospitals paid under the OPPS, and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 16 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments,

missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,421 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 87 percent of reasonable cost (weighted average PCR of 0.87). Therefore, after applying the 1.0 percentage point reduction, as required by section 16002(b) of the 21st Century Cures Act, using our standard process the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a target PCR equal to 0.86 for each cancer hospital.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81586 through 81589), we explained that we believe we should begin to take into consideration the PCR of non-cancer hospitals based on the most recently available data for calculating the target PCR. We noted that we do not know if the changes in the data that have yielded lower PCRs for non-cancer hospitals are likely to continue in future years or if, when data from after the PHE is available, we will see the target PCR increase toward its historical norm. Therefore, in the CY 2024 OPPS/ASC final rule with comment period, we finalized our proposal to transition from the target PCR of 0.89 we finalized for

CYs 2020 through 2024 (which included the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act) and incrementally reduce the target PCR by an additional 1.0 percentage point for each calendar year, beginning with CY 2024, until the target PCR equals the PCR of non-cancer hospitals calculated using the most recent data minus 1.0 percentage point as required by section 16002(b) of the 21st Century Cures Act. Therefore, utilizing this methodology for the CY 2025 OPPS/ASC proposed rule, since

the target PCR that would otherwise apply under our standard process would be a target PCR of 0.86, we propose to reduce the CY 2024 target PCR of 0.88 by 1 percentage point and propose a cancer hospital target PCR of 0.87 for CY 2025.

Table 8 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2025, due to the cancer hospital payment adjustment policy. The actual, final amount of the CY 2025 cancer hospital payment adjustment for each cancer

hospital will be determined at cost report settlement and will depend on each hospital's CY 2025 payments and costs from the settled CY 2025 cost report. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

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TABLE 8: ESTIMATED CY 2025 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2025 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	51.5%
050660	USC Norris Cancer Hospital	44.3%
100079	Sylvester Comprehensive Cancer Center	32.4%
100271	H. Lee Moffitt Cancer Center & Research Institute	23.9%
220162	Dana-Farber Cancer Institute	46.6%
330154	Memorial Sloan-Kettering Cancer Center	56.3%
330354	Roswell Park Cancer Institute	21.3%
360242	James Cancer Hospital & Solove Research Institute	16.0%
390196	Fox Chase Cancer Center	30.0%
450076	M.D. Anderson Cancer Center	45.1%
500138	Seattle Cancer Care Alliance	47.7%

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G. Proposed Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated

aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain dollar amount). In CY 2024, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times the APC payment amount (the multiplier threshold) and exceeded the APC payment amount plus \$7,750

(the fixed-dollar amount threshold) (88 FR 81589 through 81591). If the hospital's cost of furnishing a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the hospital's cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with

comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPPS. Our estimate of total outlier payments as a percent of total CY 2023 OPPS payments, using CY 2023 claims available for this CY 2025 OPPS proposed rule, is approximately 0.68 percent. Therefore, for CY 2023, we estimate that we did not meet the outlier target by 0.32 percent of total aggregated OPPS payments.

For this proposed rule, using CY 2023 claims data and CY 2024 payment rates, we estimate that the aggregate outlier payments for CY 2024 would be approximately 0.85 percent of the total CY 2024 OPPS payments. We provide estimated CY 2025 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital-Specific Impacts—Provider-Specific Data file on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

2. Outlier Calculation for CY 2025

For CY 2025, we propose to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We propose that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments), would be allocated to CMHCs for partial hospitalization program (PHP) and intensive outpatient program (IOP) outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. We propose to continue our outlier policy that if a CMHC's cost for PHP and IOP services exceeds 3.40 times the APC payment rate, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC payment rate.

For further discussion of CMHC outlier payments, we refer readers to section VIII.C of this proposed rule.

To ensure that the estimated CY 2025 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we propose that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds

the APC payment amount plus the fixed-dollar threshold.

We calculated the proposed fixed-dollar threshold using the standard methodology most recently used for CY 2024 (88 FR 81589 through 81591). For purposes of estimating outlier payments for CY 2025, we use the hospital-specific overall ancillary CCRs available in the April 2024 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we generally use to model each OPPS update lag by 2 years.

In order to estimate the CY 2025 hospital outlier payments, we inflate the charges on the CY 2023 claims using the same proposed charge inflation factor of 1.084555 that we used to estimate the IPPS fixed-loss cost threshold for the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36572). We used an inflation factor of 1.04142 to estimate CY 2024 charges from the CY 2023 charges reported on CY 2023 claims before applying CY 2024 CCRs to estimate the percent of outliers paid in CY 2024. The proposed methodology for determining these charge inflation factors is discussed in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36572). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65844 through 65846), we believe that the use of the same charge inflation factors is appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we propose to apply the same CCR adjustment factor that we proposed to apply for the FY 2025 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2025 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2025, we propose to apply an adjustment factor of 1.03331 to the CCRs that were in the April 2024 OPSF to trend them forward from CY 2024 to CY 2025. The methodology for calculating the proposed CCR adjustment factor is discussed in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36572 through 36573).

To model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2024 OPSF

after adjustment (using the proposed CCR inflation adjustment factor of 1.03331 to approximate CY 2025 CCRs) to charges on CY 2023 claims that were adjusted (using the proposed charge inflation factor of 1.084555 to approximate CY 2025 charges). We simulated aggregated CY 2023 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiplier threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2025 OPPS payments. We estimated that a proposed fixed-dollar threshold of \$8,000, combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, we propose that, if a CMHC's cost for partial hospitalization or intensive outpatient services exceeds 3.40 times the APC payment rate, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that would apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital Outpatient Quality Reporting (OQR) Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, we proposed to continue the policy that we implemented in CY 2010 that the hospitals' costs would be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to section XV of this proposed rule.

H. Proposed Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment

The national unadjusted payment rate is the payment rate for most APCs before accounting for the wage index adjustment or any applicable adjustments. The basic methodology for determining prospective payment rates for HOPD services under the OPSS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this proposed rule, the payment rate for most services and procedures for which payment is made under the OPSS is the product of the conversion factor calculated in accordance with section II.B of this proposed rule and the relative payment weight described in section II.A of this proposed rule. The national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is available via the CMS website “*Hospital Outpatient Regulations and Notices*”) and for most HCPCS codes to which separate payment under the OPSS has been assigned in Addendum B to this proposed rule (which is available on the CMS website link above) is calculated by multiplying the proposed CY 2025 scaled weight for the APC by the CY 2025 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIV of this proposed rule.

Below we demonstrate the steps used to determine the APC payments that will be made in a CY under the OPSS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: “J1,” “J2,” “P,” “Q1,” “Q2,” “Q3,” “Q4,” “R,” “S,” “T,”

“U,” or “V” (as defined in Addendum D1 to this proposed rule, which is available via the internet on the CMS website), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of “Q1” and “Q2”) qualify for separate payment. We note that, although blood and blood products with status indicator “R” and brachytherapy sources with status indicator “U” are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they would receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this proposed rule (which are available via the internet on the CMS website) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the “full” national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the “reduced” national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.9805 times the “full” national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements to receive the full CY 2025 OPSS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPSS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPSS/ASC final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPSS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies

the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

$X = .60 * (\text{national unadjusted payment rate}).$

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. The wage index values assigned to each area would reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2025 under the IPPS, reclassifications through the Medicare Geographic Classification Review Board (MGCGRB), section 1886(d)(8)(B) “Lugar” hospitals, and reclassifications under section 1886(d)(8)(E) of the Act, as implemented in § 412.103 of the regulations. We are continuing to apply for the CY 2025 OPSS wage index any adjustments for the FY 2025 IPPS post-reclassified wage index, including, but not limited to, the rural floor adjustment, a wage index floor of 1.00 in frontier states, in accordance with section 10324 of the Affordable Care Act of 2010, and an adjustment to the wage index for certain low wage index hospitals. For further discussion of the wage index we are applying for the CY 2025 OPSS, we refer readers to section II.C of this proposed rule.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173). Addendum L to this proposed rule (which is available via the internet on the CMS website) contains the qualifying counties and the associated wage index increase developed for the proposed FY 2025 IPPS wage index, which are listed in Table 3 associated with the FY 2025 IPPS proposed rule and available via the internet on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps>. (Click on the link on the left side of the screen titled “FY 2025 IPPS Proposed Rule Home Page” and select “FY 2025 Proposed Rule Tables.”) This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1

that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

X_a = labor-portion of the national unadjusted payment rate * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

$Y = 0.40 \times (\text{national unadjusted payment rate}).$

Step 6. If a provider is an SCH, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

Step 7. The adjusted payment rate is the sum of the wage adjusted labor-related portion of the national unadjusted payment rate and the nonlabor-related portion of the national unadjusted payment rate.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

Y is the nonlabor-related portion of the national unadjusted payment rate.

Adjusted Medicare Payment = $X_a + Y$

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that would apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined previously. For purposes of this example, we are using a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The proposed CY 2025 full national unadjusted payment rate for APC 5071 is \$700.10. The proposed reduced national adjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is \$686.45. This reduced rate is calculated by multiplying the reporting ratio of 0.9805 by the full unadjusted payment rate for APC 5071.

Step 1. The labor-related portion of the proposed full national unadjusted payment is approximately \$420.06 ($0.60 \times \$700.10$). The labor-related portion of the proposed reduced national adjusted payment is approximately \$411.87 ($0.60 \times \$686.45$).

Step 2 & 3. The FY 2025 wage index for a provider located in CBSA 35614 in New York, which includes the adoption of the proposed IPPS 2025 wage index policies, is 1.2867.

Step 4. The wage adjusted labor-related portion of the proposed full national unadjusted payment is approximately \$540.49 ($\$420.06 \times 1.2867$). The wage adjusted labor-related portion of the proposed reduced national adjusted payment is approximately \$529.95 ($\$411.87 \times 1.2867$).

Step 5. The nonlabor-related portion of the proposed full national unadjusted payment is approximately \$280.04 ($0.40 \times \$700.10$). The nonlabor-related portion of the proposed reduced national adjusted payment is approximately \$274.58 ($0.40 \times \$686.45$).

Step 6. For this example of a provider located in Brooklyn, New York, the rural adjustment for rural SCHs does not apply.

Step 7. The sum of the labor-related and nonlabor-related portions of the proposed full national unadjusted payment is approximately \$820.53 ($\$540.49 + \$280.04$). The sum of the portions of the proposed reduced national adjusted payment is approximately \$804.53 ($\$529.95 + \$274.58$) as shown in Table 9.

TABLE 9: PROPOSED FULL NATIONAL UNADJUSTED PAYMENT RATE AND PROPOSED REDUCED NATIONAL ADJUSTED PAYMENT RATE

Proposed Full national unadjusted payment rate	Proposed Reduced national adjusted payment rate
\$820.53	\$804.53

I. Proposed Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such

services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPIs in CY 2006, and in CYs thereafter, shall not

exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure

(including items such as drugs and biologicals) performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Medicare Part B coinsurance for preventive services furnished on and after January 1, 2011, that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. For a discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, we refer readers to section XII.B of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

Section 122 of the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116–260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amended section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. We refer readers to section X.B, “Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests,” of the CY 2022 OPPS/ASC final rule with comment period for the full discussion of this policy (86 FR 63740 through 63743). Under the regulation at 42 CFR 410.152(l)(5)(i)(B), the Medicare Part B payment percentage for colorectal cancer screening tests described in the regulation at § 410.37(j) that are furnished in CY 2023 through CY 2026 is 85 percent, with beneficiary coinsurance equal to 15 percent.

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169) was signed into law. Section 11101(a) of the IRA amended section 1847A of the Act by adding a new subsection (i), which requires the payment of rebates into the Supplementary Medical Insurance Trust Fund for Part B rebatable drugs if the payment limit amount exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The provisions of section 11101 of the IRA thus far have primarily been implemented through program instruction, as permitted under section 1847A(c)(5)(C) of the Act. As such, we

issued guidance for the computation of inflation-adjusted beneficiary coinsurance under section 1847A(i)(5) of the Act and amounts paid under section 1833(a)(1)(EE) of the Act on February 9, 2023.^{8,9} For additional information regarding implementation of section 11101 of the IRA, please see the inflation rebates resources page at <https://www.cms.gov/inflation-reduction-act-and-medicare/inflation-rebates-medicare>.

Section 11101(b) of the IRA amended sections 1833(i) and 1833(t)(8) of the Act by adding a new paragraph (9) and subparagraph (F), respectively. Section 1833(i)(9) requires under the ASC payment system that in the case of a Part B rebatable drug, in lieu of calculation of coinsurance that would otherwise apply under the ASC payment system, the provisions of section 1847A(i)(5) of the Act shall, as determined appropriate by the Secretary, apply for calculation of beneficiary coinsurance in the same manner as the provisions of section 1847A(i)(5) of the Act apply under that section. Similarly, section 1833(t)(8)(F) of the Act requires under the OPPS that in the case of a Part B rebatable drug (except for a drug that has no copayment applied under subparagraph (E) of such section or for which payment is packaged into the payment for a covered OPD service or group of services), in lieu of the calculation of the copayment amount that would otherwise apply under the OPPS, the provisions of section 1847A(i)(5) of the Act shall, as determined appropriate by the Secretary, apply in the same manner as the provisions of section 1847A(i)(5) of the Act apply under that section. Section 1847A(i)(5) of the Act requires that for Part B rebatable drugs, as defined in section 1847A(i)(2)(A) of the Act, furnished on or after April 1, 2023, in quarters in which the payment amount described in section 1847A(i)(3)(A)(ii)(I) of the Act (or, in the case of selected drugs described under section 1192(c) of the Act, the payment amount described in section 1847A(b)(1)(B) of the Act), exceeds the inflation-adjusted payment amount determined in accordance with section 1847A(i)(3)(C) of the Act, the

coinsurance will be 20 percent of the inflation-adjusted payment amount for such quarter (hereafter, the inflation-adjusted coinsurance amount). This inflation-adjusted coinsurance amount is applied as a percent, as determined by the Secretary, to the payment amount that would otherwise apply for such calendar quarter in accordance with section 1847A(b)(1)(B) or (C) of the Act, as applicable, including in the case of a selected drug.

Paragraph (9) of section 1833(i) of the Act and subparagraph (F) of section 1833(t)(8) of the Act, as added by section 11101(b) of the IRA, also provide that in lieu of the amounts of payment otherwise applicable under the ASC payment system and the OPPS, the provisions of paragraph (1)(EE) of subsection (a) of section 1833 of the Act shall apply, as determined appropriate by the Secretary. Section 11101(b) of the IRA amended section 1833(a)(1) of the Act by adding a new subparagraph (EE), which requires that if the payment amount under section 1847A(i)(3)(A)(ii)(I) of the Act or, in the case of a selected drug, the payment amount described in section 1847A(b)(1)(B) of the Act, for that drug exceeds the inflation-adjusted payment amount for a Part B rebatable drug, the Part B payment amount would, subject to the Part B deductible and sequestration, equal the difference between such payment amount and the inflation-adjusted coinsurance amount. Consistent with the policy adopted in section 40 of the revised Medicare Part B Drug Inflation Rebate Guidance, the calculation to determine the applicable beneficiary coinsurance amount would not be adjusted for sequestration. CMS codified the Medicare payment for Part B rebatable drugs in the CY 2024 PFS final rule by adding new paragraph (m) to § 410.152.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81594), we codified the OPPS program payment and cost sharing amounts for Part B rebatable drugs as required by section 1833(t)(8)(F) by adding a new paragraph (e) to § 419.41, which cross-references the regulations adopted in the CY 2024 PFS final rule (§§ 410.152(m) and 489.30(b)(6)). We also amended the regulation text to reflect our longstanding policies for calculating the Medicare program payment and cost sharing amounts for separately payable drugs and biologicals by adding a new paragraph (d) to § 419.41. Similarly, we codified the ASC cost sharing amounts for Part B rebatable drugs as required by section 1833(i)(9) of the Act by revising § 416.172(d) to include a cross-reference to 42 CFR 489.30(b)(6), which codified

⁸ <https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf>.

⁹ In addition, beginning with the April 2023 ASP Drug Pricing file, the file includes the coinsurance percentage for each drug and specifies “inflation-adjusted coinsurance” in the “Notes” column if the coinsurance for a drug is less than 20 percent of the Medicare Part B payment amount. Drug pricing files are available at <https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcpartbdrugavgsalesprice>.

the cost sharing amounts for Part B rebatable drugs with prices increasing at a rate faster than inflation.

In the CY 2025 Medicare PFS proposed rule, CMS proposes to adopt new provisions at § 427.200 and § 427.201 to codify the policies regarding the computation of the inflation-adjusted beneficiary coinsurance, defined in § 427.200, for Part B rebatable drugs as required by section 1847A(i)(5) of the Act. This proposed new provision includes references to the existing provisions at §§ 410.152(m), 419.41(e), and 489.30(b)(6) of this title. CMS further proposes at § 427.201(c) that any category of products that is excluded from the identification of Part B rebatable drugs at § 427.101(b) is not subject to the inflation-adjusted beneficiary coinsurance. Examples of these excluded products include separately payable radiopharmaceuticals, skin substitute products, and qualifying biosimilar biological products.

Additionally, CMS proposes at § 427.201(b) that CMS will use the published payment amount in quarterly pricing files^{10 11 12} to determine if a Part B rebatable drug should have an adjusted beneficiary coinsurance equal to 20 percent of the inflation-adjusted payment amount as described in section 1847A(i)(3)(C) for a calendar quarter. This proposed approach deviates from the rebate calculation approach proposed in § 427.302, which relies on the specified amount defined at § 427.20 even when the specified amount and the published payment amount in quarterly pricing files differ. The approach proposed at § 427.201(b) would be used only to determine whether there should be a coinsurance adjustment and would not impact the applicability or calculation of inflation rebates. CMS believes this approach is consistent with the statutory language and appropriately reflects the differences in the statutory text of section 1847A(i)(5) of the Act, which sets forth the payment amount that is used to determine whether coinsurance should be adjusted, and section 1847A(i)(3)(A) of the Act, which sets forth the “specified amount” used to determine rebate amounts.

We refer readers to the CY 2025 Medicare PFS proposed rule for a detailed discussion of proposals related

to the Part B inflation rebates, including inflation-adjusted beneficiary coinsurance and Medicare payment for Medicare Part B rebatable drugs.

2. Proposed OPPS Copayment Policy

For CY 2025, we propose to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period for a discussion of that methodology (68 FR 63458).) In addition, we propose to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2025, are included in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

As discussed in section XIV.E of this proposed rule, for CY 2025, the Medicare beneficiary’s minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates, due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs, and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid

under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.

- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.

- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than* the prior year’s rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).

- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year’s rate, the copayment amount is calculated as the product of the new payment rate and the prior year’s coinsurance percentage.

- If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).

- If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in the CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which achieves a 20-percent copayment percentage when fully phased in and gives the Secretary the

¹⁰ See: <https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files>.

¹¹ See: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates>.

¹² See: <https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-payment-rates-addenda>.

authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459).

3. Proposed Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its proposed payment rate. For example, using APC 5071, \$140.02 is approximately 20 percent of the full national unadjusted payment rate of \$700.10. For APCs with only a minimum unadjusted copayment in Addenda A and B to this proposed rule (which are available via the internet on the CMS website), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

$B = \text{National unadjusted copayment for APC} / \text{national unadjusted payment rate for APC}.$

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H of this with comment period. Calculate the rural adjustment for eligible providers, as indicated in Step 6 under section II.H of this final rule with comment period.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H of this proposed rule, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

$\text{Wage-adjusted copayment amount for the APC} = \text{Adjusted Medicare Payment} * B.$

$\text{Wage-adjusted copayment amount for the APC (SCH or EACH)} = (\text{Adjusted Medicare Payment} * 1.071) * B.$

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.9805.

The unadjusted copayments for services payable under the OPSS that would be effective January 1, 2025, are shown in Addenda A and B to proposed rule (which are available via the CMS website). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the proposed CY 2025 OPD fee schedule increase factor discussed in section II.B of this proposed rule.

In addition, as noted earlier, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

III. Proposed OPSS Ambulatory Payment Classification (APC) Group Policies

A. Proposed OPSS Treatment of New and Revised HCPCS Codes

Payments for OPSS procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on HOPD claims. HCPCS codes are used to report surgical procedures, medical services, items, and supplies under the hospital OPSS. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system that is established and maintained by the American Medical Association (AMA), and consists of Category I, II, III, MAAA, and PLA CPT codes. Level II, which is established and maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes.

Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the OPSS payment system. Specifically, we recognize the following codes on OPSS claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;

- Category III CPT codes, which describe new and emerging technologies, services, and procedures;

- MAAA CPT codes, which describe laboratory multianalyte assays with algorithmic analyses (MAA);

- PLA CPT codes, which describe proprietary laboratory analyses (PLA) services; and

- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

The codes are updated and changed throughout the year. CPT and Level II HCPCS code changes that affect the OPSS are published through the annual rulemaking cycle and through the OPSS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or October 1. CPT code changes are released by the AMA (via their website) while Level II HCPCS code changes are released to the public via the CMS HCPCS website. CMS recognizes the release of new CPT and Level II HCPCS codes outside of the formal rulemaking process via OPSS quarterly update CRs. Based on our review, we assign the new codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPSS/ASC final rules. This quarterly process offers hospitals access to codes that more accurately describe the items or services furnished and provides payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on the new CPT and Level II HCPCS codes, status indicators, and APC assignments through our annual rulemaking process.

We note that, under the OPSS, the APC assignment determines the payment rate for an item, procedure, or service. The items, procedures, or services not exclusively paid separately under the hospital OPSS are assigned to appropriate status indicators. Certain payment status indicators provide separate payment while other payment status indicators do not. In section XI "Proposed CY 2025 Payment Status and Comment Indicators" of this proposed rule, we discuss the various status indicators and comment indicators used under the OPSS. We also provide a complete list of the proposed status indicators and their definitions in Addendum D1 to this proposed rule.

1. April 2024 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2024 update, 73 new HCPCS codes were established and

made effective on April 1, 2024. Through the April 2024 OPPS quarterly update CR (Transmittal 12552, Change Request 13568, dated March 21, 2024), we recognized several new HCPCS codes for payment under the OPPS. In this proposed rule, we solicit public comments on the proposed APC and status indicator assignments for the codes listed in Table 10 (New HCPCS Codes Effective April 1, 2024). The proposed status indicator, APC	assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. The new codes effective April 1, 2024, are assigned to comment indicator “NP” in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and comments will be accepted on their interim APC assignments. The complete list of proposed status indicators and definitions used under the OPPS can be	found in Addendum D1 to this proposed rule, while the complete list of proposed comment indicators and definitions can be found in Addendum D2. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the CMS website.
		BILLING CODE 4120–01–P

TABLE 10: NEW HCPCS CODES EFFECTIVE APRIL 1, 2024

CY 2025 HCPCS Code	CY 2024 Long Descriptor
A2026	Restrata minimatrix, 5 mg
A4271	Integrated lancing and blood sample testing cartridges for home blood glucose monitor, per month
A4438	Adhesive clip applied to the skin to secure external electrical nerve stimulator controller, each
A4564	Pessary, disposable, any type
A4593	Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, controller
A4594	Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, mouthpiece each
A9293	Fertility cycle (contraception & conception) tracking software application, FDA cleared, per month, includes accessories (e.g., thermometer)
C9166	Injection, secukinumab, intravenous, 1 mg
C9167	Injection, adamts13, recombinant-krhn, 10 iu
C9168	Injection, mirikizumab-mrkz, 1 mg
C9796	Repair of enterocutaneous fistula small intestine or colon (excluding anorectal fistula) with plug (e.g., porcine small intestine submucosa [SIS])
C9797	Vascular embolization or occlusion procedure with use of a pressure-generating catheter (e.g., one-way valve, intermittently occluding), inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
E0152	Walker, battery powered, wheeled, folding, adjustable or fixed height
E0468	Home ventilator, dual-function respiratory device, also performs additional function of cough stimulation, includes all accessories, components and supplies for all functions
E0736	Transcutaneous tibial nerve stimulator
E0738	Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, include microprocessor, all components and accessories
E0739	Rehab system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors
E2104	Home blood glucose monitor for use with integrated lancing/blood sample testing cartridge
E2298	Complex rehabilitative power wheelchair accessory, power seat elevation system, any type
G0138	Intravenous infusion of cipaglucosidase alfa-atga, including provider/supplier acquisition and clinical supervision of oral administration of miglustat in preparation of receipt of cipaglucosidase alfa-atga
H0051	Traditional healing service
J0177	Injection, aflibercept hd, 1 mg
J0209	Injection, sodium thiosulfate (hope), 100 mg
J0577	Injection, buprenorphine extended-release (brixadi), less than or equal to 7 days of therapy
J0578	Injection, buprenorphine extended-release (brixadi), greater than 7 days of therapy and up to 28 days of therapy

J0589	Injection, daxibotulinumtoxina-lanm, 1 unit
J0650	Injection, levothyroxine sodium, not otherwise specified, 10 mcg
J0651	Injection, levothyroxine sodium (fresenius kabi), not therapeutically equivalent to J0650, 10 mcg
J0652	Injection, levothyroxine sodium (hikma), not therapeutically equivalent to J0650, 10mcg
J1010	Injection, methylprednisolone acetate, 1 mg
J1202	Miglustat, oral, 65 mg
J1203	Injection, cipaglucoasidase alfa-atga, 5 mg
J1323	Injection, elranatamab-bcmm, 1 mg
J1434	Injection, fosaprepitant (focinvez), 1 mg
J2277	Injection, motixafortide, 0.25 mg
J2782	Injection, avacincaptad pegol, 0.1 mg
J2801	Injection, risperidone (rykindo), 0.5 mg
J2919	Injection, methylprednisolone sodium succinate, 5 mg
J3055	Injection, talquetamab-tgvs, 0.25 mg
J3424	Injection, hydroxocobalamin, intravenous, 25 mg
J7165	Injection, prothrombin complex concentrate, human-lans, per i.u. of factor ix activity
J7354	Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg)
J9073	Injection, cyclophosphamide (ingenus), 5 mg
J9074	Injection, cyclophosphamide (sandoz), 5 mg
J9075	Injection, cyclophosphamide, not otherwise specified, 5 mg
J9248	Injection, melphalan (hepzato), 1 mg
J9249	Injection, melphalan (apotex), 1 mg
J9376	Injection, pozelimab-bbfg, 1 mg
K1037	Docking station for use with oral device/appliance used to reduce upper airway collapsibility
L1320	Thoracic, pectus carinatum orthosis, sternal compression, rigid circumferential frame with anterior and posterior rigid pads, custom fabricated
L5783	Addition to lower extremity, user adjustable, mechanical, residual limb volume management system
L5841	Addition, endoskeletal knee-shin system, polycentric, pneumatic swing, and stance phase control
Q4305	American amnion ac tri-layer, per square centimeter
Q4306	American amnion ac, per square centimeter
Q4307	American amnion, per square centimeter
Q4308	Sanopellis, per square centimeter
Q4309	Via matrix, per square centimeter
Q4310	Procenta, per 100 mg
Q5133	Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg
Q5134	Injection, natalizumab-sztn (tyruko), biosimilar, 1 mg
S4988	Penile contracture device, manual, greater than 3 lbs traction force
S9002	Intra-vaginal motion sensor system, provides biofeedback for pelvic floor muscle rehabilitation device
0439U	Cardiology (coronary heart disease [CHD]), DNA, analysis of 5 single-nucleotide polymorphisms (SNPs) (rs11716050 [LOC105376934], rs6560711 [WDR37], rs3735222 [SCIN/LOC107986769], rs6820447 [intergenic], and rs9638144 [ESYT2]) and 3 DNA methylation markers (cg00300879 [transcription start site {TSS200} of CNKSR1], cg09552548 [intergenic], and cg14789911 [body of SPATC1L]), qPCR and digital PCR, whole blood, algorithm reported as a 4-tiered risk score for a 3-year risk of symptomatic CHD

0440U	Cardiology (coronary heart disease [CHD]), DNA, analysis of 10 single-nucleotide polymorphisms (SNPs) (rs710987 [LINC010019], rs1333048 [CDKN2B-AS1], rs12129789 [KCND3], rs942317 [KTN1-AS1], rs1441433 [PPP3CA], rs2869675 [PREX1], rs4639796 [ZBTB41], rs4376434 [LINC00972], rs12714414 [TMEM18], and rs7585056 [TMEM18]) and 6 DNA methylation markers (cg03725309 [SARS1], cg12586707 [CXCL1], cg04988978 [MPO], cg17901584 [DHCR24-DT], cg21161138 [AHRH], and cg12655112 [EHD4]), qPCR and digital PCR, whole blood, algorithm reported as detected or not detected for CHD
0441U	Infectious disease (bacterial, fungal, or viral infection), semiquantitative biomechanical assessment (via deformability cytometry), whole blood, with algorithmic analysis and result reported as an index
0442U	Infectious disease (respiratory infection), Myxovirus resistance protein A (MxA) and C-reactive protein (CRP), fingerstick whole blood specimen, each biomarker reported as present or absent
0443U	Neurofilament light chain (NfL), ultra-sensitive immunoassay, serum or cerebrospinal fluid
0444U	Oncology (solid organ neoplasia), targeted genomic sequence analysis panel of 361 genes, interrogation for gene fusions, translocations, or other rearrangements, using DNA from formalin-fixed paraffin-embedded (FFPE) tumor tissue, report of clinically significant variant(s)
0445U	β -amyloid (A β 42) and phospho tau (181P) (pTau181), electrochemiluminescent immunoassay (ECLIA), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology
0446U	Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 10 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic risk score for current disease activity
0447U	Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 11 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic prognostic risk score for developing a clinical flare
0448U	Oncology (lung and colon cancer), DNA, qualitative, nextgeneration sequencing detection of single-nucleotide variants and deletions in EGFR and KRAS genes, formalin-fixed paraffinembedded (FFPE) solid tumor samples, reported as presence or absence of targeted mutation(s), with recommended therapeutic options
0449U	Carrier screening for severe inherited conditions (eg, cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia), regardless of race or self-identified ancestry, genomic sequence analysis panel, must include analysis of 5 genes (CFTR, SMN1, HBB, HBA1, HBA2)

BILLING CODE 4120-01-C**2. July 2024 HCPCS Codes Proposed Rule Comment Solicitation**

For the July 2024 update, 127 new codes were established and made effective July 1, 2024. Through the July 2024 OPPS quarterly update CR (Transmittal 12665, Change Request 13632, dated May 31, 2024), we recognized several new codes for payment and assigned them to appropriate interim OPPS status indicators and APCs. In this proposed rule, we solicit public comments on the

proposed APC and status indicator assignments for the codes listed in Table 11 (New HCPCS Codes Effective July 1, 2024). The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. The complete list of proposed status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this proposed rule. In addition, the new codes are assigned to comment indicator “NP” in Addendum B to this proposed rule to indicate that the codes are

assigned to an interim APC assignment and comments will be accepted on their interim APC assignments. The complete list of proposed comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

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TABLE 11: NEW HCPCS CODES EFFECTIVE JULY 1, 2024

CY 2025 HCPCS Code	CY 2025 Long Descriptor
90637	Influenza virus vaccine, quadrivalent (qIRV), mRNA; 30 mcg/0.5 mL dosage, for intramuscular use
90638	Influenza virus vaccine, quadrivalent (qIRV), mRNA; 60 mcg/0.5 mL dosage, for intramuscular use
C9901	Endoscopic defect closure within the entire gastrointestinal tract, including upper endoscopy (including diagnostic, if performed) or colonoscopy (including diagnostic, if performed), with all system and tissue anchoring components
C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation
C1606	Adapter, single-use (i.e. disposable), for attaching ultrasound system to upper gastrointestinal endoscope
G0519	Management of new patient-caregiver dyad with dementia, low complexity, for use in CMMI Model
G0520	Management of new patient-caregiver dyad with dementia, moderate complexity, for use in CMMI Model
G0521	Management of new patient-caregiver dyad with dementia, high complexity, for use in CMMI Model
G0522	Management of a new patient with dementia, low complexity, for use in CMMI Model
G0523	Management of a new patient with dementia, moderate to high complexity, for use in CMMI Model
G0524	Management of established patient-caregiver dyad with dementia, low complexity, for use in CMMI Model
G0525	Management of established patient-caregiver dyad with dementia, moderate complexity, for use in CMMI Model
G0526	Management of established patient-caregiver dyad with dementia, high complexity, for use in CMMI Model
G0527	Management of established patient with dementia, low complexity, for use in CMMI Model
G0528	Management of established patient with dementia, moderate to high complexity, for use in CMMI Model
G0529	In-home respite care, 4-hour unit, for use in CMMI Model
G0530	Adult day center, 8-hour unit, for use in CMMI Model
G0531	Facility-based respite, 24-hour unit, for use in CMMI Model
G9037	Interprofessional telephone/Internet/electronic health record clinical question/request for specialty recommendations by a treating/requesting physician or other qualified health care professional for the care of the

	patient (i.e. not for professional education or scheduling) and may include subsequent follow up on the specialist's recommendations; 30 minutes
G9038	Co-management services with the following elements: New diagnosis OR acute exacerbation and stabilization of existing condition; Condition which may benefit from joint care planning; Condition for which specialist is taking a co-management role; Condition expected to last at least 3 months; Comprehensive care plan established, implemented, revised or monitored in partnership with co-managing clinicians; Ongoing communication and care coordination between co-managing clinicians furnishing care
J0211	Injection, sodium nitrite 3 mg and sodium thiosulfate 125 mg (nithiodote)
J0687	Injection, cefazolin sodium (wg critical care), not therapeutically equivalent to j0690, 500 mg
J0872	Injection, daptomycin (xellia), unrefrigerated, not therapeutically equivalent to j0878 or j0873, 1 mg
J0911	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis)
J1597	Injection, glycopyrrolate (glyrx-pf), 0.1 mg
J1598	Injection, glycopyrrolate (fresenius kabi), not therapeutically equivalent to J1596, 0.1 mg
J2183	Injection, meropenem (wg critical care), not therapeutically equivalent to j2185, 100 mg
J2246	Injection, micafungin in sodium (baxter), not therapeutically equivalent to j2248, 1 mg
J2267	Injection, mirikizumab-mrkz, 1 mg
J2373	Injection, phenylephrine hydrochloride (immphentiv), 20 micrograms
J2468	Injection, palonosetron hydrochloride (avyxa), not therapeutically equivalent to J2469, 25 micrograms
J2470	Injection, pantoprazole sodium, 40 mg
J2471	Injection, pantoprazole (hikma), not therapeutically equivalent to J2470, 40 mg
J3247	Injection, secukinumab, intravenous, 1 mg
J3263	Injection, toripalimab-tpzi, 1 mg
J3393	Injection, betibeglogene autotemcel, per treatment
J3394	Injection, lovotibeglogene autotemcel, per treatment
J7171	Injection, adamts13, recombinant-krhn, 10 iu
J7355	Injection, travoprost, intracameral implant, 1 microgram
J8611	Methotrexate (jylamvo), oral, 2.5 mg
J8612	Methotrexate (xatmep), oral, 2.5 mg
J9361	Injection, efbemalenograstim alfa-vuxw, 0.5 mg

Q4311	Acesso, per square centimeter
Q4312	Acesso ac, per square centimeter
Q4313	Dermabind fm, per square centimeter
Q4314	Reeva ft, per square centimeter
Q4315	Regenelink amniotic membrane allograft, per square centimeter
Q4316	Amchoplast, per square centimeter
Q4317	Vitograft, per square centimeter
Q4318	E-graft, per square centimeter
Q4319	Sanograft, per square centimeter
Q4320	Pellograft, per square centimeter
Q4321	Renograft, per square centimeter
Q4322	Caregraft, per square centimeter
Q4323	Alloply, per square centimeter
Q4324	Amniotx, per square centimeter
Q4325	Acapatch, per square centimeter
Q4326	Woundplus, per square centimeter
Q4327	Duoamnion, per square centimeter
Q4328	Most, per square centimeter
Q4329	Singlay, per square centimeter
Q4330	Total, per square centimeter
Q4331	Axolotl graft, per square centimeter
Q4332	Axolotl dualgraft, per square centimeter
Q4333	Ardeograft, per square centimeter
Q5136	Injection, infliximab-dyyb (zymfentra), biosimilar, 10 mg
Q5137	Injection, ustekinumab-auub (wezlana), biosimilar, subcutaneous, 1 mg
Q5138	Injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg
0867T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume greater than or equal to 50 mL
0868T	High-resolution gastric electrophysiology mapping with simultaneous patient symptom profiling, with interpretation and report

0869T	Injection(s), bone-substitute material for bone and/or soft tissue hardware fixation augmentation, including intraoperative imaging guidance, when performed
0870T	Implantation of subcutaneous peritoneal ascites pump system, percutaneous, including pump-pocket creation, insertion of tunneled indwelling bladder and peritoneal catheters with pump connections, including all imaging and initial programming, when performed
0871T	Replacement of a subcutaneous peritoneal ascites pump, including reconnection between pump and indwelling bladder and peritoneal catheters, including initial programming and imaging, when performed
0872T	Replacement of indwelling bladder and peritoneal catheters, including tunneling of catheter(s) and connection with previously implanted peritoneal ascites pump, including imaging and programming, when performed
0873T	Revision of a subcutaneously implanted peritoneal ascites pump system, any component (ascites pump, associated peritoneal catheter, associated bladder catheter), including imaging and programming, when performed
0874T	Removal of a peritoneal ascites pump system, including implanted peritoneal ascites pump and indwelling bladder and peritoneal catheters
0875T	Programming of subcutaneously implanted peritoneal ascites pump system by physician or other qualified health care professional
0876T	Duplex scan of hemodialysis fistula, computer-aided, limited (volume flow, diameter, and depth, including only body of fistula)
0877T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging
0878T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; obtained with concurrent CT examination of the same structure
0879T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; radiological data preparation and transmission
0880T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; physician or other qualified health care professional interpretation and report
0881T	Cryotherapy of the oral cavity using temperature regulated fluid cooling system, including placement of an oral device, monitoring of patient tolerance to treatment, and removal of the oral device
0882T	Intraoperative therapeutic electrical stimulation of peripheral nerve to promote nerve regeneration, including lead placement and removal, upper extremity, minimum of 10 minutes; initial nerve (List separately in addition to code for primary procedure)
0883T	Intraoperative therapeutic electrical stimulation of peripheral nerve to promote nerve regeneration, including lead placement and removal, upper

	extremity, minimum of 10 minutes; each additional nerve (List separately in addition to code for primary procedure)
0884T	Esophagoscopy, flexible, transoral, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for esophageal stricture, including fluoroscopic guidance, when performed
0885T	Colonoscopy, flexible, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed
0886T	Sigmoidoscopy, flexible, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed
0887T	End-tidal control of inhaled anesthetic agents and oxygen to assist anesthesia care delivery (List separately in addition to code for primary procedure)
0888T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including imaging guidance
0889T	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold-starting location, neuronavigation files and target report, review and interpretation
0890T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day
0891T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day
0892T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day
0893T	Noninvasive assessment of blood oxygenation, gas exchange efficiency, and cardiorespiratory status, with physician or other qualified health care professional interpretation and report
0894T	Cannulation of the liver allograft in preparation for connection to the normothermic perfusion device and decannulation of the liver allograft following normothermic perfusion
0895T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; initial 4 hours of monitoring time, including hourly physiological and laboratory assessments (eg, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment)

0896T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; each additional hour, including physiological and laboratory assessments (eg, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment) (List separately in addition to code for primary procedure)
0897T	Noninvasive augmentative arrhythmia analysis derived from quantitative computational cardiac arrhythmia simulations, based on selected intervals of interest from 12-lead electrocardiogram and uploaded clinical parameters, including uploading clinical parameters with interpretation and report
0898T	Noninvasive prostate cancer estimation map, derived from augmentative analysis of image-guided fusion biopsy and pathology, including visualization of margin volume and location, with margin determination and physician interpretation and report
0899T	Noninvasive determination of absolute quantitation of myocardial blood flow (AQMBF), derived from augmentative algorithmic analysis of the dataset acquired via contrast cardiac magnetic resonance (CMR), pharmacologic stress, with interpretation and report by a physician or other qualified health care professional (List separately in addition to code for primary procedure)
0900T	Noninvasive estimate of absolute quantitation of myocardial blood flow (AQMBF), derived from assistive algorithmic analysis of the dataset acquired via contrast cardiac magnetic resonance (CMR), pharmacologic stress, with interpretation and report by a physician or other qualified health care professional (List separately in addition to code for primary procedure)
0450U	Oncology (multiple myeloma), liquid chromatography with tandem mass spectrometry (LCMS/MS), monoclonal paraprotein sequencing analysis, serum, results reported as baseline presence or absence of detectable clonotypic peptides
0451U	Oncology (multiple myeloma), LCMS/MS, peptide ion quantification, serum, results compared with baseline to determine monoclonal paraprotein abundance
0452U	Oncology (bladder), methylated PENK DNA detection by linear target enrichment-quantitative methylation-specific real-time PCR (LTE-qMSP), urine, reported as likelihood of bladder cancer
0453U	Oncology (colorectal cancer), cellfree DNA (cfDNA), methylationbased quantitative PCR assay (SEPTIN9, IKZF1, BCAT1, Septin9-2, VAV3, BCAN), plasma, reported as presence or absence of circulating tumor DNA (ctDNA)
0454U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping
0455U	Infectious agents (sexually transmitted infection), Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis, multiplex amplified

	probe technique, vaginal, endocervical, gynecological specimens, oropharyngeal swabs, rectal swabs, female or male urine, each pathogen reported as detected or not detected
0456U	Autoimmune (rheumatoid arthritis), next-generation sequencing (NGS), gene expression testing of 19 genes, whole blood, with analysis of anticyclic citrullinated peptides (CCP) levels, combined with sex, patient global assessment, and body mass index (BMI), algorithm reported as a score that predicts nonresponse to tumor necrosis factor inhibitor (TNFi) therapy
0457U	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 9 PFAS compounds by LC-MS/MS, plasma or serum, quantitative
0458U	Oncology (breast cancer), S100A8 and S100A9, by enzymelinked immunosorbent assay (ELISA), tear fluid with age, algorithm reported as a risk score
0459U	β -amyloid (A β 42) and total tau (tTau), electrochemiluminescent immunoassay (ECLIA), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology
0460U	Oncology, whole blood or buccal, DNA single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, with variant analysis and reported phenotypes
0461U	Oncology, pharmacogenomic analysis of single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, whole blood or buccal swab, with variant analysis, including impacted gene-drug interactions and reported phenotypes
0462U	Melatonin levels test, sleep study, 7 or 9 sample melatonin profile (cortisol optional), enzyme-linked immunosorbent assay (ELISA), saliva, screening/preliminary
0463U	Oncology (cervix), mRNA gene expression profiling of 14 biomarkers (E6 and E7 of the highest-risk human papillomavirus [HPV] types 16, 18, 31, 33, 45, 52, 58), by real-time nucleic acid sequence-based amplification (NASBA), exo- or endocervical epithelial cells, algorithm reported as positive or negative for increased risk of cervical dysplasia or cancer for each biomarker
0464U	Oncology (colorectal) screening, quantitative real-time target and signal amplification, methylated DNA markers, including LASS4, LRRC4 and PPP2R5C, a reference marker ZDHHC1, and a protein marker (fecal hemoglobin), utilizing stool, algorithm reported as a positive or negative result
0465U	Oncology (urothelial carcinoma), DNA, quantitative methylationspecific PCR of 2 genes (ONECUT2, VIM), algorithmic analysis reported as positive or negative
0466U	Cardiology (coronary artery disease [CAD]), DNA, genomewide association studies (564856 single-nucleotide polymorphisms [SNPs], targeted variant genotyping), patient lifestyle and clinical data, buccal swab, algorithm reported as polygenic risk to acquired heart disease

0467U	Oncology (bladder), DNA, nextgeneration sequencing (NGS) of 60 genes and whole genome aneuploidy, urine, algorithms reported as minimal residual disease (MRD) status positive or negative and quantitative disease burden
0468U	Hepatology (nonalcoholic steatohepatitis [NASH]), miR-34a5p, alpha 2-macroglobulin, YKL40, HbA1c, serum and whole blood, algorithm reported as a single score for NASH activity and fibrosis
0469U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis for chromosomal abnormalities, copy number variants, duplications/deletions, inversions, unbalanced translocations, regions of homozygosity (ROH), inheritance pattern that indicate uniparental disomy (UPD), and aneuploidy, fetal sample (amniotic fluid, chorionic villus sample, or products of conception), identification and categorization of genetic variants, diagnostic report of fetal results based on phenotype with maternal sample and paternal sample, if performed, as comparators and/or maternal cell contamination
0470U	Oncology (oropharyngeal), detection of minimal residual disease by next-generation sequencing (NGS) based quantitative evaluation of 8 DNA targets, cell-free HPV 16 and 18 DNA from plasma
0471U	Oncology (colorectal cancer), qualitative real-time PCR of 35 variants of KRAS and NRAS genes (exons 2, 3, 4), formalin-fixed paraffin-embedded (FFPE), predictive, identification of detected mutations
0472U	Carbonic anhydrase VI (CA VI), parotid specific/secretory protein (PSP) and salivary protein (SP1) IgG, IgM, and IgA antibodies, enzyme-linked immunosorbent assay (ELISA), semiquantitative, blood, reported as predictive evidence of early Sjögren syndrome
0473U	Oncology (solid tumor), nextgeneration sequencing (NGS) of DNA from formalin-fixed paraffinembedded (FFPE) tissue with comparative sequence analysis from a matched normal specimen (blood or saliva), 648 genes, interrogation for sequence variants, insertion and deletion alterations, copy number variants, rearrangements, microsatellite instability, and tumor-mutation burden
0474U	Hereditary pan-cancer (eg, hereditary sarcomas, hereditary endocrine tumors, hereditary neuroendocrine tumors, hereditary cutaneous melanoma), genomic sequence analysis panel of 88 genes with 20 duplications/deletions using nextgeneration sequencing (NGS), Sanger sequencing, blood or saliva, reported as positive or negative for germline variants, each gene
0475U	Hereditary prostate cancer-related disorders, genomic sequence analysis panel using next-generation sequencing (NGS), Sanger sequencing, multiplex ligation-dependent probe amplification (MLPA), and array comparative genomic hybridization (CGH), evaluation of 23 genes and duplications/deletions when indicated, pathologic mutations reported with a genetic risk score for prostate cancer

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3. October 2024 HCPCS Codes Final Rule Comment Solicitation

As has been our practice in the past, we will solicit comments on the new CPT and Level II HCPCS codes that will be effective October 1, 2024, in the CY 2025 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2025 OPPS/ASC final rule with comment period. The HCPCS codes will be released to the public through the October 2024 OPPS Update CR and the CMS HCPCS website while the CPT codes will be released to the public through the AMA website.

For CY 2025, we propose to continue our established policy of assigning comment indicator “NI” in Addendum B to the OPPS/ASC final rule with comment period to those new HCPCS codes that will be effective October 1, 2024, to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2025 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2026 OPPS/ASC final rule with comment period.

4. January 2025 HCPCS Codes

a. New Level II HCPCS Codes Final Rule Comment Solicitation

Consistent with past practice, we will solicit comments on the new Level II HCPCS codes that will be effective January 1, 2025, in the CY 2025 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2026 OPPS/ASC final rule with comment period. Unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the proposed new C-codes and G-codes listed in Addendum O of this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Consequently, for CY 2025, we propose to include the new Level II HCPCS codes effective January 1, 2025, in Addendum B to the CY 2025 OPPS/ASC final rule with comment period, which would be incorporated in the January 2025 OPPS quarterly update CR. Specifically, for CY 2025, we propose to continue our established policy of assigning comment indicator “NI” in Addendum B to the OPPS/ASC

final rule with comment period to the new HCPCS codes that will be effective January 1, 2025, to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2025 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2026 OPPS/ASC final rule with comment period.

b. New CPT Codes Proposed Rule Comment Solicitation

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA’s CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year’s rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the PFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid resorting to use of HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, we finalized our proposal to make interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), to solicit public comments in the final rule, and to finalize the specific APC and status indicator assignments for those codes in the following year’s final rule.

For the CY 2025 OPPS update, we received the CPT codes that will be effective January 1, 2025, from the AMA in time to be included in this proposed rule. The new, revised, and deleted CPT codes can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website). We note that the new and revised CPT codes are assigned to comment indicator “NP” in Addendum B of this proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC assignment and status indicator. Further, we note that the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we are including the 5-digit placeholder codes and the long descriptors for the new and revised CY 2025 CPT codes in Addendum O, specifically under the column labeled “CY 2025 OPPS/ASC Proposed Rule 5-Digit AMA/CMS Placeholder Code.” The final HCPCS code numbers will be included in the CY 2025 OPPS/ASC final rule with comment period. In summary, we solicit public comments on the proposed CY 2025 status indicators and APC assignments for the new and revised CPT codes that will be effective January 1, 2025. The CPT codes listed in Addendum B appear with short descriptors only, therefore, we list them again in Addendum O to this proposed rule with long descriptors. In addition, we propose to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2025 OPPS/ASC final rule with comment period. The proposed status indicator and APC assignment for these codes can be found in Addendum B to this proposed rule. In addition, the complete list of proposed comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

Finally, in Table 12 (Comment and Finalization Timeframes for New and Revised OPPS-Related HCPCS Codes) below, we summarize our current

process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the

treatment of these codes under the OPPS.

TABLE 12: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED OPPS-RELATED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2024	HCPCS (CPT and Level II codes)	April 1, 2024	CY 2025 OPPS/ASC proposed rule	CY 2025 OPPS/ASC final rule with comment period
July 2024	HCPCS (CPT and Level II codes)	July 1, 2024	CY 2025 OPPS/ASC proposed rule	CY 2025 OPPS/ASC final rule with comment period
October 2024	HCPCS (CPT and Level II codes)	October 1, 2024	CY 2025 OPPS/ASC final rule with comment period	CY 2026 OPPS/ASC final rule with comment period
January 2025	CPT Codes	January 1, 2025	CY 2025 OPPS/ASC proposed rule	CY 2025 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2025	CY 2025 OPPS/ASC final rule with comment period	CY 2026 OPPS/ASC final rule with comment period

B. Proposed OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. In addition, section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in regulations at 42 CFR 419.31.

We use Level I (also known as CPT codes) and Level II HCPCS codes (also known as alphanumeric codes) to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

We have packaged into the payment for each procedure or service within an APC group, the costs associated with

those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to, the items and services listed in regulations at 42 CFR 419.2(b). A further discussion of packaged services is included in section II.A.3 of this proposed rule.

Under the OPPS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which

the independent service or combination of services is assigned. For CY 2025, we propose that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

2. Application of the 2 Times Rule

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to consider changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights. We note that the Advisory Panel on Hospital Outpatient Payment (also known as the HOP Panel or the Panel) recommendations for specific services for the CY 2025 OPps update will be discussed in the relevant specific sections throughout the CY 2025 OPps/ASC final rule with comment period.

In addition, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable regarding the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the “2 times rule”). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as for low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or

procedure codes that both have more than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 or fewer claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and that comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost (75 FR 71832). In this section of this proposed rule, for CY 2025, we propose to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as for certain low-volume items and services.

For the CY 2025 OPps update, we identified the APCs with violations of the 2 times rule, and we propose changes to the procedure codes assigned to these APCs (with the exception of those APCs for which we propose a 2 times rule exception) in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this proposed rule. Rather, it is published and made available via the internet on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>. To eliminate a violation of the 2 times rule and improve clinical and resource homogeneity in the APCs for which we are not proposing a 2 times rule exception, we propose to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed HCPCS code reassignments and associated APC reconfigurations for CY 2025 included in this proposed rule are related to changes in costs of services that were observed in the CY 2023 claims data available for CY 2025 ratesetting. Addendum B to this proposed rule identifies with a comment indicator “CH” those procedure codes for which we propose a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2024, OPps Addendum B Update, which is available via the internet on the CMS website at: [*prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*.](https://www.cms.gov/medicare/payment/</p>
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3. Proposed APC Exceptions to the 2 Times Rule

While considering the APC changes that we propose for CY 2025, we reviewed all of the APCs for which we identified 2 times rule violations to determine whether any of the APCs would qualify for an exception. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

For a detailed discussion of these criteria, we refer readers to the April 7, 2000 final rule (65 FR 18457 through 18458).

Based on the CY 2023 claims data available for this proposed rule, we found 23 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we propose to make exceptions under the 2 times rule for CY 2025 and found that all of the 23 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2023 claims data available for this proposed rule. We note that, on an annual basis, based on our analysis of the latest claims data, we identify violations to the 2 times rule and propose changes when appropriate. Those APCs that violate the 2 times rule are identified and appear in Table 13 below. In addition, we did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as APC 5401 (Dialysis), which only has two HCPCS codes assigned to it that have similar geometric mean costs and do not create a 2 times rule violation. Therefore, we have only identified those APCs, including those with criteria-based costs, such as device-dependent CPT/HCPCS codes, with violations of the 2 times rule, where a 2 times rule violation is a relevant concept.

Table 13 of this proposed rule lists the 23 APCs for which we propose to make an exception under the 2 times rule for CY 2025 based on the criteria cited above and claims data submitted between January 1, 2023, and December 31, 2023, and processed on or before December 31, 2023, and CCRs, if available. The proposed geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of

this proposed rule can be found on the CMS website at: <https://www.cms.gov/medicare/payment/prospective->

[payment-systems/hospital-outpatient/regulations-notice](https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice).

TABLE 13: PROPOSED CY 2025 APC EXCEPTIONS TO THE 2 TIMES RULE

APC	APC Group Title
5012	Clinic Visits and Related Services
5053	Level 3 Skin Procedures
5071	Level 1 Excision/Biopsy/Incision and Drainage
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5572	Level 2 Imaging with Contrast
5593	Level 3 Nuclear Medicine and Related Services
5611	Level 1 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5733	Level 3 Minor Procedures
5734	Level 4 Minor Procedures
5741	Level 1 Electronic Analysis of Devices
5743	Level 3 Electronic Analysis of Devices
5791	Pulmonary Treatment
5811	Manipulation Therapy
5821	Level 1 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. Proposed New Technology APCs

1. Background

In the CY 2002 OPPS final rule (66 FR 59903), we finalized changes to the time period in which a service can be eligible for payment under a New Technology APC. Beginning in CY 2002, we retain

services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a

New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

We also adopted in the CY 2002 OPPS final rule the following criteria for assigning a complete or comprehensive service to a New Technology APC: (1)

the service must be truly new, meaning it cannot be appropriately reported by an existing HCPCS code assigned to a clinical APC and does not appropriately fit within an existing clinical APC; (2) the service is not eligible for transitional pass-through payment (however, a truly new, comprehensive service could qualify for assignment to a new technology APC even if it involves a device or drug that could, on its own, qualify for pass-through payment); and (3) the service falls within the scope of Medicare benefits under section 1832(a) of the Act and is reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act (66 FR 59898 through 59903). For additional information about our New Technology APC policy, we refer readers to <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/pass-through-payment-status-new-technology-ambulatory-payment-classification-apc> on the CMS website and then follow the instructions to access the MEARIS™ system for OPPTS New Technology APC applications.¹³

In the CY 2004 OPPTS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs: one set with a status indicator of “S” (Significant Procedures, Not Discounted when Multiple. Paid under OPPTS; separate APC payment) and the other set with a status indicator of “T” (Significant Procedure, Multiple Reduction Applies. Paid under OPPTS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

For CY 2024, there were 52 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level 1A (\$0–\$10)) to the highest cost band assigned to APC 1908 (New Technology—Level 52 (\$145,001–\$160,000)). We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599 and 1901 through 1908, vary with increments ranging from \$10 to \$14,999. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPTS. Payment for each APC is made at the mid-point of the APC’s assigned cost band. For

example, payment for New Technology APC 1507 (New Technology—Level 7 (\$501–\$600)) is made at \$550.50.

Under the OPPTS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPTS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital market basket increase reduced by the productivity adjustment. We believe that our payment rates reflect the costs that are associated with providing care to Medicare beneficiaries and are adequate to ensure access to services (80 FR 70374). For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the technologies and their clinical utility. Quite often, parties request that Medicare make higher payments under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per-use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPTS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare’s and other payers’ payment policies. We refer readers to the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.

Some services assigned to New Technology APCs have low annual volume, which we consider to be fewer than 100 claims in the year of claims data used for ratesetting (86 FR 63528). Where utilization of services assigned to a New Technology APC is low, it can lead to wide variation in payment rates from year to year, resulting in even lower utilization and potential barriers to access to new technologies, which ultimately limits our ability to assign the service to the appropriate clinical APC. To mitigate these issues, we finalized a policy in the CY 2019 OPPTS/

ASC final rule with comment period to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determine the costs for low-volume services assigned to New Technology APCs (83 FR 58892 through 58893). Specifically, in the CY 2019 OPPTS/ASC final rule with comment period (83 FR 58893), we established that, in each of our annual rulemakings, we would calculate and present the result of each statistical methodology (arithmetic mean, geometric mean, and median) based on up to 4 years of claims data and solicit public comment on which methodology should be used to establish the payment rate for the low-volume new technology service. In the CY 2022 OPPTS/ASC final rule (86 FR 63529), we replaced the New Technology APC low volume policy with the universal low volume APC policy. Unlike the New Technology APC low volume policy, the universal low volume APC policy applies to clinical APCs and brachytherapy APCs, in addition to procedures assigned to New Technology APCs, and uses the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data to set the payment rate for the APC. We refer readers to the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63529) for further discussion regarding this policy.

Finally, we note that, in a budget-neutral system, payments may not fully cover hospitals’ costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high-cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPTS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPTS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314). For CY 2025, we included the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to this proposed rule (which is available on the CMS website at <https://>

¹³ Currently approved under OMB control number 0938–0860; expires 07/31/2024.

www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice.

2. Proposal To Exempt Services With Very Low Claims Volume From APC Reassignment Based on the Universal Low Volume Policy

We continue to be concerned about payment stability for services assigned to New Technology APCs, specifically services with very low claims volume of fewer than 10 claims in the 4-year lookback period used under the universal low volume APC policy. Historically, we have used our equitable adjustment authority at section 1833(t)(2)(E) of the Act to exempt a number of services with very low claims volume from the universal low volume APC policy in instances where application of the universal low volume policy would lead to significant fluctuations in payment. Given the frequency with which we have needed to utilize our equitable adjustment authority to address significant fluctuations in payment for very low volume services, we believe that refinements to our universal low volume policy for services assigned to New Technology APCs may be necessary. We also recognize that determining initial cost estimates for these services may be particularly challenging, given the lack of cost information for new and innovative technologies.

To allow time for us to consider these issues, we propose for CY 2025 to exempt services assigned to New Technology APCs with fewer than 10 claims over the 4-year lookback period used for the universal low volume policy. Instead of assigning these services to a different New Technology APC based on the very few claims available, we propose that we would maintain the New Technology APC assignment for each service from the prior year, which in this case would be the New Technology APC assignment for CY 2024. We believe it is appropriate to apply this policy to New Technology APCs because services assigned to New Technology APCs represent new technologies for which it may be more challenging to determine an appropriate cost than for other, more established services. We believe 10 claims is an appropriate ceiling for exempting services from reassignment based on the universal low volume policy because we believe that at 10 claims a rough standard distribution begins to appear. We also believe that services with so few claims over the 4-year lookback period would be especially vulnerable to large changes in payment rates year-

to-year as a result of one or two new claims being available or one or two claims from what was previously the fourth year of the lookback period no longer being included in that period.

Consistent with our overall policy regarding use of updated claims data in the final rule, we propose to perform a similar analysis for the final rule using updated claims data, including determining whether specific HCPCS codes continue to meet the criteria for our universal low volume APC policy or our proposal to exempt services with fewer than 10 claims in the 4-year lookback period from the universal low volume APC policy and maintain their CY 2024 New Technology APC assignment. We will update the APC placement as needed in the final rule.

3. Procedures Assigned to New Technology APCs for CY 2025

As we described in the CY 2002 OPPS final rule (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC. In addition, in cases where we find that our initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), where we obtain new information that was not available at the time of our initial New Technology APC assignment, or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with our current policy, for CY 2025, we propose to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to an appropriate clinical APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if we have obtained sufficient claims data. It also allows us to retain a service in a New Technology APC for more than 2 years if we have not obtained sufficient claims data upon which to base a reassignment decision (66 FR 59902).

a. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1563)

Effective January 1, 2021, CMS established HCPCS code C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) and assigned it to a New Technology APC based on the geometric mean cost of CPT code 67036 (Vitrectomy, mechanical, pars plana approach) due to similar resource utilization. For CY 2021, HCPCS code C9770 was assigned to APC 1561 (New Technology—Level 24 (\$3,001–\$3,500)). This code may be used to describe the administration of HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes). This procedure was previously discussed in depth in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85939 through 85940). For CY 2022, we maintained the APC assignment of APC 1561 (New Technology—Level 24 (\$3,001–\$3,500)) for HCPCS code C9770 (86 FR 63531 through 63532).

HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes) is for a gene therapy product indicated for a rare mutation-associated retinal dystrophy. Voretigene neparvovec-rzyl (Luxturna[®]) was approved by FDA in December of 2017 and is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.¹⁴ This therapy is administered through a subretinal injection, which interested parties describe as an extremely delicate and sensitive surgical procedure. The FDA-approved package insert describes one of the steps for administering Luxturna as, “after completing a vitrectomy, identify the intended site of administration. The subretinal injection can be introduced via pars plana.”

Interested parties, including the manufacturer of Luxturna[®], recommended CPT code 67036 (Vitrectomy, mechanical, pars plana approach) for the administration of the gene therapy.¹⁵ However, the manufacturer previously contended the administration was not accurately described by any existing codes as CPT code 67036 (Vitrectomy, mechanical,

¹⁴ Luxturna. FDA Package Insert. Available: <https://www.fda.gov/media/109906/download>.

¹⁵ LUXTURNA REIMBURSEMENT GUIDE FOR TREATMENT CENTERS. <https://mysparkgeneration.com/uploads/2022/09/LUXTURNA-Reimbursement-Guide-for-Treatment-Centers-ISI-Update-April-2022-P-RPE65-US-320025.pdf>.

pars plana approach) does not account for the administration itself.

CMS recognized the need to accurately describe the unique procedure that is required to administer the therapy described by HCPCS code J3398. Therefore, in the CY 2021 OPPS/ASC proposed rule (85 FR 48832), we proposed to establish a new HCPCS code, C97X1 (Vitreotomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) to describe this process. We stated that we believed this new HCPCS code accurately described the unique service associated with intraocular administration of HCPCS code J3398. We recognized that CPT code 67036 represents a clinically similar procedure and process that approximates similar resource utilization to C97X1. However, we also recognized that it is not prudent for the code that describes the administration of this unique gene therapy, C97X1, to be assigned to the same C-APC to which CPT code 67036 is assigned, as this would package the primary therapy, HCPCS code J3398, into the code that represents the process to administer the gene therapy.

Therefore, for CY 2021, we proposed to assign the services described by C97X1 to a New Technology APC with a cost band that contains the geometric mean cost for CPT code 67036. The placeholder code C97X1 was replaced by HCPCS code C9770. For CY 2021, we finalized our proposal to create HCPCS code C9770 (Vitreotomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent), and we assigned this code to APC 1561 (New Technology—Level 24 (\$3,001–\$3,500)) using the geometric mean cost of CPT code 67036. For CY 2022, we continued to assign HCPCS code C9770 to APC 1561 (New Technology—Level 24 (\$3,001–\$3,500)) using the geometric mean cost of CPT code 67036.

CY 2023 was the first year that claims data were available for HCPCS code C9770; therefore, we proposed and finalized a policy to base the payment rate of HCPCS code C9770 on claims data for that code rather than on the

geometric mean cost of CPT code 67036. Given the low number of claims for this procedure, we designated HCPCS code C9770 as a low volume procedure under our universal low volume APC policy and used the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data to calculate an appropriate payment rate for purposes of assigning HCPCS code C9770 to a New Technology APC.

Based on the claims data available for the CY 2023 OPPS/ASC final rule with comment period, we found the median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology fell within the cost band for New Technology APC 1562 (New Technology—Level 25 (\$3,501–\$4,000)). Therefore, we finalized our proposal to assign HCPCS code C9770 to APC 1562 for CY 2023.

For CY 2024, we proposed and finalized that we would delete HCPCS code C9770 effective December 31, 2023 and recognize CPT code 0810T (Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies) starting January 1, 2024 (88 FR 81617 through 81619). We determined the payment rate for CPT code 0810T using the claims data for HCPCS code C9770 and designated CPT code 0810T as a low volume procedure under our universal low volume APC policy and used the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data for HCPCS code C9770 to calculate an appropriate payment rate for purposes of assigning CPT code 0810T to a New Technology APC. For CY 2024, we finalized assignment of CPT code 0810T to APC 1563 (New Technology—Level 26 (\$4,001–\$4,500)) (88 FR 81617 through 81619).

Since CMS recognized CPT code 0810T starting January 1, 2024, we do not have claims data for CPT code 0810T available for CY 2025 rulemaking. However, as HCPCS code C9770 was still in use until December 31, 2023, we propose to determine the

payment rate for CPT code 0810T using the claims data for HCPCS code C9770. This is similar to the policy we finalized for CY 2024. For CY 2025, we propose to designate CPT code 0810T as a low volume procedure under our universal low volume APC policy, given that there are only 34 claims available for HCPCS code C9770 and none for CPT code 0810T. This is below the threshold of 100 claims for a service within a year required to designate a service as a low volume service and apply our universal low volume APC policy. Therefore, we propose to use the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data for HCPCS code C9770 to calculate an appropriate payment rate for purposes of assigning CPT code 0810T to a New Technology APC.

Using all available claims from the 4-year lookback period, based on 34 claims, we determined the geometric mean cost to be \$3,934, the arithmetic mean cost to be \$4,173, and the median cost to be \$4,103. Because the arithmetic mean is the statistical methodology that estimated the highest cost for the service, we propose to use this cost to determine the New Technology APC placement. The arithmetic mean of \$4,173 falls within the cost band for New Technology APC 1563 (New Technology—Level 26 (\$4,001–\$4,500)). Therefore, we propose to assign CPT code 0810T to APC 1563 for CY 2025. Additionally, we propose to perform a similar analysis using updated claims data, including determining if CPT code 0810T continues to meet the criteria for our universal low volume APC policy, in the CY 2025 OPPS/ASC final rule with comment period and update the APC assignment as needed.

Please refer to Table 14 below for the proposed OPPS New Technology APC and status indicator assignments for CPT code 0810T for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 14: FINAL CY 2024 AND PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0810T

HCPCS Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies	T	1563	T	1563

b. BgRT (APC 1521)

Biology Guided Radiation Therapy (BgRT) uses positron-emitting radiopharmaceuticals to control delivery of radiation therapy to treat primary and metastatic lung or bone tumors. During radiation treatment delivery, the same system applies these firing filters to the real-time positron emission tomography (PET) data collected by the radiation treatment delivery machine. Effective January 1, 2024, CMS created HCPCS codes C9794 (Therapeutic radiology simulation-aided field setting; complex, including acquisition of PET and CT imaging data required for radiopharmaceutical-directed radiation therapy treatment

planning (*i.e.*, modeling) and C9795 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance and real-time positron emissions-based delivery adjustments to 1 or more lesions, entire course not to exceed 5 fractions) to describe the modeling and treatment delivery portions of the BgRT service. We assigned HCPCS code C9794 to APC 1521 (New Technology—Level 21 (\$1,901–\$2,000)) and HCPCS code C9795 to APC 1525 (New Technology—Level 25 (\$3,501–\$4,000)) for CY 2024.

For CY 2025, the proposed OPPS payment rates are based on available CY 2023 claims data. As HCPCS codes

C9794 and C9795 were effective January 1, 2024, we do not have any claims data for the service. Therefore, for CY 2025, we propose to continue to assign HCPCS code C9794 to APC 1521 (New Technology—Level 21 (\$1,901–\$2,000)) with a payment rate of \$1,950.50 and HCPCS code C9795 to APC 1525 (New Technology—Level 25 (\$3,501–\$4,000)) with a payment rate of \$3,750.50.

Please refer to Table 15 below for the proposed OPPS New Technology APC and status indicator assignment for HCPCS codes C9794 and C9795 for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 15: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BIOLOGY GUIDED RADIATION THERAPY

HCPCS	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9794	Therapeutic radiology simulation-aided field setting; complex, including acquisition of PET and CT imaging data required for radiopharmaceutical-directed radiation therapy treatment planning (<i>i.e.</i> , modeling)	S	1521
C9795	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance and real-time positron emissions-based delivery adjustments to 1 or more lesions, entire course not to exceed 5 fractions	S	1525

c. Blinded Procedure for NYHA Class III/IV Heart Failure (APC 1590)

A randomized, double-blinded, controlled IDE study is currently in progress for the V-Wave interatrial shunt. The V-Wave interatrial shunt is for patients with severe symptomatic heart failure and is designed to regulate left atrial pressure in the heart. All participants who passed initial screening for the study receive a right heart catheterization procedure described by CPT code 93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed). Participants assigned to the experimental group also receive the V-Wave interatrial shunt procedure while participants assigned to the control group only receive right heart catheterization. The developer of V-Wave was concerned that the current coding of these services by Medicare would reveal to the study participants whether they had received the interatrial shunt because an additional procedure code, CPT code 93799 (Unlisted cardiovascular service or procedure), would be included on the claims for participants receiving the interatrial shunt. Therefore, for CY 2020, we created a temporary HCPCS code to describe the V-Wave interatrial shunt procedure for both the experimental group and the control group in the study. Specifically, we established HCPCS code C9758 (Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization,

trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study) to describe the service, and we assigned the service to New Technology APC 1589 (New Technology—Level 38 (\$10,001–\$15,000)) with a payment rate of \$12,500.50.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85946), we stated that we believe similar resources and device costs are involved with the V-Wave interatrial shunt procedure and the Corvia Medical interatrial shunt procedure (HCPCS code C9760), except that payment for HCPCS codes C9758 and C9760 differs based on how often the interatrial shunt is implanted when each code is billed. An interatrial shunt is implanted one-half of the time HCPCS code C9758 is billed, whereas an interatrial shunt is implanted every time HCPCS code C9760 is billed. Accordingly, for CY 2021, we reassigned HCPCS code C9758 to New Technology APC 1590 (New Technology—Level 39 (\$15,001–\$20,000)), which reflects the cost of furnishing the interatrial shunt one-half of the time the procedure is performed.

For CY 2022, we used the same claims data from CY 2019 that we did for the CY 2021 OPPS/ASC final rule with comment period. Because there were no claims reporting HCPCS code C9758, we continued to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of \$17,500.50 for CY 2022. For CY 2023 we used claims data from

CY 2019 through CY 2022. Because there were no claims reporting HCPCS code C9758 in CY 2023 or CY 2024, we continued to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of \$17,500.50 for CY 2023 and 2024.

For CY 2025, the OPPS payment rates are proposed to be based on available CY 2023 claims data. There were only three claims for HCPCS code C9758 within this time period. As this is below the threshold of 100 claims for a service within a year, we would designate C9758 as a low volume service and apply our universal low volume APC policy. Under this policy, we would use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign HCPCS code C9758 to the appropriate New Technology APC. Given our proposal to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy, we propose to continue assigning HCPCS code C9758 to New Technology New Technology APC 1590 with a proposed payment rate of \$17,500.50.

Please refer to Table 16 below for the proposed OPPS New Technology APC and status indicator assignments for HCPCS code C9758 for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 16: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BLINDED INTRATRIAL SHUNT PROCEDURE

HCPCS	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9758	Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	T	1590

d. Bronchoscopy With Transbronchial Ablation of Lesion(s) by Microwave Energy (APC 1562)

Effective January 1, 2019, CMS established HCPCS code C9751 (Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)). This microwave ablation procedure utilizes a flexible catheter to access the lung tumor via a working channel and may be used as an alternative procedure to a percutaneous microwave approach. Based on our review of the New Technology APC application for this service and the service's clinical similarity to existing services paid under the OPPS, we estimated the likely cost of the procedure would be between \$8,001 and \$8,500. We assigned the procedure to New Technology APC 1571 (New Technology—Level 34 (\$8,001–\$8,500)) for CY 2019.

In claims data available from CY 2019 for the CY 2021 OPPS/ASC final rule with comment period, there were four claims reported for bronchoscopy with transbronchial ablation of lesions by microwave energy. Given the low

volume of claims for the service, we proposed for CY 2021 to apply the universal low volume APC policy we adopted in CY 2019, under which we utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs to determine an appropriate payment rate for purposes of assigning bronchoscopy with transbronchial ablation of lesions by microwave energy to a New Technology APC. We found the geometric mean cost for the service to be approximately \$2,693, the arithmetic mean cost to be approximately \$3,086, and the median cost to be approximately \$3,708. The median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology fell within the cost band for New Technology APC 1562 (New Technology—Level 25 (\$3,501–\$4,000)). Therefore, we assigned HCPCS code C9751 to APC 1562 for CY 2021.

In CY 2022, we again used the claims data from CY 2019 for HCPCS code C9751. Because the claims data was unchanged from when it was used in CY 2021, the values for the geometric mean cost (\$2,693), the arithmetic mean cost (\$3,086), and the median cost (\$3,708) for the service described by HCPCS code C9751 remained the same. The highest cost metric using these methodologies was again the median and within the cost band for New Technology APC 1562 (New Technology—Level 25

(\$3,501–\$4,000)). Therefore, we continued to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 (\$3,501–\$4,000)), with a payment rate of \$3,750.50 for CY 2022.

There have been no separately payable claims reported for HCPCS code C9751 since 2019. Therefore, we continued to use claims from CY 2019 to determine to payment rate for this service; and the reported claims are the same claims used to calculate the payment rate for the service in the CY 2023 and CY 2024 OPPS/ASC final rules with comment period. We continued to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 (\$3,501–\$4,000)), with a payment rate of \$3,750.50.

For CY 2025, there are no new claims for HCPCS code C9751. Given our proposal to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy, we propose for CY 2025 to continue to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 (\$3,501–\$4,000)), with a payment rate of \$3,750.50.

Please refer to Table 17 below for the proposed OPPS New Technology APC and status indicator assignments for HCPCS code C9751 for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 17: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9751

HCPCS Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies])	T	1562

e. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APCs 1520 and 1522)

For CY 2025, the OPPS payment rates for the service described by CPT codes 78431, 78432, and 78433 are proposed to be based on available CY 2023 claims data. CPT code 78431 had over 26,000 single frequency claims in CY 2023. The geometric mean for CPT code 78431 is approximately \$2,350. The geometric mean falls within APC 1522 (New Technology—Level 22 (\$2,001–\$2,500)) with a payment rate of \$2,250.50, which is the current APC assignment for this service. Therefore, we propose, for CY 2025, to assign CPT code 78431 to APC 1522 (New Technology—Level 22 (\$2,001–\$2,500)) with a payment rate of \$2,250.50.

There were only 19 single frequency claims in CY 2023 for CPT code 78432. As this is below the threshold of 100 claims for a service within a year, we

propose to apply our universal low volume New Technology APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT code 78432 to the appropriate New Technology APC. Using available claims data from CY 2021, CY 2022, and CY 2023, our analysis found the geometric mean cost of the service is approximately \$1,762, the arithmetic mean cost of the service is approximately \$1,923, and the median cost of the service is approximately \$1,544. The arithmetic mean is the statistical methodology that estimates the highest cost for the service. The arithmetic mean cost of \$1,923, is an amount that is above the cost band for APC 1520 (New Technology—Level 20 (\$1,801–\$1,900)), where the procedure is currently assigned. Therefore, we propose, for CY 2025, to assign CPT code 78432 to APC 1521 (New Technology—Level 21

(\$1,901–\$2,000)) with a payment rate of \$1950.50.

There were over 1,400 single frequency claims for CPT code 78433 in CY 2023. The geometric mean for CPT code 78433 is approximately \$2,010, which is an amount that is above the current New Technology APC cost band APC 1521 (New Technology—Level 21 (\$1,901–\$2,000)) to which it is assigned. Therefore, for CY 2025, we propose to reassign CPT code 78433 to APC 1522 (New Technology—Level 22 (\$2,001–\$2,500)) with a payment rate of \$2,250.50.

Please refer to Table 18 below for the proposed OPPS New Technology APC and status indicator assignments for CPT codes 78431, 78432, and 78433 for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to the CY 2025 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 18: FINAL CY 2024 AND PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 78431, 78432, AND 78433

CPT Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	S	1522	S	1522
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability);	S	1520	S	1521
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan	S	1521	S	1522

f. CardiAMP (APC 1590)

The CardiAMP cell therapy IDE studies are two randomized, double-blinded, controlled IDE studies: the CardiAMP Cell Therapy Chronic Myocardial Ischemia Trial¹⁶ and the CardiAMP Cell Therapy Heart Failure Trial.¹⁷ The two trials are designed to

¹⁶ ClinicalTrials.gov. "Randomized Controlled Pivotal Trial of Autologous Bone Marrow Cells Using the CardiAMP Cell Therapy System in Patients With Refractory Angina Pectoris and Chronic Myocardial Ischemia." Accessed May 10, 2022. <https://clinicaltrials.gov/ct2/show/NCT03455725?term=NCT03455725&rank=1>.

¹⁷ ClinicalTrials.gov. "Randomized Controlled Pivotal Trial of Autologous Bone Marrow Mononuclear Cells Using the CardiAMP Cell

investigate the safety and efficacy of autologous bone marrow mononuclear cell treatment for the following: (1) patients with medically refractory and symptomatic ischemic cardiomyopathy; and (2) patients with refractory angina pectoris and chronic myocardial ischemia. On April 1, 2022, we established HCPCS code C9782 to describe the CardiAMP cell therapy IDE studies and assigned HCPCS code C9782 to APC 1574 (New Technology—Level 37 (\$9,501–\$10,000)) with the status indicator "T." We subsequently

Therapy System in Patients With Post Myocardial Infarction Heart Failure." Accessed May 10, 2022. <https://clinicaltrials.gov/ct2/show/NCT02438306>.

revised the descriptor for HCPCS code C9782 to: (Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound,

fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study) to clarify the inclusion of the Helix trans endocardial injection catheter device in the descriptor. Additionally, we determined that APC 1590 (New Technology—Level 39 (\$15,001–\$20,000)) most accurately accounted for the resources associated with furnishing the procedure described by HCPCS code C9782.

For CY 2025, the OPPS payment rates are proposed to be based on available CY 2023 claims data. We have identified three single frequency paid claims for C9782 for ratesetting for CY 2025. As this is below the threshold of 100 claims for a service within a year, we would designate C9782 as a low volume service and apply our universal low

volume APC policy. Under this policy, we would use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT codes C9782 to the appropriate New Technology APC. Our analysis of the data found the geometric mean cost of the service is approximately \$18,045, the arithmetic mean cost of the service is approximately \$18,332, and the median cost of the service is approximately \$20,394. The median was the statistical methodology that estimated the highest cost for the service. However, because there are only three claims for HCPCS code C9782 from the CY 2023 claims data, we have concerns that the universal low volume APC policy calculations do not

accurately capture the cost of the service. Given our proposal to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy, we therefore propose to continue to assign HCPCS code C9782 to New Technology APC 1590 with a payment rate of \$17,050.50.

Please refer to Table 19 below for the proposed OPPS New Technology APC and status indicator assignments for HCPCS code C9782 for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 19: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE CARDIAMP CELL THERAPY IDE STUDIES

HCPCS Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9782	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study	T	1590

g. Atherosclerosis Imaging-Quantitative Computer Tomography (AI-QCT) (APC 1511)

Atherosclerosis Imaging-Quantitative Computer Tomography (AI-QCT) is a Software as a Service (SaaS) that assesses the extent of coronary artery disease severity. This procedure is performed to quantify the extent of coronary plaque and stenosis in patients who have undergone coronary computed tomography analysis (CCTA). The AMA CPT Editorial Panel established the following four codes associated with this service, effective January 1, 2021:

0623T: Automated quantification and characterization of coronary

atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission, computerized analysis of data, with review of computerized analysis output to reconcile discordant data, interpretation and report.

0624T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission.

0625T: Automated quantification and characterization of coronary

of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography.

0626T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; review of computerized analysis output to reconcile discordant data, interpretation and report.

Of these four CPT codes, only CPT code 0625T was determined to be separately payable in the OPPS and was assigned to status indicator = “S” (Procedure or Service, Not Discounted

When Multiple) starting October 1, 2022. We assigned CPT code 0625T to a separately payable status indicator based on the technology and its potential utilization in the HOPD setting, our evaluation of the service, as well as input from our medical advisors. The procedure was assigned to APC 1511 (New Technology—Level 11 (\$900–\$1,000)) with a payment rate of \$950.50.

For CY 2024, the OPPTS payment rates were proposed to be based on available CY 2022 claims data. There were 37 claims for CPT code 0625T during this time period. As this was below the threshold of 100 claims for a service within a year, we explained that we could propose to designate CPT code 0625T as a low volume service under our universal low volume New Technology APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign code 0625T to the appropriate New Technology APC. We found the geometric mean cost for the service to be approximately \$3.70, the arithmetic mean cost to be approximately \$4.10, and the median cost to be approximately \$3.50. Under our universal low volume New Technology APC policy, we would use the greatest of the statistical methodologies, the arithmetic mean, to assign CPT code 0625T to New Technology 1491 (New Technology Level 1A—(0–\$10)) with a

payment rate of \$5.00. However, we acknowledged that, because CPT code 0625T was only made separately payable as part of the OPPTS in October 2022, and, therefore, the claims available only reflect two months of data, we were concerned that we do not have sufficient claims data to justify reassignment to another New Technology APC (66 FR 69902). Therefore, consistent with our current policy to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment (66 FR 59902), for CY 2024 we adopted as final our proposal to maintain CPT code 0625T's current assignment to APC 1511 (New Technology—Level 11 (\$901–\$1,000)) with a payment rate of \$950.50.

For setting CY 2025 payment rates, there were only three separately payable claims in the CY 2023 data reported for CPT code 0625T that have a geometric mean of approximately \$180, which is substantially lower than the current payment rate of \$950.50. In CY 2022 and CY 2023, there are a total of 40 separately payable claims reported for CPT code 0625T, but it is unlikely that a service with a current payment rate of \$950.50 would have a geometric mean of \$4.20, an arithmetic mean of \$6.60, and a median of \$3.52. These findings lead to uncertainty about the appropriate payment rate for the service described by CPT code 0625T. A review of the evidence submitted by the

developer of the procedure when this procedure was originally assigned to a New Technology APC before any claims data were available indicated the procedure had a cost between \$901 and \$1,000. Claims assigned to CPT code 0625T from CY 2021 and CY 2022, indicate that the cost of the procedure is less than \$10, which would not appear to cover basic cost of this procedure including computing time, generating a report, and having medical personnel interpret the report. For CY 2023, the geometric mean cost of approximately \$180 based on three claims may better reflect the cost of the procedure described by CPT code 0625T, but there are not enough claims to be confident about the result. Therefore, we propose to use our authority under section 1833(t)(2)(E) for CY 2025 to continue to assign CPT code 0625T to APC 1511 (New Technology—Level 11 (\$901–\$1,000)) with a payment rate of \$950.50 based on the data currently available to us, which we believe best reflects the cost of the service as described by the New Technology APC application.

Refer to Table 20 below for the proposed OPPTS New Technology APC and status indicator assignments for CPT code 0625T for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to the CY 2025 OPPTS/ASC proposed rule via the internet on the CMS website.

TABLE 20: PROPOSED CY 2025 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR ATHEROSCLEROSIS IMAGING-QUANTITATIVE COMPUTER TOMOGRAPHY (AI-QCT) HCPCS CODE 0625T

HCPCS Code	Long Descriptor	Proposed CY 2025 OPPTS SI	Proposed CY 2025 OPPTS APC
0625T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography	S	1511

h. Corvia Medical Interatrial Shunt Procedure (APC 1592)

On July 1, 2020, we established HCPCS code C9760 (Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter

implantation of interatrial shunt, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without

guidance (for example, ultrasound, fluoroscopy) performed in an approved investigational device exemption (ide) study, performed in an approved investigational device exemption (ide) study) to facilitate payment for the

implantation of the Corvia Medical interatrial shunt.

As we stated in the CY 2021 OPPS final rule with comment period (85 FR 85947), we believe that similar resources and device costs are involved with the Corvia Medical interatrial shunt procedure and the V-Wave interatrial shunt procedure. Unlike the V-Wave interatrial shunt, which is implanted half the time the associated interatrial shunt procedure described by HCPCS code C9758 is billed, the Corvia Medical interatrial shunt is implanted every time the associated interatrial shunt procedure (HCPCS code C9760) is billed. Therefore, for CY 2021, we assigned HCPCS code C9760 to New

Technology APC 1592 (New Technology—Level 41 (\$25,001–\$30,000)) with a payment rate of \$27,500.50. We also modified the code descriptor for HCPCS code C9760 to remove the phrase “or placebo control,” from the descriptor. In CY 2022, we generally used the same claims data as was used in the CY 2021 OPPS final rule to set the payment rates for that year. Accordingly, because there were no claims for this service in CY 2019, we continued to assign HCPCS code C9760 to New Technology APC 1592 in CY 2022. There continued to be no claims data for this service in CYs 2021 or 2022, so we continued to assign HCPCS code C9760 to New Technology

APC 1592 in CY 2023 and CY 2024, the years for which we used CY 2021 and CY 2022 data, respectively, for ratesetting.

For CY 2025, the OPPS payment rates are proposed to be based on available CY 2023 claims data. There were no claims for HCPCS code C9760 in CY 2023. Therefore, we propose to continue assigning HCPCS code C9760 to New Technology APC 1592.

Refer to Table 21 below for the proposed OPPS New Technology APC and status indicator assignments for CPT code C9760. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 21: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR NON-BLINDED INTRATRIAL SHUNT PROCEDURE

HCPCS	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9760	(Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (for example, ultrasound, fluoroscopy) performed in an approved investigational device exemption (ide) study	T	1592

i. DARI Motion Procedure (APC 1505)

Effective January 1, 2022, CPT code 0693T (Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report) is associated with the DARI Motion Procedure, a service that provides human motion analysis to aid clinicians in pre- and post-operative surgical intervention and in making other treatment decisions, including selecting the best course of physical therapy and rehabilitation. The technology consists of eight cameras that surround a patient, which send live video to a computer workstation that analyzes the video to create a 3D reconstruction of the patient without the

need for special clothing, markers, or devices attached to the patient's clothing or skin. For CY 2022, we assigned CPT code 0693T to New Technology APC 1505 (New Technology—Level 5 (\$301–\$400)). For CY 2023, the OPPS payment rates were based on claims submitted between January 1, 2021, and December 31, 2021, processed through June 30, 2022. Due to its effective date of January 1, 2022, there were no claims available for CPT code 0693T for rate setting in CY 2023. Therefore, in CY 2023, we continued to assign CPT code 0693T to New Technology APC 1505. For CY 2024, there were no claims available, so we again continued to assign CPT code 0693T to New Technology APC 1505.

For CY 2025, the OPPS payment rates are proposed based on available CY 2023 claims data. Although CPT code 0693T was effective January 1, 2022, we have no claims data at this time. Because we have no claims data, for CY 2025, we propose to continue to assign CPT code 0693T to APC 1505 with a proposed payment rate of \$350.50.

Please refer to Table 22 below for the proposed OPPS New Technology APC and status indicator assignments for CPT code 0693T for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 22: PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE DARI MOTION PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0693T	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report	S	1505

j. Instillation of Anti-Neoplastic Pharmacologic/Biologic Agent Into Renal Pelvis (APC 1558)

Effective October 1, 2023, CMS established HCPCS code C9789 (Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed) and assigned it to New Technology APC 1559 (New Technology—Level 22 (\$2,001–\$2,500)), with a payment rate of \$2,250.50 based on our review of the clinical and resource characteristics of this service.

This code may be used to describe the unique procedure associated with the

administration of the drug described by HCPCS code J9281 (Mitomycin pyelocalyceal instillation, 1 mg) or similar products. HCPCS code J9281 may be used to describe the product, Jelmyto (mitomycin for pyelocalyceal solution). The FDA approved Jelmyto in 2020, and the FDA approved indication and usage for Jelmyto is as an alkylating drug indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG–UTUS).¹⁸

Because we created HCPCS code C9789 effective October 1, 2023, we have limited claims data from CY 2023 available for CY 2025 rulemaking. Specifically, we only have 6 claims available. Given our proposal to

maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy, we therefore propose to continue to assign HCPCS code C9789 to New Technology APC 1559 (New Technology—Level 22 (\$2,001–\$2,500)).

Please refer to Table 23 below for the proposed OPPS New Technology APC and status indicator assignments for CPT code C9789 for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 23: FINAL CY 2024 AND PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9789

HCPCS Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9789	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed	T	1559	T	1559

k. LimFlow TADV Procedure CPT Code 0620T (APC 1579)

The LimFlow TADV procedure, which is described by CPT code 0620T (Endovascular venous arterialization, tibial or peroneal vein, with

transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural

roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed), is an endovascular procedure that is used to treat patients with chronic limb-

¹⁸ Jelmyto Package Insert. 01/14/2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/211728s002lbl.pdf.

threatening ischemia. According to the developer, these patients are no longer eligible for conventional endovascular or open bypass surgery to treat their artery blockage, and without this procedure, they are likely to face limb amputation.

CPT code 0620T was established in January 2021 and was assigned to APC 5194 (Level 4 Endovascular Procedures) with a payment rate of approximately \$17,400, which is the highest-paying APC for endovascular procedures. While we proposed to continue to assign CPT code 0620T to APC 5194 for CY 2024, we finalized a reassignment to a New Technology APC with a higher payment rate based on comments received expressing concern that the low payment rate of the procedure would discourage providers from performing the procedure and deny access to the procedure. To determine the appropriate New Technology APC assignment for CY 2024, we looked at the available cost information. There were only 15 claims for the procedure

for CY 2021 and CY 2022, so the LimFlow TADV procedure was subject to our new technology procedure low volume APC policy. An analysis of the median, arithmetic mean, and geometric mean of CPT code 0620T for CY 2024 rulemaking found that the median was approximately \$25,800, the arithmetic mean was approximately \$28,600, and the geometric mean was approximately \$26,700. Because the arithmetic mean had the highest value of the three cost statistics, for CY 2024, we assigned CPT code 0620T to New Technology APC 1578 (New Technology—Level 41 (\$25,001–\$30,000)) with a payment rate of \$27,500.50.

For CY 2025, the OPPS payment rates are proposed to be based on available CY 2023 claims data. There are only six single frequency claims for CPT code 0620T in the CY 2023 claims data. As this is below the threshold of 100 claims for a service within a year, we propose to again apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean

cost, or median cost based on up to 4 years of claims data to assign HCPCS code 0620T to the appropriate New Technology APC. Considering the available claims data for HCPCS code 0620T, the arithmetic mean is approximately \$35,000; the median is approximately \$36,000; and the geometric mean cost is approximately \$33,000. Of these, the median is the statistical methodology that estimates the highest cost for the service. The payment rate calculated using this methodology falls within the cost band for New Technology APC 1579 (New Technology—Level 42 (\$30,001–\$40,000)) with a payment rate of \$35,000.50. Therefore, for CY 2024, we propose to assign HCPCS code 0620T to New Technology APC 1579.

Please refer to Table 24 for the proposed New Technology APC and status indicator assignments for CPT code 0620T. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 24: PROPOSED CY 2025 OPPS APC STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0620T

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0620T	Endovascular venous arterialization, tibial or peroneal vein, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed	S	1579

1. Liver Histotripsy Service (APC 1576)

CPT code 0686T (Histotripsy (*i.e.*, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance) was first effective July 1, 2021, and describes the histotripsy service associated with the use of the HistoSonics system. Histotripsy is a non-invasive, non-thermal, mechanical process that uses a focused beam of sonic energy to destroy cancerous liver tumors and is currently in a non-

randomized, prospective clinical trial to evaluate the efficacy and safety of the device for the treatment of primary or metastatic tumors located in the liver.¹⁹ When HCPCS code 0686T was first effective, the histotripsy procedure was designated as a Category A IDE clinical study (NCT04573881). Since devices in Category A IDE studies are excluded

¹⁹ *ClinicalTrials.gov*. “The HistoSonics System for Treatment of Primary and Metastatic Liver Tumors Using Histotripsy (#HOPE4LIVER) (#HOPE4LIVER).” Accessed May 10, 2022. <https://clinicaltrials.gov/ct2/show/study/NCT04573881>.

from Medicare payment, payment for CPT code 0686T only reflected the cost of the service that is performed (absent the cost of the device) each time it is reported on a claim. On March 2, 2023, the histotripsy IDE clinical study was re-designated as a Category B (Non-experimental/Investigational) IDE study. Due to this new designation, payment for CPT code 0686T in CY 2024 reflects payment for both the service that is performed and the device used each time it is reported on a claim. For CY 2024, we assigned CPT code 0686T to

New Technology APC 1576 (New Technology—Level 39 (\$15,001–\$20,000)) with a payment rate of \$17,500.50.

For CY 2025, OPPS payment rates are proposed to be based on available CY 2023 claims data. We have identified one claim for CPT code 0686T within the CY 2023 claims data. As the available claims data is below the threshold of 100 claims for a service within a year, we would propose to designate CPT code 0686T as a low volume service under our universal low volume APC policy, and use the highest

of the geometric mean cost, arithmetic mean cost, or median cost to assign CPT code 0686T to the appropriate New Technology APC. However, because there is only a single claim in the CY 2023 data, we have concerns that the universal low volume APC policy calculations do not accurately capture the cost of the service.

Given our proposal to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-

volume APC policy, and based on the fact that there have only been 3 claims for CPT code 0686T in the prior 4-year period, we propose to continue to assign CPT code 0686T to APC 1576 (New Technology—Level 39 (\$15,001–\$20,000)) with a payment rate of \$17,500.50 as shown in Table 25.

Please refer to Table 25 below for the proposed OPPS New Technology APC and status indicator assignments for CPT code 0686T for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule.

TABLE 25: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER HISTOTRIPSY SERVICE

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0686T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	S	1576

m. LiverMultiScan Service (APC 1511)

Effective July 1, 2021, CPT codes 0648T (Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session; single organ) and 0649T (Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure); single organ (list separately in addition to code for primary procedure)) are associated with the LiverMultiScan service. LiverMultiScan is a Software as a medical Service (SaaS) that is intended to aid the diagnosis and management of chronic liver disease, the most prevalent of which is Non-Alcoholic Fatty Liver Disease (NAFLD). It provides standardized, quantitative

imaging biomarkers for the characterization and assessment of inflammation, hepatocyte ballooning, and fibrosis, as well as steatosis, and iron accumulation. LiverMultiScan receives MR images acquired from patients' providers and analyzes the images using their proprietary Artificial Intelligence (AI) algorithms. It then sends the providers a quantitative metric report of the patient's liver fibrosis and inflammation. In accordance with our SaaS add-on codes policy (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes. Thus, CPT code 0649T, the add-on code for LiverMultiScan, is assigned to the identical APC and status indicator as CPT code 0648T, the standalone code for the same service. For CY 2024, we assigned CPT codes 0648T and 0649T to New Technology APC 1511 (New Technology—Level 11 (\$901–\$1,000) with a payment rate of \$950.50.

For CY 2025, the OPPS payment rates are proposed to be based on available CY 2023 claims data. We identified 71 claims for CPT code 0648T and 72

claims CPT code 0649T for CY 2023. As this is below the threshold of 100 claims for each code within a year, we propose to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT codes 0648T and 0649T to the appropriate New Technology APC. There are available claims data from CY 2021 and CY 2022 for CPT codes 0648T and 0649T. Our analysis of the combined data, 114 claims for CPT code 0648T and 115 claims for CPT code 0649T, yielded a geometric mean cost of approximately \$180, an arithmetic mean cost of approximately \$234, and a median cost of approximately \$197. We believe it is appropriate to utilize our universal low volume APC policy to assign the LiverMultiScan service to a New Technology APC because we believe that the combined claims data from CY 2021 to CY 2023 provide sufficient claims to capture the cost of the service. The arithmetic mean was the statistical methodology that estimated the highest cost for CPT codes 0648T and 0649T. Therefore, we

propose to reassign CPT codes 0648T and 0649T to New Technology APC 1504 (New Technology—Level 4 (\$201–\$300)) with a payment rate of \$250.50 as shown in Table 26.

TABLE 26: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER MULTISCAN SERVICE

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0648T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session; single organ	S	1504
0649T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	S	1504

n. Optellum Lung Cancer Prediction (LCP) (APC 1508)

CPT codes 0721T (Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging) and 0722T (Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (list separately in addition to code for primary procedure)) became effective July 1, 2022, and are associated with the Optellum LCP technology. The Optellum LCP applies an algorithm to a patient’s CT scan to produce a raw risk score for a patient’s pulmonary nodule. The physician uses the risk score to quantify the risk of lung cancer and to determine what the next management step should be for the patient (for example, CT surveillance versus invasive procedure). In accordance with our SaaS add-on codes policy (87 FR

72032 to 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes. Thus, CPT code 0722T, the add-on code for the Optellum LCP service, is assigned to the identical APC and status indicator as CPT code 0721T, the standalone code for the same service. For CY 2024, we assigned CPT codes 0721T and 0722T to APC New Technology 1508 (New Technology—Level 8 (\$601–\$700)). For CY 2025, the OPPS payment rates are proposed to be based on available CY 2023 claims data. We identified three claims for CPT codes 0721T and 0722T for ratesetting for CY 2025. As this is below the threshold of 100 claims for a service within a year, we would usually propose to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT codes 0721T and 0722T to the appropriate New Technology APC. There are available claims data only from CY 2023 for CPT codes 0721T and 0722T. Our analysis of the data for CPT

code 0721T found the geometric mean cost of the service is approximately \$84, the arithmetic mean cost of the service is approximately \$98, and the median cost of the service is approximately \$130. We did not identify any reported claims for CPT code 0722T. However, because there are only three claims for the Optellum LCP service and these claims show a much lower cost than would be expected based on the current APC assignment of this service, we have concerns that the universal low volume APC policy calculations do not accurately capture the cost of the service. We believe it is appropriate to continue assigning the Optellum LCP service to its current APC assignment determined from the New Technology APC application review due to insufficient claims data to capture the cost of this service at this time. Given our proposal to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy, we propose to continue to assign CPT codes

0721T and 0722T to New Technology APC 1508 (New Technology—Level 8 (\$601–\$700)) with a proposed payment rate of \$650.50.

Please refer to Table 27 below for the proposed OPPS New Technology APC and status indicator assignments for HCPCS codes 0721T and 0722T for CY

2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 27: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE OPTELLUM LCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	S	1508
0722T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (list separately in addition to code for primary procedure)	S	1508

o. Quantitative Magnetic Resonance (QMR) for Analysis of Tissue Composition (APC 1511)

Effective January 1, 2022, CPT codes 0697T (Quantitative magnetic resonance for analysis of tissue composition (*e.g.*, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (*e.g.*, organ, gland, tissue, target structure) during the same session; multiple organs) and 0698T (Quantitative magnetic resonance for analysis of tissue composition (*e.g.*, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic mri examination of the same anatomy (*e.g.*, organ, gland, tissue, target structure); multiple organs (list separately in addition to code for primary procedure)) are associated with the CoverScan Software as a medical Service (SaaS). This service is a medical image management and processing

software package that analyzes MR data and provides quantified metrics of multiple organs such as the heart, lungs, liver, spleen, pancreas, and kidney. In accordance with our SaaS add-on codes policy (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes. Thus, CPT code 0698T, the add-on code for CoverScan is be assigned to the identical APC and status indicator as CPT code 0697T, the standalone code for the same service. For CY 2024, we assigned CPT codes 0697T and 0698T to New Technology APC 1511 (New Technology—Level 11 (\$900–\$1,000)).

For CY 2025, the OPPS payment rates are proposed to be based on available CY 2023 claims data. We identified 46 claims for CPT code 0698T and no claims for CPT code 0697T in CY 2023. As this is below the threshold of 100 claims for a service within a year, we propose to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up

to 4 years of claims data to assign CPT codes 0697T and 0698T to the appropriate New Technology APC. There are available claims data from CY 2022 and CY 2023 for CPT code 0697T and 0698T. Our analysis of the combined data, zero claims for CPT code 0697T and 46 claims for CPT code 0698T, yielded a geometric mean cost of approximately \$444, an arithmetic mean cost of approximately \$622, and a median cost of approximately \$786. The median cost is the statistical methodology that estimates the highest cost for CPT codes 0697T and 0698T. Therefore, we propose, for CY 2025, to reassign CPT codes 0697T and 0698T to APC 1509 (New Technology—Level 9 (\$701–\$800)) with a payment rate of \$750.50.

Refer to Table 28 below for the proposed OPPS New Technology APC and status indicator assignments for CPT codes 0697T and 0698T for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 28: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE QMRCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0697T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session; multiple organs	S	1509
0698T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic mri examination of the same anatomy (eg, organ, gland, tissue, target structure); multiple organs (list separately in addition to code for primary procedure)	S	1509

p. Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP) (APC 1511)

Effective July 1, 2022, CPT codes 0723T (Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session) and 0724T (Quantitative magnetic resonance cholangiopancreatography (QMRCP), including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (list separately in addition to code for primary procedure)) are associated with the QMRCP Software as a medical Service (SaaS). The service performs quantitative assessment of the biliary tree and gallbladder. It uses a proprietary algorithm that produces a three-dimensional reconstruction of the biliary tree and pancreatic duct and also provides precise quantitative information of biliary tree volume and

duct metrics. In accordance with our SaaS add-on codes policy (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes. Consistent with our SaaS add-on codes policy, CPT code 0724T, the add-on code for QMRCP is assigned to the identical APC and status indicator as CPT code 0723T, the standalone code for the same service. For CY 2024, we assigned CPT codes 0723T and 0724T to New Technology APC 1511 (New Technology—Level 11 (\$900–\$1,000)).

For CY 2025, the OPPS payment rates are proposed to be based on available CY 2023 claims data. We identified 3 claims for CPT code 0724T and no claims for CPT code 0723T in CY 2023. As this is below the threshold of 100 claims for a service within a year, we would usually propose to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT codes 0723T and 0724T to the appropriate New Technology APC. There is only a single claim from CY 2022 for CPT code 0724T and no claims for CPT code 0723T. For CY 2023, we received 3 claims for CPT

code for CPT 0724T and no claims for CPT code 0723T. Our analysis of the combined CY 2022 and CY 2023 data for CPT code 0723T and 0724T found the geometric mean cost of the service is approximately \$26, the arithmetic mean cost of the service is approximately \$26, and the median cost of the service is approximately \$27. However, because there are only three claims for CPT codes 0723T and 0724T and these claims show costs far below what would be expected for these services given their current APC assignments, we have concerns that the universal low volume APC policy calculations do not accurately capture the cost of the service. Given our proposal to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy, we propose to continue to assign the CPT codes 0723T and 0724T to New Technology APC 1511 (New Technology—Level 11 (\$901–\$1,000)) with a payment rate of \$950.50.

Refer to Table 29 below for the proposed OPPS New Technology APC and status indicator assignments for

CPT codes 0723T and 0724T for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to

this proposed rule via the internet on the CMS website.

TABLE 29: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE QMRCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session	S	1511
0724T	Quantitative magnetic resonance cholangiopancreatography (QMRCP), including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (list separately in addition to code for primary procedure)	S	1511

q. Scalp Cooling (APC 1514)

CPT code 0662T (Scalp cooling, mechanical; initial measurement and calibration of cap) became effective on July 1, 2021, to describe initial measurement and calibration of a scalp cooling device for use during chemotherapy administration to prevent hair loss. According to Medicare's National Coverage Determination (NCD) policy, specifically, NCD 110.6 (Scalp Hypothermia During Chemotherapy to Prevent Hair Loss), the scalp cooling cap itself is classified as an incident to supply to a physician service, and would not be paid under the OPPS; however, interested parties have indicated that there are substantial resource costs of around \$1,900 to \$2,400 associated with calibrating and fitting the cap. CPT guidance states that CPT code 0662T should be billed once per chemotherapy session, which we interpret to mean once per course of chemotherapy. Therefore, if a course of chemotherapy involves, for example, 6 or 18 sessions, HOPDs should report

CPT 0662T only once for that 6 or 18 therapy sessions. For CY 2022, we assigned CPT code 0662T to APC New Technology 1520 (New Technology—Level 20 (\$1,801–\$1,900)) with a payment rate of \$1,850.50. For CY 2023, we did not have any claims data, so we continued to assign CPT code 0662T to APC 1520. For CY 2024 we finalized reassignment of CPT code 0662T to APC 1514 (New Technology—Level 14 (\$1,201–\$1,300)) with a payment rate of \$1,250.50 based on 11 single frequency claims.

For CY 2025, the OPPS payment rates are proposed to be based on available CY 2023 claims data. The Scalp Cooling service became effective in the OPPS in CY 2022, and we have identified 38 single frequency paid claims for CPT code 0662T for CY 2023. As this is below the threshold of 100 claims for a service within a year, we propose to designate CPT code 0662T as a low volume service under our universal low volume APC policy and to use the highest of the geometric mean cost,

arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the service to the appropriate New Technology APC. Based on our review of the available claims, the geometric mean cost for CPT code 0662T is approximately \$841; the median is approximately \$1,351; and the arithmetic mean is approximately \$1,361. Therefore, for CY 2025, we propose to designate this service as a low volume service under our universal low volume APC policy and to reassign CPT code 0662T to APC 1515 (New Technology—Level 15 (\$1,301–\$1,400)) with a payment rate of \$1,350.50 for CY 2025 based on the arithmetic mean of approximately \$1,361.

Refer to Table 30 below for the current and proposed OPPS New Technology APC and status indicator assignments for CPT code 0662T. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 30: FINAL CY 2024 AND PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR SCALP COOLING

HCPCS	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	S	1514	S	1515

r. Supervised Visits for Esketamine Self-Administration (APCs 1513 and 1518)

On March 5, 2019, FDA approved Spravato™ (esketamine) nasal spray, used in conjunction with an oral antidepressant, for treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (treatment-resistant depression (TRD)). This is the first FDA approval of esketamine for any use.

Esketamine is a noncompetitive N-methyl D-aspartate (NMDA) receptor antagonist. It is a nasal spray supplied as an aqueous solution of esketamine hydrochloride in a vial with a nasal spray device. Each device delivers two sprays containing a total of 28 mg of esketamine. Patients would require either two (2) devices (for a 56 mg dose) or three (3) devices (for an 84 mg dose) per treatment.

Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by esketamine nasal spray administration, and the potential for misuse of the product, it is only available through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. The Spravato™ REMS program requires the esketamine nasal spray to be dispensed and administered to enrolled patients in health care settings that are certified in the REMS. See www.fda.gov for more information regarding the Spravato™ REMS program compliance requirements.

A treatment session of esketamine consists of instructed nasal self-administration by the patient followed by a period of at least 2 hours post-administration observation of the patient under direct supervision of a health care professional in the certified health care setting. Refer to the CY 2020 PFS final rule and interim final rule for more information about supervised visits for esketamine nasal spray self-administration (84 FR 63102 through 63105).

To facilitate prompt beneficiary access to the new, potentially life-saving treatment for TRD using esketamine, we created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020. HCPCS code G2082 is for an outpatient visit for the evaluation and management of an established patient who requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine through nasal self-administration and includes two hours of post-administration observation. For CY 2020, HCPCS code G2082 was assigned to New Technology APC 1508 (New Technology—Level 8 (\$601–\$700)) with a payment rate of \$650.50. HCPCS code G2083 describes a similar service to HCPCS code G2082 but involves the administration of more than 56 mg of esketamine. For CY 2020, HCPCS code G2083 was assigned to New Technology APC 1511 (New Technology—Level 11 (\$901–\$1,000)) with a payment rate of \$950.50. Updates to the APC assignments for G2082 and G2083 have been made in past rules. See the CY 2021 OPPS/ASC final rule with comment period (85 FR 85948), CY 2022 OPPS/ASC final rule with comment

period (86 FR 63538), CY 2023 OPPS/ASC final rule with comment period (87 FR 71816–71817), and CY 2024 OPPS/ASC final rule with comment period (88 FR 81628–81630) for these updates.

For CY 2025, the OPPS payment rates are proposed based on available CY 2023 claims data as the available single frequency claims exceed the 100 claims threshold generally used for our universal low volume policy. Therefore, for CY 2025, we propose to assign HCPCS codes G2082 and G2083 to New Technology APCs based on the codes' geometric mean costs. Specifically, we propose to assign HCPCS code G2082 to New Technology APC 1512 (New Technology—Level 12 (\$1,001–\$1,100)) with a payment rate of \$1,050.50 based on its geometric mean cost of \$1,087, which was calculated using the available 424 single frequency claims from CY 2023 claims data. We also propose to assign HCPCS code G2083 to New Technology APC 1518 (New Technology—Level 18 (\$1,601–\$1,700)) with a payment rate of \$1,650.50 based on its geometric mean cost of \$1,643, which was calculated using the available 2,482 single frequency claims from CY 2023 claims data. We note, as we have begun to gather adequate claims data on these codes, we are considering placing HCPCS codes G2082 and G2083 in clinical APCs through future rulemaking.

The proposed New Technology APC and status indicator assignments for HCPCS codes G2082 and G2083 are shown in Table 31. The proposed CY 2025 payment rates for these HCPCS codes can be found in Addendum B to this proposed rule.

**TABLE 31: FINAL CY 2024 AND PROPOSED CY 2025
NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS
FOR HCPCS CODES G2082 AND G2083**

HCPCS Code	Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation	S	1513	S	1512
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	S	1520	S	1518

s. Surfacar® Inside-Out® Access Catheter System (APC 1534)

HCPCS code C9780 (Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance) describes the procedure associated with the use of the Surfacar® Inside-Out® Access Catheter System that is designed to address central venous occlusion.

HCPCS code C9780 was established on October 1, 2021, and since its establishment the code has been assigned to New Technology APC 1534 (New Technology—Level 34 (\$8,001–\$8,500)).

For CY 2025, there were only 3 single frequency claims in CY 2023 for HCPCS code C9780. There were no available claims from CY 2021 or CY 2022. Given our proposal to maintain current New Technology APC assignments for CY

2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy, we propose to continue to assign HCPCS code C9780 to APC 1534 (New Technology—Level 34 (\$8,001–\$8,500)) with a payment rate of \$8,250.50. Refer to Table 32 for the proposed New Technology APC and status indicator assignments for HCPCS code C9780.

TABLE 32: PROPOSED CY 2025 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR SURFACER® INSIDE-OUT® ACCESS CATHETER SYSTEM PROCEDURE

HCPCS Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9780	Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance	S	1534

t. TASS (APC 1537)

The Transcatheter Atrial Shunt System (TASS) is a nitinol self-expanding cardiovascular implant consisting of four arms including two left atrial (LA) arms and two coronary sinus (CS) arms placed between the left atrium and coronary sinus to create a 7mm flow diameter channel for blood to flow from the high pressure region of the left atrium to the lower pressure region of the right atrium via the coronary sinus. TASS is currently in a Category B IDE clinical trial. Effective October 1, 2023 CMS created HCPCS code C9792 (Blinded or nonblinded

procedure for symptomatic New York Heart Association (NYHA) Class II, III, IVa heart failure; transcatheter implantation of left atrial to coronary sinus shunt using jugular vein access, including all imaging necessary to intra procedurally map the coronary sinus for optimal shunt placement (e.g., TEE or ICE ultrasound, fluoroscopy), performed under general anesthesia in an approved investigational device exemption (IDE) study) to describe the TASS service and assigned it to APC 1537 (New Technology—Level 37 (\$9,501–\$10,000)) with a payment rate of \$9750.50.

For CY 2025, the proposed OPPS payment rates are based on available CY 2023 claims data. Due to the effective date of the code of October 1, 2023, there were no claims available for HCPCS code C9792 for rate setting in CY 2024. Therefore, in CY 2025, we propose to continue to assign HCPCS code C9792 to APC 1537.

Please refer to Table 33 below for the current and proposed OPPS New Technology APC and status indicator assignment for HCPCS code C9792. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 33: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR TRANSCATHETER ATRIAL SHUNT SYSTEM

HCPCS	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9792	Blinded or nonblinded procedure for symptomatic New York Heart Association (NYHA) Class II, III, IVa heart failure; transcatheter implantation of left atrial to coronary sinus shunt using jugular vein access, including all imaging necessary to intra procedurally map the coronary sinus for optimal shunt placement (e.g., TEE or ICE ultrasound, fluoroscopy), performed under general anesthesia in an approved investigational device exemption (IDE) study	S	1537

u. Magnetic Resonance Imaging With Inhaled Hyperpolarized Xenon-129 Contrast Agent (APC 1551)

HCPCS code C9791 (Magnetic resonance imaging with inhaled

hyperpolarized xenon-129 contrast agent, chest, including preparation and administration of agent) was established on October 1, 2023. For CY 2023, we assigned HCPCS code C9791 to New Technology APC 1551 (New

Technology—Level 14 (\$1,201–\$1,300)). For CY 2024, the OPPS payment rates were based on claims submitted between January 1, 2022, and December 31, 2022, processed through June 30, 2023. Due to the effective date of the

service of October 1, 2023, there were no claims available for HCPCS code C9791 for rate setting in CY 2024. Therefore, in CY 2024, we continued to assign HCPCS code C9791 to New Technology APC 1551.

For CY 2025, the proposed OPPS payment rates are generally based on

available CY 2023 claims data. Although HCPCS code C9791 was effective October 1, 2023, we do not have any claims data for the service. Therefore, for CY 2025, we propose to continue to assign HCPCS code C9791 to APC 1551 with a proposed payment rate of \$1,250.50.

Refer to Table 34 for the proposed OPPS New Technology APC and status indicator assignment for HCPCS code C9791 for CY 2025. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 34: PROPOSED CY 2025 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR MAGNETIC RESONANCE IMAGING WITH INHALED HYPERPOLARIZED XENON-129 CONTRAST AGENT PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9791	Magnetic resonance imaging with inhaled hyperpolarized xenon-129 contrast agent, chest, including preparation and administration of agent	T	1551

D. Universal Low Volume APC Policy for Clinical and Brachytherapy APCs

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a policy to designate clinical and brachytherapy APCs as low volume APCs if they have fewer than 100 single claims that can be used for ratesetting purposes in the claims year used for ratesetting for the prospective year. For the CY 2025 OPPS/ASC proposed rule, CY 2023 claims are generally the claims used for ratesetting; and clinical and brachytherapy APCs with fewer than 100 single claims from CY 2023 that can be used for ratesetting would be low volume APCs subject to our universal low volume APC policy. As we stated in the CY 2022 OPPS/ASC final rule with comment period, we adopted this policy to reduce the volatility in the payment rate for those APCs with fewer than 100 single claims. Where a clinical or brachytherapy APC has fewer than 100 single claims that can be used for ratesetting, under our low volume APC payment adjustment policy, we

determine the APC cost as the greatest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data. We excluded APC 5853 (Partial Hospitalization for CMHCs) and APC 5863 (Partial Hospitalization for Hospital-based PHPs) from our universal low volume APC policy given the different nature of policies that affect the partial hospitalization program. We also excluded APC 2698 (Brachytx, stranded, nos) and APC 2699 (Brachytx, non-stranded, nos) as our current methodology for determining payment rates for non-specified brachytherapy sources is appropriate.

Based on claims data available for the CY 2025 OPPS/ASC proposed rule, we proposed to designate six brachytherapy APCs and five clinical APCs as low volume APCs under the OPPS. The six brachytherapy APCs and five clinical APCs meet our criteria of having fewer than 100 single claims in the claims' year used for ratesetting (CY 2023 for the CY 2025 OPPS/ASC proposed rule). Nine of the 11 APCs were designated as

low volume APCs in CY 2024. Based on data for the CY 2025 OPPS/ASC proposed rule, APC 2645 (Brachytx, non-stranded, gold-198) and APC 5881 (Ancillary Outpatient Services When Patient Dies) now meet our criteria to be designated a Low Volume APCs; and we proposed to designate those APCs as such for CY 2025.

Table 35 includes the CY 2023 claims available for ratesetting for each of the APCs we are proposing to be designated as low volume APCs for CY 2025. The cost statistics for our proposed low volume APCs, such as the median, arithmetic mean, and geometric mean cost are available for download with this proposed rule on the CMS website. We refer readers to our website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices>; click on the relevant regulation to download the low volume APC cost statistics under the comprehensive (OPPS) ratesetting methodology in the downloads section of the web page.

TABLE 35: PROPOSED LOW VOLUME APCS USING COMPREHENSIVE (OPPS) RATESETTING METHODOLOGY FOR CY 2025

APC	APC Description	CY 2023 Claims Available for Ratesetting
2632	Iodine I-125 sodium iodide	0
2635	Brachytx, non-str, HA, p-103	13
2636	Brachy linear, non-str, p-103	1
2642	Brachytx, stranded, c-131	90
2645	Brachytx, non-str, gold-198	86
2647	Brachytx, NS, Non-HDRIr-192	2
5244	Level 4 Blood Product Exchanges and Related Services	47
5494	Level 4 Intraocular Procedures	81
5495	Level 5 Intraocular Procedures	57
5496	Level 6 Intraocular Procedures	26
5881	Ancillary Outpatient Services When Patient Dies	55

* For this proposed rule, there are no CY 2023 claims that contain the HCPCS code assigned to APC 2632 that are available for CY 2025 OPPS/ASC ratesetting.

E. APC-Specific Policies

1. Request for Information on Cardiac CT Services

For the 2006 coding update, the AMA’s CPT Editorial Panel established six Category III CPT codes to describe cardiac computed tomography angiography (cardiac CT services) with contrast materials effective January 1, 2006. The codes were active and separately payable under the OPPS between January 1, 2006 and December 31, 2009. The CPT Editorial Panel deleted the Category III CPT codes and replaced them with Category I CPT codes 75572 through 75574 effective January 1, 2010. With the deletion of the Category III CPT codes on December 31, 2009, we crosswalked the APC assignments from the Category III CPT codes (predecessor codes) to the new

Category I CPT codes effective January 1, 2010. Since 2010, the Category I CPT codes describing cardiac computed tomography angiography with contrast materials are CPT codes 75572, 75573, and 75574. The codes and their long descriptors are listed below.

- 75572: Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed).
- 75573: Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of left ventricular (LV) cardiac function, right ventricular (RV) structure and function

and evaluation of vascular structures, if performed).

- 75574: Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed).

The cardiac CT codes that are described by CPT codes 75572, 75573, and 75574 have been paid separately under the OPPS since 2010. From CY 2015 through CY 2024, the OPPS payment rate, based on the geometric mean cost (GMC) for the cardiac CT codes, has ranged between \$175 and \$265 for these codes, as listed in Table 36 below.

TABLE 36: CY 2015 – CY 2024 OPPTS PAYMENT RATES FOR CPT CODES 75572 – 75574

CPT Codes	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
75572- 75574	\$216.05	\$236.86	\$265.02	\$252.74	\$201.74	\$182.22	\$178.55	\$182.43	\$180.34	\$175.06

We note that the OPPTS payment rate applies only to the hospital outpatient facility and does not include the physician service payment. Physician services are paid under Medicare's Physician Fee Schedule (PFS).

As we have stated in every OPPTS/ASC proposed and final rule, we update the OPPTS payment rates on an annual basis consistent with the requirements set forth in section 1833(t)(9)(A) of the Act, which requires the HHS Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Because of the annual updates, OPPTS payment rates for services may fluctuate from year to year. We note that we generally use the latest claims data available to set the annual payment rates. Payment rates for the CY 2025 OPPTS/ASC final rule will be based on claims with dates of service between January 1, 2023, and December 31, 2023, processed through June 30, 2024.

Over the years we have received comments noting that the payment for these codes has declined since 2017. Commenters have indicated that the payment amount is insufficient to cover the cost of providing the service and have stated that the payment amount does not consider the hospital resources required to perform these services, including the use of the equipment, medication administration, staff time, and scanner time. We have maintained over the years that an analysis of our claims data for these three (3) codes have shown geometric mean costs consistent with the geometric mean cost

for APC 5571 (Level 1 Imaging with Contrast).

We have also received comments in the past urging CMS to allow hospitals the flexibility to submit charges for cardiac CT services with a revenue code other than CT scan (035X) and Radiology Diagnostic (032X) revenue codes, implying that MACs had applied edits to the cardiac CT codes that prevented hospitals from reporting a cardiology (048X) revenue code when appropriate. It is longstanding CMS policy that hospital outpatient facilities are responsible for reporting the appropriate cost centers and revenue codes on claims. As stated in section 20.5 in Chapter 4 (Part B Hospital) of the Medicare Claims Processing Manual, CMS “does not instruct hospitals on the assignment of HCPCS codes to revenue codes for services provided under OPPTS since hospitals’ assignment of cost vary. Where explicit instructions are not provided, HOPDs should report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report.” We have consistently stated that hospital outpatient facilities must determine the most appropriate cost center and revenue code for the cardiac CT codes (87 FR 71849, 88 FR 81664).

After we issued the CY 2024 OPPTS/ASC final rule, interested parties notified CMS of a specific claims edit that may have affected the revenue codes reported with the cardiac CT codes in prior years’ claims data. CMS confirmed the existence of the revenue code edit and removed the revenue code edit in early December 2023. We informed the public of our findings and the changes that we made in the January 2024 OPPTS Update (Transmittal 12421, Change Request 13488), dated December

21, 2023. Specifically, we stated the following: “We recently identified an outdated return-to-provider (RTP) Healthcare Common Procedure Coding System-to-revenue code edit that resulted in certain claims submissions being limited to specific revenue codes for CPT codes 75572, 75573, and 75574. These claims were returned to the providers for resubmission. The outdated edit has been removed; and providers, when appropriate, may begin billing these codes with any appropriate revenue code.”

We believe the edit may have prevented some providers from reporting the cardiology revenue code (048X), which maps to the cardiology cost center (03140), when billing for cardiac CT services. In the past, commenters have indicated that the cardiology cost center has a higher cost-to-charge ratio (CCR) than the imaging cost centers, and they believe the inability to report the cardiology revenue code has resulted in a lower payment rate for cardiac CT services. Since the OPPTS ratesetting process utilizes the applicable cost center’s CCR to reduce the charges on the claim to estimated cost, utilizing cost centers with lower CCRs results in a lower OPPTS payment compared to utilizing cost centers with higher CCRs. With the edit no longer in place, hospitals may bill for cardiac CT services with whichever revenue code they believe appropriate for CY 2024, and the CY 2026 OPPTS payment rates (which most likely will be based on CY 2024 claims) will reflect those updated revenue code billing patterns.

We note that for CY 2025, based on our standard ratesetting methodology using claims submitted during CY 2023, our analysis reveals that the angiocardiology and CT scan revenue

codes were reported with CPT codes 75572–75574, which were mapped to

cost centers angiocardiology and CT scan, as shown in Table 37.

TABLE 37: STANDARD OPPS RATESETTING METHODOLOGY – REVENUE CODES AND COST CENTERS REPORTED WITH THE CARDIAC COMPUTED TOMOGRAPHY (CT) CPT CODES 75572, 75573, AND 75574

2023 Revenue Code	Revenue Code Description (applicable to CY 2023 claims)	Used in 2025 OPPS (2023 claims)	Primary Cost Center	Primary Cost Center Description
0321	Radiology - Diagnostic: Angiocardiology	Y	03030	Angiocardiology
0350	Computed tomographic (CT scan) - general	Y	05700	CT Scan
0351	Computed tomographic (CT scan) - head scan	Y	05700	CT Scan
0352	Computed tomographic (CT scan) - body scan	Y	05700	CT Scan
0359	Computed tomographic (CT scan) - other CT scans	Y	05700	CT Scan

Because we wanted to determine the extent to which the revenue edit may have affected the GMC for CPT codes 75572–75574, we conducted a study to calculate HCPCS geometric mean costs for these codes based on a simulation that assumed that differing numbers of HOPDs (specifically 25 percent, 50 percent, and 75 percent of the total number of HOPDs billing for these services) would have assigned these

services to the cardiology revenue code (048X) and cardiology cost center (03140). Based upon the results of the study, we found that if 50 percent or more of HOPDs had billed these services with the cardiology revenue code (048X) and cardiology cost center (03140), the GMC for these codes would have increased and would have resulted in a revised APC assignment from APC 5571 (Level 1 Imaging with Contrast) to APC

5572 (Level 2 Imaging with Contrast). Specifically, as noted in Table 38, under our standard ratesetting methodology, the GMC for the cardiac CT codes would be approximately \$182, which maps to APC 5571, while an assumption that 50 percent of HOPDs billed with the cardiology revenue code (048X) and cardiology cost center (03140) on CY 2023 claims would result in a GMC of about \$386, which maps to APC 5572.

TABLE 38: STANDARD OPPS RATESETTING METHODOLOGY VS. SIMULATED 50 percent OF HOPDs UTILIZING THE CARDIOLOGY REVENUE CODE AND CARDIOLOGY COST CENTER

Code	Number of Claims Used for Ratesetting	Standard OPPS Methodology GMC	Standard OPPS Methodology Ambulatory APC	50% HOPD GMC	50% HOPD Methodology APC
75572	26,819	\$148.88	APC 5571	\$240.70	APC 5572
75573	647	\$182.26	GMC \$181.72	\$278.20	GMC \$386.46
75574	69,377	\$185.98		\$299.80	

Because the RTP edit associated with the cardiac CT codes may have affected the CY 2023 data we have available to establish the CY 2025 OPPS payment rates for these services, in this CY 2025 OPPS/ASC proposed rule, we are requesting information on the following topics regarding hospitals' billing practices for cardiac CT services:

(1) Where are cardiac CT services performed in a hospital? Are cardiac CT services performed in a dedicated cardiology department, radiology department, or some other hospital outpatient department?

(2) What factors determine the revenue code assignment for cardiac CT services (*i.e.*, the department in which the service is performed, the type of service that is performed, or some other factor)?

(3) What revenue codes are HOPDs reporting for these services in CY 2024? Are HOPDs using the cardiology revenue code on claims for cardiac CT services now that they are no longer restricted from using this revenue code?

In addition to reviewing comments received, we will review the limited CY 2024 claims data for Cardiac CT services to ascertain the percentage of HOPDs that are utilizing the cardiology revenue code (048X) and cardiology cost center (03140) with the understanding that many HOPDs may still be updating their current billing practices. The comments received and the information we glean from the CY 2024 claims data will help us identify whether the current OPPS payment is appropriate for the cardiac CT codes, or whether we should consider revising the payment methodology for the CY 2025 OPPS. If these comments indicate a number of HOPDs sufficient to affect the geometric mean and APC assignment for these codes (*i.e.*, 50 percent or more of HOPDs) are now billing these codes with the cardiology revenue code and cardiology cost center, we would change the payment methodology for these codes to simulate the GMC these codes would have had for CY 2025 ratesetting, with the assumption that 50 percent or more of HOPDs would have billed in CY 2023 using the cardiology revenue code (048X) and cardiology cost center (03140) if not for the revenue code edit. We would assign these services to the APC that corresponds to the simulated GMC, which we currently project to be APC 5572 (Level 2 Imaging with Contrast). We note that if a revision in payment methodology is implemented for CY 2025 for the cardiac CT codes, specifically, CPT codes 75572, 75573, and 75574, for CY 2025, such a change would not involve reprocessing of claims with dates prior to January 1,

2025. If, after comments are received and the limited CY 2024 claims data for cardiac CT services is reviewed, we are not persuaded that 50 percent or more of HOPDs would have billed using the cardiology revenue codes (048X) and cardiology cost center (03140) in CY 2023 if not for the revenue code edit, we would maintain our standard ratesetting for these services as proposed in this proposed rule.

2. Neurostimulator and Related Procedures (APCs 5461 Through 5465)

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66807 through 66808), we finalized a restructuring of what were previously several neurostimulator procedure-related APCs into a four-level series. In addition to that restructuring, in the CY 2015 OPPS/ASC final rule with comment period, we also made the Levels 2 through 4 APCs comprehensive APCs (79 FR 66807 through 66808). Later, in the CY 2020 OPPS/ASC final rule with comment period, we also made the Level 1 Neurostimulator and Related Procedure APC (APC 5461) a comprehensive APC (84 FR 61162 through 61166).

In reviewing the claims data available for the CY 2021 OPPS/ASC proposed rule, we believed that it was appropriate to create an additional Neurostimulator and Related Procedures level, between what were then the Levels 2 and 3 APCs. Creating this APC allowed for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. Therefore, for the CY 2021 OPPS, we finalized a five-level APC structure for the Neurostimulator and Related Procedures series (85 FR 85968 through 85970). In addition to creating the new level, we also assigned CPT code 0398T (Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed) to the new Level 3 APC (85 FR 85970).

Some interested parties requested for the CY 2023 OPPS/ASC proposed rule that we create a Level 6 Neurostimulator and Related Procedures APC, due to their concerns around clinical and resource cost similarity in the Level 5 Neurostimulator and Related Procedures APC. Based on our review of the data available for the CY 2023 OPPS/ASC proposed rule, we believed that the five-level structure for the Neurostimulator and Related Procedures APC series remained appropriate. The proposed geometric mean cost for the Level 5

Neurostimulator and Related Procedures was \$30,198.36 with the geometric means of cost significant codes in Level 5 ranging from approximately \$28,000 to \$36,000, which was well within the range of the 2 times rule. In addition, a review of the clinical characteristics of the services in the APC suggested that the current structure was appropriate. Finally, as discussed in the CY 2021 OPPS/ASC final rule with comment period, we reiterated that the OPPS is a prospective payment system. We group procedures with similar clinical characteristics and resource costs into APCs and establish a payment rate that reflects the geometric mean of all services in the group even though the cost of any individual service within the APC may be higher or lower than the APC's geometric mean. As a result, in the OPPS any individual procedure may potentially be overpaid or underpaid because the payment rate is based on the geometric mean of the entire group of services in the APC. However, the impact of these payment differences should be mitigated when distributed across a large number of APCs (85 FR 85968).

While we did not propose any changes in the CY 2023 OPPS/ASC proposed rule to the 5-level structure of the Neurostimulator and Related Procedures APC series, we recognized the interested parties' concerns regarding the granularity of the current APC levels and their request to create an additional level to address such concerns. Accordingly, we solicited comments on the potential creation of a new Level 6 APC. After consideration of those comments, we finalized a five level APC structure for the series and reassigned HCPCS code 0424T to New Tech APC 1581 (87 FR 71869).

In the CY 2024 OPPS/ASC final rule with comment period, we did not make any changes to the 5 level APC structure for the Neurostimulator and Related Procedures series. However, we made temporary changes to services previously assigned to the neurostimulator APCs: reassigning HCPCS codes 0424T and 33276 from New Tech APC 1581 to New Tech APC 1580 (88 FR 81645 through 81647) and assigning HCPCS code 0266T to New Tech APC 1580 (88 FR 81658).

For this CY 2025 OPPS/ASC proposed rule, we believe that the 5 level APC structure for the series remains appropriate. We note that while we have claims data available for HCPCS codes 0424T, 0266T, and several other codes in the APC series that are no longer active, there will be cost and coding changes associated with the new CPT codes as their claims data become

available. For example, CPT codes 33276 (Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed) and 33287 (Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator) both became newly active in CY 2024. With the changes associated with those codes we believe that it is appropriate to

reassign HCPCS codes 0266T and 33276 to the clinical APCs, specifically to the level 5 APC in the series. We will continue to monitor as more claims data become available for the new codes.

While we continue to believe that a five-level structure for the Neurostimulator and Related Procedures APC series remains appropriate, we continue to solicit comments from interested parties on the need for a Level 6 APC given the clinical and estimated cost characteristics of the services currently assigned to the Level 5 APC.

In summary, for the CY 2025 OPPI, we propose to maintain the current 5-

level structure for the Neurostimulator and Related Procedure APC series and assign HCPCS codes 0424T, 0266T, and 33276 to the level 5 APC. However, we are also soliciting comment on potentially creating an additional Level 6 APC in the series from the current Level 5 APC that would include HCPCS codes 33276, 0266T, 64568, 0424T, 0427T, and 0431T.

See Table 39 for the services that will be reassigned to the Level 5 APC and Table 40 below for the proposed CY 2025 Neurostimulator and Related Procedures APCs.

**TABLE 39: FINAL CY 2024 AND PROPOSED CY 2025 APC AND STATUS
INDICATOR ASSIGNMENTS**

HCPCS Code	HCPCS Long Descriptor	Final CY 2024 OPPS SI	Final CY 2024 OPPS APC	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	S	1580	J1	5465
0424T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)	D	N/A	D	N/A
33276	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed	S	1580	J1	5465

TABLE 40: PROPOSED CY 2025 NEUROSTIMULATOR AND RELATED PROCEDURES APCS

APC	Group Title	SI	Proposed CY 2025 APC Geometric Mean Cost
5461	Level 1 Neurostimulator and Related Procedures	J1	\$3,653.12
5462	Level 2 Neurostimulator and Related Procedures	J1	\$6,779.89
5463	Level 3 Neurostimulator and Related Procedures	J1	\$13,472.02
5464	Level 4 Neurostimulator and Related Procedures	J1	\$21,777.61
5465	Level 5 Neurostimulator and Related Procedures	J1	\$31,222.52

3. Focal Laser Ablation (APC 5374)

Focal laser ablation is an MRI directed and image guided, minimally invasive procedure that targets prostate cancer tissue. The focal laser ablation procedure, represented by CPT code 0655T (Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with mr-fused images or other enhanced ultrasound imaging), became effective July 1, 2021, and describes the destruction of localized prostate cancer tissue with the high energy source of focal laser radiation. The procedure utilizes real-time intraoperative prostate ultrasound fused with MRI guidance to allow the surgeon to precisely plan the ablation and guide the laser targeting as well as providing real-time feedback to minimize changes to the tissues outside of the targeted ablation zone. This procedure offers another therapy option for select patients with localized intermediate risk prostate cancer.

For CY 2024, we assigned CPT code 0655T to APC 5374 (Level 4 Urology and Related Services) with a payment rate of \$3,321.58 based on its geometric mean cost of approximately \$10,323, which was calculated using the available 16 single frequency claims from the CY 2022 claims data.

For this CY 2025 OPPS/ASC proposed rule, we reviewed the CY 2023 claims submitted between January 1, 2023, through December 31, 2023, that were processed on or before December 31, 2023, for CPT code 0655T and found seven single frequency claims available for ratesetting, with a resulting geometric mean cost of \$12,777. Additionally, for this CY 2025 OPPS/ASC proposed rule, we examined the

procedures assigned to the Urology Procedures APCs. Based on our examination of the procedures assigned to Urology and Related Procedures APCs and the available CY 2023 claims data, we believe it is appropriate to move CPT code 0655T to APC 5375 (Level 5 Urology and Related Services) from APC 5374 (Level 4 Urology and Related Services) because 0655T shares more resource cost and clinical homogeneity with procedures in APC 5375. Specifically, we believe CPT code 0655T shares resource and clinical homogeneity with CPT code 0714T (Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance), and CPT code 52648 (Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)). We note that the seven available CY 2023 single frequency claims for CPT code 0655T would not significantly impact the geometric mean cost calculations for APC 5374 and APC 5375. Therefore, for CY 2025, we propose to reassign CPT code 0655T from APC 5374 (Level 4 Urology and Related Services) to APC 5375 (Level 5 Urology and Related Services).

4. Bone Mass Measurement: Biomechanical Computed Tomography (BCT) Analysis With Vertebral Fracture Assessment (APCs 5521, 5523, and 5731)

CPT code 0743T (Bone strength and fracture risk using finite element analysis of functional data and bone

mineral density (BMD), with concurrent vertebral fracture assessment, utilizing data from a computed tomography scan, retrieval and transmission of the scan data, measurement of bone strength and BMD and classification of any vertebral fractures, with overall fracture-risk assessment, interpretation and report) became effective January 1, 2023. This code describes the service associated with BCT analysis with concurrent vertebral fracture assessment (VFA).

In the CY 2023 OPPS/ASC final rule (87 FR 71844 through 71846), we stated that, based on our review and understanding of the service, BCT analysis does not meet Medicare's definition of bone mass measurement, as specified in § 410.31(a), which specifies the coverage of, and payment for, bone mass measurements for Medicare beneficiaries. Therefore, we assigned the BCT codes (CPT codes 0554T–0558T) and CPT code 0743T to status indicator “E1” to indicate that these codes are not covered by Medicare, and not paid by Medicare when submitted on outpatient claims (any outpatient bill type). The complete long descriptors for the codes can be found in Table 41 below.

In the CY 2024 OPPS/ASC proposed rule, we proposed to continue to assign the codes to status indicator “E1” to indicate non-coverage and non-payment for the services. (See Addendum B for CY 2024/ASC proposed rule via the internet on the CMS website.) However, as discussed in the CY 2024 OPPS/ASC final rule (88 FR 81660 through 81661), based on comments received and further review of the issue, we did not finalize our proposal. We instead assigned CPT code 0555T to APC 5731 (Level 1 Minor

Procedures) and SI of “S,” (Procedure or Service, Not Discounted When Multiple; Paid under OPPS; separate APC payment.), CPT code 0556T to APC 5523 (Level 3 Imaging without Contrast) and SI of “S,” and CPT code 0558T to APC 5521 (Level 1 Imaging without Contrast) with SI of “S,” which were the same APC assignments for the codes between CY 2019 and CY 2022. In addition, we assigned CPT codes 0554T, 0557T, and 0743T to SI of “M” (Items and Services Not Billable to the MAC. Not paid under OPPS.) to indicate that these codes are not payable under the OPPS because they describe physician-only services. The final payment rates for these codes were listed in the OPPS Addendum B that was released with the CY 2024 OPPS/ASC final rule via the internet on the CMS website.

For CY 2025, we propose to continue to assign CPT codes 0554T and 0557T to status indicator of “M” as the codes include or describe a professional component of the service that is provided by a physician as evidenced by “interpretation and report” in the descriptor. It is important to note that CPT code 0554T is a comprehensive code (or “parent code”) that includes both technical and professional components. Because there are additional CPT codes (“child codes”) that facilities can use to describe the technical components of BCT analysis, it is appropriate for the comprehensive code that includes the professional component to be assigned a SI of “M”.

In addition, we propose to continue to assign CPT code 0555T to APC 5731 (Level 1 Minor Procedures) and a SI of “S,” CPT code 0556T to APC 5523 (Level 3 Imaging without Contrast) and a SI of “S,” and CPT code 0558T to APC 5521 (Level 1 Imaging without Contrast) with a SI of “S.” However, for CY 2025, based on input from our medical advisors, we now believe the service described by CPT code 0743T is a comprehensive code and involves both a technical component and a professional component that are performed by hospital outpatient facilities. Unlike CPT 0554T, there are no additional codes to describe the technical component(s) of this service (BCT analysis and VFA) and there is a parenthetical note instructing facilities to not report the BCT analysis codes (0554T–0557T) with CPT code 0743T. Consequently, we propose to assign CPT code 0743T to APC 5523 (Level 3 Imaging without Contrast) and we propose to change the status indicator for 0743T from a “M” in CY 2024 to a “S” (Procedure or Service, Not

Discounted When Multiple; Paid under OPPS; separate APC payment) for CY 2025. As a reminder, Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment. Accordingly, we emphasize that HOPDs would only receive payment for these services when the appropriate MAC determines that the service meets the relevant conditions for coverage and payment. As we have consistently stated in past OPPS/ASC final rules (see, *e.g.*, 87 FR 71879 and 88 FR 81660 through 81661), the fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program (see, *e.g.*, Pub 100–04 Medicare Claims Processing, Transmittal 11937).

Please refer to Table 41 below for the proposed APCs and status indicator assignment for CPT codes 0554T–0558T and CPT code 0743T for CY 2025. The proposed CY 2025 payment rates, where applicable, can be found in Addendum B to this proposed rule via the internet on the CMS website.

**TABLE 41—PROPOSED CY 2025 APC AND STATUS INDICATOR ASSIGNMENTS
FOR CPT CODES 0554T-0558T AND CPT CODE 0743T**

CPT Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
0554T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; retrieval and transmission of the scan data, assessment of bone strength and fracture risk and bone-mineral density, interpretation and report	M	
0555T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; retrieval and transmission of the scan data	S	5731
0556T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone-mineral density	S	5523
0557T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; interpretation and report	M	
0558T	Computed tomography scan taken for the purpose of biomechanical computed tomography analysis	S	5521
0743T	Bone strength and fracture risk using finite element analysis of functional data and bone mineral density (BMD), with concurrent vertebral fracture assessment, utilizing data from a computed tomography scan, retrieval and transmission of the scan data, measurement of bone strength and BMD and classification of any vertebral fractures, with overall fracture-risk assessment, interpretation and report	S	5523

IV. Proposed OPPS Payment for Devices*A. Proposed Pass-Through Payment for Devices***1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments****a. Background**

The intent of transitional device pass-through payment, as implemented at § 419.66, is to facilitate access for beneficiaries to the advantages of new

and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861). Under section 1833(t)(6)(B)(iii) of the Act, the period for which a device category eligible for transitional pass-through payments under the OPPS can be in effect is at least 2 years but not more than 3 years. Prior to CY 2017, our regulation at § 419.66(g) provided that this pass-

through payment eligibility period began on the date CMS established a particular transitional pass-through category of devices, and we based the pass-through status expiration date for a device category on the date on which pass-through payment was effective for the category. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79654), in accordance with section 1833(t)(6)(B)(iii)(II) of the Act, we amended § 419.66(g) to provide that the pass-through eligibility period for a

device category begins on the first date on which pass-through payment is made under the OPPS for any medical device described by such category.

In addition, prior to CY 2017, our policy was to propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS annual update. This means that device pass-through status would expire at the end of a calendar year when at least 2 years of pass-through payments had been made, regardless of the quarter in which the device was approved. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79655), we changed our policy to allow for quarterly expiration of pass-through payment status for devices, beginning with pass-through devices approved in CY 2017 and subsequent calendar years, to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment

devices. We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763).

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79648 through 79661) for a full discussion of the current device pass-through payment policy.²⁰

In the CY 2023 OPPS/ASC final rule with comment period, we finalized our policy to publicly post online OPPS device pass-through applications received on or after March 1, 2023, beginning with the issuance of the CY

²⁰ To apply for OPPS transitional device pass-through status, applicants complete an application that is subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). This information collection (CMS-10052) is currently approved under OMB control number 0938-0857 and has an expiration date of November 30, 2025.

2025 proposed rule and for each OPPS rulemaking thereafter. We refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71934 through 71938) for a full discussion of the policy to publicly post OPPS device pass-through applications.

b. Expiration of Transitional Pass-Through Payments for Certain Devices

As stated earlier, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. Currently, there are 13 device categories eligible for pass-through payment. These devices are listed in Table 42 of this proposed rule where we detail the expiration dates of pass-through payment status for each of the 13 devices currently receiving device pass-through payment.

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**TABLE 42: DEVICES WITH PASS-THROUGH STATUS EXPIRING IN 2024, IN
2025, IN 2026, OR IN 2027**

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1831	Personalized, anterior and lateral interbody cage (implantable)	10/01/2021	09/30/2024
C1832	Autograft suspension, including cell processing and application, and all system components	01/01/2022	12/31/2024
C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)	01/01/2022	12/31/2024
C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system	01/1/2023	12/31/2025
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller	01/01/2023	12/31/2025
C1747	Endoscope, single-use (i.e. disposable), urinary tract, imaging/illumination device (insertable)	01/01/2023	12/31/2025
C1600	Catheter, transluminal intravascular lesion preparation device, bladed, sheathed (insertable)	01/01/2024	12/31/2026
C1601	Endoscope, single-use (i.e. disposable), pulmonary, imaging/illumination device (insertable)	01/01/2024	12/31/2026
C1602	Orthopedic/device/drug matrix/absorbable bone void filler, antimicrobial-eluting (implantable)	01/01/2024	12/31/2026
C1603	Retrieval device, insertable, laser (used to retrieve intravascular inferior vena cava filter)	01/01/2024	12/31/2026
C1604	Graft, transmural transvenous arterial bypass (implantable), with all delivery system components	01/01/2024	12/31/2026
C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation	07/01/2024	06/30/2027
C1606	Adapter, single-use (i.e. disposable), for attaching ultrasound system to upper gastrointestinal endoscope	07/01/2024	06/30/2027

As discussed in section IV.A.2. New Device Pass-Through Applications for CY 2024 of the CY 2024 OPPS/ASC final rule with comment period, we approved HCPCS code C1601 (Endoscope, single-use (*i.e.* disposable), pulmonary, imaging/illumination device (insertable)), as a new device category for pass-through status under the OPPS, with an effective date of January 1, 2024. For the full discussion of the criteria used to evaluate device pass-through applications, refer to the CY 2024 OPPS/ASC final rule with comment period, which was published in the **Federal Register** on November 22, 2023 (88 FR 81729 through 81743). We note that HCPCS code C1601 was established for a bronchoscope that can only be used for a single procedure and cannot be reprocessed. As such, HCPCS code C1601 only describes devices that cannot be reprocessed.

In addition, as discussed in section IV.A.2. New Device Pass-Through Applications for CY 2023 of the CY 2023 OPPS/ASC final rule with comment period, we approved HCPCS code C1747 (Endoscope, single-use (*i.e.*, disposable), urinary tract, imaging/illumination device (insertable)), as a new device category for pass-through status under the OPPS, with an effective date of January 1, 2023. For the full discussion on the criteria used to evaluate device pass-through applications, refer to the CY 2023 OPPS/ASC final rule with comment period, which was published in the **Federal Register** on November 23, 2022 (87 FR 71929 through 71934). We note that HCPCS code C1747 was established for a ureteroscope that can only be used for a single procedure and cannot be reprocessed. As such, HCPCS code C1747 only describes devices that cannot be reprocessed.

2. New Device Pass-Through Applications for CY 2025

a. Background

Section 1833(t)(6) of the Act provides for pass-through payments for devices, and section 1833(t)(6)(B) of the Act requires CMS to use categories in determining the eligibility of devices for pass-through payments. As part of implementing the statute through regulations, we have continued to believe that it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or

no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for those devices where cost considerations are most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629).

As specified in regulations at § 419.66(b)(1) through (3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria:

- If required by FDA, the device must have received FDA approval or clearance and FDA marketing authorization (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA), or meet another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA marketing authorization, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA marketing authorization is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;

- The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and

- The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

In addition, according to § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, as set forth under § 419.66(c), to determine whether a new category of pass-through payment devices should

be established. The device to be included in the new category must—

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;

- Have an average cost that is not “insignificant” relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d) by demonstrating: (1) the estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices; (2) the estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoablation, which are exempt from the cost requirements as specified at § 419.66(c)(3) and (e)); and

- Demonstrate a substantial clinical improvement, that is, substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment, or, for devices for which pass-through payment status will begin on or after January 1, 2020, as an alternative pathway to demonstrating substantial clinical improvement, a device is part of the FDA’s Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

Beginning in CY 2016, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to CMS through the quarterly subregulatory process, but the applications are subject to notice and comment rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review will have the option of being

included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Under this notice-and-comment process, applicants may submit new evidence, such as clinical trial results published in a peer-reviewed journal or other materials, for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meet all of the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications (80 FR 70417 through 70418).

In the CY 2020 annual rulemaking process, we finalized an alternative pathway for devices that are granted a Breakthrough Device designation (84 FR 61295) and receive FDA marketing authorization for the indication covered by the Breakthrough Device designation. Under this alternative pathway, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for the purposes of determining device pass-through payment status, but do need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Devices that are part of the Breakthrough Devices Program, have received FDA marketing authorization for the indication covered by the Breakthrough Devices designation, and meet the other criteria in the regulation can be approved through the quarterly process and announced through that process (81 FR 79655). Proposals regarding these devices and whether pass-through payment status should continue to apply are included in the next applicable OPPS rulemaking cycle. This process promotes timely pass-through payment status for innovative devices, while also recognizing that such devices may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization.

More details on the requirements for device pass-through payment applications are included on the CMS website in the application form itself at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html, in the “Downloads” section. In addition, CMS is amenable to meeting with applicants or potential applicants to facilitate information sharing to support the evaluation of an OPPS device pass-through payment

application or discuss general application criteria, including the substantial clinical improvement criterion.

b. Applications Received for Device Pass-Through Status for CY 2025

We received 14 complete applications by the March 1, 2024 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in this proposed rule. Of the complete applications, we received two applications in the second quarter of 2023, two applications in the third quarter of 2023, three applications in the fourth quarter of 2023, and seven applications in the first quarter of 2024. Three of the applications were approved for device pass-through payment during the quarterly review process: The DETOUR™ System, which received was preliminarily approved upon quarterly review under the alternative pathway effective January 1, 2024, and the AVEIR™ DR Dual Chamber Leadless Pacemaker System and the EndoSound Vision System® (EVS) which both were preliminarily approved upon quarterly review under the alternative pathway effective July 1, 2024. As previously stated, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle. Therefore, the DETOUR™ System, the AVEIR™ DR Dual Chamber Leadless Pacemaker System, and the EndoSound Vision System® (EVS) are discussed in the following section IV.2.b.1.

We note that the quarterly application process and requirements have not changed because of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment application are included on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf>.

Discussions of the applications we received by the March 1, 2024 deadline are included in this proposed rule.

(1) Alternative Pathway Device Pass-Through Applications

We received 10 device pass-through applications by the March 2024 quarterly application deadline for devices that have received Breakthrough Device designation from FDA and FDA marketing authorization for the indication for which they have a Breakthrough Device designation, and therefore were eligible to apply under the alternative pathway.

(a) AGENT™ Paclitaxel-Coated Balloon Catheter

Boston Scientific Corporation submitted an application for a new device category for transitional pass-through payment status for AGENT™ Paclitaxel-Coated Balloon Catheter for CY 2025. Per the applicant, AGENT™ Paclitaxel-Coated Balloon Catheter is a device/drug combination product consisting of a semi-compliant intracoronary balloon catheter with a paclitaxel/acetyl tributyl citrate drug coating on the balloon component. The applicant asserted that AGENT™ Paclitaxel-Coated Balloon Catheter delivers paclitaxel, an antiproliferative drug, directly to the arterial tissue which inhibits the proliferation of neointimal smooth muscle cells without introducing an additional stent layer, thereby reducing the rate of restenosis. According to the applicant, AGENT™ Paclitaxel-Coated Balloon Catheter is intended for use in adult patients, after appropriate vessel preparation, undergoing percutaneous coronary intervention (PCI) in coronary arteries 2.0 mm to 4.0 mm in diameter and lesions up to 26 mm in length for the purpose of improving myocardial perfusion when treating in-stent restenosis (ISR) and the management of atherosclerotic coronary artery disease.

Please refer to the online application posting for the AGENT™ Paclitaxel-Coated Balloon Catheter, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP2402295H2TU>, for additional detail describing this device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), AGENT™ Paclitaxel-Coated Balloon Catheter received FDA Breakthrough Device designation effective January 22, 2021, as a combination product indicated for percutaneous transluminal coronary angioplasty in coronary arteries 2.0 mm to 4.0 mm in diameter to treat ISR, up to 26 mm in length, for the purpose of improving myocardial perfusion. FDA approved the premarket approval application (PMA) for AGENT™ Paclitaxel-Coated Balloon Catheter on February 29, 2024, as indicated for use after appropriate vessel preparation in adult patients undergoing PCI in coronary arteries 2.0 mm to 4.0 mm in diameter and lesions up to 26 mm in length for the purpose of improving myocardial perfusion when treating ISR. We note that while the indication for

the FDA Breakthrough Device designation and the indication for the FDA premarket approval vary slightly, we believe that FDA premarket approval indication is the indication covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for AGENT™ Paclitaxel-Coated Balloon Catheter on February 29, 2024, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether AGENT™ Paclitaxel-Coated Balloon Catheter meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not explicitly indicate whether the AGENT™ Paclitaxel-Coated Balloon Catheter is integral to the service provided. The applicant stated that the AGENT™ Paclitaxel-Coated Balloon Catheter is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted as required by § 419.66(b)(3).

We are inviting public comments on whether AGENT™ Paclitaxel-Coated Balloon Catheter meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant did not indicate whether AGENT™ Paclitaxel-Coated Balloon Catheter is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if AGENT™ Paclitaxel-Coated Balloon Catheter is a supply or material furnished incident to a service.

We are inviting public comments on whether AGENT™ Paclitaxel-Coated Balloon Catheter meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories

are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the AGENT™ Paclitaxel-Coated Balloon Catheter. Per the applicant, while device category C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) describes related or similar products to the AGENT™ Paclitaxel-Coated Balloon Catheter, the AGENT™ Paclitaxel-Coated Balloon Catheter is not appropriately described by C2623 because the devices in this category differ from AGENT™ Paclitaxel-Coated Balloon Catheter in both size and indicated use, and therefore, the device is not appropriately described by C2623. The applicant further claimed that the devices described by C2623 are approved for use in the femoral or popliteal arteries in vessels with a diameter of at least 4.0 mm, whereas AGENT™ Paclitaxel-Coated Balloon Catheter is indicated for use in coronary arteries that are between 2.0 mm to 4.0 mm in diameter. In addition, the applicant also noted that the length of the lesions (up to 180 mm) treated with devices in this device category greatly exceeds the maximum lesion size of 26 mm for AGENT™ Paclitaxel-Coated Balloon Catheter. Moreover, the applicant asserted that the devices described by C2623 are used to treat peripheral arterial disease and are contraindicated for use in coronary arteries. Per the applicant, the AGENT™ Paclitaxel-Coated Balloon Catheter is used in conjunction with transluminal PCIs which are described by different procedure codes than the percutaneous transluminal angioplasty services used for the devices in C2623. Lastly, the applicant stated that an analysis of claims found that the devices described by C2623 are typically reported with femoral or popliteal revascularization procedures (CPT® codes from 37224 to 37227).

We note that, based on the description the applicant provided, the AGENT™ Paclitaxel-Coated Balloon Catheter is a device/drug combination product consisting of a semi-compliant intracoronary balloon catheter with a paclitaxel/acetetyl tributyl citrate drug coating on the balloon component and thus could be appropriately described by C2623. Specifically, we believe that

C2623 may appropriately describe the AGENT™ Paclitaxel-Coated Balloon Catheter because it is a non-laser, drug-coated catheter used for transluminal angioplasty procedures. In this context, we believe the AGENT™ Paclitaxel-Coated Balloon Catheter may be similar to the devices described by C2623, and therefore, the AGENT™ Paclitaxel-Coated Balloon Catheter may also be appropriately described by C2623.

In addition, while we acknowledge that when C2623 was established as a device category code effective April 1, 2015, the procedure codes with which C2623 could be reported (CPT® 37224 and CPT® 37226) were limited to use in the femoral or popliteal arteries. However, based on the subsequent changes that were made to the procedure codes with which C2623 could be reported, we do not agree that C2623 is limited to use with femoral or popliteal revascularization procedures. First, we note that effective August 25, 2017, while C2623 was in device pass-through payment status, CMS added two procedure codes with which C2623 could be reported that were for procedures other than femoral popliteal revascularization procedures. Specifically, based on the FDA approval of a new indication for an existing device (a drug-coated balloon catheter for use with dialysis circuit procedures for the treatment of patients with dysfunctional arteriovenous fistulae²¹), CMS added two procedure codes, CPT® codes 36902 and 36903 (transluminal balloon angioplasty procedures in peripheral dialysis segments), with which C2623 could be reported effective August 25, 2017. The devices used with these two added CPT® codes, 36902 and 36903, which are also described by C2623, are drug-coated balloon catheters used for dialysis circuit procedures in the upper extremities. We believe that the inclusion of these additional reportable procedure codes illustrates our belief that devices that may be described by C2623 were neither intended to be restricted to the treatment of vascular lesions of a specified dimension nor anatomically limited to femoral or popliteal revascularization procedures and is inconsistent with the applicant's assertion that AGENT™ Paclitaxel-Coated Balloon Catheter is not appropriately described by C2623 because the category is only applicable for devices used in femoral or popliteal

²¹ Centers for Medicare & Medicaid Services (2017). Pub 100-04 Medicare Claims Processing (Transmittal 3941) in CMS Manual System. Accessed at <https://www.cms.gov/regulations-and-guidance/guidance/transmittals/2017/downloads/r3941cp.pdf>.

arteries with a diameter of at least 4.0 mm, and not smaller coronary arteries.

Further, beginning January 1, 2018, upon the expiration of device pass-through payment status for C2623, CMS packaged the payment for the costs of each of the devices described by C2623 into the payment for the costs related to the procedure with which each device is reported in the hospital claims data (FR 82 59321 through 59323). We further note that upon becoming packaged for payment, C2623 effectively became reportable with other transluminal angioplasty procedure codes, including procedure codes for percutaneous coronary transluminal angioplasty services. Finally, we note that while, per the applicant, the devices described by C2623 are typically reported with femoral or popliteal revascularization procedures, other procedure codes, including procedure codes for other percutaneous transluminal angioplasty services and other related coronary procedure codes can and have been performed with devices described by C2623. As such, we believe that the procedures with which AGENT™ Paclitaxel-Coated

Balloon Catheter is utilized could be reported with C2623.

In this context, based on the description the applicant provided, we believe the AGENT™ Paclitaxel-Coated Balloon Catheter may be similar to the devices described by C2623, and therefore, the AGENT™ Paclitaxel-Coated Balloon Catheter may also be appropriately described by C2623.

We are inviting public comment on whether AGENT™ Paclitaxel-Coated Balloon Catheter meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough

Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. AGENT™ Paclitaxel-Coated Balloon Catheter has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether AGENT™ Paclitaxel-Coated Balloon Catheter meets the device category criterion at § 419.66(c)(2)(ii).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that AGENT™ Paclitaxel-Coated Balloon Catheter would be reported with the HCPCS codes as shown in Table 43.

Table 43: HCPCS CODES REPORTED WITH AGENT™ PACLITAXEL-COATED BALLOON CATHETER

HCPCS Code	Long Descriptor	SI	APC
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch	J1	5192
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch	J1	5193
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	J1	5193
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	J1	5194
C9600	Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	J1	5193
C9602	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	J1	5194

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost

criterion for at least one APC. As we explained in the CY 2005 OPPI final rule (69 FR 65775), we generally use the

lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost

significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note the applicant utilized the CY 2024 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5192, which had a CY 2024 payment rate of \$5,445.84 at the time the application was received. HCPCS code 92920 in APC 5192 had a device offset amount of \$1,662.61 at the time the application was received. According to the applicant, the cost of AGENT™ Paclitaxel-Coated Balloon Catheter is \$5,500.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of \$5,500.00 for AGENT™ Paclitaxel-Coated Balloon Catheter is 101.00 percent of the applicable APC payment amount for the service related to the category of devices of \$5,445.84 ($(\$5,500.00/\$5,445.84) \times 100 = 101.00$ percent). Therefore, we believe AGENT™ Paclitaxel-Coated Balloon Catheter meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$5,500.00 for AGENT™ Paclitaxel-Coated Balloon Catheter is 330.81 percent of the cost of the device-related portion of the APC payment amount for the related service of \$1,662.61 ($(\$5,500.00/\$1,662.61) \times 100 = 330.81$ percent). Therefore, we believe that AGENT™ Paclitaxel-Coated Balloon Catheter meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$5,500.00 for AGENT™ Paclitaxel-Coated Balloon Catheter and the portion

of the APC payment amount for the device of \$1,662.61 is 70.46 percent of the APC payment amount for the related service of \$5,445.84

($(\$5,500.00 - \$1,662.61)/\$5,445.84 \times 100 = 70.46$ percent). Therefore, we believe that AGENT™ Paclitaxel-Coated Balloon Catheter meets the third cost significance requirement.

We are inviting public comment on whether the AGENT™ Paclitaxel-Coated Balloon Catheter meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(b) Aveir™ DR Dual Chamber Leadless Pacemaker System

Abbott Laboratories submitted an application for a new device category for transitional pass-through payment status for the Aveir™ DR Dual Chamber Leadless Pacemaker System (Aveir™ DR System) for CY 2025. Per the applicant, the Aveir™ DR System is comprised of two leadless pacemakers, one atrial and one ventricular with each containing a generator and electrodes, that provide dual-chamber pacing therapy after being placed within the heart's myocardium through a minimally invasive catheter-based procedure. According to the applicant, the Aveir™ DR System is a programmable system equipped with bidirectional implant-to-implant communication without the need for traditional wire electrodes and can provide beat-to-beat communication and synchrony between the two pacemakers for the treatment of arrhythmia/bradycardia. Per the applicant, patients with indication for dual-chamber pacing would benefit from a dual-chamber leadless pacemaker system that provides atrial and ventricular bradycardia therapy, while eliminating the complications associated with conventional pacing systems.

Please refer to the online application posting for the Aveir™ DR System, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP230831B8DX0>, for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), the Aveir™ DR System received FDA Breakthrough Device designation effective March 27, 2020, as a pacemaker implantation indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to

arrhythmia/bradycardia, or any combination of these symptoms. FDA approved the premarket approval application (PMA) for the Aveir™ DR System on June 29, 2023, for the indication covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the Aveir™ DR System on March 23, 2023, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether the Aveir™ DR System meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not indicate whether the Aveir™ DR System is integral to the service furnished. The applicant also did not explicitly state that the Aveir™ DR System is single-use; however, the applicant stated that one Aveir™ DR System is required per patient per procedure. While the applicant did not explicitly state whether the Aveir™ DR System comes in contact with human tissue or is surgically inserted or implanted, the applicant noted that the two Aveir™ Delivery Catheters are inserted into the peripheral vasculature and the cardiovascular system to deliver and implant the Aveir™ AR Atrial Leadless Pacemaker and the Aveir™ VR Ventricular Leadless Pacemaker into the right atrium and right ventricle of the heart, respectively.

We are inviting public comments on whether the Aveir™ DR System meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant did not indicate whether the Aveir™ DR System is equipment, an instrument, apparatus, implement, or item of this type for which depreciating and financing expenses are recovered, or if the Aveir™ DR System is a supply

or material furnished incident to a service.

We are inviting public comments on whether the Aveir™ DR System meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant asserted that the Aveir™ DR System is the only dual-chamber leadless pacemaker authorized by FDA and indicated for implantation in patients with one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combination of those conditions. Per the applicant, the Aveir™ DR System is a modular dual-chamber leadless pacemaker system with bidirectional implant-to-implant communication that can accommodate all pacing indications. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the Aveir™ DR System. The applicant stated that device categories

C1785 (Pacemaker, dual-chamber, rate-responsive (implantable)) and C1889 (Insertable/implantable device, not otherwise classified) do not appropriately describe the Aveir™ DR System because the Aveir™ DR System received Breakthrough Device designation from FDA and has specific functionality and capabilities that are new to the market. The applicant also asserted that the Aveir™ DR system is modular, such that a single device can be implanted in a heart chamber initially, and the second pacemaker added to the other heart chamber in the future should the clinical need arise; and therefore, it is not appropriately described by either C1785 or C1889.

We have not identified an existing pass-through payment category that describes the Aveir™ DR System. We are inviting public comment on whether the Aveir™ DR System meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established

category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The Aveir™ DR System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion), and therefore, is not evaluated for substantial clinical improvement.

We are inviting public comment on whether Aveir™ DR System meets the device category criterion at § 419.66(c)(2)(ii).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the Aveir™ DR System would be reported with HCPCS codes as shown in Table 44.

Table 44: HCPCS CODES REPORTED WITH THE AVEIR™ DR SYSTEM

HCPCS Code	Long Descriptor	SI	APC
0801T**	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; dual-chamber system (ie, right atrial and right ventricular pacemaker components)	J1	5224
0795T**	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; complete system (ie, right atrial and right ventricular pacemaker components)	J1	5224

**Denotes a HCPCS code that was not included in Addendum P to the CY 2023 OPPS/ASC final rule with comment period, with no CY 2023 HCPCS/CPT code level device offset amount available. We note the applicant used the CY 2023 payment rates for the three tests of the cost criterion. Since neither of the HCPCS/CPT codes provided by the applicant had a CY 2023 HCPCS/CPT code level device offset amount available at the time the application was received, we used the CY 2023 APC level device offset amount to assess whether the device meets the cost significance criterion.

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note the applicant used the CY 2023 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5224, which had a CY 2023 payment rate of \$18,672.01 at the time the application was received. We used the CY 2023 APC level device offset amount of \$11,739.09 for APC 5224, as HCPCS codes 0795T and 0801T provided by the applicant were not included in Addendum P to the CY 2023 OPPS/ASC final rule with comment period and no CY 2023 HCPCS/CPT code level device offset amount was available at the time the

application was received.²² According to the applicant, the cost of the Aveir™ DR System is \$24,000.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of \$24,000.00 for the Aveir™ DR System is 128.54 percent of the applicable APC payment amount for the service related to the category of devices of \$18,672.01 ($[(\$24,000.00 / \$18,672.01) \times 100 = 128.54 \text{ percent}]$). Therefore, we believe the Aveir™ DR System meets the first cost significance requirement.

²² We note that the applicant originally utilized APC 5231 (Level 1 ICD and Similar Procedures) for the three tests of the cost criteria in the application. However, the applicant provided supplemental information indicating that, HCPCS codes 0795T and 0801T were assigned to APC 5224 (Level 4 Pacemaker and Similar Procedures) in the corrected Addendum B to the CY 2024 OPPS/ASC final rule with comment period and they believed that APC 5224 is currently the appropriate APC for the purposes of performing the cost significance calculations. We agree with the applicant and selected APC 5224 for our calculation, which we believe is a more appropriate APC to use based on the assignment of HCPCS codes 0795T and 0801T to APC 5224 and the clinical similarity to other pacemaker insertion codes in APC 5224.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$24,000.00 for the Aveir™ DR System is 204.45 percent of the cost of the device-related portion of the APC payment amount for the related service of \$11,739.09 ($[(\$24,000.00 / \$11,739.09) \times 100 = 204.45 \text{ percent}]$). Therefore, we believe that the Aveir™ DR System meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$24,000.00 for the Aveir™ DR System and the portion of the APC payment

amount for the device of \$11,739.09 is 65.66 percent of the APC payment amount for the related service of \$18,672.01 ($((\$24,000.00 - \$11,739.09) / \$18,672.01) \times 100 = 65.66$ percent). Therefore, we believe that the Aveir™ DR System meets the third cost significance requirement.

We are inviting public comment on whether the Aveir™ DR System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(c) CANTURIO™ Tibial Extension (CTE) With Canary Health Implanted Reporting Processor (CHIRP®) System

Canary Medical, Inc. submitted an application for a new device category for transitional pass-through payment status for the CTE with CHIRP® System for CY 2025. The applicant is only seeking a new device category for transitional pass-through payment status for the CTE component (hereinafter referred to as “CTE”) of the CTE with CHIRP® System. According to the applicant, the CTE implant is a physical implant that is attached to the tibial baseplate as part of a total knee arthroplasty (TKA) to form the patient's knee prosthesis and provide additional stability to the replacement knee joint. Per the applicant the software and electronics within the CTE implant with CHIRP® system collects unprocessed 3-D accelerometer and 3-D gyroscopic sensor data using its Inertial Measurement Unit on the patient's functional movement and gait parameter post-surgery and transmits the encrypted data via the Home Base Station to the cloud platform. According to the applicant, the CTE implant with CHIRP® System is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 58 mm sized tibial stem extension.

Please refer to the online application posting for the CTE implant with CHIRP® System, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP240229Q7CYC>, for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), the CTE implant with CHIRP® System received FDA Breakthrough Device designation effective October 24, 2019, as indicated for use with the Zimmer Persona® Personalized Knee System (K113369) for TKA in patients with severe knee pain

and disabilities, including: (1) rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis; (2) collagen disorders, and/or avascular necrosis of the femoral condyle; (3) post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy; (4) moderate valgus, varus, or flexion deformities; and (5) the salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery. The CTE implant with CHIRP® System is indicated to provide objective kinematic data from the implanted medical device during a patient's TKA post-surgical care. FDA noted that the kinematic data are an adjunct to standard of care and physiological parameter measurement tools applied or utilized by the physician during the course of patient monitoring and treatment post-surgery. FDA granted De Novo classification for the CTE implant with CHIRP® System on August 27, 2021, with the following indications for use: (1) to provide objective kinematic data from the implanted medical device during a patient's TKA post-surgical care. The kinematic data are an adjunct to other physiological parameter measurement tools applied or utilized by the physician during the course of patient monitoring and treatment post-surgery; (2) for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 58 mm sized tibial stem extension; (3) the objective kinematic data generated by the CTE implant with CHIRP® System are not intended to support clinical decision-making and have not been shown to provide any clinical benefit; and (4) the CTE implant with CHIRP® System is compatible with Zimmer Persona® Personalized Knee System. We note that while the indication for the FDA Breakthrough Device designation and the indication for the FDA premarket approval vary slightly, we believe that FDA premarket approval indication is the indication covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the CTE implant with CHIRP® System on February 29, 2024, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether the CTE implant with CHIRP® System meets the newness criterion at § 419.66(b)(1).

Regarding the eligibility criterion at § 419.66(b)(3), the device must be an integral part of the service furnished,

used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not indicate whether the CTE implant is integral to the service furnished. We note that in CY 2014 final rule with comment period (78 FR 75005), we stated that we have interpreted the term “integral” to mean that the device is necessary to furnish or deliver the primary procedure with which it is used. For example, a pacemaker is integral to the procedure of implantation of a pacemaker. Per the applicant, the CTE implant is a physical implant that is attached to the tibial baseplate as part of a TKA to form the patient's knee prosthesis and provide additional stability to the replacement knee joint. We question whether the CTE implant is integral to the service furnished because utilization of the CTE implant during the primary procedure, TKA, appears to be purely additive in nature and not necessary to furnish or deliver the TKA consistent with our previous interpretation of integral. Further, we note that the indications for use of the CTE implant with CHIRP® System listed in the FDA DeNovo review letter states that the objective kinematic data generated by the CTE implant with CHIRP® System are not intended to support clinical decision-making and have not been shown to provide any clinical benefit. Moreover, a warning included in the device IFU for the CTE implant with CHIRP® System provides that the kinematic data obtained from this device have not been demonstrated to have clinical benefit. It is not intended to be utilized for clinical decision-making, and no data have been evaluated by FDA regarding clinical benefits. We note that the inclusion of the CTE implant does not appear to be necessary to furnish or deliver a TKA, nor does it appear that the data generated from the CTE implant post-procedure is necessary to furnish or deliver the primary service. In this context, we question whether the CTE implant can be considered integral in accordance with eligibility criteria at § 419.66(b)(3).

The applicant stated that the CTE implant was single-use, intended to be used with one patient only, comes into contact with human tissue, and is implanted into the patient's knee prosthesis.

We are inviting public comments on whether the CTE implant meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1)

equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant did not indicate whether the CTE implant is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if the CTE implant is a supply or material furnished incident to a service.

We are inviting public comments on whether the CTE implant meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant asserted that the CTE implant with CHIRP® System is the only device

authorized by FDA with an indication to provide objective kinematic data from the implanted medical device during a patient's TKA post-surgical care. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the CTE implant. Per the applicant, the device category code C1776 (Joint device (implantable)) does not appropriately describe the CTE implant because C1776 was created for older technology that performs the function of the joint and does not describe a device that captures activity and kinematic data but is not a substitute for the natural knee.

We have not identified an existing pass-through payment category that describes the CTE implant. We are inviting public comment on whether the CTE implant meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or

(ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The CTE implant with CHIRP® system has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the CTE implant meets the device category criterion at § 419.66(c)(2)(ii).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the CTE implant would be reported with the HCPCS code as shown in Table 45.

Table 45: HCPCS CODES REPORTED WITH CTE IMPLANT

HCPCS Code	Long Descriptor	SI	APC
27447	Arthroplasty, knee, condyle, and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)	J1	5115

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note the applicant utilized the CY 2024 payment rates for the three cost criterion tests. For our calculations, we used APC 5115, which had a CY 2024 payment rate of \$12,539.82 at the time the application was received. HCPCS code 27447 had a device offset amount

of \$5,659.22 at the time the application was received. According to the applicant, the cost of the CTE implant part of the CTE implant with CHIRP® System is \$7,250.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of \$7,250.00 for the CTE implant is 57.82 percent of the applicable APC payment amount for the service related to the category of devices of \$12,539.82 ($(\$7,250.00/\$12,539.82) \times 100 = 57.82$ percent). Therefore, we believe the CTE implant meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides

that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$7,250.00 for the CTE implant is 128.11 percent of the cost of the device-related portion of the APC payment amount for the related service of \$5,659.22 ($(\$7,250.00/\$5,659.22) \times 100 = 128.11$ percent). Therefore, we believe that the CTE implant meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the

devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$7,250 for the CTE implant and the portion of the APC payment amount for the device of \$5659.22 is 12.69 percent of the APC payment amount for the related service of \$12,539.82 ($((\$7,250 - \$5,659.22)/\$12,539.82) \times 100 = 12.69$ percent). Therefore, we believe that the CTE implant meets the third cost significance requirement.

We are inviting public comment on whether the CTE implant meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(d) The DETOUR™ System

Endologix, LLC submitted an application for a new device category for transitional pass-through payment status for the DETOUR™ System for CY 2025. According to the applicant, the DETOUR™ System is an implantable component, used to create a femoropopliteal bypass routed through the femoral vein. The DETOUR™ System is comprised of two main components: (1) the TORUS™ Stent Graft System, which is comprised of the TORUS™ Stent Graft and the TORUS™ Stent Graft Delivery System, and (2) the ENDOCROSS™ Device. Per the applicant, the DETOUR™ System is used to treat patients with advanced peripheral vascular disease, specifically those with long complex femoropopliteal artery stenoses and occlusions resulting in lifestyle limiting claudication or severe lower limb threatening ischemia. According to the applicant, the DETOUR™ System can restore arterial blood flow to the lower limb around the blocked femoral artery and allows for venous blood flow around the conduit for normal venous return, to reduce signs and symptoms of lower limb ischemia and prevent amputation.

Please refer to the online application posting for the DETOUR™ System, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP23090164QL2>, for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), the DETOUR™ System received FDA Breakthrough Device designation effective September 2, 2020,

under the name the PQ Bypass System, as a device intended for percutaneous revascularization of symptomatic femoropopliteal lesions 200mm to 460mm with a chronic total occlusion 100mm to 425mm, and/or moderate-to-severe calcification, and/or in-stent-restenosis in patients with severe peripheral arterial disease. FDA approved the premarket approval application (PMA) for the DETOUR™ System on June 7, 2023, indicated for use for percutaneous revascularization in patients with symptomatic femoropopliteal lesions from 200 mm to 460 mm in length with chronic total occlusions (100 mm to 425 mm) or diffuse stenosis >70 percent who may be considered suboptimal candidates for surgical or alternative endovascular treatments. The DETOUR™ System, or any of its components, is not for use in the coronary and cerebral vasculature. We note that while the indication for the FDA Breakthrough Device designation and the indication for the FDA premarket approval vary slightly, we believe that FDA premarket approval indication is the indication covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the DETOUR™ System on September 1, 2023, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether the DETOUR™ System meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. Per the applicant, the DETOUR™ System is integral to the service provided and is used for one patient only. While the applicant did not indicate whether the DETOUR™ System comes in contact with human tissue, the applicant did specify that both components of the DETOUR™ System, the TORUS™ Stent Graft System and the ENDOCROSS™ Device, are inserted or implanted during the percutaneous transmural femoropopliteal bypass procedure, as required by § 419.66(b)(3).

We are inviting public comments on whether the DETOUR™ System meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus,

implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant asserted that the DETOUR™ System meets the device eligibility requirements because it is not an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

We are inviting public comments on whether the DETOUR™ System meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant described that the DETOUR™ System is a minimally invasive, single-use device with an implantable component, used to create a femoropopliteal bypass routed through the femoral vein. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the DETOUR™ System. The applicant provided a list of existing and previous device categories for pass-through payment for other stents and explained why they do not believe any of the categories describe the DETOUR™ System. In summary, the applicant asserted that the referenced device categories do not adequately describe the DETOUR™ System because, in contrast to the DETOUR™ System, the referenced device categories do not have: (1) a crossing device with long needle for transmural access, (2) a crossing device with high pressure needle delivery for heavily calcified and atherosclerotic arteries, (3) a high radial strength transmural stent graft capable of self-support and sustaining blood flow through conduit bridging artery to vein and back to artery, (4) a percutaneous stent graft delivery catheter, (5) a covered stent graft to allow for arterial blood flow within the conduit as venous blood flows around it in the vein, or (6) a permanent implant to maintain arterial and venous blood flow. The reasons the applicant asserted

for why the DETOUR™ System is not adequately described by each of the device categories are shown in Table 46.

TABLE 46: POTENTIAL EXISTING/PREVIOUS DEVICE CATEGORIES

HPCPS Code	Device Category Description	Applicant Assertion: The DETOUR™ System Is Not Appropriately Described by Existing/Previous Device Category
C1874	Stent, coated/covered, with delivery system	(1) No crossing device with long needle for transmural access; (2) No crossing device with high pressure needle delivery for heavily calcific and atherosclerotic arteries; (3) No high radial strength transmural stent graft capable of self-support and sustaining blood flow through conduit bridging artery to vein and back to artery
C1875	Stent, coated/covered, without delivery system	Reasons (1); (2); (3); and (4) No percutaneous stent graft delivery catheter
C1876	Stent, non-coated/non-covered, with delivery system	Reasons (1); (2); (3); and (5) No covered stent graft to allow for arterial blood flow within the conduit as venous blood flows around it in the vein
C1877	Stent, non-coated/non-covered, without delivery system	Reasons (1); (2); (3); (4); and (5)
C2625	Stent, non-coronary, temporary, with delivery system	Reasons (1); (2); (3); (5) and (6) No permanent implant to maintain arterial and venous blood flow
C2617	Stent, non-coronary, temporary, without delivery system	Reasons (1); (2); (3); (4); (5); and (6)
C1768	Graft, vascular	Reasons (1); (2); (3); and (5)
C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser	Reasons (1); (2); (3); and (5)
C2629	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, laser	Reasons (1); (2); (3); and (5)

We have not identified an existing pass-through payment category that describes the DETOUR™ System. We are inviting public comment on whether the DETOUR™ System meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part

compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The DETOUR™ System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by

the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the DETOUR™ System meets the device category criterion at § 419.66(c)(2)(i).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost

significance criteria that must each be met. The applicant provided the following information in support of the

cost significance requirements. The applicant stated that the DETOUR™

System would be reported with HCPCS code as shown in Table 47.

Table 47: HCPCS CODE REPORTED WITH THE DETOUR™ SYSTEM

HCPCS Code	Long Descriptor	SI	APC
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion.	J1	5193

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note the applicant used the CY 2023 payment rates for the three tests of the cost criterion. For our calculations, like the applicant, we used APC 5193, which had a CY 2023 payment rate of \$10,615.31 at the time the application was received. HCPCS code 0505T in APC 5193 had a CY 2023 device offset amount of \$5,229.10 at the time the application was received. According to the applicant, the cost of the DETOUR™ System is \$25,000.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of \$25,000.00 for the DETOUR™ System is 235.51 percent of the applicable APC payment amount for the service related to the category of devices of \$10,615.31 ($(\$25,000.00 / \$10,615.31) \times 100 = 235.51$ percent). Therefore, we believe the DETOUR™ System meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$25,000.00 for the DETOUR™ System is 478.09 percent of the cost of the device-related portion of the APC payment amount for the related service of \$5,229.10 ($(\$25,000.00 / \$5,229.10) \times 100 = 478.09$ percent). Therefore, we believe that the DETOUR™ System meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$25,000.00 for the DETOUR™ System and the portion of the APC payment amount for the device of \$5,229.10 is 186.25 percent of the APC payment amount for the related service of \$10,615.31 ($(\$25,000.00 - \$5,229.10) / \$10,615.31 \times 100 = 186.25$ percent). Therefore, we believe that the DETOUR™ System meets the third cost significance requirement.

We are inviting public comment on whether the DETOUR™ System meets the device pass-through payment criteria discussed in this section,

including the cost criterion for device pass-through payment status.

(e) EndoSound Vision System™ (EVST™)

EndoSound, Inc. submitted an application for a new device category for transitional pass-through payment status for the EVST™ for CY 2025. The applicant is only seeking a new device category for transitional pass-through payment status for the Ultrasound Disposable Kit—Diagnostic/Therapeutic (UDK–T) component (hereinafter referred to as “UDK–T”) of the EVST™. According to the applicant, the EVST™ is an ultrasound system designed to externally attach to an upper gastrointestinal (GI) endoscope (gastroscope/upper (EGD) endoscope). Per the applicant, the EVST™ is a device that, once attached to an EGD endoscope, temporarily converts the EGD endoscope to a fully capable endoscopic ultrasound (EUS) endoscope. The applicant asserted that the EVST™ can be coupled with an upper GI endoscope device to enable real-time ultrasound imaging, ultrasound guided needle aspiration, and other EUS guided procedures within the upper GI tract and surrounding organs. According to the applicant, the EVST™ consists of: (1) the EVSScanner, a beamformer/scanner that performs ultrasound signal processing; (2) the Ultrasound Transducer Module (UTM), a reusable transducer assembly that converts the electrical signals from the scanner into ultrasound energy; (3) the Transducer Extension Cable (TEC), a cable/connector to interface the UTM to the EVSScanner; and (4) the UDK–T, a disposable mounting kit with an operator control mechanism used to

externally affix the EVS™ to a standard EGD endoscope and to provide needle and transducer angulation while maintaining the native gastroscope controls.

Please refer to the online application posting for the EVS™, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP240228GJTOX>, for additional detail describing this device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), the EVS™, which includes the UDK–T, received FDA Breakthrough Device designation effective July 29, 2021, as a device intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the upper GI tract including but not restricted to the organs, tissues, and subsystems: esophagus, stomach, duodenum, and underlying areas. The instrument is introduced “per orally” when indications consistent with the requirement for procedure are observed in adult patient populations. FDA granted the applicant 510(k) clearance for the EVS™ on December 27, 2023, indicated for use such that when affixed to an endoscope, is intended to provide ultrasonic visualization of, and ultrasound guided therapeutic access to the upper GI tract including but not restricted to the organs, tissues, and subsystems: esophagus, stomach, duodenum, and underlying areas. The EVS™, mounted on an endoscope, is introduced orally when indications consistent with the requirement for a GI procedure are met. The EVS™ is a prescription-only device to be used by a qualified physician. The clinical environments where the system can be used include clinics, hospitals, and ambulatory surgery centers. We note that while the indication for the FDA Breakthrough Device designation and the indication for the FDA premarket approval vary slightly, we believe that FDA premarket approval indication is the one covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the EVS™ on February 28, 2024, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether the EVS™, inclusive of the UDK–T component, meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not indicate whether the UDK–T component of the EVS™ is integral to the service furnished; however, the applicant did indicate that the UDK–T is single-use, comes in contact with human tissue, and is inserted as part of an endoscopy procedure. We preliminarily approved the EndoSound Vision System® (EVS) HCPCS code C1606 (Adapter, single-use (*i.e.* disposable), for attaching ultrasound system to upper gastrointestinal endoscope) upon quarterly review under the alternative pathway with an effective of July 1, 2024. We note that HCPCS code C1606 was established for an adapter for attaching an ultrasound system to an upper gastrointestinal endoscope that can only be used for a single procedure and cannot be reprocessed. As such, HCPCS code C1606 only describes devices that cannot be reprocessed.

We are inviting public comments on whether the UDK–T component of the EVS™ meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant claimed that the UDK–T meets the device eligibility requirements because it is not equipment or an item for which depreciation and financing expenses are recovered. In addition, the applicant asserted that the UDK–T is not a supply or material.

We are inviting public comments on whether the UDK–T component of the EVS™ meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the

existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. According to the applicant, the EVS™ is an ultrasound system designed to externally attach to an upper gastrointestinal (GI) endoscope (gastroscope/upper (EGD) endoscope). According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the UDK–T. Per the applicant, device category C1748 (Endoscope, single-use (*i.e.*, disposable), Upper GI, imaging/illumination device (insertable)) does not appropriately describe the EVS™, inclusive of the UDK–T, because: (1) the EVS™, inclusive of the UDK–T, enables an endoscope that a hospital has to have added functionalities such as the ability to perform an EUS procedure, but is not an endoscope like the devices in C1748; (2) the EVS™, inclusive of the UDK–T, when used with an endoscope allows EUS procedures to be done without an elevator, unlike the other devices described in C1748; and (3) the EVS™, inclusive of the UDK–T, and the devices described in C1748 are used in different procedures. The applicant explained that CMS indicated that C1748 should always be billed with a CPT code in the ranges of 43260–43265 and 43274–43278, but there is no overlap between those CPT codes billed with C1748 and the CPT codes the applicant stated that the EVS™ would be reported with as shown in Table 48.

We have not identified an existing pass-through payment category that describes the UDK–T component of the EVS™.

We are inviting public comment on whether the UDK–T component of the EVS™ meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA’s Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The EVS™, inclusive of the UDK–T, has a Breakthrough Device designation and

marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the EVS™, inclusive of the

UDK–T component, meets the device category criterion at § 419.66(c)(2)(ii).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be

met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the EVS™ would be reported with HCPCS codes as shown in Table 48.

Table 48: HCPCS CODES REPORTED WITH THE EVS™

HCPCS Code	Long Descriptor	SI	APC
43231	Esophagoscopy, flexible, transoral; with endoscopic ultrasound examination	J1	5302
43232	Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s)	J1	5302
43237	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures	J1	5302
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)	J1	5302
43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)	J1	5302
43259	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination, including the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis	J1	5302

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note the applicant used the CY 2024 payment rates for the three tests of the

cost criterion. For our calculations, we used APC 5302, which had a CY 2024 payment rate of \$1,812.99 at the time the application was received. HCPCS code 43232 in APC 5302 had a CY 2024 device offset amount of \$14.50 at the time the application was received.²³

²³ We note that the applicant selected the APC payment rate of \$1,814.88 and the APC level device offset amount of \$178.95 for APC 5302. However, the values selected are inconsistent with the APC payment rate and the APC level device offset amount found in CY 2024 OPPS APC Offset File, which were corrected as described in the CY 2024 OPPS/ASC final rule with comment period correction (89 FR 9002). The HCPCS/CPT code level device offset amounts for the HCPCS/CPT codes provided by the applicant are available in the

According to the applicant, the cost of the disposable, single-use UDK–T component of the EVS™ is \$500.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25

corrected Addendum P to the CY 2024 OPPS/ASC final rule with comment period. For our calculation, we selected the APC payment rate of \$1,812.99 and the HCPCS/CPT code level device offset amount of \$14.50 related to HCPCS 43232 in APC 5302 found in the corrected Addendum P, which are the accurate values for these codes. Based on our initial assessment for this proposed rule, using the APC payment rate of \$1,812.99 and the device offset amount of \$14.50 would result in the EVS™ meeting the cost significance requirement.

percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of \$500.00 for the UDK–T is 27.59 percent of the applicable APC payment amount for the service related to the category of devices of \$1,812.99 ($(\$500.00/\$1,812.99) \times 100 = 27.59$ percent). Therefore, we believe the UDK–T component of the EVS™ meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$500.00 for the UDK–T is 3,448.28 percent of the cost of the device-related portion of the APC payment amount for the related service of \$14.50 ($(\$500.00/\$14.50) \times 100 = 3,448.28$ percent). Therefore, we believe that the UDK–T component of the EVS™ meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$500.00 for the UDK–T and the portion of the APC payment amount for the device of \$14.50 is 26.78 percent of the APC payment amount for the related service of \$1,812.99 ($(\$500.00 - \$14.50)/\$1,812.99 \times 100 = 26.78$ percent). Therefore, we believe that the UDK–T component of the EVS™ meets the third cost significance requirement.

We are inviting public comment on whether the UDK–T component of the EVS™ meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(f) iFuse Bedrock Granite™ Implant System

SI–BONE submitted an application for a new device category for transitional pass-through payment status for the iFuse Bedrock Granite™ Implant System for CY 2025. According to the applicant, the iFuse Bedrock Granite™ Implant System consists of iFuse Granite™ implants of various lengths and diameters and associated instruments sets. The titanium (Ti-6Al-

4V ELI) iFuse Granite™ implant consists of a porous fusion sleeve with threaded length attached to a solid post that has connection and implant placement features of a typical pedicle fixation screw. The iFuse Granite™ implant is intended to provide sacropelvic fusion of the sacroiliac joint (when placed in the sacral-alar-iliac (SAI) trajectory) and fixation to the pelvis when used in conjunction with commercially available pedicle screw fixation systems as a foundational element for segmental spinal fusion only when performing both a lumbar and a sacroiliac joint (SIJ) fusion procedure in the same operative session. The applicant asserted that joint fusion occurs as a result of the device's porous surface and interstices and fixation occurs through the device's helical threaded design and traditional posterior fixation rod connection.

Per the applicant, the device can be placed into the pelvis in two trajectories: the SAI trajectory (*i.e.*, into the sacrum, across the SIJ and into the ilium), or directly into the ilium. The applicant explained that the iFuse Granite™ implant is typically placed in the SAI trajectory, bilaterally, and oftentimes stacked to achieve two points of fusion and fixation/stabilization across each SIJ. According to the applicant, the iFuse Granite™ implant may also be used in a single, but bilateral, configuration, where only two implants may be required when replacing traditional pedicle screws in either a SAI trajectory or iliac trajectory. The applicant asserted that the iFuse Bedrock Granite™ Implant System is always used in addition to lumbar fusion instrumentation when used to perform lumbar and SIJ fusion at the same time.

Please refer to the online application posting for the iFuse Bedrock Granite™ Implant System, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP240220LPFNM>, for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), the iFuse Bedrock Granite™ Implant System received FDA Breakthrough Device designation effective November 23, 2021, as a treatment of the acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine, including: (1) degenerative disc disease (DDD), as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history

and radiographic studies; (2) severe spondylolisthesis (Grades 3 and 4) of the L5–S1 vertebra; (3) skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion; (4) spondylolisthesis; (5) trauma (*i.e.*, fracture or dislocation); (6) spinal stenosis; (7) deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis); (8) spinal tumor; and (9) pseudarthrosis, and/or failed previous fusion. Subsequently, FDA also granted the applicant 510(k) clearance for the iFuse Bedrock Granite™ Implant System on May 26, 2022 and December 22, 2022, for the indication covered by the Breakthrough Device designation with one additional indication for use: SIJ dysfunction that is a direct result of SIJ disruption and degenerative sacroiliitis, including conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months. We note that the 510(k) clearance dated December 22, 2022, expanded the previously cleared indication of the iFuse Bedrock Granite™ Implant System to include general compatibility with certain compatible pedicle screw systems, whereas the indications under the May 26, 2022, 510(k) clearance only addressed compatibility of the iFuse Bedrock Granite™ Implant System with the SeaSpine Mariner Pedicle Screw System. Each 510(k) clearance, the May 26, 2022, and the December 22, 2022, are covered by the November 23, 2021 Breakthrough Device designation for the iFuse Bedrock Granite™ Implant System. We received the application for a new device category for transitional pass-through payment status for the iFuse Bedrock Granite™ Implant System on February 20, 2024, which is within three years of the dates of the May 26, 2022 and December 22, 2022 FDA marketing authorizations for the iFuse Bedrock Granite™ Implant System.

We are inviting public comments on whether the iFuse Bedrock Granite™ Implant System meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not indicate if the iFuse Bedrock Granite™ Implant System is integral to the service furnished. The applicant provided that

the iFuse Bedrock Granite™ Implant is single-use, permanently implanted, and surgically inserted into the patient. However, we note that we do not have sufficient information to determine if the associated instruments sets included in the iFuse Bedrock Granite™ Implant System meet the eligibility criterion at § 419.66(b)(3).

We are inviting public comments on whether the iFuse Bedrock Granite™ Implant System meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant did not indicate whether the iFuse Bedrock Granite™ Implant System is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if the iFuse Bedrock Granite™ Implant System is a supply or material furnished incident to a service.

We are inviting public comments on whether the iFuse Bedrock Granite™ Implant System meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the iFuse Bedrock Granite™ Implant System. Per the applicant, the device category C1821 (Interspinous process distraction device) does not appropriately describe the iFuse Bedrock Granite™ Implant System because the iFuse Bedrock Granite™ Implant System is used to fixate and fuse, while the devices described in C1821 are interspinous spacers which, after implantation, are opened or expanded to distract the neural foramina and decompress the nerves.

The applicant asserted that device category C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) also does not appropriately describe the iFuse Bedrock Granite™ Implant System because the iFuse Bedrock Granite™ Implant System allows for simultaneous fusion of the SIJ and fixation of the pelvis by connecting via Tulip Connector to the base of the stabilizing rods within the lumbosacral spinal construct, while C1713 includes implantable pins and/or screws that are used to oppose soft tissue-to-bone, tendon-to-bone, or bone-to-bone. Per the applicant, the device category C1889 (Implantable/insertable device, not otherwise classified) also does not appropriately describe the iFuse Bedrock Granite™ Implant System because it does not describe any specific device category, and therefore does not uniquely describe the device category proposed for the iFuse Bedrock Granite™ Implant System.

We note that, according to the applicant, the iFuse Bedrock Granite™ implant is intended to provide sacropelvic fusion of the sacroiliac joint (when placed in the sacral-alar-iliac (SAI) trajectory) and fixation to the pelvis when used in conjunction with commercially available pedicle screw fixation systems as a foundational element for segmental spinal fusion only when performing both a lumbar and sacroiliac joint (SIJ) fusion procedure in the same operative session. The applicant asserted that joint fusion occurs as a result of the device's porous surface and interstices and fixation occurs through the device's helical threaded design and traditional posterior fixation rod connection. We believe that the device category C1713 may appropriately describe the iFuse Bedrock Granite™ Implant System and question whether a transfixing device utilizing the Tulip Connector is sufficiently distinguishable from traditional implantable pins or screws that it is meant to replace. In this context, based on the description the applicant provided, we believe the iFuse Bedrock Granite™ Implant System may be similar to the devices described by C1713, and therefore, the iFuse Bedrock Granite™ Implant System may also be appropriately described by C1713.

In addition, we believe that the device category C1889 may appropriately describe the iFuse Bedrock Granite™ Implant System because C1889 may be used to describe any implantable/insertable device that is not otherwise described by a more specific device

category and is, therefore, sufficiently broad to include implantable devices that allow for simultaneous fusion of the SIJ and fixation of the pelvis. We note that in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79562), CMS created C1889 with the specific intent to recognize devices furnished during a device intensive procedure that are not described by a specific Level II HCPCS Category C-code. In this context, we believe the iFuse Bedrock Granite™ Implant System may be appropriately described by either C1713 or C1889.

We are inviting public comment on whether the iFuse Bedrock Granite™ Implant System meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category at § 419.66(c)(2) provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The iFuse Bedrock Granite™ Implant System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the iFuse Bedrock Granite™ Implant System meets the device category criterion at § 419.66(c)(2)(ii).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the iFuse Bedrock Granite™ Implant System would be reported with HCPCS codes shown in Table 49.

**Table 49: HCPCS CODES REPORTED WITH THE IFUSE BEDROCK
GRANITE™ IMPLANT SYSTEM**

HCPCS Code	Long Descriptor	SI	APC
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device	J1	5116
22612	Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)	J1	5116
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar	J1	5116
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace, lumbar	J1	5116

According to the applicant, the iFuse Bedrock Granite™ Implant System is only used when both a SIJ fusion procedure and a lumbar fusion procedure are performed in the same operative session. The applicant stated that the iFuse Bedrock Granite™ Implant System is not utilized when only a SIJ fusion procedure is performed (HCPCS code 27279) or when only a lumbar fusion procedure is performed (HCPCS code 22612, 22630 or 22633). Rather, per the applicant, the appropriate coding of the procedure where the iFuse Bedrock Granite™ Implant System is used should include the CPT code for SIJ fusion (HCPCS code 27279) and a CPT code for lumbar fusion (HCPCS code 22612, 22630 or 22633). Per the applicant, the selection of the primary lumbar fusion CPT code (HCPCS code 22612, 22630 or 22633) is dependent on the procedure performed.

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note the applicant utilized the CY 2024 payment rates for the three tests of

the cost criterion. For our calculations, we used APC 5116, which had a CY 2024 payment rate of \$17,756.28 at the time the application was received. The applicant stated the iFuse Bedrock Granite™ Implant System device should be reported with the SIJ fusion procedure HCPCS code 27279 along with one of the three lumbar fusion procedures (HCPCS code 22612, 22630 or 22633). While the applicant utilized HCPCS code 22612 for the device offset amount for test two of the cost criterion, we believe that HCPCS code 27279 is the appropriate HCPCS code for the offset and subsequent calculation. Specifically, it is our understanding that code 27279 is always reported when the iFuse device is used along with only one of the three specified lumbar fusion codes. That is to say, the SIJ fusion procedure described by code 27279 is always performed when the iFuse device is used along with just one of three possible lumbar procedures, depending on the specific surgical approach used. Therefore, we believe that neither HCPCS code 22612, 22630, nor 22633 is appropriate to use for the cost criterion calculation. As such, we used HCPCS 27279, the code that should always be reported with the iFuse device, for our calculations.

HCPCS code 27279 in APC 5116 had a CY 2024 device offset amount of \$12,264.26 at the time the application was received. According to the applicant, the cost of the iFuse Bedrock Granite™ Implant System is \$11,689.00. Section 419.66(d)(1), the first cost

significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of \$11,689.00 for the iFuse Bedrock Granite™ Implant System is 65.83 percent of the applicable APC payment amount for the service related to the category of devices of \$17,756.28 ($(\$11,689.00/\$17,756.28) \times 100 = 65.83$ percent). Therefore, we believe the iFuse Bedrock Granite™ Implant System meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$11,689.00 for the iFuse Bedrock Granite™ Implant System is 95.31 percent of the cost of the device-related portion of the APC payment amount for the related service of \$12,264.26 ($(\$11,689.00/\$12,264.26) \times 100 = 95.31$ percent). Therefore, we believe that the iFuse Bedrock Granite™ Implant System does not meet the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides

that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$11,689.00 for the iFuse Bedrock Granite™ Implant System and the portion of the APC payment amount for the device of \$12,264.26 is negative 3.24 percent of the APC payment amount for the related service of \$17,756.28 ($((\$11,689.00 - \$12,264.26) / \$17,756.28) \times 100 = -3.24$ percent). Therefore, we believe that the iFuse Bedrock Granite™ Implant System does not meet the third cost significance requirement.

We are inviting public comment on whether the iFuse Bedrock Granite™ Implant System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(g) Paradise® Ultrasound Renal Denervation (RDN) System

ReCor Medical, Inc. submitted an application for a new device category for transitional pass-through payment status for the Paradise® Ultrasound RDN System for CY 2025. Per the applicant, the Paradise® Ultrasound RDN System is a catheter-based system that delivers ultrasound energy in the location of sympathetic nerves surrounding the renal arteries. The applicant explained that the Paradise® Ultrasound RDN System is indicated to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. According to the applicant, the Paradise® Catheter, when used with the other Paradise® Ultrasound RDN System components, provides complete 360-degree energy delivery and targeted ablation depth with each energy emission with the goal of disrupting the nerves and consequently achieving a reduction in systemic arterial blood pressure. The applicant asserted that the Paradise® Catheter protects the artery walls using a cooling system during periods of ultrasound energy emission (also called sonications).

Per the applicant's instructions for use, the Paradise® Ultrasound RDN System includes the following components: (1) Paradise® Generator, which circulates coolant fluid and electrical energy to the Paradise® Catheter via the Paradise® Cable and Paradise® Cartridge; (2) Paradise® Catheter, which connects with the

Paradise® Generator and has a distal balloon (available in six different diameters that correspond to varying artery diameter ranges) that is pressurized using coolant fluid; (3) Paradise® Cartridge, which controls the fluid flow into and out of the Paradise® Catheter when used in conjunction with the Paradise® Generator; (4) Paradise® Connection Cable, which transfers electrical energy from the Paradise® Generator to the Paradise® Catheter; (5) Paradise® Remote, included with the Paradise® Generator for optional use; and (6) Paradise® Cart, an optional wheeled cart to which the Paradise® Generator can be mounted to stabilize the Paradise® Generator during a procedure and to transport the Paradise® Generator from one location to another. Per the applicant, additional items required for the procedure include: (1) a bag of coolant fluid for inflation and cooling of balloon; (2) a 0.014 inch guidewire to track the Paradise® Catheter into position for delivery of ultrasound energy; (3) a Push/Pull style hemostasis valve; (4) a 6 French (Fr) or larger guide sheath; and (5) a 7 Fr or larger guide catheter.

According to the applicant, the Paradise® Catheter, Paradise® Cartridge, and Paradise® Connection Cable are single-patient, one-time use components of the system. According to the applicant, key steps for operating the Paradise® Ultrasound RDN System include: (1) gaining access to the femoral artery using standard interventional techniques and placing a 7 Fr (or larger) guide catheter; (2) advancing the 7 Fr guide catheter into the left or right renal artery under fluoroscopic guidance; (3) performing an angiogram to verify the patency of the left or right renal artery; (4) measuring the distal, mid, and proximal artery diameters and selecting the appropriate Paradise® Catheter balloon size; (5) preparing and attaching the Paradise® Cartridge, Paradise® Connection Cable, and sterile water supply, and connecting the Paradise® Cartridge extension tubing to the Paradise® Catheter; (6) preparing and flushing the Paradise® Catheter; removing access devices from the lumen of the guide catheter and inserting a 0.014 inch guidewire; (7) verifying the balloon on the Paradise® Catheter is deflated; (8) tracking the Paradise® Catheter over the guidewire and gently inserting the Paradise® Catheter into the push/pull style hemostasis valve and guide catheter; (9) advancing and positioning the Paradise® Catheter in desired locations within the renal arteries; (10) inflating the balloon via

the Paradise® Generator; (11) verifying the position of the balloon and catheter transducer via fluoroscopy and contrast injection; (12) performing denervation of the left and/or right renal artery by delivery of ultrasound energy; (13) verifying balloon deflation via fluoroscopy before moving to the next location; (14) withdrawing the Paradise® Catheter back into the guide catheter prior to moving the device into an alternate artery or accessory vessel, continuing to another position and exchanging the balloon catheter, as needed; (15) removing the Paradise® Catheter, ensuring that Paradise® Catheter balloon is in a deflated state prior to removal, by slowly withdrawing the Paradise® Catheter through the guide catheter, until completely withdrawn, and removing the guidewire and guide catheter; and (16) closing the wound per standard of practice.

Please refer to the online application posting for the Paradise® RDN System, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP231128137E1>, for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), the Paradise® Ultrasound RDN System received FDA Breakthrough Device designation effective December 4, 2020, as a device with the indicated use to reduce blood pressure in adult (≥ 22 years of age) patients with uncontrolled hypertension, who may be inadequately responsive to, or who are intolerant to anti-hypertensive medications. FDA approved the premarket approval application (PMA) for the Paradise® Ultrasound RDN System on November 7, 2023 for the indicated use to reduce blood pressure as an adjunctive treatment in hypertension patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. We note that while the indication for the FDA Breakthrough Device designation and the indication for the FDA premarket approval vary slightly, we believe that FDA premarket approval indication is the one covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the Paradise® Ultrasound RDN System on November 28, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether the Paradise® Ultrasound RDN System meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, be used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not explicitly state whether the Paradise® Ultrasound RDN System is integral to the service furnished. With respect to whether the Paradise® Ultrasound RDN System is used for one patient only, the applicant asserted that the Paradise® Catheter, Paradise® Cartridge, and Paradise® Connection Cable are single patient use. However, the Paradise® Generator, Paradise® Remote, and Paradise® Cart are reusable and are capital equipment. While the applicant did not explicitly state whether the Paradise® Ultrasound RDN System comes into contact with human tissue, the applicant provided that the Paradise® Catheter is placed within the renal artery. According to the applicant, the Paradise® Ultrasound RDN System is an implantable device. We note that the Paradise® Generator, Paradise® Remote, and Paradise® Cart are reusable, do not come in contact with the patient's tissue, are not surgically implanted or inserted, or applied in or on a wound or other skin lesion, as required by § 419.66(b)(3).

We are inviting public comments on whether the Paradise® Ultrasound RDN System meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). While the applicant did not explicitly state whether the Paradise® Ultrasound RDN System, or select components, is equipment, an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, per the applicant, the Paradise® Catheter, Paradise® Cartridge, and Paradise® Connection Cable are single-use only. The applicant further explained that the Paradise® Generator, Paradise® Cart, and Paradise® Remote

are capital equipment; as such, they are excluded from device pass-through payment eligibility under § 419.66(b)(4). The applicant did not explicitly state whether the Paradise® Ultrasound RDN System is a supply or material furnished incident to a service.

The applicant requested pass-through payment for the Paradise® Ultrasound RDN System, but we question whether only the Paradise® Catheter component of the Paradise® Ultrasound RDN System, as opposed to the whole system, is eligible for pass-through payments under § 419.66(b)(3) or at § 419.66(b)(4). We do not believe that the Paradise® Generator, Paradise® Cable, Paradise® Cartridge, Paradise® Connection Cable, Paradise® Remote, or Paradise® Cart meet the eligibility requirements under § 419.66(b)(3) or at § 419.66(b)(4), and, as such, are not eligible for pass-through payments.

We are inviting public comments on whether the Paradise® Ultrasound RDN System meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. Per the applicant, the Paradise® Ultrasound RDN System is a catheter-based system that delivers ultrasound energy in the location of sympathetic nerves surrounding the renal arteries. According to the applicant, no previous or existing device categories for pass-through payment have encompassed the Paradise® Ultrasound RDN System. Per the applicant, device categories C1753 (Catheter, intravascular ultrasound) and C1888 (Catheter, ablation, noncardiac, endovascular (implantable)) do not appropriately describe the Paradise® Ultrasound RDN System. The applicant asserted that C1753 does not appropriately describe the Paradise® Ultrasound RDN System because the Paradise® Ultrasound RDN System is used to treat a disease and denervates renal nerves, whereas C1753 was created to describe ultrasound catheter devices that are not used to treat a disease and are used for imaging of the vessel. According to the applicant, C1888 does not appropriately describe the Paradise® Ultrasound RDN System because the Paradise® Ultrasound RDN System is intended to denervate renal nerves by using ultrasound energy that

does not otherwise affect the blood vessel tissue, whereas C1888 was created to describe devices that use radiofrequency or laser technologies to occlude or obliterate blood vessels.²⁴

We have not identified an existing pass-through payment category that describes the Paradise® Ultrasound RDN System. We are inviting public comment on whether the Paradise® Ultrasound RDN System meets the device category criterion at § 419.66(c)(1).

We note that the applicant indicated the Paradise® Ultrasound RDN System is the only device authorized by FDA with an indication for renal denervation using ultrasound energy to achieve reductions in blood pressure. However, we note that the Symplicity Spyral™ Catheter (Symplicity Spyral™ RDN System) device, for which we also received an application for transitional pass-through payments for CY 2025 as discussed in this proposed rule, is authorized by FDA with an indication for renal denervation using a radiofrequency modality to achieve reductions in blood pressure. Accordingly, we note that while the Paradise® Ultrasound RDN System device may have a different modality (*i.e.*, ultrasound compared to radiofrequency) to that of the Symplicity Spyral™ Catheter device, the Paradise® Ultrasound RDN System device may have a similar mechanism of action to that of the Symplicity Spyral™ Catheter device. We question whether the device descriptions provided in the respective applications support establishing two modality specific pass-through payment device categories or a single device category that would encompass both RDN device modalities. We address this question in detail immediately following the full discussion of all other applicable eligibility criteria for both the Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System applications.

We are inviting public comment on whether Paradise® Ultrasound RDN System meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part

²⁴ The applicant referenced the Medicare Claims Processing Manual, Chapter 4 to support these assertions.

compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. As previously stated, the Paradise® Ultrasound RDN

System has Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the Paradise® Ultrasound RDN System meets the device category criterion at § 419.66(c)(2)(ii).

The third criterion for establishing a device category, at § 419.66(c)(3),

requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that Paradise® Ultrasound RDN System would be reported with HCPCS codes shown in Table 50.

Table 50: HCPCS CODES REPORTED WITH PARADISE® ULTRASOUND RDN

SYSTEM

HCPCS Code	Long Descriptor	SI	APC
0338T**	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; unilateral	J1	5192
0339T**	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral	J1	5192

**Denotes a HCPCS code that was not included in Addendum P to the CY 2023 OPPS/ASC final rule with comment period, with no CY 2023 HCPCS/CPT code level device offset amount available. We note the applicant used the CY 2023 payment rates for the three tests of the cost criterion. Since neither of the HCPCS/CPT codes provided by the applicant had a CY 2023 HCPCS/CPT code level device offset amount available at the time the application was received, we used the CY 2023 APC level device offset amount to assess whether the device meets the cost significance criterion.

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the

lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY

2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note the applicant used the CY 2023 payment rates for the three tests of the cost criterion. For our calculations, we

used APC 5192, which had a CY 2023 payment rate of \$5,215.40 at the time the application was received. We used the CY 2023 APC level device offset amount of \$1,491.08 for APC 5192, since HCPCS codes 0338T and 0339T were not included in Addendum P to the CY 2023 OPPS/ASC final rule with comment period and no CY 2023 HCPCS/CPT code level device offset amount was available at the time the application was received.²⁵ According to the applicant, the operating cost²⁶ of the Paradise® Ultrasound RDN System is \$23,000.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of \$23,000.00 for the Paradise® Ultrasound RDN System is 441.00 percent of the applicable APC payment amount for the service related to the category of devices of \$5,215.40 ($(\$23,000.00/\$5,215.40) \times 100 = 441.00$ percent). Therefore, we believe the Paradise® Ultrasound RDN System meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$23,000.00 for the Paradise® Ultrasound RDN System is 1,542.51 percent of the

cost of the device-related portion of the APC payment amount for the related service of \$1,491.08 ($(\$23,000.00/\$1,491.08) \times 100 = 1,542.51$ percent). Therefore, we believe that the Paradise® Ultrasound RDN System meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$23,000.00 for the Paradise® Ultrasound RDN System and the portion of the APC payment amount for the device of \$1,491.08 is 412.41 percent of the APC payment amount for the related service of \$5,215.40 ($(\$23,000.00 - \$1,491.08)/\$5,215.40 \times 100 = 412.41$ percent). Therefore, we believe that the Paradise® Ultrasound RDN System meets the third cost significance requirement.

We are inviting public comment on whether the Paradise® Ultrasound RDN System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(h) Precision GI

Limaca Medical submitted an application for a new device category for transitional pass-through payment status for Precision GI for CY 2025. According to the applicant, Precision GI is a motorized, battery operated, single-use, fully disposable endoscopic ultrasound-guided (EUS) fine needle biopsy device used to obtain biopsies of tissue for definitive diagnosis of pancreatic cancer and other life-threatening GI abnormalities. Per the applicant, Precision GI is untethered and battery operated with an internally powered and controlled motor, featuring a long flexible shaft transferring the proximal force of the motor through the inserted endoscope to the needle circumferential cutting tip. The device is controlled by a physician, who inserts the device into the patient's gastrointestinal (GI) tract via the ultrasound endoscope. Upon reaching the designated biopsy site, the physician operates the device's motorized mechanism that automatically rotates the needle (which is included in the device's package) to cut and extract tissue. The biopsy site is accessed through the instrument channel of an ultrasound imaging endoscope that detects the device's echogenic needle tip.

Please refer to the online application posting for Precision GI, available at <https://mearis.cms.gov/publications/device-ntp/DEP23113023REE>, for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), Precision GI received FDA Breakthrough Device designation effective March 24, 2022, as a device used with an ultrasound endoscope for fine needle biopsy of submucosal lesions, mediastinal masses, lymph nodes, and intraperitoneal masses within or adjacent to the GI tract. FDA granted the applicant 510(k) clearance for Precision GI on August 28, 2023, for the indication covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for Precision GI on November 30, 2023, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether Precision GI meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not indicate whether Precision GI is an integral part of the service furnished. The applicant stated that the device is intended for single-use. While the applicant did not explicitly state whether Precision GI comes in contact with human tissue and is surgically inserted or implanted, the applicant noted that Precision GI is used to sample targeted submucosal lesions, mediastinal masses, lymph nodes, and intraperitoneal masses within or adjacent to the GI tract and this is achieved by a physician who inserts Precision GI into the patient's GI tract using an ultrasound endoscope. However, we note that, while the needle (which is a component of the device and is included in the device's package) does come into contact with human tissue and is surgically inserted, the motorized mechanism of the Precision GI device itself may not come in contact with human tissue and may not be surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion, as required at § 419.66(b)(3).

²⁵ The applicant stated as neither HCPCS code 0338T nor 0339T had a device offset amount listed in Addendum P to the CY 2023 OPPS/ASC final rule with comment period, it selected a device offset amount of \$0.00. However, for our calculation, we selected the CY 2023 APC level device offset amount of \$1,491.08 for APC 5192 found in CY 2023 NFRM OPPS APC Offset File, as no CY 2023 HCPCS/CPT code level device offset amount was available at the time the application was received. Based on our initial assessment for this proposed rule, using the device offset amount of \$1,491.08 would result in Paradise® RDN meeting the cost significance requirement.

²⁶ According to the applicant, the current total cost of the Paradise® Ultrasound RDN System device is \$23,235.00. For the cost criteria estimates, the applicant submitted an operating cost of \$23,000.00 for the Paradise® Ultrasound RDN System device. Per the applicant, the individual component costs are as follows: Paradise® Remote (capital equipment) is \$5.00; Paradise® Cart (capital equipment) is \$5.00; Paradise® Generator (capital equipment) is \$225.00; Paradise® RDN Catheter Kit (one time use) is \$22,000.00; Paradise RDN Cable (one time use) is \$250.00; and the Paradise® RDN Cartridge (one time use) is \$750.00.

We are inviting public comments on whether Precision GI meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant indicated that Precision GI is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets, the applicant noted that Precision GI is a motorized, single-use, fully disposable EUS fine needle biopsy device that functions with no related capital component. The applicant stated that Precision GI is not a material or supply furnished incident. However, based on the description of the device as a biopsy device, we question whether Precision GI may be considered a supply or material furnished incident to a service and excluded from device pass-through payment eligibility under § 419.66(b)(4).

Specifically, in the CY 2001 OPPS interim final rule with comment period (65 FR 67804 through 67805), we explained how we interpreted § 419.43(e)(4)(iv). We stated that we consider a device to be surgically implanted or inserted if it is introduced into the human body through a surgically created incision. We also stated that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. We consider items used to create incisions, such as scalpels, electrocautery units, biopsy apparatuses, or other commonly used operating room instruments, to be supplies or capital equipment not eligible for transitional pass-through payments. We stated that we believe the function of these items is different and distinct from that of devices that are used for surgical implantation or insertion. Finally, we stated that, generally, we would expect that surgical implantation or insertion of a device occurs after the surgeon uses certain primary tools, supplies, or instruments to create the surgical path or site for

implanting the device. Further, in the CY 2006 OPPS final rule with comment period (70 FR, 68629 through 68630), we adopted as final our interpretation that the surgical insertion or implantation criterion can be met by devices that are surgically inserted or implanted via a natural or surgically created orifice, as well as those devices that are inserted or implanted via a surgically created incision. We reiterated that we maintain all of the other criteria in § 419.66 of the regulations, namely, that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. We reiterated this interpretation in the CY 2024 OPPS final rule (88 FR 81543, 81743).

We note that Precision GI, is inserted into the patient's GI tract via the ultrasound endoscope to reach the designated biopsy site where the device's motorized mechanism is then used for cutting and extraction of tissue endoscopically from within or adjacent to the patient's GI tract. However, we question whether Precision GI, which is described as a biopsy device, may be considered a supply or material furnished incident to a service consistent with our previous interpretation of § 419.43(e)(4)(iv) and therefore excluded from device pass-through payment eligibility under § 419.66(b)(4).

We welcome additional evidence regarding whether Precision GI should be considered a material or supply incident to a service based on our previous interpretation of § 419.43(e)(4)(iv) as it has been applied to biopsy devices and we invite public comments on whether Precision GI meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant asserted that Precision GI is authorized by FDA with an indication to sample targeted submucosal lesions, mediastinal masses, lymph nodes, and intraperitoneal masses within or adjacent to the gastrointestinal tract. Per the applicant, the device category C1830

(Powered bone marrow biopsy needle) does not appropriately describe Precision GI because Precision GI is not targeting the bone marrow and instead is targeting sub-mucosal and extramural gastrointestinal lesions. According to the applicant, another device category C1782 (Morcellator) does not appropriately describe Precision GI because that device category, per Medicare Claims Processing Manual, Ch. 4, § 60.4.3, is only for laparoscopic procedures. The applicant added that Precision GI cuts and extracts tissue endoscopically, not laparoscopically.

We have not identified an existing pass-through payment category that describes Precision GI. We are inviting public comment on whether Precision GI meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. Precision GI has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the Precision GI meets the device category criterion at § 419.66(c)(2)(ii). The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that Precision GI would be reported with HCPCS codes as shown in Table 51.

Table 51: HCPCS CODES REPORTED WITH PRECISION GI

HCPCS Code	Long Descriptor	SI	APC
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)	J1	5302
43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)	J1	5302

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note the applicant utilized the CY 2024 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5302, which had a CY 2024 payment rate of \$1,812.99 at the time the application was received. HCPCS code 43242 in APC 5302 had a CY 2024 device offset amount of \$23.75 at the time the application was received.²⁷ According to the applicant, the cost of Precision GI is \$1,400.00.

²⁷ We note that the applicant selected the APC payment rate of \$1,814.88 and the APC level device offset amount of \$178.95 for APC 5302. However, the values selected are inconsistent with the APC payment rate and the APC level device offset amount found in CY 2024 OPPS APC Offset File, which were corrected as described in the CY 2024 OPPS/ASC final rule with comment period correction (89 FR 9002). The HCPCS/CPT code level device offset amounts for the HCPCS/CPT codes provided by the applicant are available in the corrected Addendum P to the CY 2024 OPPS/ASC final rule with comment period. For our calculation, we selected the APC payment rate of \$1,812.99 and the HCPCS/CPT code level device offset amount of \$23.75 related to HCPCS 43242 in APC 5302 found in the corrected Addendum P, which are the accurate values for these codes. Based on our initial assessment for this proposed rule, using the APC payment rate of \$1,812.99 and the device offset amount of \$23.75 would result in Precision GI meeting the cost significance requirement.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of \$1,400.00 for Precision GI is 77.22 percent of the applicable APC payment amount for the service related to the category of devices of \$1,812.99 ($(\$1,400.00/\$1,812.99) \times 100 = 77.22$ percent). Therefore, we believe Precision GI meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount. The estimated average reasonable cost of \$1,400.00 for Precision GI is 5894.74 percent of the cost of the device-related portion of the APC payment amount for the related service of \$23.75 ($(\$1,400.00/\$23.75) \times 100 = 5894.74$ percent). Therefore, we believe that Precision GI meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$1,400.00 for Precision GI and the portion of the APC payment amount for the device of \$23.75 is 75.91 percent of

the APC payment amount for the related service of \$1,812.99 ($(\$1,400 - \$23.75)/\$1,812.99 \times 100 = 75.91$ percent). Therefore, we believe that Precision GI meets the third cost significance requirement.

We are inviting public comment on whether Precision GI meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(i) PulseSelect™ Pulsed Field Ablation (PFA) System

Medtronic, Inc. submitted an application for a new device category for transitional pass-through payment status for the PulseSelect™ PFA System for CY 2025. Per the applicant, the PulseSelect™ PFA System is used to perform pulmonary vein isolation (PVI) via cardiac catheter ablation to treat atrial fibrillation. According to the applicant, unlike existing methods that rely on thermal energy (either radiofrequency or cryoablation), the PulseSelect™ PFA System uses non-thermal irreversible electroporation (IRE) to induce cardiac tissue cell death. The pulsed field ablation, or IRE for PVI during cardiac catheter ablation, is performed as a percutaneous, transvenous procedure under imaging guidance. The applicant stated the PulseSelect™ PFA System consists of three elements: (1) the PulseSelect™ PFA Loop Catheter (Loop Catheter), a one-time use, steerable, multi-electrode loop catheter used to deliver IRE in pulmonary vein isolation as a treatment for atrial fibrillation; (2) the PulseSelect™ PFA Catheter Interface Cable (Catheter Interface Cable), a one-time use interface cable used to connect the Loop Catheter to the PulseSelect™

PFA Generator system; and (3) the PulseSelect™ PFA Generator system (Generator system) used to deliver IRE in pulmonary vein isolation as a treatment for atrial fibrillation.

Please refer to the online application posting for the PulseSelect™ PFA System, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP240228J1461>, for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), the PulseSelect™ PFA System received FDA Breakthrough Device designation effective September 27, 2018, for the treatment of drug refractory recurrent symptomatic atrial fibrillation. The Medtronic multi-electrode cardiac ablation catheter (which is now known as PulseSelect™) is also intended to be used for cardiac electrophysiological (EP) mapping and measuring of intracardiac electrograms, delivery of diagnostic pacing stimuli, and verifying electrical isolation post-treatment. FDA approved the premarket approval application (PMA) for the PulseSelect™ PFA System on December 13, 2023, for the indication covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the PulseSelect™ PFA System on February 28, 2024, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether the PulseSelect™ PFA System meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not indicate whether the PulseSelect™ PFA System is integral to the service furnished. Per the applicant, the Loop Catheter and Catheter Interface Cable components are single-use. While the applicant did not explicitly state whether any of the device components come in contact with human tissue, based on the device description, the procedure with which the PulseSelect™ PFA System Loop Catheter is used is performed percutaneously (*i.e.*, passing through the skin) and transvenously (*i.e.*, through or across a vein) using the Loop Catheter to achieve ablation in the targeted areas.

However, neither the Generator system nor the Catheter Interface Cable which is used to connect the Loop Catheter to the Generator system appear to come in contact with the patient's tissue, be surgically implanted or inserted, or applied in or on a wound or other skin lesion, as required by § 419.66(b)(3) and therefore, we do not believe that either component is eligible for device pass-through payments. We discuss the Catheter Interface Cable in more detail in the following criteria discussions.

We are inviting public comments on whether the PulseSelect™ PFA System meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant did not indicate whether the Loop Catheter and the Catheter Interface Cable are equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered or a material or supply furnished incident to a service. However, we note that in the application for a new device category for transitional pass-through payment status for CY 2025, the applicant stated that the Catheter Interface Cable is a one-time use cable that cannot be reprocessed. This assertion appears contrary to the information provided to CMS by the applicant in their application submission for FY 2025 IPPS new technology add-on payment under the name “PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter” (<https://mearis.cms.gov/public/publications/ntap/NTP231017BMQKQ>). Specifically, in the FY 2025 IPPS/LTCH PPS proposed rule, CMS noted that the applicant stated that the PulseSelect™ PFA Interface Cable is a component of the PulseSelect™ PFA Generator Reusable Accessories. Further, CMS explained that the new technology add-on payment application is for the PulseSelect™ PFA Loop Catheter (as opposed to the PulseSelect™ PFA System) and that the applicant had specified in its application that the PulseSelect™ PFA Generator System is not the subject of this new technology add-on payment application (89 FR

36124). Therefore, we stated that we believe the total cost should be based only on the cost of the PulseSelect™ PFA Loop Catheter.

In contrast to the new technology add-on payment application, the application for a new device category for transitional pass-through payment status is for the PulseSelect™ PFA System, which includes the PulseSelect™ PFA Generator system. The PulseSelect™ PFA Interface Cable is listed as a component of the PulseSelect™ PFA Generator System, which the applicant described as capital equipment in its new technology add-on payment application. We therefore believe the PulseSelect™ PFA Generator System, including the Catheter Interface Cable, is an item for which depreciation and financing expenses are recovered as depreciation assets and thus, is ineligible for device pass-through payment under § 419.66(b)(4).

We are inviting public comments on whether the PulseSelect™ PFA System meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant asserted that the PulseSelect™ PFA System is the only device authorized by FDA with an indication for cardiac electrophysiological mapping (stimulation and recording) and for treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation or persistent atrial fibrillation (episode duration less than 1 year) through the use of IRE. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the PulseSelect™ PFA System. Per the applicant, device categories C2630 (Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, cool-tip) and C1733 (Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, other than cool-tip) do not appropriately describe the PulseSelect™ PFA System because, unlike cardiac catheter ablation technologies using thermal energy where options are either heat (radiofrequency) or cold (cryoablation), the PulseSelect™ PFA System uses non-thermal IRE to elicit targeted

cardiac tissue cell death. The applicant stated that the PulseSelect™ PFA System's non-thermal IRE mechanism of action avoids many risks present in thermal cardiac catheter ablation technologies.

We note that, based on the description the applicant provided, the PulseSelect™ PFA System is used to achieve catheter ablation to treat atrial fibrillation, and thus could be appropriately described by C1733. Specifically, we believe that C1733 may appropriately describe the PulseSelect™ PFA System because it includes a catheter used for ablation of tissue without a cool-tip. Further, C1733 does not specify the modality needed to deliver the ablation, whether thermal or by electroporation. In this context, we believe the PulseSelect™ PFA System may be similar to the devices described by C1733, and therefore, the PulseSelect™ PFA System may also be appropriately described by C1733.

We are inviting public comment on whether the PulseSelect™ PFA System meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The PulseSelect™

PFA System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the PulseSelect™ PFA System meets the device category criterion at § 419.66(c)(2)(ii).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the PulseSelect™ PFA System would be reported with the HCPCS code shown in Table 52.

Table 52: HCPCS CODES REPORTED WITH PULSESELECT™ FA SYSTEM

HCPCS Code	Long Descriptor	SI	APC
93656	Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography including imaging supervision and interpretation, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, right ventricular pacing/recording, and His bundle recording when performed.	J1	5213

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note that the applicant utilized the CY 2024 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5213, which had a CY 2024 payment rate of \$22,629.19 at the time the application was received. HCPCS code 93656 in

APC 5213 had a CY 2024 device offset amount of \$11,251.23 at the time the application was received.

According to the applicant, the cost of the one-time use Loop Catheter is \$9,750.00. We note the applicant included the cost of the Loop Catheter (\$9,750.00) and the cost of the Catheter Interface Cable (\$800.00) in the cost significance tests, totaling the cost of the device as \$10,550.00. However, as previously discussed, we believe that the PulseSelect™ PFA Generator System, including the PulseSelect™ PFA Catheter Interface Cable, is capital equipment and therefore not eligible for device pass-through status payment. As such we removed the cost of Catheter Interface Cable in our calculations and only included the cost of the Loop Catheter, which changed the total device cost from \$10,550.00 to

\$9,750.00; we have used \$9,750.00 to perform the cost significance tests. We further note that the decision to exclude the cost of the Catheter Interface Cable (\$800.00) in the cost significance tests did not change the outcome of the cost significance criterion determinations.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of \$9,750.00 for the PulseSelect™ PFA System is 43.09 percent of the applicable APC payment amount for the service related to the category of devices of \$22,629.19 $((\$9,750.00/\$22,629.19) \times 100 = 43.09$ percent). Therefore, we believe the

PulseSelect™ PFA System meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$9,750.00 for the PulseSelect™ PFA System is 86.66 percent of the cost of the device-related portion of the APC payment amount for the related service of \$11,251.23 ($(\$9,750.00/\$11,251.23) \times 100 = 86.66$ percent). Therefore, we believe that the PulseSelect™ PFA System does not meet the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$9,750.00 for the PulseSelect™ PFA System and the portion of the APC payment amount for the device of \$11,251.23 is negative 6.63 percent of the APC payment amount for the related service of \$22,629.19 ($((\$9,750.00 - \$11,251.23)/\$22,629.19) \times 100 = -6.63$ percent). Therefore, we believe that the PulseSelect™ PFA System does not meet the third cost significance requirement.

We are inviting public comment on whether the PulseSelect™ PFA System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(j) Symplicity Spyral™ Renal Denervation (RDN) System

Medtronic submitted an application for a new device category for transitional pass-through payment status for the Symplicity Spyral™ RDN System, for CY 2025. The applicant is only seeking a new device category for transitional pass-through payment status for the Symplicity Spyral™ Multi-Electrode RDN Catheter (hereinafter Symplicity Spyral™ Catheter) the Symplicity Spyral™ RDN System. According to the applicant, the Symplicity Spyral™ RDN System consists of the Symplicity Spyral™ Catheter and the Symplicity G3™ generator; the applicant requested

device pass-through status for the catheter component of the system only. The applicant further explained that the Symplicity Spyral™ RDN System is indicated to reduce blood pressure as an adjunctive treatment in hypertension patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. Per the applicant, the Symplicity Spyral™ Catheter, when used with the Symplicity G3™ generator, delivers radiofrequency (RF) energy through the wall of the renal artery to disrupt the surrounding renal nerves with the aim of modulating or suppressing sympathetic nerve hyperactivity. According to the applicant, the Symplicity Spyral™ Catheter is a single-use catheter used to deliver multiple ablations in both kidneys, in the renal main, accessory, and branch arteries, based on a patient's artery anatomy and size.

Per the applicant, the Symplicity Spyral™ Catheter is designed to be used with the Symplicity G3™ generator and includes the following components: (1) 4 gold radiopaque electrodes at the spiral (helical) distal end that are deployed into a spiral (helical) shape by partially retracting the guidewire proximal to the spiral section of the catheter; (2) self-expanding electrode array assembly which radially spaces the four gold electrodes for quadratic ablation; (3) rapid exchange port; (4) straightening tool intended to facilitate safe insertion of the guidewire into the catheter; (5) cable connector attached to the catheter handle that connects the catheter to the generator; (6) catheter handle; and (7) femoral marker. Per the applicant, additional components of the Symplicity Spyral™ RDN System include the: (1) Symplicity G3™ generator, which is only compatible with the Symplicity Spyral™ Catheter, which includes a remote control, power cable, and output for the Symplicity Spyral™ Catheter; (2) Symplicity G3™ generator cart, an optional mobile cart; and (3) foot switch, an optional component. Per the applicant, additional items required for the procedure include: (1) a 0.36 mm (0.014 in) guidewire, preferably without hydrophilic coating; (2) a dispersive electrode; (3) a sterile bag to cover the remote control if used in the sterile field; (4) a 6 French (Fr) guide-catheter; (5) an introducer sheath; (6) a stopcock sidearm; (7) a Tuohy-Borst adapter; and (8) other standard items used to aid percutaneous transluminal catheterization in renal arteries.

According to information submitted by the applicant, key steps for operating the Symplicity Spyral™ Catheter

include: (1) connecting the Symplicity Spyral™ Catheter to the Symplicity G3™ generator; (2) inserting the Symplicity Spyral™ Catheter through a small femoral incision and guiding it to the renal artery via the abdominal aorta; (3) advancing the Symplicity Spyral™ Catheter until the distal electrode is located in the desired position within the renal artery; (4) retracting the guidewire, allowing the self-expanding catheter to expand and fit the renal arterial vessel walls; (5) delivering the treatment of RF energy to ablate the renal nerves through the activation of the catheter electrodes, which is controlled using the generator; (6) if treating another vessel, repositioning the guide catheter within the next vessel and repeating the procedure for positioning the catheter and delivering treatments; (7) upon completion of all treatments, straightening the distal end by advancing the guidewire and withdrawing both the guidewire and the straightened catheter from the guide catheter; (8) retracting the guide catheter from the sheath and removing the introducer sheath from the artery; (9) using standard of care procedures to achieve hemostasis at the puncture site; and (10) disposing of the devices.

Please refer to the online application posting for the Symplicity Spyral™ RDN System, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP231130WPU4/>, for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), the Symplicity Spyral™ RDN System received FDA Breakthrough Device designation effective March 27, 2020, as a device with the following indicated use: the Symplicity Spyral™ multi-electrode renal denervation catheter and the Symplicity G3 RF Generator are indicated for the reduction of blood pressure in patients with uncontrolled hypertension despite the use of anti-hypertensive medications or in patients who may have documented intolerance to anti-hypertensive medications. FDA approved the premarket approval application (PMA) for the Symplicity Spyral™ RDN System on November 17, 2023, for the indicated use to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. We received the application for a new device category for transitional pass-

through payment status for the Symplcity Spyral™ Catheter on November 30, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether the Symplcity Spyral™ Catheter meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not indicate whether the Symplcity Spyral™ Catheter is integral to the service furnished. Per the applicant, the Symplcity Spyral™ Catheter is intended for single patient use only. While the applicant did not explicitly state whether the Symplcity Spyral™ Catheter comes into contact with human tissue, the applicant asserted that the Symplcity™ Catheter ablates renal nerve tissue by positioning the catheter within the renal artery, which expands and fits the renal arterial vessel walls. While the applicant did not explicitly state if the Symplcity Spyral™ Catheter is surgically inserted or implanted, per the device description, the Symplcity Spyral™ Catheter is inserted through a small femoral incision, after which it is inserted into the renal arterial vessel.

We are inviting public comments on whether the Symplcity Spyral™ Catheter meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant did not state whether the Symplcity Spyral™ Catheter is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered whether the Symplcity Spyral™ Catheter is a supply or material furnished incident to a service.

We are inviting public comments on whether the Symplcity Spyral™ Catheter meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. According to the applicant, the Symplcity Spyral™ Catheter is a single-use catheter used to deliver multiple ablations in both kidneys, in the renal main, accessory, and branch arteries, based on a patient's artery anatomy and size. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the Symplcity Spyral™ Catheter. The applicant asserted that two categories, C1886 (Catheter, extravascular tissue ablation, any modality (insertable)) and C1888 (Catheter, ablation, noncardiac, endovascular (implantable)), do not appropriately describe the Symplcity Spyral™ Catheter. Per the applicant, C1886 does not appropriately describe the Symplcity Spyral™ Catheter because the Symplcity Spyral™ Catheter ablates renal nerve tissue via an endovascular approach by positioning the catheter within the renal artery and was created to describe devices that ablate extravascular tissue (via an extravascular approach).²⁸ According to the applicant, C1888 does not appropriately describe the Symplcity Spyral™ Catheter because the Symplcity Spyral™ Catheter does not ablate or otherwise affect the blood vessel tissue and was created to describe devices designed to occlude or obliterate blood vessels.²⁹

We have not identified an existing pass-through payment category that describes the Symplcity Spyral™ Catheter. We are inviting public comment on whether the Symplcity Spyral™ Catheter meets the device category criterion at § 419.66(c)(1).

We note that the applicant indicated the Symplcity Spyral™ Catheter is not the only device authorized by FDA with an indication for renal denervation to achieve reductions in blood pressure. Paradise® Ultrasound RDN System, for which we also received an application for transitional pass-through payments for CY 2025 as discussed in more detail in this proposed rule, is also authorized

by FDA with an indication for renal denervation using ultrasound energy to achieve reductions in blood pressure. Per the applicant, the Paradise® Ultrasound RDN System would also be described by the applicant's proposed pass-through payment category: Ablation catheter, renal nerve, via endovascular approach, any modality. Accordingly, we note that while the Symplcity Spyral™ Catheter device may have a different modality (*i.e.*, radiofrequency compared to ultrasound), the Symplcity Spyral™ Catheter device may have a similar mechanism of action to that of the Paradise® Ultrasound RDN System device. We question whether the device descriptions provided in the respective applications support establishing two modality specific pass-through payment device categories or a single device category that would encompass both RDN device modalities. We will address this question in detail immediately following the full discussion of all other applicable eligibility criteria for the Symplcity Spyral™ RDN System application.

We are inviting public comment on whether Symplcity Spyral™ Catheter meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. As previously stated, the Symplcity Spyral™ Catheter has Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the Symplcity Spyral™ Catheter meets the device category criterion at § 419.66(c)(2)(ii).

The third criterion for establishing a device category, at § 419.66(c)(3),

²⁸ The applicant referenced CY 2013 OPPS FR (77 FR 68352) and Transmittal 2386, Change Request 7672 (Jan 13, 2012) to support these assertions.

²⁹ The applicant referenced the Medicare Claims Processing Manual, Chapter 4, section 60.4.3 to support these assertions.

requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost

significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The

applicant stated that the Symplixity Spyral™ Catheter would be reported with HCPCS codes shown in Table 53.

Table 53: HCPCS CODES REPORTED WITH THE SYMPLICITY SPYRAL™

CATHETER

HCPCS Code	Long Descriptor	SI	APC
0338T**	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; unilateral	J1	5192
0339T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral	J1	5192

**Denotes a HCPCS code that was not included in the corrected Addendum P to the CY 2024 OPPI/ASC final rule with comment period, with no CY 2024 HCPCS/CPT code level device offset amount available. We note the applicant used the CY 2024 payment rates for the three tests of the cost criterion. We used the CY 2024 HCPCS/CPT code level device offset amount for the HCPCS/CPT code included in the corrected Addendum P to assess whether the device meets the cost significance criterion.

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPI final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note the applicant used the CY 2024 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5192, which had a CY 2024 payment rate of \$5,445.84 at the time the application was received. HCPCS code 0339T in APC 5192 had a CY 2024 device offset amount of \$3,362.26 at the

time the application was received.³⁰ According to the applicant, the cost of the Symplixity Spyral™ Catheter is \$16,000.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average

³⁰ We note that the applicant selected the APC payment rate of \$5,451.51 and the HCPCS/CPT code level device offset amount of \$3,365.76 for HCPCS 0339T in APC 5192. However, the values selected are inconsistent with the APC payment rate and the device offset amount found in the corrected Addendum P to the CY 2024 OPPI/ASC final rule with comment period. For our calculation, we selected the APC payment rate of \$5,445.84 and the HCPCS/CPT code level device offset amount of \$3,362.26 for HCPCS 0339T in APC 5192 found in the corrected Addendum P, which are the accurate values for these codes. Based on our initial assessment for this proposed rule, using the APC payment rate of \$5,445.84 and the HCPCS/CPT code level device offset amount of \$3,362.26 would result in Symplixity Spyral™ Catheter meeting the cost significance requirement.

reasonable cost of \$16,000.00 for the Symplixity Spyral™ Catheter is 293.80 percent of the applicable APC payment amount for the service related to the category of devices of \$5,445.84 ($(\$16,000.00/\$5,445.84) \times 100 = 293.80$ percent). Therefore, we believe the Symplixity Spyral™ Catheter meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$16,000.00 for the Symplixity Spyral™ Catheter is 475.87 percent of the cost of the device-related portion of the APC payment amount for the related service of \$3,362.26 ($(\$16,000.00/\$3,362.26) \times$

100 = 475.87 percent). Therefore, we believe that the Symplcity Spyral™ Catheter meets the second cost significance requirement.

The third cost significance requirement at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$16,000.00 for the Symplcity Spyral™ Catheter and the portion of the APC payment amount for the device of \$3,362.26 is 232.06 percent of the APC payment amount for the related service of \$5,445.84 $((\$16,000.00 - \$3,362.26) / \$5,445.84) \times 100 = 232.06$ percent). Therefore, we believe that the Symplcity Spyral™ Catheter meets the third cost significance requirement.

We are inviting public comment on whether the Symplcity Spyral™ Catheter meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(k) Paradise® Ultrasound RDN System and the Symplcity Spyral™ RDN System Device Category Code Establishment

As previously discussed, we received two applications, the Paradise® Ultrasound RDN System and the Symplcity Spyral™ RDN System (Symplcity Spyral™ Catheter) for transitional device pass-through payments for CY 2025 that, per the applicants, are RDN devices that use an endovascular approach to enter the renal arteries and ablate renal sympathetic nerves to achieve reductions in blood pressure. We question whether the information provided for each respective nominated device supports establishing two modality specific device pass-through payment device categories or establishing a single device category that would encompass both RDN devices.

We note that the Paradise® Ultrasound RDN System and the Symplcity Spyral™ RDN System are both authorized by FDA for the indicated use to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. In addition, based on the information provided in the respective applications, it appears that the Paradise® Ultrasound RDN System and the Symplcity Spyral™ RDN

System use the same procedure (renal sympathetic denervation, also called renal sympathetic nerve ablation), treat the same disease (hypertension) in the same patient population (patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure), and aim to achieve the same therapeutic outcome (to reduce blood pressure), using the same or similar mechanism of action (thermal ablation). We note that in addition to having the same indicated use, per the applicants, both the Paradise® Ultrasound RDN System and the Symplcity Spyral™ RDN System may be used with the same HCPCS procedure codes: 0338T³¹ or 0339T.³² In addition, the applicant for the Symplcity Spyral™ RDN System asserted that the Paradise® Ultrasound RDN System similarly generates heat to ablate the same renal sympathetic nerves to achieve reductions in blood pressure and this similarity supports establishing a single device category that would encompass RDN devices regardless of the specified modality.

Despite these similarities, the applicants have proposed different device category descriptions. Based on the information submitted, it appears that the device category proposed for the Paradise® Ultrasound RDN System does not appropriately describe the Symplcity Spyral™ RDN System, however, we believe the device category proposed for the Symplcity Spyral™ RDN System would appropriately describe the Paradise® Ultrasound RDN System. Specifically, the applicant for the Paradise® Ultrasound RDN System proposed the following device category: Catheter, intravascular renal denervation, ultrasound, with balloon cooling;³³ while the applicant for the

³¹ HCPCS procedure code 0338T (Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; unilateral).

³² HCPCS procedure code 0339T (Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral).

³³ The Paradise® Ultrasound RDN System device category does not explicitly describe using an endovascular approach; however, it does describe renal nerve ablation via a catheter. We believe that the device category describes the intravascular sonication (ultrasound treatment) delivered by the catheter. We note that this proposed device description does not preclude an endovascular approach, and that, per the applicant, the Paradise®

Symplcity Spyral™ RDN System proposed the following device category: Ablation catheter, renal nerve, via endovascular approach, any modality. The device category descriptor the applicant proposed for the Paradise® Ultrasound RDN System specifies the device's treatment or procedure (catheter renal denervation), the ablation modality (*i.e.*, ultrasound), and an attribute of the catheter (*i.e.*, the cooling balloon). We note that while the device category descriptor the applicant proposed for the Symplcity Spyral™ RDN System device also specifies the device's treatment or procedure (catheter ablation of the renal nerves), it does not specify an ablation modality or any additional attributes of the catheter; rather, the proposed device category for the Symplcity Spyral™ RDN System device more broadly describes any ablation modality (*e.g.*, radiofrequency or ultrasound).

We note several differences in procedural technique with use of the Paradise® Ultrasound RDN System device compared to the Symplcity Spyral™ RDN System device. Per the applicants, the Paradise® Ultrasound RDN System delivers ablation while positioned in the main renal arteries only, whereas the Symplcity Spyral™ RDN System may deliver ablation while positioned in the main renal, accessory and branch arteries and therefore may require advancing the catheter beyond the main renal arteries. According to the applicants, the Paradise® Ultrasound RDN System procedural technique requires the measurement of the main renal artery diameter to select the appropriate size cooling balloon catheter, whereas the Symplcity Spyral™ RDN System's one size catheter does not require this measurement. Similarly, per the applicants, the Paradise® Catheter's cooling balloon requires specific procedural techniques to ensure the balloon is appropriately inflated and deflated during the procedure, but the Symplcity Spyral™ Catheter does not have this requirement.

Both the Paradise® Ultrasound RDN System and the Symplcity Spyral™ RDN System received FDA Breakthrough Device designation and marketing authorization from FDA for the indications covered by the Breakthrough Device designation, and therefore, are not evaluated for substantial clinical improvement. However, we note that per the applicant of the Paradise® Ultrasound RDN System, a separate device category

Ultrasound RDN system is a catheter-based endovascular based system.

associated with ultrasound denervation is supported by possible differences in clinical efficacy between RDN devices using ultrasound and RDN devices using radiofrequency ablation. Specifically, the applicant of the Paradise® Ultrasound RDN System asserted that, when compared to radiofrequency RDN, on average ultrasound RDN requires fewer ablations per patient (5.4 compared to 46.9), less time per ablation (7 seconds compared to 60 seconds), less time for the total procedure (72 minutes compared to 100 minutes), and less ablation depth (1 to 6 mm compared to 2 to 3 mm). The applicant of the Paradise® Ultrasound RDN System further stated that the Paradise® Ultrasound RDN System circumferential (360 degrees) emission per individual ablation and the lack of a requirement for distal renal artery branch ablation to deliver the treatment are technological features not shared by the radiofrequency RDN device.³⁴ However, we note that we did not evaluate the validity or generalizability of these claims nor is it clear if the two different ablation modalities (*i.e.*, ultrasound and radiofrequency) would render different clinical results in larger studies or in the long term.^{35 36} We further note that we discuss these claims here solely for the purpose of determining whether the information provided supports establishing two modality-specific pass-through payment device categories or establishing a single device category that may encompass both RDN devices.

In seeking comment, we note that in accordance with section 1833(t)(6)(B)(ii)(II) of the Act, new categories must be established in such a way that no medical device is described by more than one category. We further note that CMS does not establish pass-through device categories for the purposes of describing specific devices, but rather, device categories which are intended to encompass all devices that can be appropriately described by a category. However, there are examples in which CMS has defined specific

ablation modalities such as high intensity ultrasound, microwave, and cryoablation in HCPCS codes for use with the OPPS. In addition, we note the existence of several modality specific tissue ablation procedure codes in the Current Procedural Terminology (CPT®) 2024. However, there are examples where CMS has established device categories with additional granularity to differentiate similar devices with special characteristics (*e.g.*, implantable neurostimulators). In addition, there are examples where CMS has created HCPCS codes specifying the modality of ablation (*e.g.*, ultrasound, microwave). Finally, we note as previously mentioned, the intent of transitional device pass-through payment, as implemented at § 419.66, is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861). We question whether two modality-specific device category codes may facilitate the collection of more accurate data for incorporating the costs of these two devices into the procedure APC rate as well as foster the tracking of efficacy data for these two ablation modalities.

As such, we are inviting public comment on whether the device descriptions provided in the Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System applications support establishing two modality specific pass-through payment device categories or a single device category that would encompass both RDN device modalities.

(2) Traditional Device Pass-Through Applications

(a) Ambu® aScope™ Gastro

Ambu Inc. submitted an application for a new device category for transitional pass-through payment status for the Ambu® aScope™ Gastro for CY 2025. Per the applicant, the Ambu® aScope™ Gastro is a sterile, single-use, flexible gastroscope intended to be used for: (1) endoscopic access to and examination of the upper gastrointestinal (GI) anatomy; and (2) upper GI endoscopy or esophagogastroduodenoscopy (EGD) to diagnose and treat problems in the upper GI tract, including dysphagia, gastroesophageal reflux disease, narrowing or blockages, esophageal varices, inflammation, ulcers, tumors, hiatal hernia, Celiac disease, Crohn's

disease, and infections of the upper GI tract in adult patients.

According to the applicant, the Ambu® aScope™ Gastro works with the Ambu® aBox™ 2, a compatible, reusable displaying unit. The Ambu® aScope™ Gastro endoscope is inserted into the upper GI anatomy airway through the mouth, while the Ambu® aBox™ 2 is a non-sterile digital monitor intended to display live imaging data from Ambu visualization devices. The applicant is only seeking a new device category for transitional pass-through payment status for the Ambu® aScope™ Gastro.

Please refer to the online application posting for the Ambu® aScope™ Gastro, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP2305305795M>, for additional detail describing this device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on February 3, 2022, the applicant received 510(k) clearance from FDA for the Ambu® aScope™ Gastro, Ambu® aBox™ 2, as a sterile, single-use, flexible gastroscope intended to be used for endoscopic access to and examination of the upper gastrointestinal anatomy. The Ambu® aScope™ Gastro is intended to provide visualization via a compatible Ambu displaying unit and to be used with endotherapy accessories and other ancillary equipment. We received the application for a new device category for transitional pass-through payment status for the Ambu® aScope™ Gastro on May 30, 2023, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether Ambu® aScope™ Gastro meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not indicate whether the Ambu® aScope™ Gastro is integral to the service furnished. The applicant stated that the device was single-use and is intended to be used with one patient only. We note that the Ambu® aScope™ Gastro, based on the device description provided by the applicant and the evidence provided in support of the substantial clinical improvement as discussed in detail in the § 419.66(c)(2) analysis in this

³⁴ See Application's Device Info tab, attachment, Procedural Comparison Ultrasound RDN_11.21.2023.

³⁵ Fengler K, Rommel K-P, Kriesse W, et al. Research Correspondence: 6- and 12-Month Follow-Up From a Randomized Clinical Trial of Ultrasound vs Radiofrequency Renal Denervation (RADIO SOUND-HTN). JACC: CARDIOVASCULAR INTERVENTIONS VOL. 16, NO. 3, 2023 Letters FEBRUARY 13, 2023:367–369.

³⁶ Fengler K, Rommel K-P, Blazek S, et al. A three-arm randomized trial of different renal denervation devices and techniques in patients with resistant hypertension (RADIO SOUND-HTN). Circulation. 2019;139:590–600.

application summary write-up, explicitly provides that the nominated device is intended to be used on one patient, for a single procedure and then disposed of. As such, we note that our evaluation and final decision as it relates to this potential category of devices (gastrosopes) will be based on the understanding that devices included in this device category (gastrosopes) can only be used for a single procedure, on a single patient, and cannot be reprocessed. While the applicant did not explicitly state whether the device comes in contact with human tissue or is surgically inserted, per the device description, Ambu® aScope™ Gastro is a flexible gastroscope intended to be used for endoscopic access to and examination of the upper GI anatomy.

We are inviting public comments on whether Ambu® aScope™ Gastro meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant indicated that the Ambu® aScope™ Gastro is single-use equipment, not intended for use in multiple patients, for which depreciation and financing expenses are not recovered. The applicant explained that the Ambu® aScope™ Gastro is purely an operating cost and is not subject to capitalization or a depreciation schedule.

We note that the applicant stated in the application that the Ambu® aScope™ Gastro is a supply furnished incident to a service rendered, as described, Ambu® aScope™ Gastro would be considered a supply or material furnished incident to a service and excluded from device pass-through payment eligibility under § 419.66(b)(4).

We are inviting public comments on whether the Ambu® aScope™ Gastro meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria

for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. Per the applicant, the Ambu® aScope™ Gastro is a sterile, single-use, flexible, imaging/illumination gastroscope device that uses an integrated camera module and built-in dual light-emitting diode (LED) illumination to provide access to, illumination, and imaging of the upper GI anatomy for diagnostic and therapeutic purposes for a GI patient. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the Ambu® aScope™ Gastro. Per the applicant, the two device categories, C1747 (Endoscope, single-use (*i.e.*, disposable), urinary tract, imaging/illumination device (insertable)) and C1748 (Endoscope, single-use (*i.e.*, disposable), upper gastrointestinal tract (GI), imaging/illumination device, (insertable)), do not appropriately describe the Ambu® aScope™ Gastro. Specifically, the applicant asserted that the urinary tract scopes described in C1747 are not indicated for use in the GI system and therefore, do not appropriately describe Ambu® aScope™ Gastro. The applicant further asserted that while C1748 describes a single-use endoscopic device, C1748 is only appropriate for single-use duodenoscopes and endoscopic retrograde cholangiopancreatography (ERCP) services. While the long descriptor of C1748 describes disposable endoscopes with imaging and illumination capabilities intended for use in the upper GI and the applicant describes the Ambu® aScope™ Gastro as a single-use, gastroscope with illumination and imaging intended for use in the upper GI anatomy, we note that C1748 only describes single-use duodenoscopes and ERCP services. As such, Ambu® aScope™ Gastro is not described by C1748.

We have not identified an existing pass-through payment category that describes Ambu® aScope™ Gastro. We are inviting public comment on whether the Ambu® aScope™ Gastro meets the

device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant claimed that Ambu® aScope™ Gastro represents a substantial clinical improvement over existing technologies in the diagnosis and management of endoscopic procedures and examination within the upper GI anatomy. The applicant outlined the following areas in which it claimed the Ambu® aScope™ Gastro would provide a substantial clinical improvement: (1) elimination of the risk of cross-contamination between patients and scopes, (2) elimination of the risk of cross-contamination for reusable gastroscopes, (3) elimination of the risk of resistant infections that originate from reusable gastroscopes, (4) avoidance of scope damage and debris after reprocessing, (5) avoidance of damaged and contaminated scopes from being used on patients, (6) elimination of the risk of patient-to-patient infections associated with contaminated scopes, and (7) avoidance of infection and death associated with reusable gastroscope contamination.

The applicant provided seven background articles about reusable GI endoscopes to support its claims. Table 54 summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for Ambu® aScope™ Gastro for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

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Table 54: SUBSTANTIAL CLINICAL IMPROVEMENT ASSERTIONS

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments		
Applicant statements in support	Supporting evidence provided by the applicant	Reference title*
The aScope Gastro eliminates the risk of cross-contamination between patients and scopes between patients and scopes	The literature highlights six studies that show the contamination rate of gastroscopes to be 28.2 percent. Given the aScope Gastro's disposable design, the contamination rate is eliminated since there is no reuse of the same scope. These positive cultures are a result of normally reprocessing standards being unable to fully sterilize a scope once it has been used.	Goyal, H., Larsen, S., Perisetti, A., Larsen, N. B., Ockert, L. K., Adamsen, S., Tharian, B., & Thosani, N. (2022). Gastrointestinal endoscope contamination rates - elevators are not only to blame: a systematic review and meta-analysis. Endoscopy international open, 10(6), E840–E853. https://doi.org/10.1055/a-1795-8883 *
The aScope Gastro would eliminate the contamination MAUDE reports submitted for reusable gastroscopes	More adverse event reports involving potentially contaminated gastroscopes were submitted to the FDA from 2014 -2021 than any other flexible endoscope. 1,135 MAUDE reports were submitted to the FDA for gastroscopes in 2021. Some cases involve patients infected with CRE or a related superbug.	Muscarella, L. F. (2022). Contamination of Flexible Endoscopes and Associated Infections: A Comprehensive Review and Analysis of FDA Adverse Event Reports. https://lfin-hcs.com/2022/01/contamination-of-flexible-endoscopes-and-associated-infections/
The aScope Gastro would eliminate the risk of superbug related infections that originate from reusable gastroscopes	There have been multiple cases linking a reprocessed gastroscope to infections of resistant bacteria. In some cases, this has lead to patient death. The aScope Gastro would have eliminated the risk of these infections since the scope would not be used on multiple patients.	Muscarella, L. F. (2023). Gastroscopes Have Been Linked to A Cluster of Resistant E. coli Infections — Is the Risk Sufficiently Recognized? https://lfin-hcs.com/2023/01/gastroscopes-have-been-linked-to-a-cluster-of-resistant-e-coli-infections-is-the-risk-sufficiently-recognized/
The aScope Gastro would avoid damage and debris after reprocessing since it is not reused	Visible damage and debris/residue was found in all gastroscopes observed after reprocessing. After visual inspection, all gastroscopes needed to be either repaired or refurbished due to damage and/or debris. Additional issue observed after reprocessing were gapping of distal adhesive bands, leftover	Ofstead, C. L., Smart, A. G., Hopkins, K. M., & Wetzler, H. P. (2023). The utility of lighted magnification and borescopes for visual inspection of flexible endoscopes. American journal of infection control, 51(1), 2–10.

	fluid, channel shredding, and droplet. All of these introduce issues to patients that may result in readmissions, infections, or deaths. The aScope Gastro avoids all of these issues.	
The aScope Gastro avoids damaged and contaminated scopes from being used on patients	27 percent of gastroscopes were found to have positive microbial samples after reprocessing. Additional issues found were fluid retention, channel shredding, scratches, and debris after reprocessing. These issues pose several threats to patient safety. The aScope Gastro bypasses these issues since the scope is never reused.	Wallace, M. M., Keck, T., Dixon, H., & Yassin, M. (2023). Borescope examination and microbial culture results of endoscopes in a tertiary care hospital led to changes in storage protocols to improve patient safety. American journal of infection control, 51(4), 361–366.
The aScope Gastro eliminates the risk of patient-to-patient infections associated with contaminated scopes	The all-cause infection rate for EGDs with reusable gastroscopes was found to be 3.0 per 1000 procedures. The aScope Gastro can eliminate the risk of infection associated with reusable gastroscopes since the design is single-use and will be thrown out after each use.	Wang, P., Xu, T., Ngamruengphong, S., Makary, M. A., Kalloo, A., & Hutfless, S. (2018). Rates of infection after colonoscopy and esophagogastroduodenoscopy in ambulatory surgery centres in the USA. Gut, 67(9), 1626–1636.
The aScope Gastro's single-use design avoids the issues associated with reusable gastroscope contamination such as infection and even death	3 died after testing positive (+) for antibiotic-resistant E coli after undergoing an EGD. 4 patients tested + for E coli after the gastroscope was used on them—one died. 6 patients became infected with the same superbug from the same scope—three died. 2 patients treated with the same gastroscope tested + for CRE-NDM and E coli—84 additional patients had procedures with the scope. A reusable gastroscope was used on a patient with Creutzfeldt-Jakob disease. A superbug remained after reprocessing.	The applicant provided FDA MAUDE Adverse Event Reports

*We note this source does not assess, evaluate, or review the nominated device and only provides background information in support of the applicant's claims of substantial clinical improvement.

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After review of the information provided by the applicant, we have the following concerns regarding whether Ambu® aScope™ Gastro meets the

substantial clinical improvement criterion.

First, we note that the applicant identified 11 other devices that it believed are most like the Ambu®

aScope™ Gastro: (1) Olympus GIF-HQ 190; (2) Olympus GIF-1TH190; (3) Olympus GIF-H190; (4) Olympus GIF-CP190N; (5) Fujifilm EG-760R; (6) Fujifilm EG-760CT; (7) Fujifilm EG-

760Z; (8) Fujifilm EG-740N; (9) Pentax HD Video Gastroscope EG34 i10; (10) Pentax MagniView EG 2990Zi; and (11) Pentax G EYE. According to the applicant, these devices are used during the same specific procedure(s) and/or services with which the nominated device is used. The applicant stated that the nominated device's single-use feature is unique among the comparators because its single-use feature eliminates gastroscoposcopy reprocessing. The applicant also indicated that there are no HCPCS Level I and/or Level II code(s) used to identify these existing devices. While the evidence provided demonstrates that the Ambu® aScope™ Gastro may be different than the other 11 closely related devices, it does not provide any comparative data that demonstrates that the Ambu® aScope™ Gastro offers a substantial clinical improvement when compared to the other 11 devices.

Second, we note that the nominated device was determined to be substantially equivalent to a predicate device: OLYMPUS EVIS EXERA II Gastrointestinal Videoscope GIF H180 (K100584). The FDA 510(k) summary indicated that both devices share the same technological characteristics such as insertion portion length, working channel diameter, direction of view and bending angles. We note that the 510(k) summary indicated that, unlike the predicate device, the Ambu® aScope™ Gastro is a sterile, single-use device and not intended to be reprocessed. Again, while this demonstrates that the Ambu® aScope™ Gastro may be different than the predicate device, it is unclear whether this difference demonstrates substantial clinical improvement. No comparative data demonstrating that the Ambu® aScope™ Gastro provides a substantial clinical improvement when compared to the OLYMPUS EVIS EXERA II Gastrointestinal Videoscope GIF H180 was provided. We would be interested in additional information to demonstrate whether the nominated device demonstrates a substantial clinical benefit in comparison to other existing devices.

Further, the applicant indicated that while other single-use endoscopes are available, there are no known competitive devices on the market that are single-use, transoral, and marketed in the U.S. The applicant compared the Ambu® aScope™ Gastro to the following two existing devices: (1) EndoFresh Single-Use Gastroscope; and (2) EvoEndo Model LE Single-Use Gastroscope. Specifically, the applicant noted that although EndoFresh Single-Use Gastroscope is FDA-cleared and a similar device that could also become

eligible for transitional pass-through payment under the proposed additional category, it has no commercial activity in the U.S. According to the applicant, while EvoEndo Model LE Single-Use Gastroscope is used during the same specific procedure(s) and/or services as the Ambu® aScope™ Gastro, the Ambu® aScope™ Gastro is different from EvoEndo Model LE Single-Use Gastroscope because the Ambu® aScope™ Gastro is a transoral scope, not transnasal. The applicant also indicated that there are no HCPCS Level I and/or Level II code(s) used to identify EvoEndo Model LE Single-Use Gastroscope. However, we note that EvoEndo Model LE Single-Use Gastroscope is both transoral and transnasal, which is indicated on the EvoEndo's website³⁷ and on its FDA 510(k)³⁸ clearance letter. We also note that the applicant did not compare the Ambu® aScope™ Gastro to another single-use, FDA-cleared endoscope available on the market—EXALT™ Model D, Single-Use Duodenoscope³⁹—which we believe may be similar. We would be interested in additional information to demonstrate whether the nominated device demonstrates a substantial clinical improvement in comparison to similar single-use competitive devices such as the EvoEndo Model LE Single-Use Gastroscope and the EXALT™ Model D, Single-Use Duodenoscope.

In addition, we note that the applicant's self-sponsored studies, which are background articles by Muscarella, L.F. (2022),⁴⁰ Muscarella, L.F. (2023),⁴¹ and Ofstead, et. al.

³⁷ EvoEndo® Model LE Single-Use Gastroscope and EvoEndo Controller.

³⁸ EvoEndo® Model LE Single-use Gastroscope is FDA cleared and marketed under 510(k) since 2022 (FDA 510(k)) letter: https://www.accessdata.fda.gov/cdrh_docs/pdf21/K213606.pdf. The EvoEndo Model LE Gastroscope is intended for the visualization of the upper digestive tract in adults and pediatric patients, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenal bulb in patients over the age of five years. The gastroscoposcopy is a sterile single-use device and can be inserted orally or transnasally.

³⁹ EXALT™ Model D, Single-Use Duodenoscope is FDA cleared and marketed under 510(k) since 2019 (FDA 510(k)) letter: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193202.pdf. The EXALT™ Model D, Single-Use Duodenoscope is intended for use with a Boston Scientific endoscopic video imaging system, for endoscopy and endoscopic surgery within the duodenum.

⁴⁰ Muscarella, L. F. (2022). Contamination of Flexible Endoscopes and Associated Infections: A Comprehensive Review and Analysis of FDA Adverse Event Reports. <https://lfm-hcs.com/2022/01/contamination-of-flexible-endoscopes-and-associated-infections/>.

⁴¹ Muscarella, L. F. (2023). Gastroscopies Have Been Linked to A Cluster of Resistant E. coli

(2022),⁴² lack direct comparison of the nominated device to other devices, and do not directly show any clinical improvement that results from the use of the nominated device compared to the use of other devices. In order to demonstrate substantial clinical improvement over currently available treatments, we consider supporting evidence, preferably published peer-reviewed clinical trials, that shows improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to the standard of care. Additional supporting evidence, preferably published peer-reviewed clinical trials, that shows these improved clinical outcomes would help inform our assessment of whether the Ambu® aScope™ Gastro demonstrates substantial clinical improvement over existing technologies.

Moreover, while the details provided in the application and all the articles submitted as evidence of substantial clinical improvement discuss potential adverse events from reusable gastroscoposcopy procedures, they do not appear to directly show any clinical improvement that results from the use of the Ambu® aScope™ Gastro. Rather, the applicant provided evidence which seems to rely on indirect inferences from other sources of data. Specifically, the applicant included an FDA Manufacturer and User Facility Device Experience (MAUDE) report⁴³ which provides the details of multiple adverse event reports associated with the contamination or suspected contamination of reusable gastroscopies but does not directly show any clinical improvement that results from the use of the Ambu® aScope™ Gastro.

While the applicant claims that the Ambu® aScope™ Gastro eliminates cross-contamination associated with reusable gastroscopies and eliminates the risk of infections that originate from reusable gastroscopies, we do not believe that we have sufficient information on the prevalence of infection to evaluate the applicant's substantial clinical improvement claims for the Ambu® aScope™ Gastro. We note the

Infections—Is the Risk Sufficiently Recognized? <https://lfm-hcs.com/2023/01/gastroscopies-have-been-linked-to-a-cluster-of-resistant-e-coli-infections-is-the-risk-sufficiently-recognized/>.

⁴² Ofstead, C. L., Smart, A. G., Hopkins, K. M., & Wetzler, H. P. (2023). The utility of lighted magnification and borescopes for visual inspection of flexible endoscopes. *American Journal of Infection Control*, 51(1), 2–10.

⁴³ MAUDE Adverse Event Report: AIZU OLYMPUS CO., LTD. EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE (fda.gov).

analyses^{44 45} on adverse event reports and the FDA MAUDE report⁴⁶ appear to apply to flexible, reprocessed gastroscope or endoscopes, broadly, but not to disposable, single-use devices comparable to the nominated device. Therefore, we question the direct relevance of these background articles to the nominated device and the applicant's substantial clinical improvement claims. Further, we note that many of the applicant's substantial clinical improvement claims rely on an assumption that inadequate reprocessing of reusable endoscopes is

positively correlated with heightened risk of infection. We note that the applicant's self-sponsored analyses of FDA adverse event reports and studies^{47 48 49} and the FDA MAUDE report⁵⁰ do not provide evidence on the prevalence of infection, establish a clear relationship between infection risk and reprocessing procedures, or substantiate that single-use disposable scopes, or the nominated device specifically, would be

a substantial clinical improvement over currently available devices. We would be interested in more information on the prevalence of infection due to incomplete/inadequate processing for gastroscopes in the U.S. and whether single-use gastroscopes reduce the infection rate in patients to identify the extent of the problem with existing technologies.

We are inviting public comment on whether Ambu® aScope™ Gastro meets the device category criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that Ambu® aScope™ Gastro would be reported with HCPCS codes shown in Table 55.

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⁴⁴ Muscarella, L. F. (2022). Contamination of Flexible Endoscopes and Associated Infections: A Comprehensive Review and Analysis of FDA Adverse Event Reports. <https://lfm-hcs.com/2022/01/contamination-of-flexible-endoscopes-and-associated-infections/>.

⁴⁵ Muscarella, L. F. (2023). Gastroscopes Have Been Linked to A Cluster of Resistant E. coli Infections—Is the Risk Sufficiently Recognized? <https://lfm-hcs.com/2023/01/gastroscopes-have-been-linked-to-a-cluster-of-resistant-e-coli-infections-is-the-risk-sufficiently-recognized/>.

⁴⁶ MAUDE Adverse Event Report: AIZU OLYMPUS CO., LTD. EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE ([fda.gov](https://www.fda.gov)).

⁴⁷ Muscarella, L. F. (2022). Contamination of Flexible Endoscopes and Associated Infections: A Comprehensive Review and Analysis of FDA Adverse Event Reports. <https://lfm-hcs.com/2022/01/contamination-of-flexible-endoscopes-and-associated-infections/>.

⁴⁸ Muscarella, L. F. (2023). Gastroscopes Have Been Linked to A Cluster of Resistant E. coli Infections—Is the Risk Sufficiently Recognized? <https://lfm-hcs.com/2023/01/gastroscopes-have-been-linked-to-a-cluster-of-resistant-e-coli-infections-is-the-risk-sufficiently-recognized/>.

⁴⁹ Ofstead, C. L., Smart, A. G., Hopkins, K. M., & Wetzler, H. P. (2023). The utility of lighted magnification and borescopes for visual inspection of flexible endoscopes. *American Journal of Infection Control*, 51(1), 2–10.

⁵⁰ MAUDE Adverse Event Report: AIZU OLYMPUS CO., LTD. EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE ([fda.gov](https://www.fda.gov)).

Table 55: HCPCS CODES REPORTED WITH AMBU® ASCOPE™ GASTRO

HCPCS Code	Long Descriptor	SI	APC
43192	Esophagoscopy, rigid, transoral; with biopsy, single or multiple	J1	5302
43193	Esophagoscopy, flexible, transoral; with biopsy, single or multiple	J1	5302
43194	Esophagoscopy, rigid, transoral; with removal of foreign body(s)	J1	5302
43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance	J1	5302
43205	Esophagoscopy, flexible, transoral; with band ligation of esophageal varices	J1	5302
43211	Esophagoscopy, flexible, transoral; with endoscopic mucosal resection	J1	5302
43215	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	J1	5302
43216	Esophagoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps	J1	5302
43217	Esophagoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	J1	5302
43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	J1	5303
43233	Esophagogastroduodenoscopy, flexible, transoral; with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)	J1	5302
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed	T	5301
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance	T	5301
43237	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures	J1	5302
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)	J1	5302
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple	T	5301
43240	Esophagogastroduodenoscopy, flexible, transoral; with transmural drainage of pseudocyst (includes placement of	J1	5331

HCPSC Code	Long Descriptor	SI	APC
	transmural drainage catheter[s]/stent[s], when performed, and endoscopic ultrasound, when performed)		
43241	Esophagogastroduodenoscopy, flexible, transoral; insertion of intraluminal tube or catheter	J1	5302
43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)	J1	5302
43243	Esophagogastroduodenoscopy, flexible, transoral; injection sclerosis of esophageal/gastric	J1	5302
43244	Esophagogastroduodenoscopy, flexible, transoral; with band ligation of esophageal/gastric varices	J1	5302
43245	Esophagogastroduodenoscopy, flexible, transoral; with dilation of gastric/duodenal stricture(s) (e.g., balloon, bougie)	J1	5302
43246	Esophagogastroduodenoscopy, flexible, transoral; with directed placement of percutaneous gastrostomy tube	J1	5302
43247	Esophagogastroduodenoscopy, flexible, transoral; with removal of foreign body(s)	T	5301
43248	Esophagogastroduodenoscopy, flexible, transoral; with insertion of guide wire followed by passage of dilator(s) through esophagus over guide wire	T	5301
43249	Esophagogastroduodenoscopy, flexible, transoral; transendoscopic balloon dilation of esophagus (<30 mm)	J1	5302
43250	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps	J1	5302
43251	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	J1	5302
43254	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection	J1	5302
43255	Esophagogastroduodenoscopy, flexible, transoral; with control of bleeding, any method	J1	5302
43266	Esophagogastroduodenoscopy, flexible, transoral; with placement of endoscopic stent	J1	5331
43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	J1	5302

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To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final

rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing

the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657).

We note the applicant used the CY 2023 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5301, which had a CY 2023 payment rate of \$825.51 at the time the application was received. HCPCS code 43239 in APC 5301 had a CY 2023 device offset amount of \$2.64 at the time the application was received.⁵¹

According to the applicant, the cost of Ambu® aScope™ Gastro is \$799.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of \$799.00 for Ambu® aScope™ Gastro is 96.79 percent of the applicable APC payment amount for the service related to the category of devices of \$825.51 ($(\$799.00/\$825.51) \times 100 = 96.79$ percent). Therefore, we believe Ambu® aScope™ Gastro meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$799.00 for Ambu® aScope™ Gastro is 30,265.15 percent of the cost of the device-related portion of the APC payment amount for the related service of \$2.64 ($(\$799.00/\$2.64) \times 100 = 30,265.15$ percent). Therefore, we believe that the Ambu® aScope™ Gastro meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the

estimated average reasonable cost of \$799.00 for Ambu® aScope™ Gastro and the portion of the APC payment amount for the device of \$2.64 is 96.47 percent of the APC payment amount for the related service of \$825.51 ($((\$799.00 - \$2.64)/\$825.51) \times 100 = 96.47$ percent). Therefore, we believe that Ambu® aScope™ Gastro meets the third cost significance requirement.

We are inviting public comment on whether the Ambu® aScope™ Gastro meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(b) OMEZA Wound Care Matrix (OCM™)

OMEZA LLC submitted an application for a new device category for transitional pass-through payment status for OCM™ for CY 2025. According to the applicant, OCM™ is an amorphous, solid, malleable sheet comprised of hydrolyzed fish peptides infused with cod liver oil, which acts as an anhydrous skin protectant. Per the applicant, OCM™ is indicated for the management of wounds. The applicant asserted that, when applied to a clean wound surface, OCM™ is naturally incorporated into the wound over time. Per the applicant, OCM™'s cold water fish peptides provide building blocks for tissue regeneration and cell signaling molecules stimulate tissue growth. Additionally, OCM™'s matrix-like device also contains active pharmaceutical ingredient(s) (API) and nutrients that continuously reduce biofilm impact, reduce inflammation, increase tissue proliferation, and support remodeling of tissue.

Please refer to the online application posting for the OCM™, available at <https://mearis.cms.gov/public/publications/device-ntp/DEP2403016HWP6>, for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on September 1, 2021, the applicant received 510(k) clearance from FDA for OCM™ as a device to be used for the management of wounds including: (1) partial and full-thickness wounds, (2) pressure ulcers, (3) venous ulcers, (4) diabetic ulcers, (5) chronic vascular ulcers, (6) tunneled/undermined wounds, (7) surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), (8) trauma wounds (abrasions, lacerations, superficial

partial thickness burns, skin tears), and (9) draining wounds. We received the application for a new device category for transitional pass-through payment status for OCM™ on March 1, 2024, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether OCM™ meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not indicate whether OCM™ is integral to the service furnished. We note that in the CY 2014 final rule with comment period (78 FR 75005), we stated that we have interpreted the term "integral" to mean that the device is necessary to furnish or deliver the primary procedure with which it is used. For example, a pacemaker is integral to the procedure of implantation of a pacemaker. OCM™ does not appear to be necessary to furnish or deliver the primary procedure with which it is used, specifically debridement. Rather, the use of OCM™ following the debridement procedure, including the duration of treatment and the reapplication frequency, seems to be based entirely on provider discretion. As such, we do not believe that OCM™ is integral to the service furnished as required by § 419.66(b)(3). The applicant stated that OCM™ is classified for one-time use and is designed for intimate contact with both regular and irregular wound beds, and as such, it is applied in or on a wound.

We are inviting public comments on whether OCM™ meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant did not indicate whether OCM™ is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if OCM™ is a supply or material

⁵¹ We note that the applicant selected a device offset amount of \$21.55 for APC 5301 without selecting a specific HCPCS/CPT code. However, for the HCPCS/CPT codes provided by the applicant, we note the HCPCS/CPT code level device offset amounts are available in Addendum P to the CY 2023 OPPS/ASC final rule with comment period. For our calculation, we selected the HCPCS/CPT code level device offset amount of \$2.64 related to HCPCS 43239 in APC 5301 found in Addendum P to the CY 2023 OPPS/ASC final rule with comment period. Based on our initial assessment for this proposed rule, using the device offset amount of \$2.64 would result in Ambu® aScope™ Gastro meeting the cost significance requirement.

furnished incident to a service. However, in the CY 2014 final rule, we described skin substitutes as a type of supply used in a surgical procedure (78 FR 74929 through 74930). As explained in the CY 2014 final rule, supplies are a large category of items that typically are either for single patient use or have a shorter life span in use than equipment. Supplies can be anything that is not equipment and include not only minor, inexpensive, or commodity-type items but also include a wide range of products used in the hospital outpatient setting, including certain implantable medical devices, which we have considered supplies since the inception of the OPPTS (78 FR 74929 through 74930). We clarified that we believe skin substitutes are supplies used in a surgical procedure because, as a part of a surgical repair procedure, they reinforce and aid the healing of tissue like implantable biologicals, but with skin substitutes, the tissue is skin instead of internal connective tissues. (78 FR 74931). As such, we question whether OCM™ would be considered a supply, and as such it would be excluded from device pass-through payments under § 419.66(b)(4).

We are inviting public comments on whether OCM™ meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant asserted that OCM™ is indicated for the

comprehensive treatment of advanced wounds and provides continuous delivery of pharmaceutical grade products through an amorphous, anhydrous solid, which reduces biofilm while simultaneously promoting tissue proliferation and remodeling. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe OCM™.

We have not identified an existing pass-through payment category that describes OCM™. We are inviting public comment on whether OCM™ meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant claimed that OCM™ represents a substantial clinical improvement over existing technologies in the treatment of hard to heal or chronic wounds which require advanced wound care procedures such as venous leg ulcers, diabetic foot ulcers, pressure ulcers, and wound dehiscence where proper wound preparation, product application, and

proper secondary dressings are a requirement. Specifically, the applicant claimed that OCM™ demonstrates: (1) superior clinical outcomes and healing for Diabetic Foot Ulcers (DFU) compared to standard of care; (2) faster healing rates than standard of care for Venous Leg Ulcers (VLUs); (3) superior clinical outcomes for patients who could not qualify for clinical trials due to comorbidities; (4) improved results when compared to results with standard of care for patients who failed prior treatment; (5) in vitro/in vivo antimicrobial properties and patient safety; and (6) improved patient safety.

The applicant provided the following clinical trial data and case studies to support these claims: (1) two randomized controlled trials (a single-site trial of patients with DFUs to evaluate percent area reduction, and a randomized, multicenter, open label study for a patient group with VLUs); (2) two real-world trials comprised of two separate case studies of patients receiving follow-up care at two different wound treatment centers; (3) one in vitro study; (4) one in vivo porcine study; and (5) one consumer research study assessing the safety of OCM™ using the skin prick method. Table 56 summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Note that there are multiple variations in poster presentations for the same study; these posters are identified by study number and presentation number in parentheses. Please see the online posting for OCM™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

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TABLE 56: SUBSTANTIAL CLINICAL IMPROVEMENT ASSERTIONS

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments		
Applicant statements in support	Supporting Evidence Provided by the Applicant	Reference Title
Superior clinical outcomes and healing for DFU compared to standard of care	OCM arm shows 55 percent improvement in wound size over standard of care after 12 weeks of treatment. 68 percent of patients treated with OCM had wounds present for over 3 months. 5 wounds were unhealed for over a year with 1 wound present more than 3 years. OCM healed 3 of these wounds in less than 12 weeks. One year-old wound reduced by 85 percent in size and a 72-month-old wound reduced by 73percent in 12 weeks. Every wound treated with OCM reduced by more than 70 percent in 12 weeks. All wounds previously failed treatments.	Simman, R., MD, FACS, FACCWS, Cheney, M., APRN, CNP, CWS, COCN, Shuman, S, BSN, RN, Bakewell, S., PhD, Bell, D.P., DPM, CWS, FFPM RCPS. (submitted 2023). A Clinical Study Using Combination Therapy with Standard of Care for the Treatment of Diabetic Foot Ulcers: Final Analysis. ProMedica Jobst Wound Care.
	These results show encouraging healing rates (60 percent 4-week PAR and 93 percent 12-week PAR) of DFUs managed with the combination therapy and SOC. Clinical trials evaluating the combination therapy in VLU (NCT05291169) and multiple wound types (NCT05921292) are underway.	Bell, D.P. DPM, CWS, FFPM RCPS, Shuman, S., BSN, RN, Cheney, M., APRN, CNP, CWS, COCN, Richard Simman, R., MD, FACS, FACCWS. (submitted 2023). A Clinical Study Using Combination Therapy with Standard of Care for the Treatment of Diabetic Foot Ulcers: Interim Analysis. ProMedica Jobst Wound Care.

	OCM arm shows 55 percent improvement in wound size over standard of care after 12 weeks of treatment. 68 percent of patients treated with OCM had wounds present for over 3 months. 5 wounds were unhealed for over a year with 1 wound present more than 3 years. OCM healed 3 of these wounds in less than 12 weeks. One year-old wound reduced by 85 percent in size and a 72-month-old wound reduced by 73 percent in 12 weeks. Every wound treated with OCM reduced by more than 70percent in 12 weeks. All wounds previously failed treatments.	Black, G., DPM, Bakewell, S., PhD., Bell, D.P., DPM, CWS, FFPM RCPS A (presented 2023). Novel Combination Therapy Technology: Case Studies of Complete Closure of a Diabetic Foot Ulcer and a Charcot Foot Ulcer.
	OCM arm shows 55 percent improvement in wound size over standard of care after 12 weeks of treatment. 68 percent of patients treated with OCM had wounds present for over 3 months. 5 wounds were unhealed for over a year with 1 wound present more than 3 years. OCM healed 3 of these wounds in less than 12 weeks. One year-old wound reduced by 85 percent in size and a 72-month-old wound reduced by 73 percent in 12 weeks. Every wound treated with OCM reduced by more than 70 percent in 12 weeks. All wounds previously failed treatments.	Barrett, C.L., DPM, CWS, Bakewell, S.J., PhD, Bell, D.P., DPM, CWS, FFPM RCPS. (presented 2023). A Novel Combination Therapy Technology: Case Studies of Complete Closure of Diabetic Foot Ulcers.

Faster healing rates than standard of care for VLU	OCM was compared to a standard of care treated group with Venous Leg Ulcers (NCT05291169). The average percent area reduction at 12 weeks was 66 percent. The same percent of patients (77 percent) responded in both cohorts, but OCM treatment increased the rate of healing by 22 percent.	Randomized Controlled Trial in Venous Leg Ulcers (NCT05291169) (no author or publication date given).
		Demographics for RCT in VLU (no author or publication date given).
Superior clinical outcomes for patients who could not qualify for clinical trials, due to comorbidities	OCM treatment of Multiple Etiologies (NCT05921292) enrolled 78 patients who would not have qualified for clinical trials, because of comorbidities, wound size, tobacco use, BMI, etc. Results show average reduction in wound size at 12 weeks by 73 percent, with 45 percent seeing full closure by 12 weeks. Pain score, exudate, demographics, comorbidities, and medications were collected. Wounds treated include diabetic foot, venous leg ulcers, pressure injuries, arterial, pyoderma, hematomas, surgical, and trauma.	Bettle III, G., Bell, D.P., Bakewell, S.J. (submitted 2023). A Novel Comprehensive Therapeutic Approach to the Challenges of Chronic Wounds: A Brief Review and Clinical Experience.
		OCM treating Multiple Etiologies Final Trial Data (no author or publication date given).
Improved results when compared to results with standard of care for patients who failed prior treatment	OCM was used by 16 independent investigators treating 65 patients who failed prior treatment. These case studies showed 77 percent of wounds were closed by 12 weeks and average area reduction was 90 percent. Patients were not subjected to inclusion or exclusion criteria. Six patients failed cellular tissue product therapies. The age of wounds healed ranged from 12 weeks to 15 years. Wounds treated include diabetic foot, venous leg ulcers, pressure injuries, arterial, pyoderma, hematomas, surgical, and trauma.	Bettle III, G., Bell, D.P., Bakewell, S.J. (submitted 2023). A Novel Comprehensive Therapeutic Approach to the Challenges of Chronic Wounds: A Brief Review and Clinical Experience
		OCM treating Multiple Etiologies Final Trial Data (no author or publication date given).

Demonstrated antimicrobial properties and patient safety for in vitro/in vivo studies	In vitro study showed OCM significantly inhibiting Methicillin-resistant Staphylococcus aureus (MRSA) and Pseudomonas aeruginosa compared to negative controls. OCM addresses an unmet medical need; no other product demonstrates antimicrobial properties and leads to complete wound healing.	Davis, S.C., Gil, J., Solis, M. MBA, Bell, D.P., DPM, CWS, FFPM RCPS, Bakewell, S.J., PhD., Frost, P. (2023). University of Miami Miller School of Medicine Department of Dermatology & Cutaneous Surgery. In Vitro Study Evaluating Antimicrobial Effects of a Novel Combination Therapy Technology Against Methicillin-Resistant Staphylococcus aureus and Pseudomonas aeruginosa.
	In vivo porcine study showed OCM significantly reducing MRSA and Pseudomonas counts in infected wound, with significant reductions over positive (Silver dressing treatment) and negative results (untreated wounds). OCM addresses an unmet medical need; no other product demonstrates antimicrobial properties and leads to complete wound healing.	Stephen C. Davis. S.C., Jozic, I., PhD., Gil, J., Solis, M., Abdo Abujamra, B. (2023). University of Miami Miller School of Medicine Department of Dermatology & Cutaneous Surgery. Antimicrobial Effects of a Novel Combination Therapy Against Methicillin-Resistant Staphylococcus aureus and Pseudomonas aeruginosa in a Porcine Wound Model.
Demonstrated patient safety	Data show patient safety	Princeton Consumer Research Corp. (2019). Final Report. A safety study to assess the allergy potential of OMEZA collagen matrix in human subjects using the skin prick method.

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After review of the information provided by the applicant, we identified the following concerns regarding whether the applicant presents clinical data to suggest that OCM™ provides a substantial clinical improvement over other similar skin protectant and wound healing products to meet the criterion at § 419.66(c)(2)(i). Based on the evidence submitted in the application, we note the following concerns: (1) lack of direct comparison between the nominated device and the predicate or reference devices for skin substitutes, particularly with respect to treatment of deep or persistent chronic wounds in people with DFU and VLU; (2) reliance on non-peer-reviewed studies, such as unpublished abstracts or conference posters, the results of which are only presented in a final data table; and (3)

reliance on studies which were sponsored by the device manufacturer rather than independent research. At this time, we note that the unpublished abstract for OCM™ lacked a detailed discussion of study limitations, patient population, and assurances that studies have been thoroughly peer-reviewed, and free from implicit bias. The abstract furthermore did not state if or how standard of care treatment was administered within the same time period to control groups, and therefore we are not clear if there was a direct comparison between OCM™ and its predicate or reference devices. Furthermore, the two randomized controlled trials^{52 53} and two real world

⁵² Desmond P. Bell, DPM, CWS, FFPM RCPS, et al. A Clinical Study Using Combination Therapy with Standard of Care for the Treatment of Diabetic Foot Ulcers: Interim Analysis. ProMedica Jobst

studies^{54 55} submitted by the applicant

Wound Care, Toledo, OH, US; ProMedica Jobst Vascular Institute, Sylvania, OH, US; University of Toledo College of Medicine, Toledo, OH, US, Omeza, LLC, Sarasota, FL, US (poster presented at the 20th Annual Desert Foot Conference, December 6–9, 2023, Phoenix, AZ, USA).

⁵³ Randomized Controlled Trial in Venous Leg Ulcers (NCT05291169) (no author or publication date given).

⁵⁴ A Novel Combination Therapy Technology: Case Studies of Complete Closure of a Diabetic Foot Ulcer and a Charcot Foot Ulcer Greg Black, DPM; Suzanne Bakewell, Ph.D.; Desmond Bell, DPM, CWS, FFPM RCPS 1Sylvania Podiatry, Sylvania, OH; Omeza, LLC, Sarasota, FL (poster presented at the 2023 Diabetic Foot Conference, September 28–30, 2023, Anaheim, CA).

⁵⁵ A Novel Combination Therapy Technology: Case Studies of Complete Closure of Diabetic Foot Ulcers Christopher L. Barrett, DPM, CWS; Suzanne J. Bakewell, Ph.D.; Desmond Bell, DPM, CWS, FFPM RCPS 1Wound Care Specialist, Downingtown, PA, USA; 2Omeza, Sarasota, FL,

Continued

to support its claims had relatively small sample sizes, some investigating only two patients total, which potentially limits the statistical significance of the results.

We note that the applicant did not provide a comparison of OCM™ to other devices it identified as closely related or similar to OCM™. Specifically, the FDA authorization letter dated September 1, 2021, FDA identified one predicate device, SweetBio Apis (K182725), and three reference devices, INTEGRA™ Flowable Wound Matrix (K072113), Kerecis MariGen Wound Dressing (K132343), and Southwest Technologies Stimulen Collagen (K030774) to which OCM™ may be compared. We note that we did not approve transitional device pass-through payment for Kerecis MariGen Wound Dressing (K132343) for CY 2018 after determining that the clinical data provided by the applicant did not support the claim that Kerecis Omega3 Wound Dressing provides a substantial clinical improvement over other similar skin substitute products (82 FR 59330 through 59332). The FDA authorization letter noted that OCM™ and the predicate device SweetBio Apis have similar indications and the same intended use, namely, to manage wounds by providing an animal-derived collagen product that is biodegradable and incorporates into the surrounding tissue during the body's natural wound healing processes. Both products supplement the collagen constituent with additional biocompatible materials to achieve a final product that covers and protects the wound, assists in managing wound exudate, and maintains a moist wound environment. Further, the substantial equivalence table included in the FDA authorization letter indicated that OCM™ raised no new questions of safety or effectiveness when compared to the predicate and reference devices.

In the first claim, the applicant asserted OCM™ has superior clinical outcomes and healing for DFU compared to the standard of care. Based on the evidence submitted by the applicant, we note the following concerns: (1) lack of a direct comparison to the predicate or reference devices in the two randomized controlled trials and the two real world clinical studies; (2) reliance on unpublished studies; (3) reliance on manufacturer sponsored studies; and (4) small sample sizes. First, Simman, et al. (2023) describes the results of a single-site trial in patients with DFUs to evaluate percent

area reduction in wound healing. The stated goal of this study was to demonstrate that a combination therapy, using OCM™ plus standard of care treatment, moves chronic DFUs from a stalled state to a healing state in a 4-week period. The study enrolled 25 patients, five of whom did not complete the study, and one of whom died during the study from comorbidities related to their underlying condition. Study group DFUs were managed with combination therapy from 4–12 weeks, and control group DFUs (comprised of six total study participants) were managed with standard of care treatment involving cleaning and debridement only.

Interim analyses presented as a poster (Bell, et al., 2023) as evidence to support the first claim was limited to 12 total study participants. The interim analysis concluded that healing rates showed an average of 63 percent area reduction for the remaining participants at 4 weeks following standard of care treatment, and an average of 91 percent area reduction at 12 weeks following the treatment in patients with DFUs managed with the combination therapy. The interim analysis study further showed that one patient with a 12-week percent area reduction of 73 percent continued to improve through week 14 while three patients' wounds had not healed at the time of analysis for those receiving combination therapy.

In the final results presented in Simman et al. (2023), the average 4-week percent area reduction was 60 percent, with three patients experiencing 100 percent closure with combination therapy. At 12 weeks, the median wound size was 0.0 cm² (range, 0–2.59), and the average percent area reduction was 93 percent, with five additional patients experiencing 100 percent closure with combination therapy. Average 4- and 12-week percent area reductions with standard of care alone were 42 percent and 45 percent, respectively. According to the final analysis study abstract, every wound treated with OCM™ combination therapy was reduced by more than 70 percent in 12 weeks and all wounds previously failed treatments.

We note that the Simman et al. (2023) study abstract and the interim analysis do not provide any direct comparison to standard of care treatment with another collagen-based wound matrix or device that is otherwise similar to the indications for use of OCM™ in nonhealing wounds. In addition, it is unclear if any of the control group patients received collagen-based treatments including the predicate or reference devices to draw comparisons to collagen-based skin protectants that

perform similarly to OCM™. While we recognize, given the number of skin substitute products on the U.S. market, it is not possible to compare OCM™ to each product, we believe that studies comparing the product against other powder, liquid, or gel skin substitute products could provide more evidence demonstrating the clinical superiority of OCM™. In addition to the lack of comparison to other collagen-based wound matrix devices, the standard of care treatment in this study was limited to cleaning and debridement, which, based on the applicant's description for methods for administering OCM™, is a step prior to administering OCM™.

In reference to the applicant's statements that debridement combined with application of OCM™ is more effective in the removal of biofilm compared to the standard of care of debridement alone, we note that neither the abstract nor the interim analysis for this study analyzed results on removal or prevention of biofilm in isolation from the overall metric on wound percent area reduction. We note that FDA recommends sharp debridement alone as an effective method to remove the biofilm and necrotic tissue in a chronic wound (Bettle, et al., 2023). We question whether the results describing the average percent area reduction in wounds transitioning from a nonhealing state to a healing state are sufficient to show substantial clinical improvement in removal or prevention of biofilm. We further question whether the results in percent area reduction can be attributed to debridement combined with application of OCM™ as opposed to debridement alone because it is unclear if debridement was performed on all participants in the retrospective control group. Furthermore, we note that only the effects of historic standard of care treatments administered prior to the start of the study to patients in the control group were included for analysis. While one of the selection criteria for study participants was having failed prior treatment, neither the abstract nor interim analysis discussed how other variables, such as age and comorbidities, may have contributed to treatment failure, or which specific treatments failed in each of the six control group participants. We note that not all patients in the control group received, or were eligible to receive, the same standard of care treatments prior to the study and did not receive any skin substitute or wound dressing treatments during the study as a comparison to the test group patients that were treated with OCM™. Due to the stated limitations in the

study as previously described, we do not believe that the applicant has demonstrated that OCM™ offers a substantial clinical improvement over existing treatments.

Finally, the sample size of 19 individuals (six of whom were assigned to the control group) in the Simman et al. (2023) study limits the generalizability of the findings. Therefore, we question whether OCM™ has superior clinical outcomes and healing for DFUs compared to the standard of care or the predicate or reference devices. Additionally, we note that the Simman et al. (2023) study abstract and interim analysis were sponsored by the manufacturer and have not been published, and therefore are not based on independent and peer-reviewed findings.

In addition to the Simman et al. (2023) study (including the abstract and interim results), in support of its first claim, the applicant submitted two posters presenting results from limited case studies investigating two patients who received treatment using OCM™ combination therapy at the point of care. The first poster (Black, et al., 2023) discussed the treatment of two patients seeking treatment for DFUs at a wound care clinic: (1) a 75-year-old female patient who developed a DFU on her right third toe whose DFU wound progressed from nonhealing to healing after one application of the combination OCM™ therapy; and (2) a 65-year-old female patient with a history of diabetes and a blister of 3-month duration that progressed from nonhealing (after treatment with collagen powder, a gauze covering, an absorbent dressing, and a protective bandage) to completely closed after nine applications of the combination OCM™ therapy over 63 days. The study authors concluded that these case studies demonstrated: (1) rapid and durable healing of chronic/nonhealing wounds in two patients with diabetes who received the combination therapy for their chronic wounds; (2) significantly faster closure of a DFU within 1 week using OCM™ combination therapy than the average healing rate of 84 days for a 1–3 cm² plantar ulcer managed using standard care practices; and (3) that early treatment of chronic/nonhealing wounds with OCM™ combination therapy improves outcomes and can lead to complete closure.

Similarly, the second poster (Barrett et al. (2023) presented results from a case study of two patients who received follow-up care at an outpatient wound center: (1) a 58-year-old male patient with a distal plantar lateral ulceration with infection, which required

hospitalization; and (2) a 56-year-old male patient with leg trauma that had obliterated the patient's anterior tibial and peroneal arteries, leaving him with single vessel runoff to the left foot via the posterior tibial artery. In the first patient, after 5 weeks of initial negative pressure wound therapy following surgery, the percentage area reduction of the wound was 19 percent. In comparison, after three weekly follow-up applications of OCM™ combination therapy, the patient's percentage area reduction was 95 percent. In the second patient, the amputation site was noted as completely necrotic, and therefore not a candidate for standard of care negative pressure wound therapy due to poor skin condition, ischemia, and hyperalgesia. It was noted that after three applications of OCM™ combination therapy, there was a significant improvement in the wound depth and tissue color, with visible epithelialization at the wound edges despite the patient's obvious ischemia. It was noted that the wound size improved and completely healed between the fourth and fifth application of OCM™ combination therapy and after the seventh application of OCM™ combination therapy. The researchers concluded that the case studies demonstrate complete and rapid healing of refractory DFUs in two patients with diabetes who had previously undergone lower extremity amputations and that early use of OCM™ combination therapy has the potential to reduce the rate of amputations and improve patients' quality of life.

We note that both case studies (Barrett et al. (2023) and (Black, et al., 2023), were sponsored by the manufacturer and only had two study participants treated with OCM™ combination therapy, which limits the generalizability of the findings. Although the studies suggest that the two participants treated with OCM™ combination therapy showed transition to a healing state subsequent to the application of OCM™, the results varied widely in terms of number of applications needed to achieve positive results and treatment duration. Further, these case studies provide no direct comparison to the standard of care treatment or the predicate or reference devices. We note that eligibility for standard of care treatments also varied across patients and resulted in varying degrees of percent area reduction or wound closure from prior treatments before application of OCM™ combination therapy. While in one patient, the study showed an improved clinical outcome in percentage area

reduction (19 percent to 95 percent) with treatment utilizing OCM™ combination therapy, we note that the treatment including OCM™ was not only completed subsequent to standard of care treatment with a collagen wound protectant, but also delivered to the same individual rather than as a comparison to standard of care treatments in a control group.

We question whether the submitted evidence adequately supports the claim that OCM™ has superior clinical outcomes and healing for DFU compared to the standard of care. We would be interested in additional information to demonstrate whether the nominated device demonstrates a substantial clinical improvement in comparison to similar collagen-based matrix devices.

In the second claim, the applicant asserted that OCM™ provides faster healing rates than standard of care for VLUs. However, based on the evidence submitted, we note the following concerns: (1) reliance on unpublished studies; and (2) a lack of any documentation indicating the study authors, study description, methods, limitations, information on standard of care treatment for the comparison or control groups, analysis, or discussion. The only data provided were in the form of two tables. One table⁵⁶ provided demographic information for the study participants such as race, age, gender, presence of VLUs, comorbidities, wound area, and wound age; however, there is no indication of how many initial study participants were included in the final results or how many were assigned to either the treatment or control group receiving the standard of care. The other table⁵⁷ presented one row of data from the final results of a randomized controlled trial on VLUs showing an average percent area reduction of 66 percent at 12 weeks in OCM™ treatment group (there was no comparison to the standard of care treatment group) and an average percent area reduction of 34 percent at 4 weeks in the OCM™ treatment group compared to an average percent area reduction of 31 percent at 4 weeks in the standard of care group. Due to the lack of a study report, we have insufficient information to adequately assess this study or make a determination as to whether the study supports the claim that OCM™

⁵⁶ Demographics for RCT in VLU (no author or publication date given).

⁵⁷ Randomized Controlled Trial in Venous Leg Ulcers (NCT05291169) (no author or publication date given).

provides faster healing rates than standard of care for VLU.

In order to demonstrate substantial clinical improvement over currently available treatments, we consider supporting evidence, preferably published peer-reviewed clinical trials, that shows improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to the standard of care. Additional supporting evidence, preferably published peer-reviewed clinical trials, that shows these improved clinical outcomes would help inform our assessment of whether OCM™ demonstrates substantial clinical improvement over existing technologies.

In the third claim, the applicant asserted that OCM™ provides superior clinical outcomes for patients who could not qualify for clinical trials due to comorbidities, and in the fourth claim, the applicant stated that OCM™ improved results when compared to results with standard of care for patients who failed prior treatment. The applicant used the same pair of documents as supporting evidence for both the third and fourth claims: (1) a case study by 16 independent investigators (Bettle, et al., 2023), and (2) a final summary table⁵⁸ of the results of that case study. In the case study by the 16 independent investigators, OCM™ combination therapy was administered to 65 patients with wound ages ranging from 12 weeks to 15 years who failed prior treatment, including six patients with prior failed cellular tissue product therapies. Patients were not otherwise subjected to inclusion or exclusion criteria. According to the applicant, the findings by the 16 independent investigators showed 77 percent of wounds were closed by 12 weeks and the average area reduction was 90 percent. Wounds treated included DFUs, VLUs, pressure injuries, arterial, pyoderma, hematomas, surgical, and trauma. We note that the study lacked direct comparison to a standard of care treatment. Rather, the study compared patient data to standardized data on wound closure and mean time to total wound closure by wound type based on standardized data from the U.S. Wound Registry.

We question whether the submitted evidence adequately supports the claims that OCM™ provides superior clinical outcomes for patients who could not

qualify for clinical trials, due to comorbidities, or that OCM™ improved results when compared to results with standard of care for patients who failed prior treatment. We would welcome further investigation with comparators to help determine whether the device demonstrates substantial clinical improvement over currently available treatments in the clinical setting where it is most likely to be used.

In its fifth claim, the applicant asserted that in vitro (Davis, et al., 2023) and in vivo (Davis, Jozic, et al., 2023) study results demonstrate antimicrobial properties and patient safety. The applicant further asserted that OCM™ addresses an unmet medical need, stating that no other product demonstrates antimicrobial properties and leads to complete wound healing. In the in vivo study (Davis, Jozic, et al., 2023), researchers made 31 deep reticular wounds across the paravertebral and thoracic areas on each of specific pathogen-free pigs. Pathogenic strains of Methicillin-Resistant *Staphylococcus Aureus* (USA300) or *Pseudomonas Aeruginosa* (ATCC 27312), prepared as 106 CFU/ml inoculum suspensions, were used to inoculate all wounds within 20 minutes after wounding followed by application of polyurethane dressings (Tegaderm, 3M, USA) for 72 hours before being treated. Subsequent treatment consisted of OCM™ alone in one test group, OCM™ plus a skin protectant in another test group, Aquacel Ag Advantage in the positive control group, or the wounds were left untreated in the negative control group. We note that the only in vivo study (Davis, Jozic, et al., 2023) with direct comparison to a skin protectant was conducted on non-human subjects (pigs). We question whether these data can be extrapolated to demonstrate significant clinical improvement in humans. In addition, according to the applicant, the in vitro study (Davis, et al., 2023) showed OCM™ significantly inhibiting Methicillin-resistant *Staphylococcus aureus* and *Pseudomonas aeruginosa* compared to negative controls. We note that the in vitro study (Davis, Jozic, et al., 2023) lacked a direct comparison to performance of other similar skin protectant products or wound therapies besides infection control methods such as silver sulfadiazine or Mupirocin antibiotic. We further note that both the in vitro and in vivo studies were submitted as poster presentations and that the studies have not been published and peer-reviewed in full.

We question whether the submitted evidence adequately supports the claims that OCM™ demonstrates antimicrobial

properties and patient safety. Additional supporting evidence, preferably published peer-reviewed clinical trials, that demonstrates improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process, would help inform our assessment of whether OCM™ demonstrates substantial clinical improvement over the standard of care and existing technologies.

For its sixth claim, the applicant asserted that study results demonstrated patient safety of OCM™. In support of this claim, the applicant provided one consumer research study—Princeton Consumer Research Corp. (2019)—of 25 subjects showing no immediate allergic reaction to OCM™. We note that, similar to our previously stated concerns, the study did not include a direct comparison to predicate or reference devices despite claiming an improvement over standard of care treatment. Additionally, this study was also sponsored by the manufacturer and, therefore, not an independent study. Furthermore, since this study only included one type of adverse effect (allergenicity), and was limited to only 25 research subjects, there are limitations in demonstrating safety. We note that the submitted evidence does not adequately support the claims that OCM™ demonstrates substantial clinical improvement in product safety in comparison to similar products.

Finally, we note that OCM™ may not demonstrate that it substantially improves the diagnosis or treatment of an illness when compared to the benefits of other available treatments. OCM™ was determined to be substantially equivalent to a legally marketed device, the SweetBio Apis, which received 510(k) clearance on April 29, 2019. The FDA 510(k) summary for OCM™ indicated that both devices share similar technological characteristics. Per FDA,⁵⁹ the main differences between OCM™ and the predicate are the specific collagen source (OCM™ uses whitefish skin-derived collagen, while the SweetBio Apis uses porcine skin-derived collagen) and the specific identity of the supplemental components (which serve the same fundamental purpose in enabling each wound dressing to achieve the shared intended use).

⁵⁸ OCM treating Multiple Etiologies Final Trial Data (no author or publication date given).

⁵⁹ The SweetBio Apis is FDA cleared and marketed under 510(k) since 2019 (FDA 510(k)) letter: https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211972.pdf.

We are inviting public comment on whether OCM™ meets the device category criterion at § 419.66(c)(2)(i). The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of

the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the

following information in support of the cost significance requirements. The applicant stated that OCM™ would be reported with HCPCS codes as shown in Table 57.

Table 57: HCPCS CODES REPORTED WITH OCM™

HCPCS Code	Long Descriptor	SI	APC
A2014**	Amorphous solid malleable sheet for hard to treat or chronic wounds	N	
11042	Debridement, subcutaneous tissue (includes epidermis and dermis, if performed); first 20 sq cm or less	T	5052
11043	Debridement, muscle and/or fascia (includes epidermis, dermis, and subcutaneous tissue, if performed); first 20 sq cm or less	T	5053
11044	Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); first 20 sq cm or less	J1	5072
97597	Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less	T	5051
97598**	Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof (list separately in addition to code for primary procedure	N	

**Denotes a HCPCS code that was not included in the corrected Addendum P to the CY 2024 OPPS/ASC final rule with comment period, with no CY 2024 HCPCS/CPT code level device offset amount available. We note the applicant used the CY 2024 payment rates for the three tests of the cost criterion. We used the CY 2024 HCPCS/CPT code level device offset amounts for the HCPCS/CPT codes included in the corrected Addendum P to assess whether the device meets the cost significance criterion.

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for

use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level

instead of the APC level (81 FR 79657). We note the applicant utilized the CY 2024 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5052, which had a CY 2024 payment rate of \$379.92 at the time the application was received.

HCPCS code 11042 in APC 5052 had a device offset amount of \$0.04 at the time the application was received. According to the applicant, the cost of OCM™ is \$1,320.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of \$1,320.00 of OCM™ is 347.44 percent of the applicable APC payment amount for the service related to the category of devices of \$379.92 ($(\$1,320.00/\$379.92) \times 100 = 347.44$ percent). Therefore, we believe OCM™ meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$1,320.00 for OCM™ is 3,300,000.00 percent of the cost of the device-related portion of the APC payment amount for the related service of \$0.04 ($(\$1,320.00/\$0.04) \times 100 = 3,300,000.00$ percent). Therefore, we believe that OCM™ meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$1,320.00 for OCM™ and the portion of the APC payment amount for the device of \$0.04 is 347.43 percent of the APC payment amount for the related service of \$379.92 ($((\$1,320.00 - \$0.04)/\$379.92) \times 100 = 347.43$ percent). Therefore, we believe that OCM™ meets the third cost significance requirement.

We are inviting public comment on whether OCM™ meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(c) OPN NC

SIS Medical AG submitted an application for a new device category for transitional pass-through payment status for OPN NC for CY 2025. Per the

applicant, OPN NC percutaneous transluminal coronary angioplasty (PTCA) dilatation catheter is a sterile, single-use, rapid exchange catheter with a distal non-compliant double layer balloon attached to a flexible distal polymer shaft. The applicant explained that OPN NC is intended for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. Per the applicant, the balloon dilatation catheter is also indicated for post deployment expansion of balloon expandable coronary stents. The applicant asserted that the device is inserted to position a balloon in a calcified coronary lesion where super-high pressure is used with the intention of achieving acceptable expansion of the lesion. Per the applicant, radiopaque balloon marker bands enable accurate positioning of the device, and shaft markers for brachial and femoral techniques are also in place. According to the applicant, OPN NC is intended for all patient populations.

Please refer to the online application posting for OPN NC, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP231214L8XQC>, for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on March 14, 2022, the applicant received 510(k) clearance from FDA for OPN NC as a device intended for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The balloon dilatation catheter is also indicated for post deployment expansion of balloon expandable coronary stents. We received the application for a new device category for transitional pass-through payment status for OPN NC on December 14, 2023, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether OPN NC meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. Per the applicant, OPN NC is integral to the service provided and is used for one patient only. While the applicant did not explicitly state

whether the device is surgically inserted or comes in contact with human tissue, per the device description, OPN NC is inserted into the patient for balloon dilation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

We are inviting public comments on whether OPN NC meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant did not address whether OPN NC is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if OPN NC is a supply or material furnished incident to a service.

We are inviting public comments on whether OPN NC meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant described OPN NC as a percutaneous transluminal coronary angioplasty (PTCA) dilatation catheter with a distal non-compliant double layer balloon attached to a flexible distal polymer shaft. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe the OPN NC. Per the applicant, the device category, C1725 (Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)) does not appropriately describe OPN NC because OPN NC is a super high pressure, non-compliant double (twin) layer balloon. Based on the description the applicant provided, OPN NC is a transluminal vascular dilatation catheter with a balloon intended for dilatation of the stenotic portion of a coronary artery or

bypass graft stenosis for the purpose of improving myocardial perfusion, which is consistent with the devices described by C1725. In this context, we believe OPN NC may be similar to the devices described by C1725, and therefore, OPN NC may also be appropriately described by C1725.

We are inviting public comment on whether OPN NC meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the

device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. According to the applicant, OPN NC represents a substantial clinical improvement over existing technologies in the management of patients with highly calcified coronary lesions by providing optimal lumen expansion and demonstrating better outcomes in lesion treatment compared to other devices.

The applicant provided the following evidence to support its claim: three peer-reviewed studies; a PowerPoint presenting an indirect comparison of OPN NC versus another device, Shockwave Intravascular Lithotripsy (IVL) System with Shockwave C2 Coronary Intravascular Lithotripsy (IVL) Catheter (Shockwave),⁶⁰ that uses

⁶⁰ CMS approved an application for the Shockwave IVL System with Shockwave C2 Coronary IVL Catheter as a new device category for transitional pass-through payment status and established HCPCS code C1761 as a new device

intravascular lithotripsy (IVL) to treat calcium lesions; a spreadsheet summarizing the data presented in the PowerPoint document comparing OPN NC and Shockwave; and a background article providing an expert consensus statement from the Society for Cardiovascular Angiography & Interventions on management of in-stent restenosis and stent thrombosis.⁶¹ Table 58 summarizes the applicant's assertion regarding the substantial clinical improvement criterion. Please see the online posting for OPN NC for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

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category effective July 1, 2021. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63577 through 63583) for a full discussion the Shockwave IVL System with Shockwave C2 Coronary IVL Catheter application and decision.

⁶¹ Background articles are not included in the following table but can be accessed via the online posting for the technology.

Table 58: Substantial Clinical Improvement Assertions

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments		
Applicant statements in support	Supporting evidence provided by the applicant	Reference title
Highly calcified unresponsive lumen expansion. OPN NC provides optimal lumen expansion.	Expansion of ≥ 80 percent was achieved in 40 out of 50 cases (80 percent) with a mean final expansion post intervention of 85.7 percent $\pm$ 8.9. Calcium fractures were documented in 49 (98 percent) cases; multiple in 37 (74 percent). There was 1 flow limiting dissection requiring stent deployment and 3 non-cardiovascular related deaths in 6 months follow-up. No records of perforation, no-reflow or other major adverse events.	Natalia Pinilla-Echeverri, Matthias Bossard, Ali Hillani, Jorge A Chavarria, Giacomo M Cioffi, Gustavo Dutra, Fernando Guerrero, Mehdi Madanchi, Adrian Attinger, Ellen Kossmann, Matthew Sibbald, Florim Cuculi, Tej Sheth. Treatment of Calcified Lesions Using a Dedicated Super-High Pressure Balloon: Multicenter Optical Coherence Tomography Registry. Cardiovasc Revasc Med. 2023; 52:49-58. doi: 10.1016/j.carrev.2023.02.020.
	Among patients with heavy calcified lesions undergoing OCT guided intervention with OPN NC, acceptable expansion was achieved in most cases without procedure related complications.	
	The unique possibility offered by the OPN super-high pressure dedicated balloon provides an effective and easy strategy for treatment of resistant coronary lesions non-responsive to conventional NC balloon dilatation. Moreover, our data suggest that the unique twin-layer technology offered by the OPN balloon achieves uniform balloon expansion reducing the use of additional debulking devices.	Gioel Gabrio Secco, Achim Buettner, Rosario Parisi, Gianfranco Pistis, Matteo Vercellino, Andrea Audo, Mashayckhi Kambis, Roberto Garbo, Italo Porto, Giuseppe Tarantini, Carlo Di Mario. Clinical Experience with Very High-Pressure Dilatation for Resistant Coronary Lesions. Cardiovasc Revasc Med. 2019; 20(12):1083-1087. doi: 10.1016/j.carrev.2019.02.026
	Angiographic success was achieved in 97.5 percent, procedural success in 96.6 percent; 53 percent of the lesions were responsive to a slower inflation pressure (Group I) while in the remaining 47 percent, the optimal expansion required a pressure > 40 atmosphere (Group II). The OPN alone was able to achieve adequate expansion in > 90 percent. 0.9 percent days major adverse cardiovascular events (MACE) were reported. The OPN-dedicated high-pressure balloon provides an effective and safe strategy for treatment of severe resistant coronary lesions.	

	Systematic report focusing on the super-high-pressure OPN NC for treatment of In-stent restenosis (ISR). Using this dedicated NC balloon at very high pressures is safe. Moreover, its use not only appears to be efficient in tackling moderately to severely calcified ISR lesions, but also seems to lead to a low rate of TLF/TVF in complex ISR lesions during long-term follow-up. The OPN NC might therefore represent an efficient and less expensive alternative for ISR management compared to other commonly used tools.	Thomas Seiler, Adrian Attinger-Toller, Giacomo Maria Cioffi, Mehdi Madanchi, Mario Teufer, Mathias Wolfrum, Federico Moccetti, Stefan Toggweiler, Richard Kobza, Matthias Bossard, Florim Cuculi. Treatment of In-Stent Restenosis Using a Dedicated Super High-Pressure Balloon. Cardiovasc Revasc Med. 2023; 46:29-35. doi: 10.1016/j.carrev.2022.08.018
	Double layer, noncompliant coronary balloons (OPN NC, SIS Medical) capable of inflation pressures ranging from 35 to 55 atm have recently become available in the United States. This class of percutaneous transluminal coronary angioplasty balloon has performed favorably in severely calcified de novo lesions and may be a consideration in ISR secondary to an under expanded stent.	Lloyd W. Klein, Sandeep Nathan, Akiko Maehara, John Messenger, Gary S. Mintz, Ziad A. Ali, Jennifer Rymer, Yader Sandoval, Karim Al-Azizi, Roxana Mehran, Sunil V. Rao, Amir Lotfi. SCAI Expert Consensus Statement on Management of In-Stent Restenosis and Stent Thrombosis. JSCAI. 2023; 2(23):100971. doi: 10.1016/j.jscai.2023.100971*

*We note this source does not assess, evaluate, or review the nominated device and only provides background information in support of the applicant's claims of substantial clinical improvement.

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After review of the information provided by the applicant, we have the following concerns regarding whether OPN NC meets the substantial clinical improvement criterion. The applicant presented the published results of one study of 50 patients undergoing optical coherence tomography (OCT)-guided percutaneous coronary interventions, including OPN NC, to treat calcified lesions (Natalia Pinilla-Echeverri, et al., 2023). The retrospective study aimed to gain a better understanding of OPN NC calcium modification mechanisms, such as creating deep and wide calcium fractures during percutaneous coronary interventions with the intended clinical outcome of improving myocardial perfusion. Per the applicant, the study showed a primary efficacy endpoint of ≥ 80 percent expansion of the mean reference lumen area achieved in 80 percent of the patients treated. The applicant also presented a retrospective study evaluating 326 highly resistant

coronary lesions that had failed to achieve adequate post-dilatation luminal gain with conventional NC-balloons (Secco et al., 2019). Per the study authors, an OPN NC balloon was inflated to achieve a uniform balloon expansion after the failed attempts with conventional NC-balloons. According to the authors, 413 OPN NC balloons were used (1.26 per lesion), and angiographic success was achieved in 318 lesions (97.5 percent), procedural success was achieved in 315 lesions (96.6 percent), and technical success was achieved in 288 patients (90.5 percent). The study authors also reported that the OPN NC balloon alone was able to achieve adequate expansion in 288 cases (90.5 percent), while in 30 patients, rotational atherectomy was needed and performed because of the impossibility to cross the lesion with a proper sized OPN NC balloon. The applicant presented a third study focused on patients needing treatment of in-stent restenosis (ISR) (Seiler et al., 2023). According to the

authors, 208 ISR lesions were treated in 188 patients. The study authors concluded that the use of OPN NC for treatment of ISR lesions was safe (primary endpoint of the study) and may lead to a low rate of target lesion/vessel failure (TLF/TVF) during long-term follow-up. We note that these studies were not randomized clinical trials with a comparator to demonstrate clinical improvement. Instead, the applicant presented results from registries using non-randomized, retrospective study designs without a control group, which we believe may reduce the strength of the evidence presented to support the claim. The authors noted in all three studies that randomized trials may be needed to compare OPN NC to other similar devices.

Further, we also note that in one of the studies (Natalia Pinilla-Echeverri, et al., 2023), the study authors indicated that use of other calcium lesion modification devices prior to applying

OPN NC to the patients in that study is a potential confounder that could result in overestimation of OPN NC effectiveness. The study authors stated that this was controlled by having an exclusive OCT pullback pre-OPN NC, but indicated that calcium plaque modification caused by other devices may not be evident on OCT. The study authors further noted that since other devices were used before OPN NC, they could not comment on calcium modification from OPN NC use upfront or an OPN NC-only strategy. We would welcome any additional evidence supporting the claim that that OPN NC provides optimal lumen expansion and the impact of using other calcium lesion modification devices prior to applying OPN NC to a patient.

With regards to safety, in the Natalia Pinilla-Echeverri, et al. (2023) study, one patient was found to have had a flow limiting dissection requiring stent deployment; however, no coronary perforations or no-reflow were reported. In the Secco et al. (2019) study, three patients (0.9 percent) were reported to have experienced coronary rupture after balloon inflation and were successfully treated with stent implantation. In the Seiler, et al. (2023) study, coronary perforation was reported to have occurred twice (0.96 percent) with both successfully treated by balloon inflation and implantation of a covered stent; a total of nine (4.3 percent) locally limited, but flow limiting dissections were reported to have occurred and

were successfully treated with implantation of a drug-eluting stent; 4 (1.9 percent) cases of flow deterioration due to embolization of thrombotic material (no-reflow) were found; and one patient (0.5 percent) was reported to have suffered from immediate vessel closure after stent implantation. The application did not address whether the use of the device is safe beyond the data on safety endpoints presented in the studies provided. We would welcome additional studies or evidence discussing the risk of adverse events with the use of these types of non-compliant balloons.

Finally, we are concerned that the evidence may not demonstrate that OPN NC substantially improves the treatment of an illness when compared to the benefits of other available treatments. The applicant asserted in a supporting document included in the application that OPN NC is not the only FDA-authorized device with an indication for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion and also an indication for post deployment expansion of balloon expandable coronary stents. OPN NC was determined to be substantially equivalent to a legally marketed device, the NC Euphora Rapid Exchange Balloon Dilatation Catheter (Medtronic Inc; K141090), which received 510(k) clearance on August 15, 2014. The FDA 510(k) summary for OPN NC indicated

that the devices share similar technological characteristics. In fact, the FDA 510(k) summary indicated that OPN NC differs only in the rated burst pressure of the balloon. We note that the applicant did not compare the nominated device with the NC Euphora Rapid Exchange Balloon Dilatation Catheter, which we believe may be similar. While the applicant asserted that OPN NC is the only super-high pressure, non-compliant twin layer balloon dilatation catheter available in the U.S. and the only device on the market of this nature and capability, we would be interested in additional information to demonstrate whether the nominated device demonstrates a substantial clinical benefit in comparison to other similar NC balloon devices.

We are inviting public comment on whether OPN NC meets the substantial clinical improvement criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that OPN NC would be reported with HCPCS codes shown in Table 59.

Table 59: HCPCS CODES REPORTED WITH OPN NC

HCPCS Code	Long Descriptor	SI	APC
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch.	J1	5192
C1725**	Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)	N	

**Denotes a HCPCS code that was not included in Addendum P to the CY 2023 OPPS/ASC final rule with comment period, with no CY 2023 HCPCS/CPT code level device offset amount available. We note the applicant used the CY 2023 payment rates for the three tests of the cost criterion. We used the CY 2023 HCPCS/CPT code level device offset amount for the HCPCS/CPT code included in Addendum P to assess whether the device meets the cost significance criterion.

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we

assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note the applicant did not provide

details regarding the payment rates it applied for the three tests of the cost criterion. For our calculations, we used APC 5192, which had a CY 2023 payment rate of \$5,215.40 at the time the application was received. HCPCS code 92920 in APC 5192 had a CY 2023

device offset amount of \$1609.99 at the time the application was received.

We note that the applicant provided two cost amounts for OPN NC: (1) a price list showing the cost of OPN NC as \$2,200.00; and (2) a product list that lists the cost of OPN NC as \$1,200.00. We further note that the cost included on the product list provided by the applicant for OPN NC (\$1,200.00) does not pass any of the three tests of the cost criterion, but the cost included on the price list for OPN NC (\$2,200.00) passes all three tests of the cost criterion.

When performed with the price list cost for OPN NC of \$2,200.00, we note the following calculation outcomes: section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of \$2,200.00 for OPN NC is 42.18 percent of the applicable APC payment amount for the service related to the category of devices of \$5,215.40 $((\$2,200.00/\$5,215.40) \times 100 = 42.18$ percent). Therefore, when utilizing the price list cost of \$2,200.00 provided, we believe OPN NC meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$2,200.00 for OPN NC is 136.65 percent of the cost of the device-related portion of the APC payment amount for the related service of \$1,609.99 $(\$2,200.00/\$1,609.99) \times 100 = 136.65$ percent). Therefore, when utilizing the price list cost of \$2,200.00 provided, we believe that OPN NC meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$2,200.00 for OPN NC and the portion of the APC payment amount for the device of \$1,609.99 is 11.31 percent of the APC payment amount for the related service of \$5,215.40

$((\$2,200.00 - \$1,609.99)/\$5,215.40) \times 100 = 11.31$ percent). Therefore, when utilizing the price list cost of \$2,200.00 provided, we believe that OPN NC meets the third cost significance requirement.

When performed with the product list cost for OPN NC of \$1,200.00, we note the following calculation outcomes: section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of \$1,200.00 for OPN NC is 23.01 percent of the applicable APC payment amount for the service related to the category of devices of \$5,215.40 $((\$1,200.00/\$5,215.40) \times 100 = 23.01$ percent). Therefore, when utilizing the product list cost of \$1,200.00 provided, we believe OPN NC does not meet the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$1,200.00 for OPN NC is 74.53 percent of the cost of the device-related portion of the APC payment amount for the related service of \$1,609.99 $(\$1,200.00/\$1,609.99) \times 100 = 74.53$ percent). Therefore, when utilizing the product list cost of \$1,200.00 provided, we believe OPN NC does not meet the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$1,200.00 for OPN NC and the portion of the APC payment amount for the device of \$1,609.99 is negative 7.86 percent of the APC payment amount for the related service of \$5,215.40 $((\$1,200.00 - \$1,609.99)/\$5,215.40) \times 100 = -7.86$ percent). Therefore, when utilizing the product list cost of \$1,200.00 provided, we believe that OPN NC does not meet the third cost significance requirement.

Based on the conflicting amounts provided for the reasonable cost of OPN

NC, we question whether OPN NC meets the cost significance criterion. We would welcome additional information regarding this inconsistency on the estimated average reasonable cost of OPN NC.

We are inviting public comment on whether the OPN NC meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(d) OSCAR® Peripheral Multifunctional Catheter

Biotronik, Inc. submitted an application for a new device category for transitional pass-through payment status for OSCAR® Peripheral Multifunctional Catheter (OSCAR®) for CY 2025. According to the applicant, OSCAR® is a tool used to simplify the treatment of peripheral artery disease (PAD), a disease process characterized by the narrowing of arteries that supply blood to the limbs, usually the legs. In severe cases PAD can cause tissue death and gangrene, leading to amputation. Per the applicant, OSCAR® can simplify the process of peripheral interventions, reduce the time required to perform the procedure and the need for repeat procedures, reduce the risk of complications associated with changing out multiple medical devices, minimize radiation exposure, and enhance patient comfort.

Please refer to the online application posting for OSCAR®, available at <https://mearis.cms.gov/public/publications/device-ptp/DEP230601F6NM2>, for additional detail describing the device and the disease treated by the device.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on July 5, 2022, the applicant received 510k clearance from FDA for OSCAR® as a device to be used for percutaneous transluminal interventions in the peripheral vasculature to provide support during access into and to dilate stenoses in femoral, popliteal and infrapopliteal arteries. The product is also intended for injecting radiopaque contrast media for angiography. We received the application for a new device category for transitional pass-through payment status for OSCAR® on June 1, 2023, which is within three years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether OSCAR® meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. The applicant did not explicitly state whether OSCAR® is integral to the service provided. While the applicant did not explicitly state whether the device is used for one patient only or whether it comes in contact with human tissue, per the device description, OSCAR® is surgically inserted into the lower extremity peripheral vascular system and is single-use. We are inviting public comments on whether OSCAR® meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). The applicant did not indicate whether OSCAR® is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if OSCAR® is a supply or material furnished incident to a service.

We are inviting public comments on whether OSCAR® meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not

appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant asserted that OSCAR® is a combination device authorized by FDA with an indication to diagnose and treat peripheral vascular lesions, identify obstructions, and cross the areas of obstruction and restore blood flow using a single system. According to the applicant, no previous or existing device categories for pass-through payment appropriately describe OSCAR®. Per the applicant, OSCAR® has the functionality of multiple devices currently used during lower extremity peripheral vasculature interventions. The applicant provided multiple HCPCS codes that could describe some of the components of OSCAR®; however, only one of the codes provided, C1725, is a device category HCPCS code, and, therefore, C1725 is the only device category we evaluated for this criterion. Per the applicant, the device category C1725 (Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)) does not appropriately describe OSCAR® because OSCAR® can cover the functionality of support catheters, several sizes of angioplasty balloons, chronic total occlusion crossing devices, reentry catheters, resistant lesion preparation devices, and dissection-reducing devices. According to the applicant, current pass-through coding does not adequately capture OSCAR®'s full functionality and the added clinical and economic value derived from its simplification of peripheral vascular interventions.

We note, based on the description the applicant provided, that when the OSCAR® support catheter and OSCAR® dilator are combined with the OSCAR® PTA balloon, the device is used to complete a transluminal angioplasty, which is consistent with the devices described by C1725. In this context, we

believe that OSCAR® may be similar to the devices described by C1725 and, therefore, may be appropriately described by C1725.

We are inviting public comment on whether OSCAR® meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant claimed that OSCAR® represents a substantial clinical improvement over existing technologies in the diagnosis and management of peripheral artery disease because it uses less equipment, cuts down procedure time, and mitigates risks like vascular damage, infections, and radiation exposure, thereby enhancing clinical efficiency and safety.

The applicant provided four background documents supporting its substantial clinical improvement claim.⁶² Please see the online posting for OSCAR® for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

⁶² Background articles are not included in the following table but can be accessed via the online posting for the technology.

Table 60: SUBSTANTIAL CLINICAL IMPROVEMENT ASSERTIONS

Substantial Clinical Improvement: The technology significantly improves clinical outcomes relative to services or technologies previously available		
Applicant statements in support	Supporting evidence provided by the applicant	Reference Title
OSCAR matches its counterparts in diagnostic and therapeutic prowess. Its unique advantage lies in the ability to achieve these objectives using less equipment. This cuts down procedure time and mitigates risks like vascular damage, infections, and radiation exposure, thereby enhancing clinical efficiency and safety.	This clinical evaluation report demonstrates that the OSCAR Peripheral Multifunctional Catheter, FDA approved in July 2022 for peripheral vasculature interventions, demonstrated high efficacy and safety in a U.S. study.	Deloose, K., Li, S., Salehi Evard, B. (2023) Clinical Evaluation Report. Biotronik. Unpublished.
	The Oscar Catheter presents a 93 percent success in reducing stenosis with 0percent procedural complications, surpassing other methods. It has a 90.1 percent crossing success, and 75 percent of users reported shorter procedural times, enhancing efficiency and patient safety.	Clinical Benefit Table for OSCAR. Biotronik. Unpublished.
	This document is an Evaluation of Market Acceptance for the OSCAR Peripheral Multifunctional Catheter system (EMA).	Biotronik (2024, February 7). OSCAR Peripheral Multifunctional Catheter: Real-World User Evaluation [PowerPoint slides].
	The Oscar EMA Evaluation of Market Acceptance (EMA) conducted from September 13, 2022, to November 10, 2022, assessed the performance and acceptance of Oscar Kits in 78 cases across 12 centers in the USA. The evaluation met all its ending criteria with impressive results.	Schroeder, H. (2023) Clinical OSCAR Evaluation of Market Acceptance Report. Biotronik. Unpublished.

After review of the information provided by the applicant, we have the following concerns regarding whether OSCAR® meets the substantial clinical improvement criterion. First, the applicant did not submit peer-reviewed or published clinical evidence to substantiate clinical improvement over

existing devices. The applicant submitted four background documents in support of OSCAR®: (1) a clinical benefit table, (2) a presentation on the Evaluation of Market Acceptance, (3) the OSCAR® US Evaluation of Market Acceptance Report, and the (4) OSCAR® Clinical Evaluation Report. All four of

these documents rely on data from the Evaluation of Market Acceptance. We note these documents are not published or peer-reviewed, and reflect data collected for marketing purposes rather than clinical improvement purposes. The data included appear to be opinion-based survey questions asked of

physicians recruited by the applicant for the purpose of the Evaluation of Market Acceptance and note that these documents suggest an implicit bias. We question the link between these documents and the claims the applicant made that OSCAR® shows substantial clinical improvement because it uses less equipment, cuts down procedure time, and mitigates risks like vascular damage, infections, and radiation exposure, thereby enhancing clinical efficiency and safety. We request clarification on how the support documents directly relate to the substantial clinical improvement claims.

Further, we question how a collection of devices currently available on the market consolidated into a single packaged product demonstrates substantial clinical improvement. According to the applicant, with OSCAR® some procedures may be performed with a single device which cuts down procedure time and mitigates risks like vascular damage, infections, and radiation exposure, thereby enhancing clinical efficiency and safety. The applicant asserted several benefits of using OSCAR® over multiple devices, including reducing (1) the need to remove and replace multiple devices, which may reduce the incidence of complications like infection and vessel damage; (2) the need to use ill-fitting devices; (3) the need for multiple guidewires in several procedures; and (4) the incidence of complications, such as infections and vessel damage. However, we did not receive comparative data supporting the claim that OSCAR® offers superiority over currently available treatments in terms of clinical benefit or safety. The evidence provided did not discuss any advantages of using a single system of devices rather than multiple individual devices with diverse functionalities. We would welcome any additional evidence supporting these claims.

Furthermore, per the applicant, OSCAR® is effective in preparing intravascular lesions for advanced interventions, particularly stenting, and by ensuring optimal lesion preparation, OSCAR® elevates the success rate of these procedures, enhances patient

safety, and streamlines institutional operations. According to the applicant, OSCAR® handles chronic total occlusions (CTOs) and incorporates reentry capabilities, features traditionally found in standalone devices. The applicant asserted this integration enhances patient safety, simplifies procedures, and elevates the efficiency of operations. However, we note that the applicant did not provide clinical information in support of these claims. Again, we would welcome any additional evidence supporting these claims.

Finally, we question whether OSCAR® can be sufficiently distinguished from similar existing technologies to demonstrate substantial clinical improvement. OSCAR® was determined to be substantially equivalent to a legally marketed device, the INFINITY Angioplasty Balloon Catheter™, which received 510(k) clearance on May 20, 2020. The FDA 510(k) summary for OSCAR® indicated that the devices share similar technological characteristics, and that OSCAR® differs only in that it combines support catheters to be used with the dilator and balloon catheter. We did not receive data demonstrating how OSCAR® offers a substantial clinical improvement compared to the INFINITY Angioplasty Balloon Catheter. We would be interested in additional information to demonstrate whether the nominated device demonstrates a substantial clinical benefit in comparison to INFINITY Angioplasty Balloon Catheter.

Further, per the applicant, there are six device types that it believed OSCAR® is most closely related to: (1) workhorse guidewires (Abbott, Boston Scientific, Terumo, Medtronic, Biotronik, Cook Medical, Cordis); (2) premium guidewires (Abbott, Asahi Intecc, Boston Scientific, Cook Medical and more); (3) workhorse & premium support catheters (Philips, Boston Scientific, Cook Medical, Medtronic, Asahi Intecc, Teleflex and more); (4) angioplasty balloons (Abbott, BD Interventional, Biotronik, Cook Medical, Medtronic and more); (5) lesion preparation balloons (Philips, Medtronic, BD Interventional and

Cagent Vascular); and (6) chronic total occlusion and reentry devices. We do not believe that OSCAR® is similar to the workhorse guidewires and premium guidewires listed because OSCAR® does not include guidewires. We would welcome additional information illustrating how OSCAR® is similar to the listed workhorse guidewires and premium guidewires and evidence demonstrating the benefits of OSCAR® over these other devices.

While we note that OSCAR® is comparable, we did not receive data demonstrating how OSCAR® offers a substantial clinical improvement compared to the workhorse and premium support catheters, angioplasty balloons, lesion preparation balloons, or chronic total occlusion and reentry devices and would be interested in additional evidence demonstrating the substantial clinical benefits of OSCAR® over these other devices.

Additional evidence comparing OSCAR® to existing technologies would be particularly helpful to determine whether the device demonstrates substantial clinical improvements over currently available treatments in the clinical setting where it is most likely to be used. Specifically, we would welcome published peer-reviewed clinical trials that show improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to the standard of care.

We are inviting public comment on whether OSCAR® meets the device category criterion at § 419.66(c)(2)(i).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that OSCAR® would be reported with HCPCS codes as shown in Table 61.

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Table 61: HCPCS CODES REPORTED WITH OSCAR®

HCPCS Code	Long Descriptor	SI	APC
36200**	Introduction of catheter, aorta	N	
36245**	Selective catheter placement, arterial system; each first order abdominal, pelvic, or lower extremity artery branch, within a vascular family	N	
36246**	Selective catheter placement, arterial system; initial second order abdominal, pelvic, or lower extremity artery branch, within a vascular family	N	
36247**	Selective catheter placement, arterial system; initial third order or more selective abdominal, pelvic, or lower extremity artery branch, within a vascular family	N	
36248**	Selective catheter placement, arterial system; additional second order, third order, and beyond, abdominal, pelvic, or lower extremity artery branch, within a vascular family (List in addition to code for initial second or third order vessel as appropriate)	N	
37184	Primary percutaneous transluminal mechanical thrombectomy, noncoronary, non-intracranial, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological thrombolytic injection(s); initial vessel	J1	5193
37220	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal angioplasty	J1	5192
37221	Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	J1	5193
37222**	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)	N	
37223**	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	N	
37224	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty	J1	5192
37225	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed	J1	5193

HCPCS Code	Long Descriptor	SI	APC
37226	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	J1	5193
37227	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed	J1	5194
37228	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty	J1	5193
37229	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed	J1	5194
37230	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	J1	5194
37231	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed	J1	5194
37232**	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)	N	
37233**	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	N	
37234**	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	N	
37235**	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	N	
75625	Aortography, abdominal, by serialography, radiological supervision and interpretation	Q2	5183
75630	Aortography, abdominal plus bilateral iliofemoral lower extremity, catheter, by serialography, radiological supervision and interpretation	Q2	5183

HCPCS Code	Long Descriptor	SI	APC
75710	Angiography, extremity, unilateral, radiological supervision and interpretation	Q2	5183
75716	Angiography, extremity, bilateral, radiological supervision and interpretation	Q2	5183
75774**	Angiography, selective, each additional vessel studied after basic examination, radiological supervision and interpretation (List separately in addition to code for primary procedure)	N	
0238T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; iliac artery, each vessel	J1	5194

**Denotes a HCPCS code that was not included in Addendum P to the CY 2023 OPPS/ASC final rule with comment period, with no CY 2023 HCPCS/CPT code level device offset amount available. We note the applicant used the CY 2023 payment rates for the three tests of the cost criterion. We used the CY 2023 HCPCS/CPT code level device offset amounts for the HCPCS/CPT codes included in Addendum P to assess whether the device meets the cost significance criterion.

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To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note the applicant used the CY 2023 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5183, which had a CY 2023 payment rate of \$2,978.97 at the time the application was received. HCPCS code 75625 in APC 5183 had a CY 2023 device offset amount of \$530.85 at the time the application was received.⁶³ According to the applicant, the cost of OSCAR® is \$2,020.00.

Section 419.66(d)(1), the first cost significance requirement, provides that

the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of \$2,020.00 for OSCAR is 67.81 percent of the applicable APC payment amount for the service related to the category of devices of \$2,978.97 ($(\$2,020.00/\$2,978.97) \times 100 = 67.81$ percent). Therefore, we believe OSCAR meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$2,020.00 for OSCAR® is 380.52 percent of the cost of the device-related portion of the APC payment amount for the related service of \$530.85 ($(\$2,020.00/\$530.85) \times 100 = 380.52$ percent). Therefore, we believe that OSCAR® meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related

service. The difference between the estimated average reasonable cost of \$2,020.00 for OSCAR® and the portion of the APC payment amount for the device of \$530.85 is 49.99 percent of the APC payment amount for the related service of \$2978.97 ($((\$2,020.00 - \$530.85)/\$2,978.97) \times 100 = 49.99$ percent). Therefore, we believe that OSCAR® meets the third cost significance requirement.

We are inviting public comment on whether the OSCAR® meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

B. Proposed Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent (79 FR 66795). Beginning in CY 2017, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilized devices, and the device costs for the associated HCPCS codes exceeded the 40-percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through

⁶³ We note the applicant selected APC 5192 and an APC payment rate of \$5,061.89 for the three tests of the cost criteria. However, for our calculation, we selected APC 5183, which we believe had the lowest applicable APC payment rate of \$2,978.97 found in Addendum P to the CY 2023 OPPS/ASC final rule with comment period, among the APCs related to the HCPCS/CPT codes provided by the applicant. We selected the HCPCS/CPT code level device offset amount of \$530.85 related to HCPCS 75625 in APC 5183. Based on our initial assessment for this proposed rule, using the APC payment rate of \$2,978.97 and the device offset amount of \$530.85 would result in OSCAR® meeting the cost significance requirement.

66873) applies to device-intensive procedures and is discussed in detail in section IV.B.4 of this proposed rule. A related device policy was the requirement that certain procedures assigned to device-intensive APCs require the reporting of a device code on the claim (80 FR 70422) and is discussed in detail in section IV.B.3 of this proposed rule. For further background information on the device-intensive APC policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70421 through 70426).

a. HCPCS Code-Level Device-Intensive Determination

As stated earlier, prior to CY 2017, under the device-intensive methodology we assigned device-intensive status to all procedures requiring the implantation of a device that were assigned to an APC with a device offset greater than 40 percent and, beginning in CY 2015, that met the three criteria as listed. Historically, the device-intensive designation was at the APC level and applied to the applicable procedures within that APC. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we changed our methodology to assign device-intensive status at the individual HCPCS code level rather than at the APC level. Under this policy, a procedure could be assigned device-intensive status regardless of its APC assignment, and device-intensive APC designations were no longer applied under the OPPS or the ASC payment system.

We believe that a HCPCS code-level device offset is, in most cases, a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that this methodological change results in a more accurate representation of the cost attributable to implantation of a high-cost device, which ensures consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset removes inappropriate device-intensive status for procedures without a significant device cost that are granted such status because of their APC assignment.

Under our existing policy, procedures that meet the criteria listed in section

IV.C.1.b of this proposed rule are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive status under our established methodology, including our policies on device edits and no cost/full credit and partial credit devices discussed in sections IV.C.3 and IV.C.4 of this proposed rule.

b. Use of the Three Criteria To Designate Device-Intensive Procedures

We clarified our established policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52474), where we explained that device-intensive procedures require the implantation of a device and additionally are subject to the following criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed;
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and
- The device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

We changed our policy to apply these three criteria to determine whether procedures qualify as device-intensive in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), where we stated that we would apply the no cost/full credit and partial credit device policy—which includes the three criteria listed previously—to all device-intensive procedures beginning in CY 2015. We reiterated this position in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), where we explained that we were finalizing our proposal to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which the CY 2016 device intensive policy will apply. Under the policies we adopted in CYs 2015, 2016, and 2017, all procedures that require the implantation of a device and meet the previously described criteria are assigned device-intensive status, regardless of their APC placement.

2. Proposed Device-Intensive Procedure Policy

As part of our effort to better capture costs for procedures with significant device costs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948), for CY 2019, we modified our criteria for device-intensive procedures. We had heard

from interested parties that the criteria excluded some procedures that interested parties believed should qualify as device-intensive procedures. Specifically, we were persuaded by interested party arguments that procedures requiring expensive surgically inserted or implanted devices that are not capital equipment should qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We agreed that a broader definition of device-intensive procedures was warranted, and made two modifications to the criteria for CY 2019 (83 FR 58948). First, we allowed procedures that involve surgically inserted or implanted single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We established this policy because we no longer believe that whether a device remains in the patient's body should affect a procedure's designation as a device-intensive procedure, as such devices could, nonetheless, comprise a large portion of the cost of the applicable procedure. Second, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent, to allow a greater number of procedures to qualify as device-intensive. We stated that we believe allowing these additional procedures to qualify for device-intensive status will help ensure these procedures receive more appropriate payment in the ASC setting, which will help encourage the provision of these services in the ASC setting. In addition, we stated that this change would help to ensure that more procedures containing relatively high-cost devices are subject to the device edits, which leads to more correctly coded claims and greater accuracy in our claims data. Specifically, for CY 2019 and subsequent years, we finalized that device-intensive procedures will be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost (83 FR 58945).

In addition, to further align the device-intensive policy with the criteria used for device pass-through payment status, we finalized, for CY 2019 and subsequent years, that for purposes of

satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE), and has been classified as a Category B device by FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;

- Is an integral part of the service furnished;

- Is used for one patient only;
- Comes in contact with human tissue;

- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not either of the following:

- ++ Equipment, an instrument, apparatus, implement, or item of the type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

- ++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker) (83 FR 58945).

In addition, for new HCPCS codes describing procedures requiring the implantation of devices that do not yet have associated claims data, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we finalized a policy for CY 2017 to apply device-intensive status with a default device offset set at 41 percent for new HCPCS codes describing procedures requiring the implantation or insertion of a device that did not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent was not calculated from claims data; instead, it was applied as a default until claims data were available upon which to calculate an actual device offset for the new code. The purpose of applying the 41-percent default device offset to new codes that describe procedures that implant or insert devices was to ensure ASC access for new procedures until claims data become available.

As discussed in the CY 2019 OPPS/ASC proposed rule and final rule with comment period (83 FR 37108 through 37109 and 58945 through 58946, respectively), in accordance with our policy stated previously to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to

greater than 30 percent, for CY 2019 and subsequent years, we modified this policy to apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a device that do not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. In conjunction with the policy to lower the default device offset from 41 percent to 31 percent, we continued our current policy of, in certain rare instances (for example, in the case of a very expensive implantable device), temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer (81 FR 79658). Once claims data are available for a new procedure requiring the implantation or insertion of a device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent, according to our policy of determining device-intensive status by calculating the HCPCS code-level device offset.

In addition, in the CY 2019 OPPS/ASC final rule with comment period, we clarified that since the adoption of our policy in effect as of CY 2018, the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, for CY 2019 and subsequent years, in limited instances where a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code (83 FR 58946).

Clinically related and similar procedures for purposes of this policy are procedures that have few or no clinical differences and use the same devices as the new HCPCS code. In addition, clinically related and similar codes for purposes of this policy are codes that either currently or previously describe the procedure described by the new HCPCS code. Under this policy, claims data from clinically related and similar codes are included as associated claims data for a new code, and where an existing HCPCS code is found to be

clinically related or similar to a new HCPCS code, we apply the device offset percentage derived from the existing clinically related or similar HCPCS code's claims data to the new HCPCS code for determining the device offset percentage. We stated that we believe that claims data for HCPCS codes describing procedures that have minor differences from the procedures described by new HCPCS codes will provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and will be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. If a new HCPCS code has multiple predecessor codes, the claims data for the predecessor code that has the highest individual HCPCS-level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status. Similarly, in the event that a new HCPCS code does not have a predecessor code but has multiple clinically related or similar codes, the claims data for the clinically related or similar code that has the highest individual HCPCS level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status.

a. Proposed Change to the Device-Intensive Status Default Offset Methodology for New HCPCS Codes

As described above, under our existing policies for assigning a device offset percentage to new HCPCS codes, we first rely on the associated claims data for new HCPCS codes. For new HCPCS codes that do not have available claims data yet, we rely on any available claims data from a predecessor code for the new HCPCS code, as described by CPT coding guidance. We assign the device offset percentage to the new HCPCS code that is the device offset percentage of the predecessor code for which we have available claims data. If claims data from the new HCPCS or any predecessor code is unavailable, we use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining a device offset percentage to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have few or no clinical differences and use the same devices. If a clinically similar procedure that uses the same devices is not available, then for new HCPCS codes

describing procedures requiring the insertion or implantation of devices that do not yet have claims data (from either the new HCPCS code or any predecessor code), we apply a default device offset set at 31 percent.

As we stated previously, the purpose of applying the default device offset to new codes that describe procedures that implant or insert devices is to ensure access in the ASC setting for new procedures until claims data become available. Also, under the OPPS, the default device offset is useful for establishing a device amount for new device-intensive procedures. For example, under our policy for no cost/full credit or partial credit devices, we reduce the OPPS payment for device-intensive procedures by the lesser of the full or partial credit a hospital receives for a replaced device or the device offset amount. Additionally, we may remove the device offset amount from the OPPS payment for procedures that are terminated prior to administering anesthesia (since the device was not used for the procedure).

While we do allow for additional information in consideration of a higher offset percentage than the default device offset, it would be extremely rare that the appropriate determination of a device offset percentage would rely on pricing data or invoices from a device manufacturer rather than the default device offset percentage. However, we are aware that there may be certain situations where the default device offset percentage would not adequately reflect the existing device portion of the procedure's costs when compared to the cost of similar devices. This difference could impede our ability to accurately remove device offset amounts from new device-intensive procedures under the OPPS. As HOPDs and ASCs perform new procedures with significant device costs, we believe it is appropriate to modify our default device offset methodology to pay HOPDs and ASCs more appropriately when we lack claims data for these newer procedures. Therefore, for this CY 2025 OPPS/ASC proposed rule and subsequent calendar years, we propose to modify our default device offset percentage policy for new device-intensive procedures. Specifically, for new HCPCS codes that describe a procedure that requires the implantation or insertion of a single-use device that meets our requirements of a device as described above and the procedure lacks claims data (from either the new HCPCS code or any predecessor code), we would apply a default device offset percentage that is the greater of 31 percent or the device offset percentage of the APC to which the procedure has

been assigned. We propose this methodological change for both the OPPS and ASC Payment System for CY 2025 and subsequent calendar years. We still believe that a HCPCS code-level device offset is, in most cases, a more accurate representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all the procedures assigned to an APC. However, because newer device-intensive procedures lack claims data, we believe the APC-wide average device offset percentage is, in many cases, a better reflection of the estimated device costs of the procedure than a default 31 percent offset. Additionally, there can be instances where the typical device costs of procedures in an APC can be significantly greater than the 31 percent default device offset. For these reasons, we propose to modify our default device offset percentage for new device-intensive procedures that describe the implantation or insertion of a single-use device that meets our requirements of a device (as described above) and that do not yet have associated claims data, by applying a default device offset percentage that is the greater of 31 percent or the device offset percentage of the APC to which the procedure has been assigned. This proposal would apply to new procedures assigned to clinical APCs, but not new procedures assigned to New Technology APCs.

As we indicated in the CY 2019 OPPS/ASC proposed rule and final rule with comment period, we may consider additional information for an offset percentage greater than the default offset percentage (which, for this proposed rule, is the greater of 31 percent or the APC-level offset percentage) for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a device that do not yet have associated claims data, such as pricing data or invoices from a device manufacturer. This would be for our consideration in extremely rare circumstances, such as an extremely high-cost implantable device. While we believe our proposed modification of a default device offset will improve payment under the OPPS and ASC payment system, we will continue to accept additional information in consideration of an alternative offset percentage. This information should be directed to the Division of Outpatient Care, Mail Stop C4-01-26, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850, or electronically at outpatientpps@cms.hhs.gov. Additional information can be submitted prior to

issuance of an OPPS/ASC proposed rule or as a public comment in response to an issued OPPS/ASC proposed rule. Device offset percentages will be set in each year's final rule.

The full listing of the proposed CY 2025 device-intensive procedures, which incorporates our proposed changes to the default device offset policy, can be found in Addendum P to this proposed rule (which is available via the internet on the CMS website). Further, our claims accounting narrative contains a description of our device offset percentage calculation. Our claims accounting narrative for this proposed rule can be found under supporting documentation for the CY 2025 OPPS/ASC proposed rule on our website at: <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps>.

3. Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPS/ASC final rule with comment period (the CY 2015 device-dependent APCs) was reported on the claim. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device assigned to a device-intensive APC. In the CY 2016 OPPS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422)), will satisfy the edit.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658 through 79659), we changed our policy for CY 2017 and subsequent years to apply the CY 2016 device coding requirements to the newly defined device-intensive procedures. For CY 2017 and subsequent years, we also specified that any device code, when reported on a claim with a device-intensive procedure, will satisfy the edit. In addition, we created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code. Reporting HCPCS code C1889

with a device-intensive procedure will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure. In the CY 2019 OPPS/ASC final rule with comment period, we revised the description of HCPCS code C1889 to remove the specific applicability to device-intensive procedures (83 FR 58950). For CY 2019 and subsequent years, the description of HCPCS code C1889 is “Implantable/insertable device, not otherwise classified.”

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81758 through 81759), we finalized our proposal to establish a procedure-to-device edit for the procedures assigned to APC 5496 (Level 6 Intraocular Procedures) and require hospitals to report the correct device HCPCS codes when reporting any of the four procedures—CPT codes 0308T, 0616T, 0617T, and 0618T. While we noted that interested parties have previously recommended in past rulemaking that we reestablish all of our previous procedure-to-device edits, we did not expect to extend this policy beyond the procedures assigned to APC 5496 (Level 6 Intraocular Procedures). This APC represents a unique situation—the APC (which was the Level 5 Intraocular APC in previous years) had been a Low Volume APC (fewer than 100 claims in a claims year) since we established our Low Volume APC policy, the procedures associated with this APC have significant procedure costs often greater than \$15,000, and the procedures associated with this APC require the implantation of a high-cost intraocular device. Additionally, in our review of claims data for some of the procedures, we noticed unusual coding, charge, and cost data. These claims had an outsized impact because of the low volume of claims for the APC which impeded our ability to determine a payment rate accurately and appropriately for APC 5496 (Level 6 Intraocular Procedures). Further, because of the low volume of procedures assigned to this APC, we did not believe the reinstatement of procedure-to-device edits for the four procedures assigned to this APC would be administratively burdensome to hospitals. We finalized our proposal to modify our device edits policy to require a procedure-to-device edit for procedures assigned to APC 5496 (Level 6 Intraocular Procedures) for CY 2024. We propose to continue this policy for APC 5496 (Level 6 Intraocular Procedures) for CY 2025 and subsequent CYs and note that new CPT placeholder code 6X004 (Implantation of iris

prosthesis, including suture fixation and repair or removal of iris, when performed) is replacing CPT code 0616T (Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens) effective January 1, 2025. Additionally, CPT codes 0617T and 0618T currently assigned to APC 5496 (Level 6 Intraocular Procedures) will be deleted effective January 1, 2025. Therefore, for CY 2025, the procedure-to-device edit for procedures assigned to APC 5496 (Level 6 Intraocular Procedures) will apply to CPT code 0308T and 6X004.

We are not proposing any other changes to our device edit policy for CY 2025.

4. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the “FB” modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than \$1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital’s usual charge for the device being implanted and the hospital’s usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the “FC” modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment

period for more background information on the “FB” and “FC” modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code “FD” (Credit Received from the Manufacturer for a Replaced Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the “FD” value code appears on a claim. For CY 2015, we continued our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Policy for No Cost/Full Credit and Partial Credit Devices

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79659 through 79660), for CY 2017 and subsequent years, we finalized a policy

to reduce OPPS payment for device-intensive procedures, by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit. Under our current policy, hospitals continue to be required to report on the claim the amount of the credit in the amount portion for value code “FD” when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), we adopted a policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the amount of the credit. We adopted this change in policy in the preamble of the CY 2014 OPPS/ASC final rule with comment period and discussed it in subregulatory guidance, including Chapter 4, Section 61.3.6 of the Medicare Claims Processing Manual. Further, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86017 through 86018, 86302), we made conforming changes to our regulations at § 419.45(b)(1) and (2) that codified this policy.

We are not proposing any changes to our policies regarding payment for no cost/full credit and partial credit devices for CY 2025.

V. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals

A. Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or “transitional pass-through payments” for certain drugs and biologicals. Throughout this proposed rule, the term “biological” is used because this is the term that appears in section 1861(t) of the Act. A “biological” as used in this proposed rule includes (but is not necessarily limited to) a “biological product” or a “biologic” as defined under section 351 of the PHS Act. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: current orphan drugs for rare diseases and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and

biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. “Current” refers to those types of drugs or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain “new” drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996, and whose cost is “not insignificant” in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as “drugs.” As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug as a hospital outpatient service under Medicare Part B. Proposed CY 2025 pass-through drugs and biologicals and their designated APCs are assigned status indicator “G” in Addenda A and B to this proposed rule (which are available on the CMS website).⁶⁴

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. The methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological.

Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this proposed rule, the term

“ASP methodology” and “ASP-based” are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on our website at: <https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price>.

The pass-through application⁶⁵ and review process for drugs and biologicals is described on our website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/pass-through-payment-status-new-technology-ambulatory-payment-classification-apc>.

2. Transitional Pass-Through Payment Period for Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Quarterly Expiration of Pass-Through Status

As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug or biological as a hospital outpatient service under Medicare Part B. Our current policy is to accept pass-through applications on a quarterly basis and to begin pass-through payments for approved pass-through drugs and biologicals on a quarterly basis through the next available OPPS quarterly update after the approval of a drug’s or biological’s pass-through status. However, prior to CY 2017, we expired pass-through status for drugs and biologicals on an annual basis through notice-and-comment rulemaking (74 FR 60480). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79662), we finalized a policy change, beginning with pass-through drugs and biologicals approved in CY 2017 and subsequent calendar years, to allow for a quarterly expiration of pass-through payment status for drugs, biologicals, and radiopharmaceuticals to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through drugs, biologicals, and radiopharmaceuticals.

This change eliminated the variability of the pass-through payment eligibility period, which previously varied based

⁶⁴ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

⁶⁵ To apply for OPPS transitional Pass-Through Payment Status and New Technology Ambulatory Payment Classification (APC), applicants complete an application that is subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). This information collection (CMS-10008) is currently approved under OMB control number of 0938-0802 and has an expiration date of January 31, 2025.

on when a particular application was initially received. We adopted this change for pass-through approvals beginning on or after CY 2017, to allow, on a prospective basis, for the maximum pass-through payment period for each pass-through drug without exceeding the statutory limit of 3 years. Notice of drugs for which pass-through payment status is ending during the calendar year is included in the quarterly OPPS Change Request transmittals.

3. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2024

There are 25 drugs and biologicals for which pass-through payment status expires by December 31, 2024, as listed in Table 62. These drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of April 1, 2021 through December 31, 2024. In accordance with the policy finalized in CY 2017 and described earlier, pass-through payment status for drugs and biologicals approved in CY

2017 and subsequent years will expire on a quarterly basis, with a pass-through payment period as close to 3 years as possible.

With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals⁶⁶ that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and

⁶⁶ We propose to pay separately for diagnostic radiopharmaceuticals with per-day costs above a proposed threshold. If our proposal is finalized, this category of policy-packaged drugs that function as supplies in a diagnostic test or procedure would include diagnostic radiopharmaceuticals with per-day costs below the threshold for the applicable year. Please refer to Section II.A.3.c. for more information regarding our proposal.

compare it with the OPPS drug packaging threshold for that calendar year, which is proposed to be \$140 for CY 2025 for all drugs, biologicals, and therapeutic radiopharmaceuticals (for diagnostic radiopharmaceuticals we propose separate payment when their per day cost exceeds the proposed threshold of \$630). These proposals are discussed further in section V.B.1 of this proposed rule. If the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we provide separate payment at the applicable ASP methodology-based payment amount (which is generally ASP plus 6 percent), as discussed further in section V.B.2 of this proposed rule.

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TABLE 62: DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS WILL END BY DECEMBER 31, 2024

CY 2024 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0224	Injection, lumasiran, 0.5 mg	G	9407	04/01/2021	03/31/2024
J7212	Factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram	G	9395	04/01/2021	03/31/2024
Q5122	Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg	G	9406	04/01/2021	03/31/2024
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	G	9409	07/01/2021	06/30/2024
A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	G	9410	07/01/2021	06/30/2024
J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg	G	9414	07/01/2021	06/30/2024
J1305	Injection, evinacumab-dgnb, 5mg	G	9416	07/01/2021	06/30/2024
J1426	Injection, casimersen, 10 mg	G	9412	07/01/2021	06/30/2024
J1448	Injection, trilaciclib, 1mg	G	9415	07/01/2021	06/30/2024
J9247	Injection, melphalan flufenamide, 1mg	G	9417	07/01/2021	06/30/2024
J9348	Injection, naxitamab-gqgk, 1 mg	G	9408	07/01/2021	06/30/2024
J9353	Injection, margetuximab-cmkb, 5 mg	G	9418	07/01/2021	06/30/2024
Q2054	Lisocabtagene maraleucel, up to 110 million	G	9413	07/01/2021	06/30/2024

CY 2024 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
	autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose				
Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg	G	9411	07/01/2021	06/30/2024
J1823	Injection, inebilizumab-cdon, 1 mg	G	9394	10/01/2021	09/30/2024
J2406	Injection, oritavancin (kimyrsa), 10 mg	G	9427	10/01/2021	09/30/2024
J9061	Injection, amivantamab-vmjw, 10 mg	G	9432	10/01/2021	09/30/2024
J9272	Injection, dostarlimab-gxly, 100 mg	G	9431	10/01/2021	09/30/2024
J9359	Injection, loncastuximab tesirine-lpyl, 0.075 mg	G	9205	10/01/2021	09/30/2024
Q2055	Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9422	10/01/2021	09/30/2024
A9595	Piflufolastat f-18, diagnostic, 1 millicurie	G	9430	01/01/2022	12/31/2024
J0219	Injection, avalglucosidase alfa-ngpt, 4 mg	G	9433	01/01/2022	12/31/2024
J0491	Injection, anifrolumab-fnia, 1 mg	G	9434	01/01/2022	12/31/2024
J9021	Injection, asparaginase, recombinant, (rylaze), 0.1 mg	G	9437	01/01/2022	12/31/2024
J9071	Injection, cyclophosphamide, (auromedics), 5 mg	G	9203	01/01/2022	12/31/2024

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4. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Expiring in CY 2025

We propose to end pass-through payment status in CY 2025 for 28 drugs and biologicals. These drugs and biologicals, which were initially approved for pass-through payment status between April 1, 2022 and January 1, 2023, are listed in Table 63. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will end by December 31, 2025, are assigned status indicator “G” (Pass-Through Drugs and Biologicals) in Addenda A and B to this proposed rule (which are available on the CMS website).⁶⁷ The APCs and HCPCS codes for these drugs and biologicals are assigned status indicator “G” only for the duration of their pass-through status.

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2025, we are continuing our policy to pay for pass-through drugs and biologicals using the ASP methodology, meaning a payment rate based on ASP, WAC, or AWP, as applicable. This payment rate is generally ASP plus 6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician’s office setting in CY 2025. We note that, under the OPD fee schedule, separately payable drugs assigned to an APC are generally

payable at ASP plus 6 percent. Therefore, a \$0 pass-through payment amount would continue to be paid for pass-through drugs and biologicals under the CY 2025 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is generally ASP plus 6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is generally ASP plus 6 percent, is \$0.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals⁶⁸ that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure), their pass-through payment amount will continue to be equal to a payment rate calculated using the ASP methodology, meaning a payment rate based on ASP, WAC, or AWP. This payment rate will generally continue to be ASP plus 6 percent for CY 2025, minus a payment offset for the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. We note that if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure and therefore, there are associated OPD fee schedule amounts for them.

We will continue our policy to update pass-through payment rates on a quarterly basis on the CMS website during CY 2025 if later quarter ASP

submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2025, consistent with our CY 2024 policy for diagnostic and therapeutic radiopharmaceuticals, we would continue to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2025, we would continue to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is generally ASP plus 6 percent. If ASP data are not available for a radiopharmaceutical, we would continue to provide pass-through payment at WAC plus 3 percent (consistent with our policy in section V.B.2.a of this proposed rule), the equivalent payment provided for pass-through drugs and biologicals without ASP information. Additional detail on the WAC plus 3 percent payment policy can be found in section V.B.2.a of this proposed rule. If WAC information also is not available, we would continue to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

We refer readers to Table 63 below for the list of drugs and biologicals with pass-through payment status expiring during CY 2025.

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⁶⁷ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

⁶⁸ We propose to pay separately for diagnostic radiopharmaceuticals with per-day costs above a proposed threshold. If our proposal is finalized, this category of policy-packaged drugs that function as supplies in a diagnostic test or procedure would include diagnostic radiopharmaceuticals with per-day costs below the threshold for the applicable year. Please refer to Section II.A.3.c. for more information regarding our proposal.

**TABLE 63: DRUGS AND BIOLOGICALS WITH PASS-THROUGH
PAYMENT STATUS EXPIRING IN CY 2025**

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0248	J0248	Injection, remdesivir, 1 mg	G	9200	04/01/2022	03/31/2025
J9304	J9304	Injection, pemetrexed (PEMFEXY), 10mg	G	9442	04/01/2022	03/31/2025
J3299	J3299	Injection, triamcinolone acetonide (xipere), 1 mg	G	9358	04/01/2022	03/31/2025
J2779	J2779	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg	G	9439	04/01/2022	03/31/2025
J9331	J9331	Injection, sirolimus protein-bound particles, 1 mg	G	9241	04/01/2022	03/31/2025
J2998	J2998	Injection, plasminogen, human-tvmh, 1 mg	G	9206	04/01/2022	03/31/2025
J9273	J9273	Injection, tisotumab vedotin-tftv, 1 mg	G	9204	04/01/2022	03/31/2025
C9088	C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	G	9440	04/01/2022	03/31/2025
Q2056	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9498	07/01/2022	06/30/2025
J1302	J1302	Injection, sutimlimab-jome, 10 mg	G	9444	07/01/2022	06/30/2025
A9596	A9596	Gallium ga-68 gozetotide, diagnostic,	G	9443	07/01/2022	06/30/2025

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		(illuccix), 1 millicurie				
J9274	J9274	Injection, tebentafusp-tebn, 1 microgram	G	9446	07/01/2022	06/30/2025
J1306	J1306	Injection, inclisiran, 1 mg	G	9004	07/01/2022	06/30/2025
Q5125	Q5125	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram	G	9447	07/01/2022	06/30/2025
J2356	J2356	Injection, tezepelumab-ekko, 1 mg	G	9008	07/01/2022	06/30/2025
J2777	J2777	Injection, faricimab-svoa, 0.1 mg	G	9496	07/01/2022	06/30/2025
J9332	J9332	Injection, efgartigimod alfa-fcab, 2 mg	G	9010	07/01/2022	06/30/2025
A9800	A9800	Gallium ga-68 gozetotide, diagnostic, (locametz), 1 millicurie	G	9055	10/01/2022	09/30/2025
C9101	C9101	Injection, oliceridine, 0.1 mg	G	9049	10/01/2022	09/30/2025
A9607	A9607	Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie	G	9054	10/01/2022	09/30/2025
J9298	J9298	Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg	G	9057	10/01/2022	09/30/2025
A9602	A9602	Fluorodopa f-18, diagnostic, per millicurie	G	9053	10/01/2022	09/30/2025
J1952	J1952	Leuprolide injectable, camcevi, 1 mg	G	9050	10/01/2022	09/30/2025
Q5126	Q5126	Injection, bevacizumab-maly, biosimilar, (alymys), 10 mg	G	9048	10/01/2022	09/30/2025

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0225	J0225	Injection, vutrisiran, 1 mg	G	9009	01/01/2023	12/31/2025
J1932	J1932	Injection, lanreotide, (cipl), 1 mg	G	9051	01/01/2023	12/31/2025
J2327	J2327	Injection, risankizumab-rzaa, intravenous, 1 mg	G	9013	01/01/2023	12/31/2025
Q5124	Q5124	Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg	G	9017	01/01/2023	12/31/2025

BILLING CODE 4120-01-C**5. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Continuing Through CY 2025**

We propose to continue pass-through payment status in CY 2025 for 57 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status with effective dates beginning between April 1, 2023 and April 1, 2024, are listed in Table 64. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that would continue after December 31, 2025, are assigned status indicator “G” in Addenda A and B to this proposed rule (which are available on the CMS website).⁶⁹

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2025, we are continuing our policy to pay for pass-through drugs and biologicals at a payment rate based on the ASP methodology, which may be based on ASP, WAC, or AWP, but is generally ASP plus 6 percent, which is equivalent to the payment rate these drugs and biologicals would receive in the physician’s office setting in CY 2025. We will continue with our policy of paying a \$0 pass-through payment amount for pass-through drugs and

biologicals that are not policy-packaged under the CY 2025 OPPS, because the difference between the amount authorized under section 1842(o) of the Act, which would generally be ASP plus 6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which would also generally be ASP plus 6 percent, is \$0.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals⁷⁰ that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure), their pass-through payment amount would continue to be equal to a payment rate based on the ASP methodology, which may be based on ASP, WAC, or AWP, but would generally be ASP plus 6 percent for CY 2025, minus a payment offset for any predecessor drug products contributing to the pass-through payment. We note if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure and therefore, there are associated OPD fee schedule amounts for them. We are continuing our policy to update pass-through payment rates on a quarterly basis on our website during CY 2025 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006

OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2025, consistent with our CY 2024 policy for diagnostic and therapeutic radiopharmaceuticals, we propose to continue our policy to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2025, we will continue to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which would generally be ASP plus 6 percent. If ASP data are not available for a radiopharmaceutical, we would provide pass-through payment at WAC plus 3 percent (consistent with our policy in section V.B.2.a of this proposed rule), the equivalent payment provided for pass-through drugs and biologicals without ASP information. Additional detail on the WAC plus 3 percent payment policy can be found in section V.B.2.a of this proposed rule. If WAC information also is not available, we would provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

The drugs and biologicals that would have pass-through payment status expire after December 31, 2025, are shown in Table 64.

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⁶⁹ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

⁷⁰ We propose to pay separately for diagnostic radiopharmaceuticals with per-day costs above a

proposed threshold. If our proposal is finalized, the category of policy-packaged drugs that function as supplies in a diagnostic test or procedure would include diagnostic radiopharmaceuticals with per-

day costs below the threshold for the applicable year. Please refer to Section II.A.3.c. for more information regarding our proposal.

**TABLE 64: DRUGS AND BIOLOGICALS WITH
PASS-THROUGH PAYMENT STATUS EXPIRING AFTER CY 2025**

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass- Through Payment Effective Date	Pass- Through Payment End Date
C9144	C9144	Injection, bupivacaine (posimir), 1 mg	G	9106	04/01/2023	03/31/2026
C9145	C9145	Injection, aprepitant, (aponvie), 1 mg	G	9107	04/01/2023	03/31/2026
J9063	J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg	G	9109	04/01/2023	03/31/2026
J9347	J9347	Injection, tremelimumab-actl, 1 mg	G	9110	04/01/2023	03/31/2026
J9380	J9380	Injection, teclistamab-cqyv, 0.5 mg	G	9111	04/01/2023	03/31/2026
J9381	J9381	Injection, teplizumab-mzwv, 4 mcg	G	9112	04/01/2023	03/31/2026
J0218	J0218	Injection, olipudase alfa-rpcp, 1 mg	G	9113	04/01/2023	03/31/2026
J1411	J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose	G	9138	04/01/2023	03/31/2026
J1449	J1449	Injection, eflapeggrastim-xnst, 0.1 mg	G	9114	04/01/2023	03/31/2026
J1747	J1747	Injection, spesolimab-sbzo, 1 mg	G	9115	04/01/2023	03/31/2026
J1954	J1954	Injection, leuprolide acetate for depot suspension (lutrate), 7.5 mg	G	9136	04/01/2023	03/31/2026
J2403	J2403	Chloroprocaine hcl ophthalmic, 3% gel, 1 mg	G	9116	04/01/2023	03/31/2026
Q5128	Q5128	Injection, ranibizumab-eqrn	G	9117	04/01/2023	03/31/2026

CY 2024 HCPCS Code	CY 2025 IICPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		(cimerli), biosimilar, 0.1 mg				
Q5130	Q5130	Injection, pegfilgrastim-pbbk (fynetra), biosimilar, 0.5 mg	G	9118	04/01/2023	03/31/2026
J2329	J2329	Injection, ublituximab-xiiy, 1 mg	G	9149	07/01/2023	6/30/2026
J1440	J1440	Fecal microbiota, live - jsln, 1 ml	G	9142	07/01/2023	6/30/2026
Q5129	Q5129	Injection, bevacizumab-aded (vegzelma), biosimilar, 10 mg	G	9159	07/01/2023	6/30/2026
J9056	J9056	Injection, bendamustine hydrochloride (vivimusta), 1 mg	G	9154	07/01/2023	6/30/2026
J0208	J0208	Injection, sodium thiosulfate, 100 mg	G	9119	07/01/2023	6/30/2026
J2781	J2781	Injection, pegcetacoplan, 1 mg	G	9158	07/01/2023	6/30/2026
J1961	J1961	Injection, lenacapavir, 1 mg	G	9155	07/01/2023	6/30/2026
J9350	J9350	Injection, mosunetuzumab-axgb, 1 mg	G	9150	07/01/2023	6/30/2026
J0402	J0402	Injection, aripiprazole, (abilify asimtufii), 1 mg	G	9246	10/01/2023	9/30/2026
J7214	J7214	Injection, factor viii/von willebrand factor complex, recombinant (altuviio), per factor viii i.u.	G	9277	10/01/2023	9/30/2026
J0184	J0184	Injection, amisulpride, 1 mg	G	9247	10/01/2023	9/30/2026
J9058	J9058	Injection, bendamustine	G	9151	10/01/2023	9/30/2026

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		hydrochloride (apotex), 1 mg				
J0577	J0577	Injection, buprenorphine extended-release (brixadi), less than or equal to 7 days of therapy	G	0732	10/01/2023	9/30/2026
J0578	J0578	Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy	G	0733	10/01/2023	9/30/2026
J9321	J9321	Injection, epcoritamab-bysp, 0.1 mg	G	9250	10/01/2023	9/30/2026
A9608	A9608	Flutufolastat F 18, diagnostic, 1 millicurie	G	9254	10/01/2023	9/30/2026
J1304	J1304	Injection, tofersen, 1 mg	G	9262	10/01/2023	9/30/2026
J2799	J2799	Injection, risperidone, (uzedy), 1 mg	G	9266	10/01/2023	9/30/2026
J7353	J7353	Anacaulase-bcdb, 8.8% gcl, 1 gram	G	0742	01/01/2024	12/31/2026
J3401	J3401	Beremagene geperpavec-svdt for topical administration, containing nominal 5×10^9 pfu/mL vector genomes, per 0.1 mL	G	0716	01/01/2024	12/31/2026
J7354	J7354	Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg)	G	0707	01/01/2024	12/31/2026

CY 2024 HCPCS Code	CY 2025 HCPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
A9601	A9601	Flortaucipir f 18 injection, diagnostic, 1 millicurie	G	0709	01/01/2024	12/31/2026
J0177	J0177	Injection, aflibercept hd, 1 mg	G	0704	01/01/2024	12/31/2026
J2782	J2782	Injection, avacincaptad pegol, 0.1 mg	G	0705	01/01/2024	12/31/2026
J9072	J9072	Injection, cyclophosphamide, (dr. reddy's), 5 mg	G	0719	01/01/2024	12/31/2026
J0589	J0589	Injection, daxibotulinumtoxina-lanm, 1 unit	G	0703	01/01/2024	12/31/2026
J1413	J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose	G	0714	01/01/2024	12/31/2026
J1323	J1323	Injection, elranatamab-bcmm, 1 mg	G	0708	01/01/2024	12/31/2026
J9286	J9286	Injection, glofitamab-gxbm, 2.5 mg	G	0720	01/01/2024	12/31/2026
J0174	J0174	Injection, lecanemab-irmb, 1 mg	G	9157	01/01/2024	12/31/2026
J2508	J2508	Injection, pegunigalsidase alfa-iwxj, 1 mg	G	0715	01/01/2024	12/31/2026
J7165	J7165	Injection, prothrombin complex concentrate, human-lans, per i.u. of factor ix activity	G	0702	01/01/2024	12/31/2026
J0349	J0349	Injection, rezafungin, 1 mg	G	9267	01/01/2024	12/31/2026
J9333	J9333	Injection, rozanolixizumab-noli, 1 mg	G	0721	01/01/2024	12/31/2026

CY 2024 HCPCS Code	CY 2025 IICPCS Code	Long Descriptor	CY 2024 Status Indicator	CY 2024 APC	Pass- Through Payment Effective Date	Pass- Through Payment End Date
J3055	J3055	Injection, talquetamab-tgvs, 0.25 mg	G	0706	01/01/2024	12/31/2026
J1412	J1412	Injection, valoctocogene roxaparvovec-rvox, per mL, containing nominal 2×10^{13} vector genomes	G	0713	01/01/2024	12/31/2026
J0217	J0217	Injection, velmanase alfa-tycv, 1 mg	G	0710	01/01/2024	12/31/2026
J9029	J9029	Intravesical instillation, nadofaragene firadenovec-vncg, per therapeutic dose	G	0717	01/01/2024	12/31/2026
C9167	C9167	Injection, adamts13, recombinant-krhn, 10 iu	G	0727	04/01/2024	03/31/2027
J9248	J9248	Injection, melphalan (hepzato), 1 mg	G	0730	04/01/2024	03/31/2027
C9168	C9168	Injection, mirikizumab-mrkz, 1 mg	G	0728	04/01/2024	03/31/2027
J2277	J2277	Injection, motixafortide, 0.25 mg	G	0729	04/01/2024	03/31/2027
C9166	C9166	Injection, secukinumab, intravenous, 1 mg	G	0725	04/01/2024	03/31/2027

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B. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Proposed Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to \$50 per administration during CYs 2005 and 2006. In CY 2007, we used the four-quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the \$50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest \$5 increment in order to determine the CY 2007 threshold amount of \$55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at \$135 for CY 2024 (88 FR 81776 through 81777).

Following the CY 2007 methodology, for this proposed rule, we use the most recently available four quarter moving average PPI levels to trend the \$50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2025 and round the resulting dollar amount (\$140.81) to the nearest \$5 increment, which yielded a figure of \$140. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IGI. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the various price indexes including the PPI Pharmaceuticals for Human Use (Prescription). Based on these calculations using the CY 2007 OPPS methodology, we propose a packaging threshold for CY 2025 of \$140 for drugs, biologicals, and therapeutic radiopharmaceuticals.

We propose in section II.A.3.c of this proposed rule to pay separately for diagnostic radiopharmaceuticals with a per-day cost above the proposed packaging threshold for CY 2025 of \$630. We also propose that starting in CY 2026 and subsequent years, we

would update this threshold by the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IHS Global, Inc (IGI). For the diagnostic radiopharmaceutical packaging threshold, we propose to use the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 and 68086)) to calculate the update to the OPPS drug packaging threshold. Specifically, we propose that starting for the CY 2026 rulemaking, we would use the most recently available four quarter moving average PPI levels to trend the final CY 2025 threshold forward from the third quarter of CY 2024 to the third quarter of CY 2025 and round the resulting dollar amount to the nearest \$5 increment. We refer readers to section II.A.3.c.(4) of this proposed rule for information regarding our proposal to update the proposed diagnostic radiopharmaceutical packaging threshold in future years.

We also propose that if more recent data are subsequently available (for example, a more recent estimate of the PPI for Pharmaceutical Preparations (Prescription), we would use such data, if appropriate, to determine the CY 2025 packaging threshold for drugs, biologicals, therapeutic radiopharmaceuticals, and diagnostic radiopharmaceuticals for the CY 2025 OPPS/ASC final rule with comment period.

b. Proposed Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Certain Radiopharmaceuticals Under the Cost Thresholds

To determine the proposed CY 2025 packaging status for all nonpass-through drugs, biologicals, diagnostic and therapeutic radiopharmaceuticals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals that had a HCPCS code in CY 2023 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2023 claims processed through December 31, 2023, for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d of this proposed rule, or for the following policy-packaged items that we propose to continue to package in CY 2025: anesthesia drugs; drugs, biologicals, and contrast agents and other drugs that function as supplies when used in a

diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure. Consistent with our policy described in section V.B.5., in situations where we have no claims data and must determine if these products exceed the per-day cost threshold, we estimated the average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting and utilized the ASP methodology to determine whether their payment will be packaged as well as their payment status indicators.

In order to calculate the per day costs for drugs, biologicals, diagnostic radiopharmaceuticals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2025, we used the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate based on the ASP methodology, which is generally ASP plus 6 percent (which is the payment rate we propose for separately payable drugs and biologicals for CY 2025, as discussed in more detail in section V.A.1 of this proposed rule) to calculate the CY 2025 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2023 (data that were used for payment purposes in the physician's office setting, effective April 1, 2024) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2025, we propose to use payment rates based on the ASP data from the fourth quarter of CY 2023 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to this proposed rule (which are available via the internet on the CMS website) because these are the most recent data available for use at the time of development of the CY 2025 OPPS proposed rule. These data also are the basis for drug payments in the physician's office setting, effective April 1, 2024. Exceptions to our standard methodology include:

- For therapeutic radiopharmaceuticals that do not have pass-through status as of October 1, 2024, and do not have an ASP-based payment rate, we did not use a payment rate based on WAC or AWP for those items, consistent with our policy described in section V.B.3.a of this proposed rule. We used their mean unit cost derived from the CY 2023 hospital

claims data to determine their per day cost.

- For diagnostic radiopharmaceuticals that do not have pass-through status as of October 1, 2024, we used their mean unit cost derived from the CY 2023 hospital claims data to determine their per day cost. We did not use an ASP-based, WAC-based, or AWP-based payment rate for those items unless there was no mean unit cost reported for the product, consistent with our proposed policy described in section V.B.3.b of this proposed rule.

- For items other than diagnostic or therapeutic radiopharmaceuticals that did not have either an ASP-based payment rate, a payment rate based on WAC, or a payment rate based on AWP, we used mean unit cost of the items derived from the CY 2023 hospital claims data to determine their per day cost.

We propose to package drugs, biologicals, and therapeutic radiopharmaceuticals with a per day cost less than or equal to \$140 and identify items with a per day cost greater than \$140 as separately payable unless they are policy-packaged. For diagnostic radiopharmaceuticals, we propose to package those items with a per day cost less than or equal to \$630 and identify items with a per day cost greater than \$630 as separately payable. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2023 HCPCS codes that were reported to the CY 2023 HCPCS codes that we display in Addendum B to this proposed rule (which is available on the CMS website)⁷¹ for proposed payment in CY 2025.

Our policy during previous cycles of OPPS rulemaking has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs, biologicals, and radiopharmaceuticals in this proposed rule, we propose to use ASP data from the fourth quarter of CY 2023, which is

the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective April 1, 2024, along with updated hospital claims data from CY 2023. We note that we also propose to use these data for budget neutrality estimates and impact analyses for this proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B of this proposed rule are based on ASP data from the second quarter of CY 2024. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2024. These payment rates would then be updated in the January 2025 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2025. For drugs and biologicals that do not currently have a payment rate based on ASP, WAC, or AWP, for therapeutic radiopharmaceuticals that do not currently have an ASP payment rate, and for all diagnostic radiopharmaceuticals, we calculate their mean unit cost from all of the CY 2023 claims data and updated cost report information available for this proposed rule to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and radiopharmaceuticals in the OPPS/ASC proposed rule may be different from the same drugs' HCPCS codes' packaging status determined based on the data used for this final rule with comment period. Under such circumstances, we propose to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose costs fluctuate relative to the proposed CY 2025 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2024. These established policies have not changed for many years and are the same as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434). Specifically, for CY 2025 and subsequent years, consistent with our historical practice, we propose to apply the following policies to those HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were

paid separately in CY 2024 and that are proposed for separate payment in CY 2025, and that then have per day costs equal to or less than the CY 2025 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2025 final rule, would continue to receive separate payment in CY 2025.

- HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were packaged in CY 2024 and that are proposed for separate payment in CY 2025, and that then have per day costs equal to or less than the CY 2025 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2025 final rule, would remain packaged in CY 2025.

- HCPCS codes for drugs, biologicals, and radiopharmaceuticals for which we proposed packaged payment in CY 2025 but that then have per-day costs greater than the CY 2025 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2025 final rule, would receive separate payment in CY 2025.

c. Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, under the OPPS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in 42 CFR 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals as "policy-packaged" drugs, biologicals, and radiopharmaceuticals. These policies are either longstanding or based on longstanding principles and inherent to the OPPS and are as follows:

- Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations (§ 419.2(b)(4));

- Intraoperative items and services (§ 419.2(b)(14));

- Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including but not limited to, diagnostic radiopharmaceuticals,⁷²

⁷¹ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

⁷² We propose to pay separately for diagnostic radiopharmaceuticals with per-day costs above a

contrast agents, and pharmacologic stress agents) (§ 419.2(b)(15)); and

- Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals) (§ 419.2(b)(16)).

The policy at § 419.2(b)(16) is broader than the policy at § 419.2(b)(14). As we stated in the CY 2015 OPPS/ASC final rule with comment period: “We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy” (79 FR 66875). The category described by § 419.2(b)(15) is large and includes diagnostic radiopharmaceuticals that have a per day cost below the proposed diagnostic radiopharmaceutical packaging threshold that we discussed in section II.A.3 of this proposed rule,⁷³ contrast agents, stress agents, and some other products. The category described by § 419.2(b)(16) includes skin substitutes and some other products. We believe it is important to reiterate that cost consideration is not a factor when

proposed threshold. If our proposal is finalized, this category of policy-packaged drugs that function as supplies in a diagnostic test or procedure would include diagnostic radiopharmaceuticals with per-day costs below the threshold for the applicable year. Please refer to Section II.A.3.c. for more information regarding our proposal.

⁷³ In section II.A.3 of this proposed rule, we propose to pay separately for diagnostic radiopharmaceuticals with per-day costs above a proposed threshold. If our proposal is finalized, this category of policy-packaged drugs that function as supplies in a diagnostic test or procedure would include diagnostic radiopharmaceuticals with per-day costs below the threshold for the applicable year. Please refer to Section II.A.3.c. for more information regarding our proposal.

determining whether an item is a surgical supply (79 FR 66875).

We welcome ongoing dialogue and engagement from interested parties regarding suggestions for payment changes for consideration in future rulemaking.

d. Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we propose to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2025.

In order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2023 claims data and our pricing information, which is based on the ASP methodology, generally ASP plus 6 percent, across all of the HCPCS codes that describe each

distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for this proposed rule; and, as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the CY 2023 claims data to make the proposed packaging determinations for them: HCPCS code C9257 (Injection, bevacizumab, 0.25 mg); HCPCS code J3471 (injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)); HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units); HCPCS code J7100 (Infusion, dextran 40,500 ml); and HCPCS code J7110 (Infusion, dextran 75,500 ml).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the proposed weighted average ASP methodology based payment rate, which is generally ASP plus 6 percent, per-unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine if the estimated per day cost of each drug or biological is less than or equal to the proposed CY 2025 drug packaging threshold of \$140 (in which case all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2025 drug packaging threshold of \$140 (in which case all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2025 is displayed in Table 65.

TABLE 65: HCPCS CODES TO WHICH THE CY 2025 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2025 HCPCS Code	CY 2025 Long Descriptor	CY 2025 Status Indicator (SI)
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7100	Infusion, dextran 40, 500 ml	N
J7110	Infusion, dextran 75, 500 ml	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N

We propose that our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2025 would also apply to diagnostic radiopharmaceuticals. In order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same diagnostic radiopharmaceutical, we would aggregate our CY 2023 claims data across all of the HCPCS codes that describe each distinct diagnostic radiopharmaceutical in order to determine the mean units per day of the diagnostic radiopharmaceutical in terms of the HCPCS code with the lowest dosage descriptor. We would then analyze the aggregate per day cost of the diagnostic radiopharmaceutical to determine if the per day cost is less than or equal to the proposed CY 2025 diagnostic radiopharmaceutical packaging threshold of \$630 (in which

case all HCPCS codes for the same diagnostic radiopharmaceutical would be packaged) or greater than the proposed CY 2025 diagnostic radiopharmaceutical packaging threshold of \$630 (in which case all HCPCS codes for the same diagnostic radiopharmaceutical would be separately payable). There are currently no diagnostic radiopharmaceuticals that this policy would apply to.

2. Proposed Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Proposed Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a “specified covered outpatient drug” (known as a

SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY

2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and considering the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). We refer to this alternative methodology as the “statutory default.” Most physician Part B drugs are paid at ASP plus 6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to consider overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to consider the findings of the MedPAC study.⁷⁴

It has been our policy since CY 2006 to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. For CY 2023 and subsequent years, we finalized a policy to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section

1833(t)(14)(A)(iii)(II) of the Act to SCODs; but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP plus 6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We have continued this policy of paying for separately payable drugs and biologicals at the statutory default for CYs 2014 through 2024.

In the case of a drug or biological during an initial sales period in which data on the prices for sales of the drug or biological are not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC. Under section 1833(t)(14)(A)(iii)(II) of the Act, the amount of payment for a separately payable drug equals the average price for the drug for the year established under, among other authorities, section 1847A of the Act. As explained in greater detail in the CY 2019 PFS final rule, under section 1847A(c)(4) of the Act, although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that payments using ASP or WAC must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular add-on amount be applied to WAC-based pricing for this initial period when ASP data are not available. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS final rule (83 FR 59661 to 59666), we finalized a policy that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3-percent add-on in place of the 6 percent add-on that was being used according to our policy in effect as of CY 2018. For the CY 2019 OPPS, we followed the same policy finalized in the CY 2019 PFS final rule (83 FR 59661 to 59666). Since CY 2020, we have continued to utilize a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC pursuant to our authority under section 1833(t)(14)(A)(iii)(II) of the Act (84 FR 61318 and 85 FR 86039), which provides, in part, that the amount of payment for a SCOD is the average price

of the drug in the year established under section 1847A of the Act. We also apply this provision to non-SCOD separately payable drugs. Because we establish the average price for a drug paid based on WAC under section 1847A of the Act as WAC plus 3 percent instead of WAC plus 6 percent, we believe it is appropriate to price separately payable drugs paid based on WAC at the same amount under the OPPS. Our policy to pay for drugs and biologicals at WAC plus 3 percent, rather than WAC plus 6 percent, applies whenever WAC-based pricing is used for a drug or biological under section 1847A(c)(4). We refer readers to the CY 2019 PFS final rule (83 FR 59661 to 59666) for additional background on this policy.

Consistent with our current policy, payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. Also, the budget neutral weight scalar is not applied in determining payments for these separately payable drugs and biologicals.

Separately payable drug, biological, and radiopharmaceutical payment rates are listed in Addenda A and B to this proposed rule (available on the CMS website).⁷⁵ These addenda provide the proposed CY 2025 payment rates based on the ASP methodology for separately payable nonpass-through drugs, biologicals, and radiopharmaceuticals and the ASP methodology for pass-through drugs, biologicals, and radiopharmaceuticals. Except for proposed payment rates for radiopharmaceuticals, these rates are based either on ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician’s office setting effective April 1, 2024, or WAC, AWP, or mean unit cost from CY 2023 claims data and updated cost report information available for this proposed rule. For nonpass-through therapeutic radiopharmaceuticals, payment rates are based on ASP data or mean unit cost. We propose in section II.A.3.c.(5) to pay separately at mean unit cost for diagnostic radiopharmaceuticals with per day costs above the proposed threshold; the payment rates proposed for qualifying diagnostic radiopharmaceuticals are entirely mean unit cost. In general, these published proposed payment rates are not the same as the actual January 2025 payment rates. This is because payment rates for drugs, biologicals, and

⁷⁴ Medicare Payment Advisory Committee, June 2005 Report to the Congress. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. Available at: https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/June05_ch6.pdf.

⁷⁵ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

therapeutic radiopharmaceuticals with ASP information for January 2025 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2024 (July 1, 2024, through September 30, 2024) will be used to set the payment rates that are released for the quarter beginning in January 2025 in December 2024. In addition, in Addenda A and B to this proposed rule, payment rates for drugs, biologicals, and therapeutic radiopharmaceuticals for which there was no ASP, WAC, or AWP information available for April 2024, as well as all separately payable diagnostic radiopharmaceuticals, are based on mean unit cost in the available CY 2023 claims data. If new pricing information becomes available for payment for the quarter beginning in January 2025, we will price payment for these drugs, biologicals, therapeutic radiopharmaceuticals, and diagnostic radiopharmaceuticals based on their newly available information. Finally, there may be drugs, biologicals and therapeutic radiopharmaceuticals that have ASP, WAC, or AWP information available for this proposed rule (reflecting April 2024 ASP data) that do not have ASP, WAC, or AWP information available for the quarter beginning in January 2025. These drugs, biologicals and therapeutic radiopharmaceuticals would then be paid based on mean unit cost data derived from CY 2023 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to this proposed rule are not for January 2025 payment purposes and are only illustrative of the CY 2025 OPPS payment methodology using the most recently available information at the time of issuance of this proposed rule.

We note that payment amounts for most drugs separately payable under

Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the average sales price (ASP) plus a statutorily mandated 6 percent add-on.

For CY 2025, we propose to clarify that only ASP data or, if ASP data are not available, mean unit cost data, would be used to set payment rates for separately payable nonpass-through therapeutic radiopharmaceuticals under the OPPS as described further in section V.B.3.a of this proposed rule. We propose for CY 2025 to use mean unit cost data to set payment rates for separately payable nonpass-through diagnostic radiopharmaceuticals for which we propose separate payment because their cost exceeds the per-day threshold. Otherwise, we are not proposing any changes to our policies for payment for separately payable drugs and biologicals; and we propose to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default).

b. Biosimilar Biological Products

For CY 2024, we finalized the exception of biosimilars from the OPPS threshold packaging policy when their reference products are separately paid (88 FR 81783 through 81785). This policy allows for separate payment for biosimilars even if the biosimilar's per-day cost is below the packaging threshold if the biosimilar's reference product is separately paid. This policy removes the financial incentive to use a more expensive separately payable biological and promotes biosimilar use as a lower cost alternative to higher cost reference products.

Payment rates for drugs and biologicals (including biosimilars) under Medicare Part B are determined

using the methodology in section 1847A of the Act, and in many cases, payment is based on the average sales price (ASP) plus a statutorily mandated 6 percent add-on. Additionally, Section 11403 of the IRA requires that a qualifying biosimilar be paid at ASP plus 8 percent of the reference product's ASP rather than 6 percent during the applicable 5-year period. Section 1847A(b)(8)(B)(ii) of the Act defines the applicable 5-year period for a qualifying biosimilar for which payment has been made using ASP (that is, payment under section 1847A(b)(8) of the Act) as of September 30, 2022 as the 5-year period beginning on October 1, 2022. For a qualifying biosimilar for which payment is first made using ASP during the period beginning October 1, 2022, and ending December 31, 2027, the statute defines the applicable 5-year period as the 5-year period beginning on the first day of such calendar quarter of such payment (88 FR 81783). These payment rates are published in the quarterly release of Addendum B or ASP pricing files.

d. Invoice Drug Pricing Proposal for CY 2026

We have observed that in recent years there has been an increasing number of drug and biological HCPCS codes for which ASP, WAC, AWP, and mean unit cost information is not available. These are often HCPCS codes for new drugs or biologicals that have been approved for marketing, but for which the manufacturer does not have sales data, and WAC, AWP, and mean unit cost information is not available. As a result, we are unable to assign a payable status indicator to these drugs or biologicals due to of a lack of payment data. The numbers of drug and biological HCPCS codes without payment rates from Addendum B for the CY 2022 through CY 2024 OPPS/ASC final rules with comment period are listed in Table 66.

TABLE 66: NUMBER OF DRUG AND BIOLOGICAL HCPCS CODES WITHOUT PAYMENT INFORMATION FOR CY 2022 TO CY 2024

	CY 2022 Final Rule	CY 2023 Final Rule	CY 2024 Final Rule
Number of drug and biological HCPCS codes without payment information	77	85	109

In order to provide appropriate payment rates for these drugs and biologicals without pricing data, we propose to adopt an invoice pricing policy beginning in CY 2026. Because this policy necessitates significant operational changes to implement, we propose to implement it beginning in CY 2026, rather than CY 2025. For CY 2025, the affected drugs and biologicals would continue to be assigned a non-payable status indicator until we implement our invoice pricing policy, if adopted. We believe invoice pricing is appropriate for use under the OPPS because it provides temporary drug or biological cost information to generate a representative payment rate for a drug or biological and supports the utilization of new drug or biological HCPCS codes. Otherwise, the new drug and biological HCPCS codes would not receive payment under the OPPS, which would discourage their use by providers. Currently, the Physician Fee Schedule utilizes invoice pricing for drugs and biologicals when other types of pricing information are not available.

We propose that, for separately payable drugs or biologicals for which CMS does not provide a payment rate in Addendum B, which would indicate to MACs that CMS does not have pricing information (specifically, that ASP, WAC, AWP, and mean unit cost information is not available to determine a payment rate), MACs would calculate the payment based on provider invoices. The drug or biological invoice cost would be the net acquisition cost minus any rebates, chargebacks, or post-sale concessions. Before calculating an invoice-based payment amount, MACs would use the provider invoice to determine that: (a) the drug is not policy packaged; and (b) the per-day cost of the drug, biological, therapeutic radiopharmaceutical or diagnostic radiopharmaceutical is above the threshold packaging amount, as applicable. If both conditions are met, we propose that MACs would use the provider invoice amount to set a payment rate for the separately payable drug, biological, or radiopharmaceutical until its payment amount becomes available to CMS. We generally would expect invoice pricing to be temporary, lasting two to three quarters, for qualified drugs required to report ASP under 1847A of the Act. For drug products that are not required to report ASP under 1847A of the Act (*i.e.*, diagnostic pharmaceuticals), invoice pricing may be used longer term until a MUC can be calculated. We propose that we would not begin using invoice pricing for drugs, biologicals, and

radiopharmaceuticals without pricing information until CY 2026 because we would need to make technical updates to outpatient hospital claims to allow the hospitals to report drug invoice pricing. We intend to work with the National Uniform Billing Committee (NUBC) in order to create a value code that would allow for the reporting of invoice prices of drugs, biologicals, and radiopharmaceuticals for purposes of this policy.

3. Payment Policy for Radiopharmaceuticals

For a complete history of the OPPS payment policy for radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524).

a. Payment Policy for Therapeutic Radiopharmaceuticals

In the CY 2023 OPPS/ASC final rule with comment period, we adopted as final our proposal to continue our longstanding payment policy for therapeutic radiopharmaceuticals for CY 2023 and subsequent years. Accordingly, this payment policy for therapeutic radiopharmaceuticals will continue to apply in CY 2025.

Specifically, our policy of paying for separately payable pass-through therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals described in section V.A.1 of this proposed rule will continue to apply for CY 2025. We will pay for separately payable nonpass-through therapeutic radiopharmaceuticals through a modified ASP methodology where we pay at ASP plus 6 percent if ASP data are available. However, if ASP information is unavailable for a separately payable nonpass-through therapeutic radiopharmaceutical, we will continue to base the payment rate on mean unit cost data derived from hospital claims. Our policy not to use WAC or AWP to establish payment for separately payable nonpass-through therapeutic radiopharmaceuticals if ASP is not available will continue for CY 2025. We explained our rationale in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) when we first adopted our policy to apply the principles of separately payable drug pricing to therapeutic radiopharmaceuticals.

We note that in the CY 2024 OPPS final rule with comment period (88 FR 81786), we stated that the ASP payment

methodology for separately payable nonpass-through therapeutic radiopharmaceuticals did allow for using WAC or AWP to establish a payment rate for these items. This was an error and conflicted with the policy implemented in CY 2010 and continued in subsequent years. The statement also conflicted with the policy that we proposed and finalized for CY 2023 and subsequent years in the CY 2023 OPPS/ASC final rule with comment period (87 FR 71969). The policy implemented in CY 2010 regarding ASP payment for separately payable nonpass-through therapeutic radiopharmaceuticals remains our intended policy. Therefore, we will pay for all nonpass-through separately payable therapeutic radiopharmaceuticals at ASP plus 6 percent based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We will rely on CY 2023 mean unit cost data derived from hospital claims data for payment rates for separately payable nonpass-through therapeutic radiopharmaceuticals for which ASP data are unavailable and update the payment rates for these products according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information becomes available.

The proposed CY 2025 payment rates for separately payable nonpass-through therapeutic radiopharmaceuticals are included in Addenda A and B of this proposed rule (which are available on the CMS website).⁷⁶

b. Payment Policy for Diagnostic Radiopharmaceuticals

For CY 2025, we propose, as described in section II.A.3 of this proposed rule, to pay separately for diagnostic radiopharmaceuticals with a per day cost above our proposed diagnostic radiopharmaceutical packaging threshold (proposed at \$630 for CY 2025). We propose to pay for pass-through diagnostic radiopharmaceuticals based on ASP WAC, and AWP.

We propose to base the payment rate for separately payable nonpass-through diagnostic radiopharmaceuticals on mean unit cost data derived from hospital claims. As discussed in Section II.A.3.c.(5), we are not proposing to use

⁷⁶ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

ASP data when mean unit cost data are available for a separately payable nonpass-through diagnostic radiopharmaceutical, but we are seeking comment on using ASP for setting the payment rate for nonpass-through diagnostic radiopharmaceuticals in the future. Additionally, we are not proposing to use WAC or AWP as a basis for payment for nonpass-through diagnostic radiopharmaceuticals when mean unit cost data derived from hospital claims is available. We believe that paying for nonpass-through diagnostic radiopharmaceuticals using mean unit cost would appropriately pay for the average price of a nonpass-through separately payable diagnostic radiopharmaceutical. In our view, MUC is an appropriate proxy for the average price for a diagnostic radiopharmaceutical for a given year, as it is calculated based on the average costs for a particular year and is directly reflective of the actual cost data that hospitals submit to CMS. As we stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60523), we believe that WAC or AWP is not an appropriate proxy to provide OPPS payment for radiopharmaceuticals because these pricing methodologies do not include discounts. Specifically, the absence of appropriate ASP reporting could result in payment for a separately payable diagnostic radiopharmaceutical based on WAC or AWP indefinitely, a result which we believe would be inappropriate, as these pricing metrics do not capture all of the pricing discounts that may be reflected in the ASP.

Additionally, we propose to base the initial payment for new diagnostic radiopharmaceuticals with HCPCS codes that do not have pass-through status or claims data on ASP, and on the WAC for these products if ASP data for these diagnostic radiopharmaceuticals are not available. If the WAC also is unavailable, we propose to make payment for new diagnostic radiopharmaceuticals at 95 percent of the products' most recent AWP. We believe the volume of products in this category will typically be very low; however, in these rare situations, we believe it would be appropriate to use ASP until a MUC is established for new diagnostic radiopharmaceuticals with HCPCS codes that do not have passthrough status or claims data.

The proposed CY 2025 payment rates for separately payable nonpass-through diagnostic radiopharmaceuticals are included in Addenda A and B of this

proposed rule (which are available on the CMS website).⁷⁷

4. Proposed Payment for Blood Clotting Factors

For CY 2025, we propose to continue our established policy to provide payment for blood clotting factors using the same methodology as other separately payable drugs and biologicals under the OPPS and to continue to pay a furnishing fee. For a full discussion of our established payment policy for blood clotting factors, please refer to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71969 through 71970). In accordance with our policy as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS website at <https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price>.

5. Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes But Without OPPS Hospital Claims Data

In the CY 2023 OPPS/ASC final rule with comment period, we adopted as final our proposal to continue our longstanding payment policy for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data for CY 2023 and subsequent years. Therefore, for CY 2025, this policy will continue to apply. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70442 through 70443). Consistent with our policy, because we have no claims data and must determine if these products exceed the per-day cost threshold, we estimated the average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting and utilized the ASP methodology to determine whether their payment will be packaged as well as their payment status indicators.

⁷⁷ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

6. Requirement in the CY 2025 Physician Fee Schedule Proposed Rule for HOPDs and ASCs To Report Discarded Amounts of Certain Single-Dose or Single-Use Package Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) (“the Infrastructure Act”) amended section 1847A of the Act to re-designate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The CY 2025 PFS proposed rule includes proposals related to the discarded drug refund policy, including proposals that may impact hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs). Similar to our CY 2023 and CY 2024 notice in the OPPS/ASC proposed rule (87 FR 71988), we wanted to ensure interested parties were aware of these proposals and knew to refer to the CY 2025 PFS proposed rule for a full description of the proposed policy. Interested parties are asked to submit comments on any proposals to implement Section 90004 of the Infrastructure Act to the CY 2025 PFS proposed rule. Public comments on these proposals will be addressed in the CY 2025 PFS final rule with comment period.

7. High-Cost/Low-Cost Threshold for Packaged Skin Substitutes

a. Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to package skin substitutes, we also finalized a methodology that divides the skin substitutes into a high-cost group and a low-cost group, to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933). In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66886), we stated that skin substitutes are best characterized as either surgical supplies or devices because of their required surgical application and because they share significant clinical similarity with other surgical devices and supplies.

Skin substitutes assigned to the high-cost group are described by HCPCS codes 15271 through 15278. Skin

substitutes assigned to the low-cost group are described by HCPCS codes C5271 through C5278. Geometric mean costs for the various procedures are calculated using only claims for the skin substitutes that are assigned to each group. Specifically, claims billed with HCPCS codes 15271, 15273, 15275, or 15277 are used to calculate the geometric mean costs for procedures assigned to the high-cost group, and claims billed with HCPCS codes C5271, C5273, C5275, or C5277 are used to calculate the geometric mean costs for procedures assigned to the low-cost group (78 FR 74935).

Each of the HCPCS codes described earlier are assigned to one of the following three skin procedure APCs according to the geometric mean cost for the code: APC 5053 (Level 3 Skin Procedures): HCPCS codes C5271, C5275, and C5277; APC 5054 (Level 4 Skin Procedures): HCPCS codes C5273, 15271, 15275, and 15277; or APC 5055 (Level 5 Skin Procedures): HCPCS code 15273. In CY 2024, the payment rate for APC 5053 (Level 3 Skin Procedures) was \$599.02, the payment rate for APC 5054 (Level 4 Skin Procedures) was \$1,739.33, and the payment rate for APC 5055 (Level 5 Skin Procedures) was \$3,421.82. This information is also available in Addenda A and B of the CY 2024 final rule with comment period (88 FR 81540) (the Addenda A and B are available on the CMS website <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>).

We have continued the high-cost/low-cost categories policy since CY 2014. Under the current policy, skin substitutes in the high-cost category are reported with the skin substitute application CPT codes, and skin substitutes in the low-cost category are reported with the analogous skin substitute HCPCS C-codes. For a discussion of the CY 2014 and CY 2015 methodologies for assigning skin substitutes to either the high-cost group or the low-cost group, we refer readers to the CY 2014 OPPTS/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66882 through 66885).

For a discussion of the high-cost/low-cost methodology that was adopted in CY 2016 and has been in effect since then, we refer readers to the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70434 through 70435). Beginning in CY 2016, we adopted a policy where we determined the high-cost/low-cost status for each skin substitute product based on either a product's geometric mean unit cost

(MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. We assigned each skin substitute that exceeded either the MUC threshold or the PDC threshold to the high-cost group. In addition, we assigned any skin substitute with a MUC or a PDC that did not exceed either the MUC threshold or the PDC threshold to the low-cost group (87 FR 71976).

However, some skin substitute manufacturers have raised concerns about significant fluctuation in both the MUC threshold and the PDC threshold from year to year using the methodology developed in CY 2016. The fluctuation in the thresholds may result in the reassignment of several skin substitutes from the high-cost group to the low-cost group, which, under current payment rates, can be a difference of over \$1,000 in the payment amount for the same procedure. In addition, these interested parties were concerned that the inclusion of cost data from skin substitutes with pass-through payment status in the MUC and PDC calculations would artificially inflate the thresholds. Skin substitute interested parties requested that CMS consider alternatives to the current methodology used to calculate the MUC and PDC thresholds and whether it might be appropriate to establish a new cost group in between the low-cost group and the high-cost group to allow for assignment of moderately priced skin substitutes to a newly created middle group.

We share the goal of promoting payment stability for skin substitute products and their related procedures as price stability allows hospitals using such products to more easily anticipate future payments associated with these products. We have attempted to limit year-to-year shifts for skin substitute products between the high-cost and low-cost groups through multiple initiatives implemented since CY 2014, including: establishing separate skin substitute application procedure codes for low-cost skin substitutes (78 FR 74935); using a skin substitute's MUC calculated from outpatient hospital claims data instead of an average of ASP plus 6 percent as the primary methodology to assign products to the high-cost or low-cost group (79 FR 66883); and establishing the PDC threshold as an alternate methodology to assign a skin substitute to the high-cost group (80 FR 70434 through 70435).

To allow additional time to evaluate concerns and suggestions from

interested parties about the volatility of the MUC and PDC thresholds, in the CY 2018 OPPTS/ASC proposed rule (82 FR 33627), we proposed that a skin substitute that was assigned to the high-cost group for CY 2017 would be assigned to the high-cost group for CY 2018, even if it did not exceed the CY 2018 MUC or PDC thresholds. We finalized this policy in the CY 2018 OPPTS/ASC final rule with comment period (82 FR 59347). For more detailed information and discussion regarding the goals of this policy and the subsequent comment solicitations in CY 2019 and CY 2020 regarding possible alternative payment methodologies for graft skin substitute products, please refer to the CY 2018 OPPTS/ASC final rule with comment period (82 FR 59347); the CY 2019 OPPTS/ASC final rule with comment period (83 FR 58967 to 58968); and the CY 2020 OPPTS/ASC final rule with comment period (84 FR 61328 to 61331).

b. Proposals for Packaged Skin Substitutes for CY 2025

For CY 2025, consistent with our policy since CY 2016, we propose to continue to determine the high-cost/low-cost status for each skin substitute product based on either a product's geometric MUC exceeding the geometric MUC threshold or the product's PDC (the total units of a skin substitute multiplied by the MUC and divided by the total number of days) exceeding the PDC threshold. Consistent with the methodology as established in the CY 2014 OPPTS/ASC through CY 2018 OPPTS/ASC final rules with comment period, we analyzed CY 2023 claims data to calculate the MUC threshold (a weighted average of all skin substitutes' MUCs) and the PDC threshold (a weighted average of all skin substitutes' PDCs). The proposed CY 2025 MUC threshold is \$50 per cm² (rounded to the nearest \$1) and the proposed CY 2025 PDC threshold is \$840 (rounded to the nearest \$1). Also, the availability of a HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

For CY 2025, as we did for CY 2024, we propose to assign each skin substitute that exceeds either the MUC

threshold or the PDC threshold to the high-cost group. In addition, we propose to assign any skin substitute that does not exceed either the MUC threshold or the PDC threshold to the low-cost group except that we propose that any skin substitute product that is assigned to the high-cost group in CY 2024 would be assigned to the high-cost group for CY 2025, regardless of whether it exceeds or falls below the CY 2025 MUC or PDC threshold. This policy was established in the CY 2018 OPPI/ASC final rule with comment period (82 FR 59346 through 59348).

For CY 2025, we propose to continue to assign skin substitutes with pass-through payment status to the high-cost category. We propose to assign skin substitutes with pricing information but without claims data to calculate a geometric MUC or PDC to either the

high-cost or low-cost category based on the product's ASP plus 6 percent payment rate as compared to the MUC threshold. If ASP is not available, we propose to use WAC plus 3 percent to assign a product to either the high-cost or low-cost category. Finally, if neither ASP nor WAC is available, we propose to use 95 percent of AWP to assign a skin substitute to either the high-cost or low-cost category. We propose to continue to use WAC plus 3 percent instead of WAC plus 6 percent to conform to our proposed policy described in section V.B.2.b of this proposed rule to establish a payment rate of WAC plus 3 percent for separately payable drugs and biologicals that do not have ASP data available. We propose that any skin substitute product that is assigned a code in the HCPCS A2XXX series would be assigned to the

high-cost skin substitute group including new products without pricing information. New skin substitutes without pricing information that are not assigned a code in the HCPCS A2XXX series would be assigned to the low-cost category until pricing information is available to compare to the CY 2024 MUC and PDC thresholds. For a discussion of our policy under which we assign skin substitutes without pricing information that are not assigned a code in the HCPCS A2XXX series to the low-cost category until pricing information is available, we refer readers to the CY 2016 OPPI/ASC final rule with comment period (80 FR 70436).

Table 67 includes the proposed CY 2025 cost category assignment for each skin substitute product.

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TABLE 67: SKIN SUBSTITUTE ASSIGNMENTS TO HIGH-COST AND LOW-COST GROUPS FOR CY 2025

CY 2025 HCPCS Code	CY 2025 Short Descriptor	CY 2024 High/Low Cost Assignment	CY 2025 High/Low Cost Assignment
A2001	Innovamatrix ac, per sq cm	High	High
A2002	Mirragen adv wnd mat per sq	High	High
A2005	Microlyte matrix, per sq cm	High	High
A2006	Novosorb synpath per sq cm	High	High
A2007	Restrata, per sq cm	High	High
A2008	Theragenesis, per sq cm	High	High
A2009	Symphony, per sq cm	High	High
A2010	Apis, per square centimeter	High	High
A2011	Supra sdrm, per sq cm	High	High
A2012	Suprathel, per sq cm	High	High
A2013	Innovamatrix fs, per sq cm	High	High
A2015	Phoenix wnd mtrx, per sq cm	High	High
A2016	Permeaderm b, per sq cm	High	High
A2017	Permeaderm glove, each	High	High
A2018	Permeaderm c, per sq cm	High	High
A2019	kerecis marigen shld sq cm	High	High
A2020	ac5 wound system	High	High
A2021	neomatrix per sq cm	High	High
A2022	Innovabrn/innovamatx xl sqcm	High	High
A2024	Resolve matrix per sq cm	High	High
A2025	Miro3d per cubic cm	High	High
A4100	Skin sub fda clrd as dev nos	Low	Low
C9363	Integra meshed bil wound mat	High	High
Q4100	Skin substitute, nos	Low	Low
Q4101	Apligraf	High	High
Q4102	Oasis wound matrix	Low	Low
Q4103	Oasis burn matrix	High	High*
Q4104	Integra bmwd	High	High
Q4105	Integra drt or omnigraft	High	High
Q4106	Dermagraft	High	High
Q4107	Graftjacket	High	High
Q4108	Integra matrix	High	High
Q4110	Primatrix	High	High
Q4111	Gammagraft	Low	Low
Q4115	Alloskin	Low	Low
Q4116	Alloderm	High	High
Q4117	Hyalomatrix	Low	Low
Q4121	Theraskin	High	High
Q4122	Dermacell	High	High
Q4123	Alloskin	High	High*
Q4124	Oasis tri-layer wound matrix	Low	Low
Q4126	Memoderm/derma/tranz/integup	High	High

CY 2025 HCPCS Code	CY 2025 Short Descriptor	CY 2024 High/Low Cost Assignment	CY 2025 High/Low Cost Assignment
Q4127	Talymed	High	High
Q4128	Flexhd/allopatchhd/matrixhd	High	High
Q4132	Grafix core, grafixpl core	High	High
Q4133	Grafix stravix prime pl sqcm	High	High
Q4134	Hmatrix	High	High
Q4135	Mediskin	High	High
Q4136	Ezderm	Low	High
Q4137	Amnioexcel biodexcel, 1 sq cm	High	High
Q4138	Biodfence dryflex, 1cm	High	High
Q4140	Biodfence 1cm	High	High
Q4141	Alloskin ac, 1cm	High	High*
Q4143	Repriza, 1cm	High	High*
Q4146	Tensix, 1cm	High	High*
Q4147	Architect ecm px fx 1 sq cm	High	High
Q4148	Neox rt or clarix cord	High	High
Q4150	Allowrap ds or dry 1 sq cm	High	High
Q4151	Amnioband, guardian 1 sq cm	High	High
Q4152	Dermapure 1 square cm	High	High
Q4153	Dermavest, plurivest sq cm	High	High
Q4154	Biovance 1 square cm	High	High
Q4156	Ncox 100 or clarix 100	High	High
Q4157	Revitalon 1 square cm	High	High*
Q4158	Kerecis omega3, per sq cm	High	High*
Q4159	Affinity 1 square cm	High	High
Q4160	Nushield 1 square cm	High	High
Q4161	Bio-connekt per square cm	High	High*
Q4163	Woundex, bioskin, per sq cm	High	High
Q4164	Helicoll, per square cm	High	High*
Q4165	Keramatrix, per square cm	Low	Low
Q4166	Cytal, per square centimeter	Low	Low
Q4167	Truskin, per square centimeter	High	High
Q4169	Artacent wound, per sq cm	High	High
Q4170	Cygnus, per sq cm	High	High*
Q4173	Palingen or palingen xplus	High	High*
Q4175	Miroderm, per square cm	High	High
Q4176	Neopatch, per sq centimeter	High	High
Q4178	Floweramniopatch, per sq cm	High	High
Q4179	Flowerderm, per sq cm	High	High*
Q4180	Revita, per sq cm	High	High
Q4181	Amnio wound, per square cm	High	High
Q4182	Transcyte, per sq centimeter	High	High
Q4183	Surgigraft, 1 sq cm	High	High
Q4184	Cellesta or duo per sq cm	High	High*
Q4186	Epifix 1 sq cm	High	High
Q4187	Epicord 1 sq cm	High	High

CY 2025 HCPCS Code	CY 2025 Short Descriptor	CY 2024 High/Low Cost Assignment	CY 2025 High/Low Cost Assignment
Q4188	Amnioarmor 1 sq cm	High	High*
Q4190	Artacent ac 1 sq cm	High	High*
Q4191	Restorigin 1 sq cm	High	High*
Q4193	Coll-e-derm 1 sq cm	High	High
Q4194	Novachor 1 sq cm	High	High*
Q4195	Puraply 1 sq cm	High	High
Q4196	Puraply am 1 sq cm	High	High
Q4197	Puraply xt 1 sq cm	High	High
Q4198	Genesis amnio membrane 1 sq cm	High	High
Q4199	Cygnus matrix, per sq cm	High	High
Q4200	Skin te 1 sq cm	High	High*
Q4201	Matrion 1 sq cm	High	High
Q4203	Derma-gide, 1 sq cm	High	High
Q4204	Xwrap 1 sq cm	Low	Low
Q4205	Membrane graft or wrap sq cm	High	High
Q4208	Novafix per sq cm	High	High
Q4209	Surgraft per sq cm	High	High*
Q4211	Amnion bio or axobio sq cm	High	High
Q4214	Cellesta cord per sq cm	Low	Low
Q4216	Artacent cord per sq cm	Low	High
Q4217	Woundfix biowound plus xplus	High	High*
Q4218	Surgicord per sq cm	High	High*
Q4219	Surgigraft dual per sq cm	High	High*
Q4220	Bellacell HD, Surederm sq cm	Low	Low
Q4221	Amniowrap2 per sq cm	High	High
Q4222	Progenamatrix, per sq cm	High	High*
Q4224	Hhf10-p per sq cm	Low	Low
Q4225	Amniobind, per sq cm	Low	Low
Q4226	Myown harv prep proc sq cm	High	High
Q4227	Amniocore per sq cm	High	High
Q4229	Cogenex amnio memb per sq cm	High	High*
Q4232	Corplex, per sq cm	High	High
Q4234	Xcellerate, per sq cm	High	High
Q4235	Amniorepair or altiplay sq cm	High	High
Q4236	Carepatch per sq cm	Low	Low
Q4237	cryo-cord, per sq cm	High	High*
Q4238	Derm-maxx, per sq cm	High	High
Q4239	Amnio-maxx or lite per sq cm	High	High*
Q4247	Amniotext patch, per sq cm	Low	Low
Q4248	Dermacyte Amn mem allo sq cm	High	High
Q4249	Amniplay, per sq cm	High	High*
Q4250	AmnioAMP-MP per sq cm	High	High
Q4251	Vim, per square centimeter	Low	Low
Q4252	Vendaje, per square centimet	Low	Low
Q4253	Zenith amniotic membrane psc	High	High*

CY 2025 HCPCS Code	CY 2025 Short Descriptor	CY 2024 High/Low Cost Assignment	CY 2025 High/Low Cost Assignment
Q4254	Novafix dl per sq cm	High	High*
Q4255	Reguard, topical use per sq	Low	Low
Q4256	Mlg complet, per sq cm	Low	Low
Q4257	Relese, per sq cm	Low	Low
Q4258	Enversec, per sq cm	High	High*
Q4259	Celera per sq cm	Low	Low
Q4260	Signature apatch, per sq cm	Low	Low
Q4261	Tag, per square centimeter	Low	Low
Q4262	Dual layer impax, per sq cm	Low	High
Q4263	Surgraft tl, per sq cm	Low	Low
Q4264	Cocoon membrane, per sq cm	Low	Low
Q4265	Neostim tl per sq cm	Low	Low
Q4266	Neostim per sq cm	Low	Low
Q4267	Neostim dl per sq cm	Low	Low
Q4268	Surgraft ft per sq cm	Low	High
Q4269	Surgraft xt per sq cm	Low	Low
Q4270	Complete sl per sq cm	Low	Low
Q4271	Complete ft per sq cm	Low	Low
Q4272	Esano a, per sq cm	Low	Low
Q4273	Esano aaa, per sq cm	Low	Low
Q4274	Esano ac, per sq cm	Low	Low
Q4275	Esano aca, per sq cm	Low	Low
Q4276	Orion, per sq cm	Low	Low
Q4278	Epieffect, per sq cm	High	High*
Q4279	Vendaje ac, per sq cm	Low	Low
Q4280	Xcell amnio matrix per sq cm	Low	Low
Q4281	Barrera slor dl per sq cm	Low	Low
Q4282	Cygnus dual per sq cm	High	High
Q4283	Biovance tri or 3l, sq cm	Low	Low
Q4284	Dermabind sl, per sq cm	Low	Low
Q4285	Nudyn dl or dl mesh pr sq cm	Low	Low
Q4286	Nudyn sl or slw, per sq cm	Low	Low
Q4287	Dermabind dl, per sq cm	Low	Low
Q4288	Dermabind ch, per sq cm	Low	Low
Q4289	Revoshield+ amnio, per sq cm	Low	Low
Q4290	Membrane wrap hydr per sq cm	Low	Low
Q4291	Lamellas xt, per sq cm	Low	Low
Q4292	Lamellas, per sq cm	Low	Low
Q4293	Acesso dl, per sq cm	Low	Low
Q4294	Amnio quad-core, per sq cm	Low	Low
Q4295	Amnio tri-core, per sq cm	Low	Low
Q4296	Rebound matrix, per sq cm	Low	Low
Q4297	Emerge matrix, per sq cm	Low	Low
Q4298	Amnicore pro, per sq cm	Low	Low
Q4299	Amnicore pro+, per sq cm	Low	Low

CY 2025 HCPCS Code	CY 2025 Short Descriptor	CY 2024 High/Low Cost Assignment	CY 2025 High/Low Cost Assignment
Q4300	Acesso tl, per sq cm	Low	Low
Q4301	Activate matrix, per sq cm	Low	Low
Q4302	Complete aca, per sq cm	Low	Low
Q4303	Complete aa, per sq cm	Low	Low
Q4304	Grafix plus, per sq cm	Low	Low
Q4305	Amer am ac tri-lay per sq cm	Low	Low
Q4306	Americ amnion ac per sq cm	Low	Low
Q4307	American amnion, per sq cm	Low	Low
Q4308	Sanopellis, per sq cm	Low	Low
Q4309	Via matrix, per sq cm	Low	Low

* These products do not exceed either the MUC or PDC threshold for CY 2025 but are assigned to the high-cost group because they were assigned to the high-cost group in CY 2024.

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8. Radioisotopes Derived From Non-Highly Enriched Uranium (Non-HEU) Sources

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Technetium-99m (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, is produced through the radioactive decay of molybdenum-99 (Mo-99). Historically, most of the Mo-99 used in the United States was produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The United States wanted to eliminate domestic reliance on these reactors and promoted the conversion of all medical radioisotope production to non-HEU sources. Alternative methods for producing Tc-99m without HEU are technologically and economically viable, but it was expected that this change in the supply source for the radioisotope used for modern medical imaging would introduce increased costs into the payment system that would not be fully accounted for in the historical claims data until all Tc-99m was produced from non-HEU sources.

Therefore, beginning in CY 2013, we finalized a policy to provide an additional payment of \$10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). Under this policy, hospitals report HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) once per dose along with any diagnostic scan or scans furnished using

Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources (77 FR 68323).

We stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68321) that our expectation was that this additional payment would be needed for the duration of the industry's conversion to alternative methods of producing Tc-99m without HEU. We also stated that we would reassess, and propose, if necessary, on an annual basis whether such an adjustment continued to be necessary and whether any changes to the adjustment were warranted (77 FR 68321). The Secretaries of Energy and Health and Human Services issued a certification regarding the supply of non-HEU-sourced Mo-99 effective January 2, 2022 (86 FR 73270). Mo-99 is the precursor material from which Tc-99m is sourced. The certification by the Secretary of Energy stated that there was a sufficient global supply of Mo-99 produced without the use of HEU available to meet the needs of patients in the United States. In the CY 2023 OPPS/ASC final rule with comment period, we stated that we believed the conversion to non-HEU sources of Tc-99m had reached a point where it was necessary to reassess our policy of providing an additional payment of \$10 for the marginal cost for radioisotopes produced by non-HEU sources (87 FR 71987).

In the OPPS, diagnostic radiopharmaceuticals are currently packaged into the cost of the associated diagnostic imaging procedure no matter the per day cost of the radiopharmaceutical (though we are proposing in this rule to provide separate payment for high-cost

diagnostic radiopharmaceuticals starting in CY 2025). The cost of the radiopharmaceutical is included as a part of the cost of the diagnostic imaging procedure and is reported through Medicare claims data. Medicare claims data used to set payment rates under the OPPS generally is from 2 years prior to the payment year.

As we explained in the CY 2023 OPPS/ASC final rule with comment period (87 FR 71987), the claims data we used to set payment rates for CY 2024 (generally CY 2022 claims data) contained claims for diagnostic radiopharmaceuticals that reflect both HEU-sourced Tc-99m and non-HEU-sourced Tc-99m, rather than radiopharmaceuticals sourced solely from non-HEU Tc-99m. The cost of HEU-sourced Tc-99m is substantially lower than the cost of non-HEU-sourced Tc-99m. Therefore, we explained that providers who use radiopharmaceuticals in CY 2024 that contain only non-HEU-sourced Tc-99m might not receive a payment that is reflective of the radiopharmaceutical's current cost without the add-on payment. We believed that extending the additional \$10 add-on payment described by HCPCS code Q9969 for non-HEU-sourced Tc-99m through the end of CY 2024 would ensure adequate payment for non-HEU-sourced Tc-99m. Starting in CY 2025, we believed the Medicare claims data utilized to set payment rates (likely CY 2023 claims data) would only include claims for diagnostic radiopharmaceuticals that utilized non-HEU-sourced Tc-99m, meaning the data would reflect the full cost of the Tc-99m diagnostic radiopharmaceuticals that would be used by providers in CY 2025. As a

result, we believed there would no longer be a need for the additional \$10 add-on payment for CY 2025 or future years.

The conversion of the last major global Mo-99 producer from HEU to Low Enriched Uranium (LEU) was previously expected to complete by December 31, 2022 but did not occur until March 2023, so it is possible that some claims for diagnostic radiopharmaceuticals in CY 2023 would report the cost of HEU-sourced Tc-99m. This means that in CY 2025, as in CY 2024, there is the possibility that the payment rate for procedures using diagnostic radiopharmaceuticals could be lower than the costs providers will face for these procedures because providers will only have access to non-HEU-sourced Tc-99m. Therefore, we adopted a policy in the CY 2024 OPPS final rule with comment period (88 FR 81803) to extend the additional \$10 add-on payment described by HCPCS code Q9969 for non-HEU-sourced Tc-99m through the end of CY 2025 to continue to ensure adequate payment for non-HEU-sourced Tc-99m.

Recently, the Department of Energy and other interested parties raised another issue affecting the domestic supply chain for Mo-99 and Tc-99 that, left unaddressed, could cause payment inequity among outpatient hospital providers. Foreign Mo-99 production has historically been subsidized by foreign governments, resulting in prices below the true cost of production. These artificially low, government-subsidized prices have created a disincentive for investments in Mo-99 production infrastructure, and they also created a barrier to entry for new producers, including U.S. companies. This in turn has resulted in unreliable production and periodic shortages. In response to the 2009–2010 shortages, Congress passed the American Medical Isotopes Production Act of 2012 (AMIPA), which directs the Secretary of Energy to provide financial and technical support to U.S. companies working to build new irradiation and manufacturing facilities to produce Mo-99 without HEU.

It was expected that the transition from HEU to LEU-based production would also involve the transition to a Full Cost Recovery pricing model; however, it does not appear that this transition has occurred in practice. Foreign producers continue to rely on multipurpose nuclear research reactors for Mo-99 production, and the global Mo-99 supply chain has not established a system of verifying that all of the costs attributable to Mo-99 production are being incorporated into the price of the product.

U.S. companies have made significant progress towards establishing the infrastructure needed for large-scale Mo-99 production. Unlike many foreign producers, U.S. companies must price their products high enough to cover the full cost of operating their production facilities. Based in part on the differences in pricing models, U.S. companies have experienced challenges in competing with foreign producers for customers. Currently, there is no domestic production of Mo-99.

Once U.S. companies initiate or resume Mo-99 production, the difference in pricing models will likely create a payment inequity, as hospitals purchasing Tc-99m derived from domestically produced Mo-99 would likely pay higher prices than those purchasing Tc-99m derived from imported Mo-99. We propose to address the payment inequity resulting from the higher cost of domestically produced Tc-99m by establishing a new add-on payment of \$10 per dose for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99 starting on January 1, 2026 using our equitable adjustment authority under section 1833(t)(2)(E) of the Act. We believe the \$10 add-on payment for domestically produced Tc-99m would ensure equitable payments by paying providers who use domestically produced Tc-99m radiopharmaceuticals when available an amount that reflects the anticipated higher cost of these products. The \$10 add-on payment will help to preserve provider and beneficiary access to domestically produced Tc-99m radiopharmaceuticals by providing an additional payment amount that addresses the additional costs of domestically produced Tc-99m radiopharmaceuticals. DOE/NSA would establish the criteria to certify whether the Tc-99m radiopharmaceutical dose is domestically produced and eligible for the add-on payment, which would be included in the CY 2026 OPPS/ASC proposed rule. The CY 2026 OPPS/ASC proposed rule would include additional details on how providers would bill for this add-on payment in CY 2026.

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Amount of Additional Payment and Limit on Aggregate Annual Adjustment

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payment for drugs, biologicals, and categories of devices for a given year to an

“applicable percentage,” currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate pro rata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing a proposed estimate of pass-through spending in CY 2025 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2025. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of devices that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2024 or beginning in CY 2025. The sum of the proposed CY 2025 pass-through spending estimates for these two groups of device categories equals the proposed total CY 2025 pass-through spending estimate for device categories with pass-through payment status. We determined the device pass-through estimated payments for each device category based on the amount of payment as required by section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment methodology for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision

or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in the proposed rule, we propose to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2025, we also propose to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Consistent with current policy, we propose to apply a rate of ASP plus 6 percent to most drugs and biologicals for CY 2025, and therefore our estimate of drug and biological pass-through payment for CY 2025 for this group of items is \$10.2 million.

Payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents without pass-through payment status, is packaged into payment for the associated procedures, and these products are not separately paid. In addition, we policy-package all non-pass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, drugs and biologicals that function as supplies when used in a surgical procedure, drugs and biologicals used for anesthesia, and other categories of drugs and biologicals, as discussed in section V.B.1.c of this proposed rule. Consistent with current policy, we propose that all of these policy-packaged drugs and biologicals with pass-through payment status will be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2025, less the policy-

packaged drug APC offset amount described below. Our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2025 is not \$0. This is because the pass-through payment amount and the fee schedule amount associated with the drug or biological will not be the same, unlike for separately payable drugs and biologicals. In section V.A.6 of this proposed rule, we discuss our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we propose to offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. Consistent with current policy, if we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we propose to reduce our estimate of pass-through payments for these drugs or biologicals by the APC offset amount.

Similar to pass-through spending estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2025. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2024 or beginning in CY 2025. The sum of the CY 2025 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2025 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Proposed Estimate of Pass-Through Spending for CY 2025

For CY 2025, we propose to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2025, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2024 (88 FR 81805). The pass-through payment percentage limit is calculated

using pass-through spending estimates for devices and for drugs and biologicals.

For the first group of devices, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2025, there are 8 active categories for CY 2025. The active categories are described by HCPCS codes C1747, C1826, C1827, C1600, C1601, C1602, C1603 and C1604. Based on the information from the device manufacturers, we estimate that HCPCS code C1747 will cost \$19.5 million in pass-through expenditures in CY 2025, HCPCS code C1826 will cost \$151,991 in pass-through expenditures in CY 2025, HCPCS code C1827 will cost \$364,793 in pass-through expenditures in CY 2025, HCPCS code C1600 will cost \$21.9 million in pass-through expenditures in CY 2025, HCPCS code C1601 will cost \$14.4 million in pass-through expenditures in CY 2025, HCPCS code C1602 will cost \$8.2 million in pass-through expenditures in CY 2025, HCPCS code C1603 will cost \$6.6 million in pass-through expenditures in CY 2025, and HCPCS code C1604 will cost \$20.0 million in pass-through expenditures in CY 2025. Therefore, we propose an estimate for the first group of devices of \$91.1 million.

In estimating our proposed CY 2025 pass-through spending for device categories in the second group, we included the following: (1) device categories that we assumed at the time of the development of the proposed rule would be newly eligible for pass-through payment in CY 2025; (2) additional device categories that we estimated could be approved for pass-through status after the development of this proposed rule and before January 1, 2025; and (3) contingent projections for new device categories established in the second through fourth quarters of CY 2025. For CY 2025, we propose to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For this proposed rule, the proposed estimate of CY 2025 pass-through spending for this second group of device categories was \$523.7 million.

To estimate proposed CY 2025 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through payment status for at least one quarter in CY 2025, we propose to use

the CY 2023 Medicare hospital outpatient claims data regarding their utilization, information provided in their respective pass-through applications, other historical hospital claims data, pharmaceutical industry information, and clinical information regarding these drugs and biologicals to project the CY 2025 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals, contrast agents, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will be continuing on pass-through payment status in CY 2025, we estimated the pass-through payment amount as the difference between the general payment rate of ASP+6 percent and the payment rate for non-pass-through drugs and biologicals that would be separately paid. Because we propose to utilize a payment rate of ASP plus 6 percent for most drugs and biologicals in this proposed rule, the proposed payment rate difference between the pass-through payment amount and the non-pass-through payment amount is \$0 for this group of drugs.

Because payment for policy-packaged drugs and biologicals is packaged if the product is not paid separately due to its pass-through payment status, we propose to include in the CY 2025 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug receiving pass-through payment. Given the proposal to pay separately for diagnostic radiopharmaceuticals that exceed the proposed per-day threshold referenced in section II.A.3.c of this proposed rule, for CY 2025, all diagnostic radiopharmaceuticals that are currently on pass-through will be separately payable once their pass-through status has expired. For this first group of policy-packaged drugs and biologicals, we estimate pass-through spending for CY 2025 of \$200,000 as compared to \$90 million for CY 2024 OPPS/ASC final rule (88 FR 81806).

To estimate proposed CY 2025 pass-through spending for drugs and biologicals in the second group (that is,

drugs and biologicals that we knew at the time of development of this proposed rule were newly eligible or recently became eligible for pass-through payment in CY 2024, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2025, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2025), we propose to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2025 pass-through payment estimate. We also propose to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2025 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately \$10 million.

We estimate for this proposed rule that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2025 and the amount of pass-through spending for those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2025 would be approximately \$625 million (approximately \$614.8 million for device categories and approximately \$10.2 million for drugs and biologicals), which represents only 0.71 percent of total projected OPPS payments for CY 2025 (approximately \$88.2 billion). Therefore, we estimate that pass-through spending in CY 2025 would not exceed the 2.0 percent of total projected OPPS CY 2025 program spending limit provided for in section 1833(t)(6)(E) of the Act.

VII. Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2025, we propose to continue our current clinic and emergency department (ED) hospital outpatient visits payment policies. For a description of these policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448). We also propose to continue our payment policy for critical care services for CY 2025. For a description of this

policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of this payment policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043).

As we stated in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63663), the volume control method for clinic visits furnished by non-excepted off-campus provider-based departments (PBDs) applies for CY 2022 and subsequent years. More specifically, we finalized a policy to continue to utilize a PFS-equivalent payment rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by these departments for CY 2022 and beyond. The PFS-equivalent rate for CY 2025 is 40 percent of the proposed OPPS payment. Under this policy, these departments will be paid approximately 40 percent of the OPPS rate for the clinic visit service in CY 2025.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71748), we finalized a policy that excepted off-campus provider-based departments (PBDs) (departments that bill the modifier "PO" on claim lines) of rural Sole Community Hospitals (SCHs), as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, are exempt from the clinic visit payment policy that applies a PFS-equivalent payment rate for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For the full discussion of this policy, we refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051). For CY 2025, we propose to continue to exempt excepted off-campus PBDs of rural SCHs from the clinic visit payment policy. We will continue to monitor the effect of this change in Medicare payment policy, including on the volume of these types of OPD services.

VIII. Payment for Partial Hospitalization and Intensive Outpatient Services

This section discusses payment for partial hospitalization services as well as intensive outpatient services. Since CY 2000, Medicare has paid for partial hospitalization services under the OPPS. Beginning in CY 2024, as authorized by section 4124 of the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), Medicare began paying for intensive outpatient services furnished by hospital outpatient departments,

community mental health centers, federally qualified health centers, and rural health clinics in addition to opioid treatment programs. Additional background on the partial hospitalization and intensive outpatient benefits is included in the following paragraphs.

A. Background

1. Partial Hospitalization

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders (SUD). Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC), as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit. We refer readers to sections 1833(t)(1)(B)(i), 1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the Act and 42 CFR 419.21, for additional information regarding PHP.

Partial hospitalization program policies and payment have been addressed under OPPTS since CY 2000. In CY 2008, we began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes, by implementing two refinements to the methodology for computing the PHP median. For a detailed discussion on these policies, we refer readers to the CY 2008 OPPTS/ASC final rule with

comment period (72 FR 66670 through 66676). In CY 2009, we implemented several regulatory, policy, and payment changes. For a detailed discussion on these policies, we refer readers to the CY 2009 OPPTS/ASC final rule with comment period (73 FR 68688 through 68697). In CY 2010, we retained the two-tier payment approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP APC per diem costs, upon which PHP APC per diem payment rates are based (74 FR 60556 through 60559). In CY 2011 (75 FR 71994), we established four separate PHP APC per diem payment rates: two for CMHCs (APC 0172 and APC 0173) and two for hospital-based PHPs (APC 0175 and APC 0176) and instituted a two-year transition period for CMHCs to the CMHC APC per diem payment rates. For a detailed discussion, we refer readers to section X.B of the CY 2011 OPPTS/ASC final rule with comment period (75 FR 71991 through 71994). In CY 2012, we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively on hospital data (76 FR 74348 through 74352). In the CY 2013 OPPTS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPTS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPTS/ASC proposed rule (78 FR 43621 through 43622) and CY 2015 OPPTS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPTS/ASC final rule with comment period (78 FR 75047 through 75050). In the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70453 through 70467), we described our extensive analysis of the claims and cost data and ratesetting methodology, corrected a cost inversion that occurred in the final rule data with respect to hospital-based PHP providers, and renumbered the PHP APCs. In the CY

2017 OPPTS/ASC final rule with comment period (81 FR 79687 through 79691), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs and finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and for hospital-based PHPs. We also implemented an eight-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities. For a comprehensive description of PHP payment policy, including a detailed methodology for determining PHP per diem amounts, we refer readers to the CY 2016 and CY 2017 OPPTS/ASC final rules with comment period (80 FR 70453 through 70455 and 81 FR 79678 through 79680, respectively).

In the CYs 2018 and 2019 OPPTS/ASC final rules with comment period (82 FR 59373 through 59381 and 83 FR 58983 through 58998, respectively), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs, designated a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, and proposed updates to the PHP allowable HCPCS codes. We finalized these proposals in the CY 2020 OPPTS/ASC final rule with comment period (84 FR 61352).

In the CY 2020 OPPTS/ASC final rule with comment period (84 FR 61339 through 61350), we finalized a proposal to use the calculated CY 2020 CMHC geometric mean per diem cost and the calculated CY 2020 hospital-based PHP geometric mean per diem cost, but with a cost floor equal to the CY 2019 final geometric mean per diem costs as the basis for developing the CY 2020 PHP APC per diem rates. Also, we continued to designate a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPTS, excluding outlier payments.

In the April 30, 2020 interim final rule with comment (85 FR 27562 through 27566), effective as of March 1, 2020 and for the duration of the COVID-19 Public Health Emergency (PHE), hospital and CMHC staff were permitted to furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, as long as the location met all conditions of participation to the extent not waived. A hospital or CMHC could furnish such services using telecommunications technology to a

beneficiary in a temporary expansion location if that beneficiary was registered as an outpatient. In the CY 2023 OPPS/ASC final rule (87 FR 72247), we confirmed that these provisions applied only for the duration of the COVID-19 PHE. On May 11, 2023, the COVID-19 PHE ended, and accordingly, these flexibilities ended as well.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86073 through 86080), we continued our current methodology to utilize cost floors, as needed. Since the final calculated geometric mean per diem costs for both CMHCs and hospital-based PHPs were significantly higher than each proposed cost floor, a floor was not necessary at the time, and we did not finalize the proposed cost floors in the CY 2021 OPPS/ASC final rule with comment period.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63665 through 63666), we explained that we observed a number of changes, likely as a result of the COVID-19 PHE, in the CY 2020 OPPS claims that we would have ordinarily used for CY 2022 ratesetting, and this included changes in the claims for partial hospitalization. We explained that significant decreases in utilization and in the number of hospital-based PHP providers who submitted CY 2020 claims led us to believe that CY 2020 data were not the best overall approximation of expected PHP services in CY 2022. Therefore, we finalized our proposal to calculate the PHP per diem costs using the year of claims consistent with the calculations that would be used for other OPPS services, by using the CY 2019 claims and the cost reports that were used for CY 2021 final rulemaking to calculate the CY 2022 PHP per diem costs. In addition, for CY 2022 and subsequent years, we finalized our proposal to use cost and charge data from the Hospital Cost Report Information System (HCRIS) as the source for the CMHC cost-to-charge ratios (CCRs), instead of using the Outpatient Provider Specific File (OPSF) (86 FR 63666).

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71995), we explained that we continued to observe a decrease in the number of hospital-based and CMHC PHP days in our trimmed dataset due to the continued effects of COVID-19; however, the Medicare outpatient service volumes appeared to be returning to more normal, pre-pandemic levels. Therefore, we finalized our proposal to use the latest available CY 2021 claims but use the cost information from prior to the COVID-19 PHE for calculating the CY

2023 CMHC and hospital-based PHP APC per diem costs. The application of the OPPS standard methodology, including the effect of budget neutralizing all other OPPS policy changes unique to CY 2023, resulted in the final calculated CMHC PHP APC payment rate being unexpectedly lower than the CY 2022 final CMHC PHP APC rate. Therefore, in the interest of accurately paying for CMHC PHP services, under the unique circumstances of budget neutralizing all other OPPS policy changes for CY 2023, and in keeping with our longstanding goal of protecting continued access to PHP services provided by CMHCs by ensuring that CMHCs remain a viable option as providers of mental health care in the beneficiary's own community, we finalized utilizing the equitable adjustment authority of section 1833(t)(2)(E) of the Act to appropriately pay for CMHC PHP services at the same payment rate as for CY 2022, that is, \$142.70. In addition, we clarified the payment under the OPPS for new HCPCS codes that designate non-PHP services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder and are furnished to beneficiaries in their homes by clinical staff of the hospital would not be recognized as PHP services; however, none of the PHP regulations would preclude a patient that is under a PHP plan of care from receiving other reasonable and medically necessary non-PHP services from a hospital (87 FR 72001 and 72002).

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81811), we revised the regulation at § 424.24(e)(1)(i) to require the physician certification for PHP services to include a certification that the patient requires such services for a minimum of 20 hours per week, as required by section 1861(ff)(1) of the Act, as amended by section 4124(a) of Division FF of the CAA, 2023. In addition, we modified the regulations for PHP at § 410.43 to include references to SUD. In the same CY 2024 OPPS/ASC final rule, we also established separate payment rates for PHP days with 3 services and days with 4 or more services. Accordingly, we established four separate PHP APC per diem payment rates: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5853 and APC 5854, respectively), and one for hospital-based PHPs for 3-service days and another for hospital-based PHPs for 4-service days (APC 5863 and APC 5864, respectively). We also finalized a policy to utilize the separate CMHC

rates for 3-service and 4-service PHP days as the Medicare Physician Fee Schedule (MPFS) rates, depending upon whether a nonexcepted off-campus hospital outpatient department furnishes 3 or 4 PHP services in a day. Lastly, we finalized several changes beginning in CY 2024 to align coding, billing, and payment between PHPs and intensive outpatient programs, which are discussed in greater detail in the following sections of this CY 2025 OPPS/ASC proposed rule.

2. Intensive Outpatient Program Services

Section 4124(b) of the CAA, 2023 established Medicare coverage for intensive outpatient services effective for items and services furnished on or after January 1, 2024. An intensive outpatient program (IOP) is a distinct and organized program of psychiatric services for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and SUD. Intensive outpatient services are not required to be provided in lieu of inpatient hospitalization. Section 1861(ff)(4) of the Act defines intensive outpatient services as the items and services described in paragraph (2) prescribed by a physician for an individual determined (not less frequently than every other month) by a physician to have a need for such services for a minimum of 9 hours per week and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which plan sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in intensive outpatient services. Section 1861(ff)(4)(C) of the Act specifies that an IOP is a program furnished by a hospital to its outpatients, a CMHC, a Federally qualified health center (FQHC), or by a rural health clinic (RHC) as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit. We refer readers to sections 1833(t)(1)(B)(i), 1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the

Act and 42 CFR 419.21, for additional information regarding IOP.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81812 through 81857), we established payment and program requirements for the IOP benefit furnished by a hospital to its outpatients, or by a CMHC, an FQHC, or an RHC. In addition, we established Medicare Part B coverage for IOP services provided by Opioid Treatment Programs (OTPs) for the treatment of opioid use disorder (OUD). We refer readers to the CY 2025 Physician Fee Schedule (PFS) proposed rule, published elsewhere in the **Federal Register**, for additional information regarding CY 2025 proposed payment policies for IOP services furnished by FQHCs and RHCs.

Consistent with the statutory definition of intensive outpatient services under section 1861(ff)(2) of the Act, we finalized regulations at 42 CFR 410.44 to set forth the conditions and exclusions applicable for intensive outpatient services, and at § 424.24 to set forth the content of the certification and plan of treatment requirements for intensive outpatient services. We also revised certain existing regulations at §§ 410.2, 410.3, 410.10, 410.27, 410.150, and 419.21 to add a regulatory definition of intensive outpatient services and to include intensive outpatient services in the regulations for medical and other health services paid for under Medicare Part B, and in the case of § 419.21, under the OPPS. Additionally, we created regulations at § 410.111 to establish the requirements for coverage of IOP services furnished in CMHCs, and at § 410.173 to establish conditions of payment for IOP services furnished in CMHCs. Lastly, we revised § 410.155 to exclude IOP services from the outpatient mental health treatment limitation, consistent with the statutory requirement of section 1833(c)(2) of the Act, as amended by section 4124(b)(3) of the CAA, 2023.

In addition, as discussed in greater detail in the following sections, we established coding, billing, and payment policies for IOP that align with the policies established for PHP provided in the same settings. Specifically, we established four separate IOP APC per diem payment rates at the same rates we proposed for the PHP APCs: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5851 and APC 5852, respectively), and one for hospital-based IOPs for 3-service days and another for hospital-based IOPs for 4-service days (APC 5861 and APC 5862, respectively). Similar to the policy finalized for PHP, we finalized a policy to utilize the CMHC rates for 3-

service and 4-service IOP days as the MPFS rates, depending upon whether a nonexcepted hospital outpatient department furnishes 3 or 4 IOP services in a day.

We also established payment for IOP provided by an RHC or FQHC at the same rate as APC 5861, which is the 3-service hospital-based IOP rate (§ 405.2462(j)). Furthermore, we established a payment adjustment for IOP provided by an OTP based on 3 times the payment rate for APC 5861 beginning in CY 2024 (§ 410.67(d)(4)(i)(F)). As noted earlier in this CY 2025 OPPS/ASC proposed rule, additional information regarding CY 2025 proposed payment policies for IOP services furnished by FQHCs and RHCs can be found in the CY 2025 PFS proposed rule, published elsewhere in the **Federal Register**.

B. Coding and Billing for PHP and IOP Services Under the OPPS

In the CY 2024 OPPS/ASC final rule, we finalized a billing requirement that all providers use condition code 41 to indicate that a claim is for partial hospitalization services and use condition code 92 to identify intensive outpatient claims, effective January 1, 2024. Since the statutory definitions of both IOP and PHP generally include the same types of items and services covered, we stated in the CY 2024 final OPPS rule that we believe it is appropriate to align the programs using a consistent list of services, so that level of intensity would be the only differentiating factor between partial hospitalization services and intensive outpatient services. The use of condition codes 41 for PHP claims and 92 for IOP claims allows us to differentiate between these services for billing purposes.

We recognize that the level of intensity of mental health services that a patient requires may vary over time; therefore, we believe utilizing a consolidated list of HCPCS codes to identify services under both the IOP and PHP benefits supports a smooth transition for patients when a change in the intensity of their services is necessary to best meet their needs. For example, a patient receiving IOP services may experience an acute mental health need that necessitates more intense services through a PHP. Alternatively, an IOP patient that no longer requires the level of intensity provided by the IOP can access less intense mental health services, such as individual mental health services. The full list of HCPCS codes recognized under the PHP and IOP benefits can be found in the Medicare Claims

Processing internet Only Manual, Chapter 4, Sections 260.1 and 261.1, respectively, and their subsections, available at <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c04.pdf>.

To qualify for payment for the IOP APC (5851, 5852, 5861, or 5862) or the PHP APC (5853, 5854, 5863, or 5864), one service provided that day must be from the Partial Hospitalization and Intensive Outpatient Primary list. We refer readers to the CY 2024 OPPS final rule for further discussion regarding our expectation that at least one of the services on the PHP and IOP Primary list will be indicated per day for patients who need the level of care offered by a PHP or IOP program. The PHP and IOP Primary List can be found in the CY 2024 OPPS/ASC final rule at 88 FR 81821.

Beginning in CY 2024, we recognized caregiver training services and Principal Illness Navigation (PIN) services as PHP and IOP services. We explained that the reported costs associated with providing such services are included when we calculate the PHP and IOP payment rates; however, these services do not count toward the determination of whether a PHP or IOP day is paid at the 3-service or 4-service rate. We refer readers to the CY 2024 OPPS final rule for a detailed discussion of this policy (88 FR 81823 through 81825).

As finalized in the CY 2024 OPPS final rule, if new codes are established that represent the PHP and IOP services described under §§ 410.43(a)(4) and 410.44(a)(4), respectively, such codes are added to the list of codes recognized for payment for PHP or IOP through sub-regulatory guidance. We note that coding updates frequently occur outside of the standard rulemaking timeline. We adopted this sub-regulatory process in order to pay expeditiously when new codes are created that describe any of the services enumerated at §§ 410.43(a)(4) and 410.44(a)(4), which PHPs and IOPs, respectively, would provide. We explained that this policy applies to new codes that are crosswalked to a previously included code, or whose code descriptor is substantially similar to a descriptor for a code on the list or describes a service on the list. We stated that any additional services not described at §§ 410.43(a)(4) or 410.44(a)(4) would be added to the lists in regulation through notice and comment rulemaking. We note that for CY 2025, we are not proposing to add any new services not described at §§ 410.43(a)(4) or 410.44(a)(4) to the list of PHP and IOP services.

C. Proposed CY 2025 Payment Rates for PHP and IOP

1. Background

Beginning in CY 2024, we established four separate PHP APC per diem payment rates: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5853 and APC 5854, respectively), and one for hospital-based PHPs for 3-service days and another for hospital-based PHPs for 4-service days (APC 5863 and APC 5864, respectively). In addition, for hospital-based PHPs, we finalized a policy to calculate payment rates using the broader OPPTS data set, instead of using hospital-based PHP data only. We explained that using the broader OPPTS data set allows CMS to capture data from claims not identified as PHP, but that also include the service codes and intensity required for a PHP day. Because we established consistent coding and payment between the PHP and IOP benefits, we considered all OPPTS data for PHP days and non-PHP days that include 3 or more of the same service codes. We established four separate IOP APC per diem payment rates at the same rates we proposed for the PHP APCs: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5851 and APC 5852, respectively), and one for hospital-based IOPs for 3-service days and another for hospital-based IOPs for 4-service days (APC 5861 and APC 5862, respectively).

In the CY 2024 OPPTS/ASC final rule, we noted that the standard PHP day is typically four services or more per day. We explained that we have historically provided payment for three services a day for extenuating circumstances when a beneficiary would be unable to complete a full day of PHP treatment. As we stated in the CY 2008 OPPTS/ASC final rule with comment period (72 FR 66672), it was never our intention that days with only three units of service should represent the number of services provided in a typical PHP day. Our intention was to cover days that consisted of three units of service only in certain limited circumstances. For example, as we noted in the CY 2009 OPPTS/ASC proposed rule (73 FR 41513), we believe 3-service days may be appropriate when a patient is transitioning towards discharge (or days when a patient is at the beginning of his or her PHP stay). Another example of when it may be appropriate for a program to provide only three units of service in a day is when a patient is required to leave the PHP early for the day due to an unexpected medical appointment.

We also explained that prior to CY 2024, we historically prepared the data by first applying PHP-specific trims and data exclusions and assessing CCRs. We direct the reader to the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70463 through 70465) for a more complete discussion of these trims, data exclusions, and CCR adjustments. In prior rules, we have typically included a discussion of PHP-specific data trims, exclusions, and CCR adjustments; we did not include that discussion in the CY 2024 OPPTS/ASC proposed or final rule. We stated that these PHP-specific data trims and exclusions addressed limitations as well as anomalies in the PHP data. However, as noted earlier, we finalized a methodology for CY 2024 to calculate hospital-based PHP payment rates for 3 services per day and 4 services per day based on cost per day using the broader OPPTS data set. Accordingly, we did not apply PHP-specific trims and data exclusions, but rather we applied the same trims and data exclusions consistent with the OPPTS.

We stated in the CY 2024 OPPTS/ASC final rule (88 FR 81830) that while no IOP benefit existed prior to the CAA, 2023, the types of items and services included in IOP had been, and were, paid for by Medicare either as part of the PHP benefit or under the OPPTS more generally. Additionally, we stated that prior to the CAA, 2023, CMS had begun gathering information from interested parties on IOP under Medicare. In the CY 2023 OPPTS/ASC proposed rule (87 FR 44679), we issued a comment solicitation on intensive outpatient mental health treatment, including SUD treatment furnished by IOPs, to collect information regarding whether there are any gaps in coding that may be limiting access to needed levels of care for treatment of mental health disorders or SUDs for Medicare beneficiaries, and specific information about IOP services, such as the settings of care in which these programs typically furnish services, the range of services typically offered, and the range of practitioner types that typically furnish these services.

We explained that along with the requirements for IOP mandated by the CAA, 2023, we took into consideration information we received from the comment solicitation to construct an appropriate data set to develop proposed rates for IOP. Since IOPs furnish the same types of services as PHP, just at a lower intensity, we stated that we believe it was appropriate to use the same data and methodology for calculating payment rates for both PHP and IOP for CY 2024. We explained that

although PHP claims can be specifically identified, there was no specific identifier or billing code to indicate IOP services that may have been provided before CY 2024. However, we noted that hospitals have been permitted to furnish and bill for many of these services as outpatient services under the OPPTS. Thus, we analyzed a broader set of data that included both PHP and non-PHP days with 3 or more services in order to calculate proposed payment for PHP services. In order to establish consistent payment between PHP and IOP, we set IOP payment rates at the same rates as PHP. We stated that the primary goal in developing the payment rate methodology for IOP and PHP services was to pay providers an appropriate amount relative to the patients' needs, and to avoid cost inversion in future years. We stated that setting the IOP payment rates equal to the PHP payment rates was appropriate because IOP was a newly established benefit, and we did not have definitive data on utilization. However, we explained that both programs utilize the same services, but furnish them at different levels of intensity, with different numbers of services furnished per day and per week, depending on the program. Therefore, we stated that we expect it would be appropriate to pay the same per diem rates for IOP and PHP services unless future data analysis supports calculating rates independently.

2. CY 2025 Payment Rate Methodology for PHP and IOP

For CY 2025, we propose to use the latest available cost information, from cost reports beginning three fiscal years prior to the year that is the subject of the rulemaking, and CY 2023 OPPTS claims to update the payment rates for the four PHP APCs and the four IOP APCs finalized in the CY 2024 OPPTS/ASC final rule. This proposal is consistent with the overall proposed use of cost data for the OPPTS, which is discussed in section II.A.1.a of this proposed rule. In accordance with the methodology finalized in the CY 2024 OPPTS/ASC final rule, we propose to base the payment rate for each PHP APC on the geometric mean per diem cost for days with 3 services and 4 or more services, calculated separately for CMHCs and hospital outpatient departments. We propose to use the broader set of OPPTS data to calculate the geometric mean costs for hospital outpatient departments, and we propose to apply the same trims and exclusions consistent with the OPPTS. We also propose to set the payment rates for the four IOP APCs based on the geometric mean per diem cost for PHP days with

3 services and 4 or more services, calculated separately for CMHCs and hospital outpatient departments. Lastly, we propose that if more recent data subsequently become available after the publication of this proposed rule, we would use such updated data, if

appropriate, to determine the CY 2025 payment rates for the four PHP APCs and the four IOP APCs finalized in the CY 2024 OPPTS/ASC final rule.

Table 68 below shows the proposed APCs and the calculated geometric mean per diem costs for the CY 2025 OPPTS/ASC proposed rule. Additional

information about the data trims, data exclusions, and CCR adjustments applicable to the data used for this final rule can be found online at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>).⁷⁸

TABLE 68: PROPOSED CY 2025 PHP AND IOP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2025 APC	Group Title	Proposed PHP and IOP APC Geometric Mean Per Diem Costs
5851	Intensive Outpatient (3 services per day) for CMHCs	\$118.69
5852	Intensive Outpatient (4 or more services per day) for CMHCs	\$164.84
5853	Partial Hospitalization (3 services per day) for CMHCs	\$118.69
5854	Partial Hospitalization (4 or more services per day) for CMHCs	\$164.84
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	\$279.97
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	\$428.39
5863	Partial Hospitalization (3 services per day) for hospital-based PHPs	\$279.97
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	\$428.39

For beneficiaries in a PHP or IOP, we propose to apply the four-service payment rate (that is, payment for PHP APCs 5854 for CMHCs and 5864 for hospitals, and IOP APCs 5852 for CMHCs and 5862 for hospitals) for days with 4 or more services. For days with three or fewer services, we propose to apply the three-service payment rate (that is, payment for PHP APCs 5853 for CMHCs and 5863 for hospitals, and IOP APCs 5851 for CMHCs and 5861 for hospitals), which is consistent with the policy we established in the CY 2024 OPPTS/ASC final rule (88 FR 81833). As we noted in the CY 2024 OPPTS/ASC final rule, we expect days with fewer than three services would be very infrequent, and we intend to monitor the provision of these days among providers and individual patients.

D. Proposed Outlier Policy for CMHCs

For CY 2025, we propose to maintain the calculations of the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed dollar threshold according to previously established policies to include PHP and IOP services. We refer readers to the CY 2024 OPPTS/ASC final rule with

comment period (88 FR 81834 through 81836) for more details on CMHC outlier policies, and to section II.G.1 of this proposed rule for our general policies for hospital outpatient outlier payments.

1. Background

As discussed in the CY 2004 OPPTS final rule with comment period (68 FR 63469 through 63470), we created a separate outlier policy specific to the estimated costs and OPPTS payments provided to CMHCs. We designated a portion of the estimated OPPTS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPTS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs.

2. CMHC Outlier Percentage

In the CY 2018 OPPTS/ASC final rule with comment period (82 FR 59267 through 59268), we described the current outlier policy for hospital outpatient payments and CMHCs. We note that we also discussed our outlier policy for CMHCs in more detail in section VIII.C of that same final rule (82 FR 59381). We set our projected target

for all OPPTS aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPTS (82 FR 59267). This same policy was also reiterated in the CY 2019 OPPTS/ASC final rule with comment period (83 FR 58996), the CY 2020 OPPTS/ASC final rule with comment period (84 FR 61350), and the CY 2021 OPPTS/ASC final rule with comment period (85 FR 86082). We are not proposing any changes to the CMHC outlier percentage policy for CY 2025.

3. Cutoff Point and Percentage Payment Amount

Also described in the CY 2018 OPPTS/ASC final rule with comment period (82 FR 59381), our policy has been to pay CMHCs for outliers if the estimated cost of the day exceeds a cutoff point. In CY 2006, we set the cutoff point for outlier payments at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year (70 FR 68551). For CY 2018, the highest CMHC PHP APC payment rate was the payment rate for CMHC PHP APC 5853. In addition, in CY 2002, the final OPPTS outlier payment percentage for costs above the multiplier threshold was set at 50 percent (66 FR 59889). In CY 2018, we

⁷⁸Click on the link labeled “CY 2025 OPPTS/ASC Notice of Proposed Rulemaking”, which can be found under the heading “Hospital Outpatient

Prospective Payment System Rulemaking” and open the claims accounting document link at the

bottom of the page, which is labeled “2025 NPRM OPPTS Claims Accounting (PDF)”.

continued to apply the same 50 percent outlier payment percentage that applies to hospitals to CMHCs and continued to use the existing cutoff point (82 FR 59381). Therefore, for CY 2018, we continued to pay for partial hospitalization services that exceeded 3.4 times the CMHC PHP APC payment rate at 50 percent of the amount of CMHC PHP APC geometric mean per diem costs over the cutoff point. This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996 through 58997), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082 through 86083), the CY 2022 OPPS/ASC final rule with comment period (86 FR 63670), the CY 2023 OPPS/ASC final rule with comment period (87 FR 72004), and the CY 2024 OPPS/ASC final rule with comment period (88 FR 81835). For CY 2024, we extended this policy to intensive outpatient services. We are not proposing any changes to the cutoff point and payment amount policy for CY 2025.

4. Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599), we established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments. We addressed vulnerabilities in the OPPS outlier payment system that led to differences between billed charges and charges included in the overall CCR, which are used to estimate cost and would apply to all hospitals and CMHCs paid under the OPPS. We initiated steps to ensure that outlier payments appropriately account for the financial risk when providing an extraordinarily costly and complex service but are only being made for services that legitimately qualify for the additional payment.

For a comprehensive description of outlier reconciliation, we refer readers to the CY 2023 OPPS/ASC and CY 2019 OPPS/ASC final rules with comment period (83 FR 58874 through 58875 and 81 FR 79678 through 79680, respectively). We are not proposing any changes to the outlier reconciliation policy for CY 2025.

5. Outlier Payment Cap

In the CY 2017 OPPS/ASC final rule with comment period, we implemented a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC will receive no more than a set percentage of its CMHC total per diem payments in outlier payments (81 FR

79692 through 79695). Our analysis of CY 2014 claims data found that CMHC outlier payments began to increase similarly to the way they had prior to CY 2004. This was due to inflated cost from three CMHCs that accounted for 98 percent of all CMHC outlier payments that year and received outlier payments that ranged from 104 percent to 713 percent of their total per diem payments. To balance our concern about disadvantaging CMHCs with our interest in protecting the benefit from excessive outlier payments and to mitigate potential inappropriate outlier billing vulnerabilities, we finalized the CMHC outlier payment cap at 8 percent of the CMHC's total per diem payments (81 FR 79694 through 79695) to limit the impact of inflated CMHC charges on outlier payments. This outlier payment cap only affects CMHCs; it does not affect other provider types (that is, hospital-based PHPs), and is in addition to and separate from the current outlier policy and reconciliation policy in effect. We are not proposing any changes to the outlier payment cap for CY 2025.

6. Fixed-Dollar Threshold

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), for the hospital outpatient outlier payment policy, we set a fixed-dollar threshold in addition to an APC multiplier threshold. Fixed-dollar thresholds are typically used to drive outlier payments for very costly items or services, such as cardiac pacemaker insertions. Currently, for CY 2024, CMHC PHP APCs (5853 or 5854) and IOP APCs (5851 or 5852) are the only APCs for which CMHCs may receive payment under the OPPS, and these APCs are for providing a defined set of services that are relatively low cost when compared to other OPPS services. Because of the relatively low cost of CMHC services that are used to comprise the structure of CMHC PHP APCs (5853 or 5854) and IOP APCs (5851 or 5852), it is not necessary to also impose a fixed-dollar threshold on CMHCs. Therefore, in the CY 2018 OPPS/ASC final rule with comment period, we did not set a fixed-dollar threshold for CMHC outlier payments (82 FR 59381). This same policy was also reiterated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083), the CY 2022 OPPS/ASC final rule with comment period (86 FR 63508), the CY 2023 OPPS/ASC final rule with comment period (87 FR 72004), and the CY 2024 OPPS/ASC final rule with comment period (88 FR

81836). We are not proposing any changes to the fixed-dollar threshold policy for CY 2025.

IX. Services That Will Be Paid Only as Inpatient Services

A. Background

Established in rulemaking as part of the initial implementation of the OPPS, the inpatient only (IPO) list identifies services for which Medicare will only make payment when the services are furnished in the inpatient hospital setting because of the invasive nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged (70 FR 68695). The IPO list was created based on the premise (rooted in the practice of medicine at that time), that Medicare should not pay for procedures furnished as outpatient services that are performed on an inpatient basis virtually all of the time for the Medicare population, for the reasons described above, because performing these procedures on an outpatient basis would not be safe or appropriate, and therefore not reasonable and necessary under Medicare rules (63 FR 47571). Services included on the IPO list were those determined to require inpatient care, such as those that are highly invasive, result in major blood loss or temporary deficits of organ systems (such as neurological impairment or respiratory insufficiency), or otherwise require intensive or extensive postoperative care (65 FR 67826). There are some services designated as inpatient only that, given their clinical intensity, would not be expected to be performed in the hospital outpatient setting. For example, we have traditionally considered certain surgically invasive procedures on the brain, heart, and abdomen, such as craniotomies, coronary-artery bypass grafting, and laparotomies, to require inpatient care (65 FR 18456). Designation of a service as inpatient only does not preclude the service from being furnished in a hospital outpatient setting but rather means that Medicare will not make payment for the service if it is furnished to a Medicare beneficiary in the hospital outpatient setting (65 FR 18443). Conversely, the fact that a procedure is not on the IPO list should not be interpreted to mean the procedure is only appropriately performed in the hospital outpatient setting (70 FR 68696).

As part of the annual update process, we have historically worked with interested parties, including

professional societies, hospitals, surgeons, hospital associations, and beneficiary advocacy groups, to evaluate the IPO list and to determine whether services should be added to or removed from the list. Interested parties are encouraged to request reviews for a particular code or group of codes; and we have asked that their requests include evidence that demonstrates that the procedure was performed on an outpatient basis in a safe and appropriate manner in a variety of different types of hospitals—including but not limited to—operative reports of actual cases, peer-reviewed medical literature, community medical standards and practice, physician comments, outcome data, and post-procedure care data (67 FR 66740).

We traditionally have used five longstanding criteria to determine whether a procedure should be removed from the IPO list. As noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74353), we assess whether a procedure or service meets these criteria to determine whether it should be removed from the IPO list and assigned to an APC group for payment under the OPPS when provided in the hospital outpatient setting. We have explained that while we only require a service to meet one criterion to be considered for removal, satisfying only one criterion does not guarantee that the service will be removed; instead, the case for removal is strengthened with the more criteria the service meets. The criteria for assessing procedures for removal from the IPO list are as follows:

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be furnished in most outpatient departments.
- The procedure is related to codes that we have already removed from the IPO list.
- A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis.
- A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has

been proposed by us for addition to the ASC covered procedures list.

In the past, we have requested that interested parties submit corresponding evidence in support of their claims that a code or group of codes meet the longstanding criteria for removal from the IPO list and are safe to perform on the Medicare population in the hospital outpatient setting—including, but not limited to case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets, and patient selection protocols. Our clinicians then thoroughly review all information submitted within the context of the established criteria and if, following this review, we determine that there is sufficient evidence to confirm that the code could be safely and appropriately performed on an outpatient basis, we assign the service to an APC and include it as a payable procedure under the OPPS (67 FR 66740). We determine the APC assignment for services removed from the IPO list by evaluating the clinical similarity and resource costs of the service compared to other services paid under the OPPS and by reviewing the Medicare Severity Diagnosis Related Groups (MS-DRG) rate for the service under the IPPS, though we note we would generally expect the cost to provide a service in the outpatient setting to be less than the cost to provide the service in the inpatient setting.

We stated in prior rulemaking that, over time, given advances in technology and surgical technique, we would continue to evaluate services to determine whether they should be removed from the IPO list. Our goal is to ensure that inpatient only designations are consistent with the current standards of practice. We have asserted in prior rulemaking that, insofar as advances in medical practice mitigate concerns about these procedures being performed on an outpatient basis, we would be prepared to remove procedures from the IPO list and provide payment for them under the OPPS (65 FR 18443). Further, CMS has at times had to reclassify codes as inpatient only services with the emergence of new information.

We refer readers to the CY 2012 OPPS/ASC final rule with comment

period (76 FR 74352 through 74353) for a full discussion of our historic policies for identifying services that are typically provided only in an inpatient setting and that, therefore, will not be paid by Medicare under the OPPS, as well as the criteria we have used to review the IPO list to determine whether any services should be removed.

B. Changes to the Inpatient Only (IPO) List

As stated above, we encourage interested parties to request reviews for a particular code or group of codes for removal from the IPO list. For the CY 2025 OPPS/ASC proposed rule, we received requests from interested parties recommending that certain services be removed from the IPO list. Following our clinical review using the five criteria listed above, we did not find sufficient evidence that any of those services meet the criteria to be removed from the IPO list for CY 2025. Therefore, we are not proposing to remove any services from the IPO list for CY 2025. Interested parties may comment on this proposed rule if they believe a service should be removed from the IPO list for CY 2025 and we will consider that recommendation and address the comment in the CY 2025 OPPS/ASC final rule.

We propose to add three services for which codes were newly created by the AMA CPT Editorial Panel for CY 2025 to the IPO list. These new services are described by CPT codes 0894T, 0895T, and 0896T, which will be effective on January 1, 2025. After clinical review of these services, we found that they require a hospital inpatient admission or stay and are not appropriate for payment under the OPPS. We propose to assign these services to status indicator “C” (Inpatient Only) for CY 2025. The CPT codes, long descriptors, and the proposed CY 2025 payment indicators are displayed in Table 69.

Table 69 below contains the proposed changes to the IPO list for CY 2025. The complete list of codes describing services that we propose to designate as inpatient only services beginning in CY 2025 is also included as Addendum E to this proposed rule, which is available via the internet on the CMS website.

**TABLE 69: PROPOSED CHANGES TO THE INPATIENT ONLY (IPO)
LIST FOR CY 2025**

CY 2025 CPT Code	CY 2025 Long Descriptor	Action	CY 2025 Proposed Status Indicator
0894T	Cannulation of the liver allograft in preparation for connection to the normothermic perfusion device and decannulation of the liver allograft following normothermic perfusion	Add to the IPO list	C
0895T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; initial 4 hours of monitoring time, including hourly physiological and laboratory assessments (eg, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary	Add to the IPO list	C
0896T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; each additional hour, including physiological and laboratory assessments (eg, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment) (List separately in addition to code for primary procedure)	Add to the IPO list	C

X. Nonrecurring Policy Changes

A. Remote Services

1. Payment for Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy When Furnished by Institutional Staff to Beneficiaries in Their Homes Through Communications Technology

Section 1861(p) of the Act establishes the benefit category for outpatient PT, SLP and OT services (expressly for PT services and, through section 1861(l)(2) of the Act, for outpatient SLP services and, through section 1861(g) of the Act, for outpatient OT services).

Section 1861(p) of the Act defines outpatient therapy services in the three disciplines as those furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient; and those furnished by a therapist not under arrangements with a provider of services, clinic, rehabilitation agency, or a public health agency. As such, section 1861(p) of the Act defines outpatient therapy services very broadly to include those furnished by providers and other institutional

settings, as well as those furnished in office settings. Section 1834(k)(3) of the Act requires payment for outpatient therapy services to be made based on the PFS (via section 1848 of the Act), for all institutional providers listed at sections 1833(a)(8) and (9) of the Act. These providers include clinics, rehabilitation agencies, public health agencies, comprehensive outpatient rehabilitation agencies (CORFs), SNFs, home health agencies (HHAs) (to individuals who are not homebound), hospitals to outpatients or hospital inpatients who are entitled to benefits under Part A but have exhausted benefits for inpatient hospital services during a spell of illness or is not so entitled to benefits under Part A, and all other CORF services.

Section 1861(qq) of the Act defines Diabetes Self-Management Training (DSMT) services and authorizes CMS to regulate Medicare DSMT outpatient services. A “certified provider” of DSMT is further defined in section 1861(qq)(2)(A) of the Act as a physician or other individual or entity designated by the Secretary who meets certain quality requirements described in section 1861(qq)(2)(B) of the Act. In CY 2000, we finalized a standalone rule titled “Medicare Program; Expanded Coverage for Outpatient Diabetes Self-Management Training and Diabetes

Outcome Measurements.” In that rule, we finalized that payment for outpatient DSMT would be made under the PFS (65 FR 83132). We further established that, in the case of payments made to other approved entities, such as hospital outpatient departments, ESRD facilities, and durable medical equipment suppliers, the payment would be equal to the amounts established under the PFS and made under the appropriate payment systems (65 FR 83142).

Section 1861(s)(2)(V) of the Act authorizes Medicare Part B coverage of medical nutrition therapy services (MNT) for certain beneficiaries who have diabetes or a renal disease. In the CY 2000 PFS final rule, we established that payment for MNT services furnished in the institutional setting, including hospital outpatient departments (HOPDs), would be made under the PFS, not under the hospital Outpatient Prospective Payment System (OPPS) (66 FR 55279). Telehealth services may be paid under the PFS only when the services are furnished to a beneficiary at an originating site (defined at 410.78), which prior to the PHE was not typically defined to include a beneficiary’s home.

During the PHE for COVID-19, outpatient therapy services, DSMT, and MNT could be furnished via a telecommunications system to

beneficiaries in their homes, and bills for these services were submitted and paid either separately or as part of a bundled payment, when either personally provided by the billing practitioner or provided by institutional staff and billed for by institutions, such as HOPDs, SNFs, and HHAs. For professionals, CMS used waiver authority provided under section 1135 of the Act to expand the range of practitioners that could serve as distant site practitioners for Medicare telehealth services as described in section 1834(m)(4)(E) of the Act and 42 CFR 410.78(b)(2), as well as to waive the originating site requirements for Medicare telehealth services described in section 1834(m)(4)(C) of the Act. This allowed for outpatient therapy services to be furnished and billed by therapists (PTs, OTs and SLPs) in private practice, and for DSMT and MNT to be furnished via Medicare telehealth to beneficiaries in urban areas, as well as rural areas, including to beneficiaries located in their homes.⁷⁹

When CMS expanded the types of practitioners who may bill for their services when furnished as Medicare telehealth services from a distant site to include therapists using section 1135 waiver authority during the PHE for COVID-19, CMS generally took the position for services furnished in HOPDs that separate waiver authority was needed to allow hospitals to bill for services furnished by hospital staff through communication technology to beneficiaries in their homes. CMS implemented the Hospitals Without Walls (HWW) policy that relied on waiver authority, which allowed hospitals to reclassify patients' homes as part of the hospital. HWW allowed hospitals to bill two different kinds of fees for services furnished remotely to patients in their homes: (1) hospital facility payment in association with professional services billed under the PFS; and (2) single payment for a limited number of practitioner services, when statute or other applicable rules only allow the hospital to bill for services personally provided by their staff. These services are either billed by hospitals or by professionals, there would not be separate facility and professional billing. This latter category includes outpatient therapy services, DSMT, and MNT. However, while CMS relied upon PHE-specific waiver authority to allow hospital billing for these services, CMS also issued guidance instructing HOPDs to bill using modifiers consistent with those

used for Medicare telehealth services. For further background, we refer readers to <https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf>. In the same referenced document, CMS also issued specific guidance for other institutional providers of therapy services to use modifier 95 (indicating a Medicare telehealth service), along with the specific bill types for outpatient therapy services furnished by their staff.

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117-328) extended many of the flexibilities that were available for Medicare telehealth services during the PHE for COVID-19 under emergency waiver authorities, including adding PTs, OTs and SLPs as distant site practitioners through the end of CY 2024. In developing post-PHE guidance, CMS initially took the position that institutions billing for services furnished remotely by their employed practitioners (where the practitioners do not bill for their own services), would end with the PHE for COVID-19 along with the HWW waivers.⁸⁰ However, after reviewing input from interested parties, as well as relevant guidance, including applicable billing instructions, we considered whether certain institutions, as the furnishing providers, can bill for certain remotely furnished services personally performed by employed practitioners.

In the CY 2024 PFS final rule, we stated that, while we considered how we might address this topic in future rulemaking, in the interests of maintaining access to outpatient therapy, DSMT, and MNT services furnished remotely by institutional staff to beneficiaries in their homes consistent with the accessibility of these services when furnished by professionals via Medicare telehealth, we finalized that we would continue to allow institutional providers to bill for these services when furnished remotely in the same manner they have during the PHE for COVID-19 through the end of CY 2024. We sought comment on current practice for these services when billed, including how and to what degree they continue to be provided remotely to beneficiaries in their homes. We sought comment as to whether these services may fall within the scope of Medicare telehealth at section 1834(m) of the Act or if there are other relevant authorities CMS might consider in future rulemaking. For further information on this comment solicitation, please see the discussion in

the CY 2024 PFS final rule (88 FR 78886 through 78888).

For DSMT specifically, we stated that the clinical staff personally delivering the service may be a type of practitioner authorized to furnish Medicare telehealth services under section 1834(m) of the Act; but we also understood that DSMT may be provided by other types of staff. Accordingly, we noted in an FAQ that we were exercising enforcement discretion in reviewing the telehealth eligibility status of the practitioner personally providing any part of a remotely furnished DSMT service, so long as the persons were otherwise qualified to provide the service until the end of 2024. For more background we refer readers to <https://www.cms.gov/files/document/frequently-asked-questionscms-waivers-flexibilities-and-end-covid19-public-health-emergency.pdf>.

While the amendments made by section 4113 of the CAA, 2023 to section 1834(m) of the Act have continued to expand the range of practitioners eligible to furnish telehealth services through CY 2024, without subsequent legislation these practitioners will no longer be able to bill for Medicare telehealth services beginning January 1, 2025.

In the CY 2024 PFS final rule, we articulated the importance of maintaining access to outpatient therapy, DSMT, and MNT services furnished remotely by institutional staff to beneficiaries in their homes consistent with the availability of these services when furnished by professionals via Medicare telehealth as part of our rationale for allowing institutional providers to bill for these services when furnished remotely in the same manner they have during the PHE for COVID-19 through the end of CY 2024.

We recognize that for the past several years, through the PHE for COVID-19 and several legislative extensions of PHE-related flexibilities for Medicare telehealth services under section 1834(m) of the Act, we have generally aligned payment policies for outpatient therapy, DSMT, and MNT services furnished remotely by hospital staff to beneficiaries in their homes with policies for Medicare telehealth services. To the extent that therapists and DSMT and MNT practitioners continue to be distant site practitioners for purposes of Medicare telehealth services, we anticipate aligning our policy for these services with policies under the PFS and continuing to make payment to the hospital for these

⁷⁹ <https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf>.

⁸⁰ <https://www.cms.gov/files/document/frequently-asked-questionscms-waivers-flexibilities-and-end-covid19-public-health-emergency.pdf>.

services when furnished by hospital staff.

2. Periodic In-Person Visits for Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes

In the CY 2023 OPPTS/ASC final rule with comment period (87 FR 72017), we finalized a requirement that payment for mental health services furnished remotely to beneficiaries in their homes using telecommunications technology may only be made if the beneficiary receives an in-person service within 6 months prior to the first time the hospital clinical staff provides the mental health services remotely; and that there must be an in-person service without the use of telecommunications technology within 12 months of each mental health service furnished remotely by the hospital clinical staff. We also finalized that we would permit exceptions to the requirement that there be an in-person service without the use of communications technology within 12 months of each remotely furnished mental health service when the hospital clinical staff member and beneficiary agree that the risks and burdens of an in-person service outweigh the benefits of it. We stated that exceptions to the in-person visit requirement should involve a clear justification documented in the beneficiary's medical record including the clinician's professional judgement that the patient is clinically stable and/or that an in-person visit has the risk of worsening the person's condition, creating undue hardship on the person or their family, or would otherwise result in disengaging with care that has been effective in managing the person's illness. We also finalized that hospitals must document that the patient has a regular source of general medical care and has the ability to obtain any needed point of care testing, including vital sign monitoring and laboratory studies. We finalized that these requirements would not go into effect until the 152nd day after the PHE for COVID-19 ends to maintain consistency with similar policies implemented for professional services paid under the PFS, and for RHCs/FQHCs (87 FR 72018).

Section 4113(d) of the CAA, 2023, extended the delay in implementing the in-person visit requirements until January 1, 2025, for both professionals billing for mental health services via Medicare telehealth and for RHCs/FQHCs furnishing remote mental health visits. In the CY 2024 OPPTS we reiterated that we believe it is important to maintain consistent requirements for these policies across payment systems; therefore, we finalized delaying the in-

person visit requirements for mental health services furnished remotely by hospital staff to beneficiaries in their homes until January 1, 2025. As such, these in-person visit requirements are currently set to take effect for services furnished on or after January 1, 2025 (88 FR 81874).

However, to the extent that these in-person visit requirements are delayed in the future for professionals billing for mental health services via Medicare telehealth, we anticipate that we would align the requirements for mental health services furnished remotely to beneficiaries in their homes through communications technology with mental health services furnished via Medicare telehealth in future rulemaking.

3. Proposed HOPD Payment for Telemedicine Evaluation and Management Services

The CPT Editorial Panel created 17 new codes describing audio/video and audio-only telemedicine E/M services. For further discussion of these 17 new codes and CMS' related proposals, please see section II.E.4.18 of the CY 2025 PFS proposed rule.

In 2014, CMS established HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) to describe the service associated with a hospital outpatient clinic visit for assessment and management of a patient. In the CY 2014 OPPTS/ASC final rule with comment period (78 FR 75042), we stated that the code is applicable for hospital use only representing any clinic visit under the OPPTS. We further stated that HCPCS code G0463 replaces evaluation and management (E/M) CPT codes 99201–99205 (new patient) and 99211–99215 (established patient), thereby eliminating the distinction between new and established clinic visits.

Given the similarities between the new telemedicine E/M code set and the office/outpatient E/M code set, we believe that the telemedicine E/M codes fall within the scope of the hospital outpatient clinic visit policy because the predecessor codes (the office/outpatient E/M code set) would be reported by hospitals using HCPCS code G0463. Under the hospital outpatient clinic visit policy, the CPT codes describing office/outpatient E/M visits are not recognized under OPPTS and instead hospitals report HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) when billing for the facility costs associated with an outpatient E/M visit. Therefore, we propose not to recognize the telemedicine E/M code set

under OPPTS. We are, however, seeking comment on the hospital resources associated with the telemedicine E/M services, particularly any resource costs that would not be included in the payment for HCPCS code G0463. We are also seeking comment, should CMS finalize separate payment for these telemedicine E/M codes under the PFS, on the resource costs that would be associated with these services for hospitals and whether we should develop separate coding to describe the resource costs associated with a telemedicine E/M service.

B. Virtual Direct Supervision of Cardiac Rehabilitation (CR), Intensive Cardiac Rehabilitation (ICR), Pulmonary Rehabilitation (PR) Services and Diagnostic Services Furnished to Hospital Outpatients

1. Background

a. Virtual Direct Supervision of CR, ICR and PR Services Furnished to Hospital Outpatients (42 CFR 410.27(a)(1)(B)(1))

In the interim final rule with comment period titled "Policy and Regulatory Provisions in Response to the COVID-19 Public Health Emergency," published on April 6, 2020 (the April 6th COVID-19 IFC) (85 FR 19230, 19246, 19286), we changed the regulation at 42 CFR 410.27(a)(1)(iv)(D)⁸¹ to provide that, during a Public Health Emergency as defined in 42 CFR 400.200, the presence of the physician for purposes of the direct supervision requirement for PR, CR, and ICR services includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. Specifically, the required direct physician supervision can be provided through virtual presence using audio/video real-time communications technology (excluding audio-only) subject to the clinical judgment of the supervising practitioner. We further amended § 410.27(a)(1)(iv)(B)⁸² in the CY 2021 OPPTS/ASC final rule with comment period to provide that this flexibility continues until the later of the end of the calendar year in which the PHE as defined in § 400.200 ends or December 31, 2021 (85 FR 86113 and 86299). In

⁸¹ In the CY 2023 OPPTS/ASC final rule with comment period, we removed § 410.27(a)(1)(iv)(D) in its entirety and added its language regarding pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services and the virtual presence of a physician through audio/video real-time communications technology during the PHE to the newly designated § 410.27(a)(1)(iv)(B)(1) (87 FR 72024).

⁸² Ibid.

the CY 2021 OPPS/ASC final rule with comment period we also clarified that this flexibility excluded the presence of the supervising practitioner via audio-only telecommunications technology (85 FR 86113).

In the CY 2023 OPPS/ASC final rule with comment period, we finalized a policy to extend the revised definition of direct supervision of CR, ICR, and PR to include the presence of the supervising practitioner through two-way, audio/video telecommunications technology until December 31, 2023 (87 FR 72019 and 72020). In the CY 2024 OPPS/ASC final rule with comment period, we finalized a policy to further revise § 410.27(a)(1)(iv)(B)(1) ⁸³ to allow for the direct supervision requirement for CR, ICR, and PR to include the virtual presence of the physician through audio-video real-time communications technology (excluding audio-only) through December 31, 2024 and to extend this policy to the nonphysician practitioners, that is NPs, PAs, and CNSs, who were eligible to supervise these services beginning in CY 2024 (88 FR 81863 through 81867).

b. Virtual Direct Supervision of Diagnostic Services Furnished to Hospital Outpatients (42 CFR 410.28(e)(2)(iii))

In the April 6th COVID-19 IFC, for consistency with the revisions made to 42 CFR 410.27(a)(1)(iv)(D) ⁸⁴ and 410.32(b)(3)(ii), we changed the regulation at 42 CFR 410.28(e) to provide that, during a Public Health Emergency as defined in 42 CFR 400.200, the presence of the physician for purposes of the direct supervision requirement for diagnostic services includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider (85 FR 19245 and 19246).

In the CY 2023 OPPS/ASC final rule with comment period, to ensure consistency with additional revisions made to 42 CFR 410.27(a)(1)(iv)(B)(1) and 410.32(b)(3)(ii) extending the end date of the flexibility allowing for the virtual supervision of the services governed by those regulations, we revised § 410.28(e) to extend the end date of the flexibility allowing for the virtual supervision of outpatient diagnostic services through audio/video real-time communications technology (excluding audio-only) from the end of the PHE to the end of the calendar year

in which the PHE ends (87 FR 72024 through 72026).

In the CY 2024 final OPPS rule with comment period, to again ensure consistency with further revisions made to 42 CFR 410.27(a)(1)(iv)(B)(1) and 410.32(b)(3)(ii) extending the end date of the flexibility allowing for the virtual supervision of the services governed by those regulations, we revised § 410.28(e) to extend the end date of the flexibility allowing for the virtual supervision of outpatient diagnostic services through audio/video real-time communications technology (excluding audio-only) through December 31, 2024 (88 FR 81866 and 81867).

2. Extension of Virtual Direct Supervision of CR, ICR, PR Services and Diagnostic Services Furnished to Hospital Outpatients Through December 31, 2025

In the CY 2025 PFS proposed rule, we propose to revise the definition of direct supervision at § 410.32(b)(3)(ii) to extend the availability of virtual direct supervision of therapeutic and diagnostic services under the PFS through December 31, 2025. As explained in that proposed rule, we propose this extension based on our concern that an immediate reversion to the pre-PHE definition of direct supervision would prohibit virtual direct supervision, which may present a barrier to access to many services that have been facilitated by our PHE-related policy over the past several years; and that physicians and other practitioners need time to reorganize their practice patterns established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology. For the complete discussion of the proposed revision to § 410.32(b)(3)(ii), we refer readers to the CY 2025 PFS proposed rule.

In addition to desiring uniformity under the PFS and OPPS in how regulations are applied to similarly situated providers, the beneficiary access and provider preparedness concerns motivating us to propose extending the availability of virtual direct supervision of therapeutic and diagnostic services under the PFS through December 31, 2025, are also concerns with respect to the direct supervision of CR, ICR, PR and diagnostic services under the OPPS. Consequently, we propose to revise § 410.27(a)(1)(iv)(B)(1) and § 410.28(e)(2)(iii) to allow for the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology

(excluding audio-only) through December 31, 2025.

C. All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

1. Background

In the CY 2000 OPPS final rule (65 FR 18434), CMS implemented the PPS for hospital outpatient services furnished to Medicare beneficiaries, as set forth in section 1833(t) of the Act. In this final rule, we noted that the OPPS applies to covered hospital outpatient services furnished by all hospitals participating in the Medicare program with a few exceptions. We identified one of these exceptions as “outpatient services provided by hospitals of the Indian Health Service (IHS).” We stated that these services would “continue to be paid under separately established rates which are published annually in the **Federal Register**” and, in the CY 2002 OPPS/ASC final rule (66 FR 59856), we finalized a revision to § 419.20 (Hospitals subject to the hospital outpatient prospective payment system) by adding paragraph (b)(4), which specifies that hospitals of the IHS are excluded from the OPPS.

In the intervening years, IHS and tribal facilities have been paid under the separately established All-Inclusive Rate (AIR). On an annual basis, the IHS calculates and publishes, in the **Federal Register**, calendar year reimbursement rates.⁸⁵ Due to the higher cost of living in Alaska, separate rates are calculated for Alaska and the lower 48 States. For CY 2024, the Medicare Outpatient per Visit Rate is \$667 for the lower 48 states and \$961 for Alaska.⁸⁶

IHS and tribal facilities have continued to expand the breadth of services that they provide to their communities. Increasingly, this has meant providing higher-cost drugs along with more complex and expensive services. While the majority of IHS and tribal facilities appear to be well served by the AIR, some IHS and tribal facilities provide specialized services for which the AIR might not adequately represent Medicare’s share of costs. If providing a drug or service costs IHS and tribal facilities thousands of dollars more than the payment they receive through the AIR, it is likely not financially feasible for these facilities to routinely provide that drug or service. For example, the cost of providing a

⁸⁵ <https://www.ihs.gov/BusinessOffice/reimbursement-rates/>.

⁸⁶ <https://www.federalregister.gov/documents/2023/12/19/2023-27815/reimbursement-rates-for-calendar-year-2024>.

⁸³ Ibid.

⁸⁴ Ibid.

frequently used cancer drug such as Opdualag (HCPCS code 00003–7125), which has a per day cost of \$28,975, greatly exceeds the \$667 payment a IHS or tribal facility receives through the AIR. We are concerned that, if payments under the AIR are inadequate for high-cost drugs, this could potentially threaten the viability of the few IHS and tribal hospital outpatient specialty programs currently in operation and provide less incentive to IHS hospitals and tribal facilities not currently offering specialty services to begin doing so. This constitutes a significant equity and beneficiary access concern if IHS and tribal hospitals are not able to provide oncology services or other services that require high-cost drugs because the hospital would always receive payment for those services that is far below what it would have to pay to acquire those high-cost drugs.

Consequently, in the CY 2024 OPPI/ASC proposed rule, we sought comment on whether Medicare should pay separately for certain high-cost drugs provided by IHS and tribal facilities and, if so, how we might do so. Among other topics, we specifically requested input on which drugs it would be appropriate to pay separately for (high-cost oncology drugs or all high-cost drugs), how we might define high-cost drugs (for example, a list of named drugs versus any drugs exceeding a certain cost threshold), and what the appropriate payment amount for the separately paid drugs should be (ASP plus 6 percent, which is what hospitals are generally paid under the OPPI for separately payable drugs, or the Federal Supply Schedule (FSS), which is where IHS and tribal hospitals acquire the majority of their drugs at rates significantly lower than ASP plus 6 percent). For a full discussion of the comment solicitation, we refer readers to the CY 2024 OPPI/ASC proposed rule (88 FR 49741 through 49742).

Commenters, including a tribal facility, the CMS Tribal Technical Advisory Group (TTAG), organizations representing tribal healthcare providers, pharmaceutical companies, and other interested parties, expressed universal support for establishing a policy that would allow IHS and tribal healthcare facilities to receive separate payment outside of the AIR for high-cost drugs. The preferred approach of those commenters who provided input on how to define a high-cost drug eligible for separate payment was to treat the amount of the Medicare Outpatient per Visit Rate for the lower 48 States' AIR (hereinafter referred to as "the lower 48 AIR") as a payment threshold. Under this approach, if the cost of a particular

drug is less than or equal to the lower 48 AIR, the provider would not receive a separate payment for the drug and if the cost of the drug was more than the lower 48 AIR, then the provider would receive a separate payment for the drug. Commenters noted that this payment approach is currently being used for all drugs (oncology and otherwise) receiving payment through Arizona Medicaid (AHCCCS) for IHS and tribal facilities located in Arizona. With respect to the payment amount, several commenters requested that separately payable drugs furnished by IHS and tribal facilities be paid at a rate of ASP plus 6 percent rather than the FSS rate. These commenters argued that the IHS is chronically underfunded and that paying ASP plus 6 percent for high-cost drugs could help with remedying those funding issues. For a full discussion of the comments we received as a result of our comment solicitation and our responses to those comments, we refer readers to the CY 2024 OPPI/ASC final rule with comment period (88 FR 81896 through 81897).

2. Proposed AIR Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

In light of the equity and beneficiary access concerns that prompted our CY 2024 comment solicitation and the input received in response to that solicitation, we propose, starting January 1, 2025, to separately pay IHS and tribal hospitals⁸⁷ for high-cost drugs furnished in hospital outpatient departments through an add-on payment in addition to the AIR using the authority under which the annual AIR is calculated.⁸⁸ We emphasize the amount of this proposed add-on payment would *not* be carved out of the annual AIR payment amount calculation. In other words, we propose that the add-on payment would have no effect on the calculation of the annual AIR payment amount. We seek comment on separately paying IHS and tribal hospitals for high-cost drugs furnished in hospital outpatient departments through the establishment of an add-on payment to the AIR using the authority under which the annual AIR is calculated.

We propose that the drugs to which the add-on payment would apply would

⁸⁷ IHS Critical Access Hospitals (CAHs) are paid for covered outpatient services based on 101 percent of an all-inclusive facility specific rate rather than the national AIR rate. Consequently, they are excluded from the proposed separate payment policy.

⁸⁸ Sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248), Public Law 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*).

not be limited to high-cost oncology drugs but would include all high-cost drugs furnished in hospital outpatient departments of IHS and tribal hospitals to the extent those drugs are covered under Medicare Part B and would be paid for under the OPPI if furnished by a hospital paid under that system. In determining which drugs would be eligible for the add-on payment, we considered limiting the add-on payment to high-cost oncology drugs. However, we determined that it would be appropriate to apply the add-on payment to all high-cost drugs for several reasons. First, the same equity and access concerns that support utilizing an add-on payment for oncology drugs also support utilizing an add-on for high-cost drugs used in other care specialties. Although this issue arose in the context of removing barriers to beneficiaries' access to high-cost oncology drugs, there are presumably similar barriers to other specialties that use high-cost drugs that would be addressed through a broader application of the add-on payment. Second, applying the add-on payment to all high-cost drugs would eliminate the possibility of unintentionally excluding an oncology drug from separate payment due to the inherent challenge of defining a class of drugs. Third, the proposal would parallel how drugs are being paid for under Arizona Medicaid (AHCCCS) for IHS and tribal facilities. We seek comment on applying the add-on payment to all high-cost drugs furnished in hospital outpatient departments of IHS and tribal hospitals to the extent those drugs are covered under Medicare Part B and would be paid for under the OPPI if furnished by a hospital paid under that system.

As to what constitutes a high-cost drug, we propose to define high-cost drugs for the purpose of this policy as all drugs covered under Medicare Part B and for which payment would otherwise be made under the OPPI whose per day cost exceeds two times the lower 48 AIR (\$1,334 in CY 2024). We propose a threshold greater than the lower 48 AIR to account for the fact that IHS and tribal hospitals would continue to receive the lower 48 AIR payment, in addition to the add-on payment, for encounters that include a high-cost drug. While it is true that under the Arizona Medicaid program, IHS and tribal hospitals are paid the lower 48 AIR payment in addition to an add-on payment for drugs whose costs exceed the lower 48 AIR, we are concerned that providing separate payment for drugs whose costs only slightly exceed the lower 48 AIR could result in excessive

payment for those drugs. For example, for a drug that costs \$700, using the CY 2024 lower 48 AIR as the threshold for our proposal would result in a payment of at least \$1,367 (the \$667 AIR encounter payment plus an add-on payment for the high-cost drug as calculated under the payment methodology we propose later in this section) for the provision of a drug whose cost exceeds the lower 48 AIR by only \$33.00. Such an outcome would be at odds with the objective of the proposed policy, which is to provide adequate payment for drugs that are high cost in relation to the lower 48 AIR. Consequently, we propose two times the lower 48 AIR as the threshold triggering the add-on payment because this amount would ensure that the add-on payment would apply only to drugs whose costs significantly exceed the lower 48 AIR. This cost-multiplier approach is also consistent with how CMS has implemented thresholds relating to payments to hospitals under other payment systems. For example, the OPPS outlier policy⁸⁹ requires that the cost of a service exceed 1.75 times the payment amount for the service to qualify for an additional payment. Similarly, the OPPS two-times rule requires that the highest calculated cost of an individual procedure categorized to any given Ambulatory Payment Classification (APC) not exceed two times the calculated cost of the lowest cost procedure categorized to that same APC.

An alternative to our proposal to set the threshold at two times the lower 48 AIR would be to set the threshold at the lower 48 AIR despite our previously described concerns. Another alternative would be to set the threshold at 1.75 times the lower 48 AIR (\$1,167.25 in CY 2024) to align it with the multiplier used to calculate the threshold triggering outlier payments under the OPPS. We seek comment on the alternatives of using the lower 48 AIR or 1.75 times the lower 48 AIR as the threshold amount for triggering the add-on payment for high-cost drugs.

We also seek comment on whether we should adopt an exception to whichever AIR-based threshold we adopt that would parallel the drug packaging

threshold exception for biosimilars⁹⁰ under the OPPS. Under the OPPS, if a drug's per-day cost is less than or equal to the drug packaging threshold, then payment for the drug is packaged. Conversely, if a drug's per-day cost exceeds the drug packaging threshold, then it is paid for separately. For a more detailed discussion of the drug packaging threshold, we refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 81776 through 81778). In CY 2024, we established an exception to this threshold for biosimilars when the biosimilar's per-day cost does not exceed the threshold, but its reference product's per-day cost does. In other words, if the biosimilar's reference product is paid separately (because its per-day cost exceeds the threshold), then we also pay separately for the biosimilar even if its per-day cost does not exceed the threshold. This exception was based on our concern that packaging biosimilars when the reference product or other marketed biosimilars are separately paid might create financial incentives for providers to select more expensive, but clinically similar, products. For a more detailed discussion of the exception for biosimilars to the drug packaging threshold, we refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 81783 through 81786). Because we propose to use a threshold to trigger application of the add-on payment for high-cost drugs to IHS and tribal hospitals, we have the same concerns about financial incentives that motivated us to establish the exception for biosimilars to the drug packaging threshold. Consequently, we seek comment on whether we should pay the add-on payment to IHS and tribal hospitals for biosimilars whose per-day costs do not exceed the threshold but whose reference products do exceed the threshold.

We also propose that the amount of the add-on payment for a high-cost drug would be the average sales price (ASP) for the drug with no additional payment (*i.e.*, ASP). This payment amount would be consistent with what hospitals receive as payment for most drugs under the OPPS (ASP plus 6 percent) but would exclude the 6 percent additional payment in recognition of the fact that IHS and tribal facilities, unlike hospitals paid under the OPPS, primarily obtain their drugs through the FSS, whose rates are significantly lower than ASP. This approach is also consistent with our

existing policies of paying ASP without any additional payment for certain Opioid Treatment Program drugs under 42 CFR 410.67(d)(2)(i)(A) and (B). In the event ASP pricing information is not available for a particular drug, we propose to pay the Wholesale Acquisition Cost (WAC) plus 0 percent. If WAC pricing information is not available, we propose to pay 89.6 percent of Average Wholesale Price (AWP).

We seek comment on whether we should instead pay ASP plus 6 percent. If we were to adopt this alternative policy and pricing information is not available for a particular drug, we would pay WAC plus 6 percent and if WAC pricing information is not available, we would pay 95 percent of AWP. We seek comment on our proposal to pay an add-on of ASP plus 0 percent in addition to the AIR for drugs administered by IHS and tribal facilities with costs that exceed two times the lower 48 AIR. We also seek comment on our proposed pricing hierarchy for drugs for which ASP pricing information is not available.

To implement this policy, we propose that, starting with IHS's annual announcement in the **Federal Register** in December 2024 of the lower 48 AIR amount for CY 2025, we would multiply the lower 48 AIR amount by two and then compare the result to the estimated per day costs of all drugs covered under Part B for which payment would otherwise be made under the OPPS. To determine the calculated per day cost for each drug and biological HCPCS code, we propose to follow a methodology similar to our longstanding methodology used to calculate the per day cost of drugs and biologicals for OPPS payment purposes as discussed in section V.B.1.b of this proposed rule. Specifically, to calculate the per day cost, we propose to use an estimated payment rate based on the ASP methodology payment rate, which for purposes of this proposal is generally ASP plus 0 percent (which is the payment rate we propose for separately payable IHS drugs and biologicals) for CY 2025 to calculate the CY 2025 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2023 to determine the proposed rule per day cost. For drugs and biologicals that did not have either an ASP-based payment rate or a payment rate based on WAC, we used mean unit cost of the items derived from the CY 2023 hospital claims data to determine their per day cost.

A list of drugs whose costs exceeds two times the lower 48 AIR would be

⁸⁹ The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. Outlier payments are provided on a service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by 1.75) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain dollar amount).

⁹⁰ A biosimilar is a biologic medication. It is highly similar to a biologic medication already approved by FDA—the original biologic (also called the reference product).

generated and communicated to IHS and tribal hospitals prior to January 1, 2025. During CY 2025, IHS and tribal hospitals would submit claims for drugs included on this list. The list of drugs would be updated on a quarterly basis using existing drug compendia and CMS ASP quarterly reporting only to account for newly introduced drugs. The payment rates for drugs on the list would be updated quarterly as well based on changes in drug prices. We would then repeat this process on an annual basis each December when the lower 48 AIR amount for the following calendar year is announced by IHS. For example, had our proposed policy been in place for CY 2024, the drugs for which the add-on payment would have been made (drugs with a per day cost exceeding two times the CY 2024 lower 48 AIR) are those listed in Addendum Q. We seek comment on this proposed implementation plan.

Finally, we propose to implement this policy on a permanent basis but may revisit it in the future if we have any concerns about its impact once it has been implemented.

D. Request for Information—Paying All IHS and Tribally Operated Clinics the IHS Medicare Outpatient All Inclusive Rate

CMS established a Tribal Technical Advisory Group (TTAG) in 2004 to provide advice and input to CMS on policy and program issues impacting AI/AN populations served by CMS programs. Although not a substitute for formal consultation with tribal leaders, the TTAG enhances the government-to-government relationship between HHS and federally recognized tribes and improves understanding between CMS and tribes. The TTAG has subject specific subcommittees that meet on a regular basis in order to be more effective and perform in-depth analysis of Medicare, Medicaid, CHIP, and Health Insurance Marketplace⁹¹ policies that have tribal implications. The TTAG is composed of 17 representatives. It has historically included an elected tribal leader or an appointed representative from each of the 12 geographic areas of the IHS delivery system and a representative from each of the national Indian organizations headquartered in Washington, DC—the National Indian Health Board, the National Congress of American Indians, and the Tribal Self-Governance Advisory Group. Section 5006(e)(1) of the American Recovery

and Reinvestment Act of 2009, which became effective July 1, 2009, mandates that TTAG shall be maintained within CMS and added two new representatives: a representative from a national urban Indian health organization; and a representative from the IHS.

In June 2020, the TTAG requested that CMS amend its Medicare regulations to make all IHS and tribally-operated outpatient facilities eligible for Medicare payment at the IHS Medicare outpatient per visit rate/AIR. The TTAG explained that outpatient clinics, which are otherwise similar to grandfathered tribal FQHCs, are paid at different rates depending upon whether they meet the requirements as a provider-based facility, a grandfathered tribal FQHC, a non-grandfathered tribal FQHC, or none of the above. TTAG's position is that the rates vary based on Medicare regulatory definitions, rather than the actual costs of the outpatient clinic.⁹² There are varying payment differentials among Medicare enrolled providers and suppliers under the authorities of the SSA. For example, ASCs are paid differently than HOPDs; which are paid differently depending on whether they are located in a critical access hospital.

In the CY 2022 PFS proposed rule (86 FR 39240), we acknowledged that the TTAG is concerned about ensuring appropriate Medicare payments for similar services and is also concerned about the impact on tribal Medicare beneficiaries and on ensuring equitable access to healthcare. We take these concerns seriously but noted in the CY 2022 PFS proposed rule that we had insufficient information to evaluate the costs and benefits of potential changes to these policies. Therefore, we solicited comments on the TTAG's request for CMS to amend its Medicare regulations to make all IHS- and tribally operated outpatient facilities/clinics eligible for payment at the Medicare outpatient per visit rate/AIR, regardless of whether they were owned, operated, or leased by IHS. In response to the solicitation, we did not receive specific information on costs or specific types of clinics; however, in the CY 2022 PFS final rule (86 FR 65211 through 65214), we stated we would like to continue these discussions to evaluate the impact of the commenters' proposed changes to the current Medicare payment policies and will consider these recommendations for future rulemaking. Thus, to continue these discussions, we would like to

request this information again in this proposed rule.

Beginning in the Fall of 2023, CMS began participating in a workgroup related to the TTAG's Medicare priority to make the IHS Medicare outpatient AIR available to all IHS and tribally operated outpatient facilities that request it. Although we have received some information through the workgroup, we would like to request information consistent with our comment solicitation in the CY 2022 PFS proposed rule.

We seek information on the kinds of and number of facilities or clinics that the Medicare outpatient IHS AIR could apply to; that is, it is unclear whether TTAG anticipates that these facilities enroll in Medicare as FQHCs going forward, or whether they are referring to FQHCs that are currently paid under the FQHC PPS. Moreover, we request information on whether the facilities in question are freestanding or provider-based. We would like commenters to confirm or clarify whether the clinics are physician offices, or whether they are recommending establishment of a new provider type. We seek information regarding the relative operating costs of tribally operated outpatient clinics, as well as feedback and supporting evidence to address whether or why payment set at the IHS AIR would be more appropriate than payment rates under the FQHC PPS, the physician fee schedule, or other some other Medicare payment system. Further, we seek comment on how the Medicare outpatient AIR, which is based upon a limited number of hospital cost reports, relates to costs in tribal clinics and the kinds of services that the clinics furnish. Finally, we seek comment on the concerns that the AI/AN community may have regarding access to or inequity of care in situations where a payment differential exists.

We have information on historically excepted FQHCs, the outpatient provider-based clinics to the hospital, and some general information about the composition of IHS and tribal facilities and clinics. However, there are still gaps in the data and therefore we are soliciting answers to the following questions: If the clinic or facilities in question are not enrolled in Medicare as an FQHC or provider-based to a hospital, are they physician practices? How are these facilities organized and related?

Because paying the Medicare outpatient AIR to additional IHS and tribally operated facilities that are currently paid under another Medicare payment methodology or not yet enrolled in Medicare as all would

⁹¹ Health Insurance Marketplace[®] is a registered service mark of the U.S. Department of Health & Human Services.

⁹² <https://www.nihb.org/tribalhealthreform/wp-content/uploads/2020/06/TTAG-letter-to-CMS-requesting-IHS-rate-for-all-tribal-clinics-06.10.2020.pdf>.

potentially increase expenditures, we also solicit information on how tribally operated facilities participate in Medicare currently, which would help us to estimate the impacts of such a policy change.

E. Coverage Changes for Colorectal Cancer (CRC) Screening Services

Medicare coverage for colorectal cancer (CRC) screening tests under Part B is described in statutes (sections 1861(s)(2)(R), 1861(pp), 1862(a)(1)(H) and 1834(d) of the Social Security Act (the Act)), regulation (42 CFR 410.37), and a National Coverage Determination (NCD) (Section 210.3 of the Medicare National Coverage Determinations Manual). Section 1861(pp)(1)(D) of the Act includes in its definition of colorectal cancer screening test “[s]uch other tests or procedures, and modifications to the tests and procedures described under this subsection, with such frequency and payment limits as the Secretary determines appropriate, in consultation with appropriate organizations.”

42 CFR 410.37 lists and defines the tests and procedures covered by Medicare as colorectal cancer screening

tests. Specifically, the following tests and procedures furnished to an individual for the purpose of early detection of colorectal cancer are covered by Medicare:

- Screening fecal-occult blood tests.
- Screening flexible sigmoidoscopies.
- Screening colonoscopies, including anesthesia furnished in conjunction with the service.
- Screening barium enemas.
- Other tests or procedures established by a national coverage determination, and modifications to tests under this paragraph, with such frequency and payment limits as CMS determines appropriate, in consultation with appropriate organizations.

In recent years we have received recommendations from the public to remove Medicare coverage for the barium enema test since the test no longer meets modern clinical standards and is no longer recommended in clinical guidelines. As a replacement to the barium enema test, organizations have suggested the use of CT colonography, which is a more effective test for colorectal cancer screening. For a more extensive discussion on the background and proposal to revise the

Medicare coverage for colorectal cancer screening services, we refer readers to the CY 2025 Physician Fee Schedule (PFS) proposed rule.

For CY 2025, based on public input and consultation with specialty societies, and as discussed in the CY 2025 PFS proposed rule, we propose to exercise our authority under section 1861(pp)(1)(D) of the Act to update and expand coverage for CRC screening. As discussed in the CY 2025 PFS proposed rule, we propose to make the following revisions to § 410.37:

- Remove coverage for the barium enema procedure.
- Add coverage for the computed tomography colonography (CTC) procedure.
- Expand the existing definition of a “complete colorectal cancer screening” to include a follow-on screening colonoscopy after a Medicare covered blood-based biomarker CRC screening test (described and authorized in NCD 210.3).

The above screening tests are currently described by existing HCPCS codes. These HCPCS codes are listed in Table 70 along with their long descriptors.

TABLE 70: SCREENING HCPCS CODES FOR BARIUM ENEMA, COMPUTED TOMOGRAPHY COLONOGRAPHY, AND BLOOD-BASED BIOMARKER TESTS

Colorectal Cancer (CRC) Screening Test	HCPCS Code	Long Descriptor
Barium enema	G0106	Colorectal cancer screening; alternative to g0104, screening sigmoidoscopy, barium enema
Barium enema	G0120	Colorectal cancer screening; alternative to g0105, screening colonoscopy, barium enema
Computed tomography colonography (CTC)/Virtual colonoscopy	74263	Computed tomographic (ct) colonography, screening, including image postprocessing
Blood-based biomarker	G0327	Colorectal cancer screening; blood-based biomarker

Based on the proposed coverage changes for CRC screening, we propose to make the following changes under the OPPS for CY 2025:

- HCPCS codes G0106 and G0120 (screening barium enema): These codes were established by CMS effective January 1, 1998, to implement Medicare coverage for barium enema as a test for colorectal cancer screening. Since we

propose to remove Medicare coverage for barium enema effective January 1, 2025, and we no longer need to keep these codes active, we propose to delete them on December 31, 2024. Therefore, we are revising the status indicator for the HCPCS codes from status indicator “S” (Procedure or Service, Not Discounted When Multiple. Paid under OPPS; separate APC payment.) to “D”

(Discontinued code) to indicate that HCPCS codes G0106 and G0120 will be deleted on December 31, 2024. In addition to the deletion of these codes, we also propose to delete HCPCS code G0122 (Colorectal cancer screening; barium enema), which is already non-covered by Medicare, on December 31, 2024.

- CPT code 74263 (screening computed tomography colonography (CTC)/virtual colonoscopy): We are reassigning this code from status indicator “E1” (not covered/not payable) to status indicator “S” and APC 5522 (Level 2 Imaging Without Contrast) to indicate that the code is separately payable. Based on our review, the time and resources associated with performing a screening virtual colonoscopy is similar to a diagnostic virtual colonoscopy, which is described by CPT code 74261 (Computed tomographic (ct) colonography, diagnostic, including image postprocessing; without contrast material). Consequently, the proposed APC assignment for CPT code 74263 is

based on its clinical and resource homogeneity to CPT code 74261, which is assigned to APC 5522.

- HCPCS code G0327 (screening blood-based biomarker): This HCPCS code is currently assigned to status indicator “A” to indicate that the test is paid separately under a different Medicare payment system than the OPSS. Since HCPCS G0327 is currently separately payable under the Clinical Laboratory Fee Schedule (CLFS), we are not proposing to revise the status indicator. Specifically, with the expanded coverage to include blood-based biomarker as a screening test to detect colorectal cancer, we propose to continue to assign HCPCS code G0327 to status indicator “A” for CY 2025.

In summary, based on the proposed coverage changes for colorectal cancer screening services, we propose to revise the OPSS status indicator for certain HCPCS codes for CY 2025. Table 71 shows the long descriptors, current CY 2024 OPSS status indicators, and proposed CY 2025 OPSS status indicators for HCPCS codes G0106, G0120, G0122, 74263, and G0327. The proposed CY 2025 OPSS payment rates, where applicable, for these HCPCS codes can be found in Addendum B to this proposed rule. In addition, for the complete list of the proposed status indicators and their definitions, refer to Addendum D1 of this proposed rule.

TABLE 71: PROPOSED CY 2025 OPSS STATUS INDICATOR AND APC ASSIGNMENT FOR HCPCS CODES G0106, G0120, G0122, 74263, AND G0327

HCPCS Code	Long Descriptor	CY 2024 OPSS SI	CY 2024 OPSS APC	Proposed CY 2025 OPSS SI	Proposed CY 2025 OPSS APC
G0106	Colorectal cancer screening; alternative to g0104, screening sigmoidoscopy, barium enema	S	5571	D	
G0120	Colorectal cancer screening; alternative to g0105, screening colonoscopy, barium enema	S	5572	D	
G0122	Colorectal cancer screening; barium enema (Non-covered)	E1		D	
74263	Computed tomographic (ct) colonography, screening, including image postprocessing	E1		S	5522
G0327	Colorectal cancer screening; blood-based biomarker	A		A	

F. Request for Comment on Payment Adjustments Under the IPPS and OPSS for Domestic Personal Protective Equipment

1. General Background

As discussed in the FY 2023 IPPS/LTCH PPS and CY 2023 OPSS/ASC rules, President Biden issued Executive Order (E.O.) 13987 “Organizing and Mobilizing the United States Government To Provide a Unified and Effective Response To Combat COVID–19 and To Provide United States Leadership on Global Health and Security” on January 20, 2021 (86 FR 7019). This order launched a whole-of-government effort to combat the

coronavirus disease 2019 (COVID–19) and prepare for future biological and pandemic threats. As the COVID–19 pandemic eased, work has continued to prepare for future pandemics. As the COVID–19 pandemic demonstrated, sufficient availability of personal protective equipment (PPE) in the health care sector is a critical component of preparedness.

The CY 2023 OPSS/ASC final rule implemented payment adjustments under the OPSS and IPPS to support a resilient and reliable supply of surgical N95 respirators—a specific type of filtering facepiece respirator that is a subset of N95 masks used in some clinical settings under conditions

requiring respiratory protection from airborne pathogens and splash protection from exposure to fluids. Early on in the COVID–19 pandemic, “just-in-time” supply chains, minimal stockpiling, and overreliance on foreign imports left U.S. hospitals unable to obtain enough N95 respirators to protect health care workers. Prices for surgical N95s soared from an estimated \$0.25–\$0.40/unit to \$5.75/unit (and up to \$12.00/unit in some reported cases). Unable to obtain surgical N95s regulated by NIOSH, hospitals had to turn to KN95s—a Chinese standard respirator—and other non-NIOSH-approved respirators under Emergency Use Authorization (EUA). Skyrocketing

demand during the COVID-19 pandemic also raised counterfeit respirator concerns.

Currently available payment adjustments offset the marginal costs that hospitals face in procuring domestically made NIOSH-approved and FDA-certified surgical N95 respirators. These marginal costs are due to higher per-unit acquisition prices that stem from higher costs of inputs and labor in the U.S., as compared to international suppliers, where many N95 and other respirators are made, as well as a demonstrated record of more consistent high quality for domestically made products.⁹³ These payment adjustments offset the additional marginal costs of hospitals that purchase domestically made NIOSH-approved surgical N95 respirators to help sustain demand for—and thus domestic production of—high-quality domestically made respirators in order to ensure quality PPE is available to health care personnel when needed.

The policy goal to maintain a baseline domestic production capacity of high-quality PPE in order to ensure that quality PPE is readily available to health care personnel when needed is emphasized in the National Strategy for a Resilient Public Health Supply Chain, published in July 2021 as directed by President Biden's Executive Order 14001 on "A Sustainable Public Health Supply Chain." The U.S. Government has committed to purchase wholly domestically-made PPE in line with section 70953 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58).

2. Potential Modifications to Payment Adjustments for Domestic NIOSH-Approved Surgical N95 Respirators

Although the payment adjustments for domestic NIOSH-approved surgical N95 respirators under the OPSS and IPPS have applied to cost reporting periods beginning on or after January 1, 2023, use of the payment adjustments has been limited. Furthermore, market data suggests that a majority of surgical N95 respirators purchased by hospitals are not wholly domestically made. In the CY 2023 OPSS/ASC final rule, we stated that as we gain more experience with this policy and the data collected, we may also consider modifications to the reasonable cost-based payment approach we were finalizing. HHS has conducted stakeholder outreach to better understand barriers to awareness and uptake and seek feedback on potential modifications that could

increase effectiveness, and continues to engage hospitals and other manufacturers on these payment adjustments. We are interested in feedback and comments on potential modifications to the payment adjustment in order to reduce reporting burden and achieve the policy goal to maintain a baseline domestic production capacity of PPE in order to ensure that quality PPE is readily available to health care personnel when needed.

Payment adjustment methodology: In the CY 2023 OPSS/ASC final rule, we finalized to initially base the payment adjustments on the IPPS and OPSS shares of the estimated difference in the reasonable costs. We created a new supplemental cost reporting form to enable calculation of a hospital-specific unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators. We noted that, based on available data, our best estimate of the difference in the average unit cost of domestic and non-domestic NIOSH-approved surgical N95 respirators was \$0.20. In the CY 2023 OPSS/ASC final rule, we also noted that MedPAC, while not supportive of the proposed payment adjustments, stated that CMS should set the unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators at a national level (rather than on a hospital-by-hospital basis). MedPAC believed this would reduce the administrative burden on hospitals, encourage hospitals to purchase the most economical domestically made product, and reduce the ability of hospitals to increase their payments by artificially inflating reported N95 costs. We solicit comment on the following questions:

- Should we consider modifying the payment adjustment methodology calculation to provide a national standard unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators (rather than on a hospital-by-hospital basis)?
- If so, how should we calculate that standard unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators, and what should the current unit cost differential be?
- If we modified the payment adjustment methodology calculation to provide a national standard unit cost differential, would it be appropriate to calculate the payment adjustment by multiplying the unit cost differential by the total quantity of domestic NIOSH-approved surgical N95 respirators used by the hospital, and then multiplying by

the Medicare Part A hospital inpatient cost share (to calculate the IPPS payment adjustment) or the Medicare Part B hospital outpatient cost share (to calculate the OPSS payment adjustment)?

- Do hospitals need additional support to purchase domestic-made surgical N95 respirators as opposed to non-domestic surgical N95 respirators? If so, how much support is needed, and in what form?

Payment adjustment eligibility: In the CY 2023 OPSS/ASC final rule, we stated that we recognize that a hospital cannot fully independently determine if a NIOSH-approved surgical N95 respirator it purchases is domestic under our definition. Therefore, we finalized that a hospital may rely on a written statement from the manufacturer stating that the NIOSH-approved surgical N95 respirator the hospital purchased is domestic under our definition. We solicit comment on the following questions:

- Do hospitals have sufficient access to information on which surgical N95 models on the market are wholly domestically made?
- Have hospitals been able to obtain written statements from manufacturers stating that the NIOSH-approved surgical N95 respirator the hospital purchased is domestic under our definition?
- Would a publicly available list of products eligible for the payment adjustment (for example, if provided by CMS, NIOSH, or another government entity) make it easier for hospitals to locate products eligible for the payment adjustment?
- If we modified the payment adjustment such that hospitals that attested to purchasing wholly domestically made surgical N95 models from such a list did not need to obtain a written statement from the manufacturer, would hospitals more easily be able to utilize the payment adjustment?

Types of N95 respirators: In the CY 2023 OPSS/ASC proposed rule, for purposes of the payment adjustment policy, we proposed to categorize all NIOSH-approved surgical N95 respirators purchased by hospitals into two categories: (1) Domestic NIOSH-approved surgical N95 respirators; and (2) Non-domestic NIOSH-approved surgical N95 respirators. Feedback from external stakeholders has suggested that it is a challenge that the payment adjustments are limited to surgical N95 respirators, given some hospitals also procure non-surgical N95 respirators. Both surgical N95 respirators and non-surgical N95 respirators are primarily

⁹³ <https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html>.

used to protect the wearer from inhaling airborne particles, including infectious agents like bacteria and viruses. They are highly efficient at filtering out at least 95% of airborne particles and are commonly used by healthcare workers during procedures that may generate aerosols, such as intubation or suctioning, or when caring for patients with infectious respiratory diseases like tuberculosis or coronavirus. Both types of N95 respirators serve as frontline defense for medical professionals. They are crucial for preventing the transmission of diseases within healthcare settings and safeguarding the health and well-being of both healthcare workers and patients. Surgical N95 respirators have the added protection against fluid penetration, and may be most useful in specialized health care settings (e.g., ICU, Emergency Department, Operating Room) where the risk of fluid exposure may be greater. Additionally, during the COVID-19 pandemic, both types of N95 respirators saw issues around lack of availability and risk of counterfeit outlined in the CY 2023 OPPS/ASC final rule—issues which could compromise the safety of health care personnel and patients. We solicit comment on the following questions:

- Do hospitals procure both surgical N95 respirators and non-surgical N95 respirators?
- Has the payment adjustment's current focus on surgical N95 respirators inhibited uptake of the payment adjustments?
- Are the quality differentials between domestic and non-domestic surgical respirators also applicable to non-surgical respirators, and is a sustained and reliable source of domestically made non-surgical N95 respirators important for strengthening hospitals' ability to protect the health and safety of personnel and patients in a public health emergency?
- Should CMS consider expanding the payment adjustments to include all domestic NIOSH-approved N95 respirators—i.e., non-surgical and surgical N95 respirators?
- If we expanded the payment adjustments to include all domestic NIOSH-approved N95 respirators, and if we modified the payment adjustment methodology calculation to provide a national standard unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators (rather than on a hospital-by-hospital basis), would the unit cost differential for non-surgical N95 respirators be different than the one for surgical N95 respirators?

3. Potential Modifications To Include Nitrile Gloves

In addition to N95 respirators, nitrile gloves are another type of PPE for which it is particularly crucial to maintain a resilient, quality supply. Nitrile gloves protect health care workers and patients from the spread of micro-organisms that may potentially cause infection or illness during medical procedures and examination. They create a barrier between germs and the wearer's hands, and are generally worn anytime a health care worker touches blood, bodily fluids, bodily tissues, mucous membranes, or broken skin. They are disposable, enabling the use of new gloves for each patient. A resilient healthcare system needs readily available, high-quality nitrile gloves to respond efficiently and effectively to public health emergencies. During the COVID-19 pandemic, supply chain breakdowns limited the supply of quality nitrile gloves, putting U.S. health care workers and patients at risk. As with N95 respirators, non-domestic-sourced gloves during the COVID-19 pandemic saw counterfeit and quality challenges. The receipt of non-U.S.-made counterfeit or already-used gloves put the safety of health care workers and patients at risk.⁹⁴ Prior to 2020, over 95 percent of nitrile gloves sold in the U.S. came from other countries. As the pandemic escalated in 2020, U.S. demand for gloves outstripped available supply, leading to shortages. Around the same time, supply was also limited by coronavirus-related lockdowns in other countries that decreased production capacity, and by export restrictions of PPE. Further adding to supply pressures, forced labor violations by subsidiaries of a major glove producer led U.S. Customs and Border Protection (CBP) to issue a Withhold and Release Order, resulting in seizure of all listed products, including nitrile gloves, at CBP inspections. During the initial months of the pandemic, the cost of gloves increased, rising 18 percent from July to August 2020 (to \$0.03 per glove) and then an additional 20 percent from November to December 2020 (to \$0.05 per glove).⁹⁶

During the pandemic, the U.S. government has invested in domestic glove manufacturing capabilities. U.S. glove-manufacturing projects received approximately \$290 million in public

funding as part of a broader \$1.5-billion investment to support domestic glove manufacturing. These investments have resulted in an increase of 3.91 billion in annual production capacity for domestically manufactured nitrile gloves. The U.S. government also invested in manufacturing capacity for nitrile glove inputs such as nitrile butadiene rubber, and this manufacturing capacity is expected to become available in 2026.

However, since the pandemic began, some U.S. factories have been forced to consolidate operations or exit the industry. Further, non-U.S. nitrile glove producers have deployed cost-cutting tactics such as using lower-grade raw materials, prompting some purchasers to seek other sources out of concern for quality.⁹⁷ Producers of these lower quality products began selling gloves for the price of \$0.02 each, rapidly increasing U.S. market share, going from 13% of U.S. market share in July 2020 to 19 percent in February 2021. As of 2024, only three producers of nitrile gloves are left in the United States, and they supply an estimated .05% percent of U.S. demand for nitrile gloves.

As with N95 respirators, a resilient public health industrial base requires baseline manufacturing capacity for nitrile gloves as critical PPE items, to ensure that hospitals and other institutions will be able to procure high quality gloves reliably. To help achieve this goal, certain U.S. Government departments have committed to purchase wholly domestically made nitrile gloves in line with the requirements in section 70953 of the Infrastructure Investment and Jobs Act. However, federal demand alone cannot sustain a baseline level of nitrile glove production in the U.S. Private medical and health care users are the primary purchasers and users of medical-grade PPE, including nitrile gloves.

To ensure access to high quality products, as with N95 respirators, it is critically important to ensure that a sufficient share of nitrile gloves is wholly made in the U.S.—that is, including raw materials and components. In the CY 2023 OPPS/ASC rule, we stated our belief that the most appropriate framework for determining if a NIOSH-approved surgical N95 respirator is wholly made in the U.S. and therefore, considered domestic for purposes of the proposed adjustments, is the Berry Amendment. The Berry Amendment is a statutory requirement familiar to manufacturers that restricts the Department of Defense (DoD) from

⁹⁴ <https://www.cnn.com/2021/10/24/health/medical-gloves-us-thailand-investigation-cmd-intl/index.html>.

⁹⁵ <https://www.propublica.org/article/ppe-covid-scams-fraud-nitrile-gloves>.

⁹⁶ Glove Story Global Glove Production Amidst the COVID-19 Pandemic (usitc.gov).

⁹⁷ Glove Story Global Glove Production Amidst the COVID-19 Pandemic (usitc.gov).

using funds appropriated or otherwise available to DoD for procurement of food, clothing, fabrics, fibers, yarns, other made-up textiles, and hand or measuring tools that are not grown, reprocessed, reused, or produced in the United States. For nitrile gloves, which are not covered by the Berry Amendment, we believe the Make PPE in America domestic content requirements outlined in section 70953 of the Infrastructure Investment and Jobs Act is the most appropriate framework for determining if a nitrile glove is wholly made in the U.S. These statutory requirements, which apply to procurement of nitrile gloves and other PPE by the U.S. Departments of Health and Human Services, and Veterans Affairs, and Homeland Security, require the procurement PPE, including the materials and components thereof, that is grown, reprocessed, reused, or produced in the U.S. These statutory requirements have become familiar to manufacturers of nitrile gloves and other PPE. With respect to domestic manufacturing capabilities for raw materials and components, we understand that nitrile butadiene rubber (NBR), a key nitrile glove input, is currently not yet available domestically in sufficient quantity or quality to meet market needs. We understand that U.S. manufacturers do anticipate having the capability to source and manufacture all glove components domestically within the next two years.

Wholly domestically made, high quality nitrile gloves are generally more expensive than foreign-made ones, especially those of lower quality. This fact is also true for domestically made nitrile gloves that include non-domestically sourced NBR. These higher prices primarily stem from higher costs of manufacturing labor in the U.S. compared to costs in other countries, where most nitrile gloves and their inputs are made, and higher quality standards. These higher prices mean higher marginal costs for hospitals for procuring wholly domestically made nitrile gloves. Based on available data, our best estimate of the difference in the average unit cost of domestic and non-domestic nitrile gloves, is \$0.13 per glove.

As outlined in this section, quality nitrile gloves are a crucial component of PPE needed to ensure the safety of health care workers and patients. The COVID-19 pandemic highlighted how overreliance on foreign imports of gloves jeopardized public health and the health and safety of healthcare workers and patients. We solicit comment on the following questions:

- Would modifying the payment adjustment to include nitrile gloves help offset the marginal costs that hospitals face in procuring high quality domestically made nitrile gloves?
- Would modifying the payment adjustment to include nitrile gloves help to sustain a baseline level of domestic manufacturing of nitrile gloves to ensure that hospitals and other stakeholders have ongoing, reliable access to an adequate supply of quality product?
- Would having access to a sustained and reliable source of domestically made nitrile gloves strengthen hospitals' ability to protect the health and safety of personnel and patients in a public health emergency?
- Are there other reasons why hospitals would benefit from an extension of the payment adjustment to include nitrile gloves not covered in the preceding questions?
- Do stakeholders believe a significant portion of hospitals would use domestic nitrile gloves if the payment adjustment were offered?
- If the payment adjustment was modified to include nitrile gloves, how should CMS define wholly domestically made nitrile gloves? Would it be appropriate to categorize all nitrile gloves purchased by hospitals into two categories: (1) domestic nitrile gloves that—with the exception of nitrile butadiene rubber (NBR)—comply with the Infrastructure Investment and Jobs Act's Make PPE in America Act domestic content requirements; and (2) non-domestic nitrile gloves?
- If the payment adjustment was modified to include nitrile gloves, and the categories were defined as described previously, would it be appropriate to eliminate the domestic content exception for NBR if domestic NBR production reaches a sufficient level to meet market needs?

- If the payment adjustment was modified to include nitrile gloves, should a national standard unit cost differential between domestic and non-domestic nitrile gloves be used to calculate the payment adjustment, and if so, what should the current unit cost differential be (or, what should the data source be)?

4. Potential Modifications To Include Other PPE and Medical Devices

As noted in the CY 2023 OPPS/ASC final rule, we received many comments urging CMS to expand this policy to cover other forms of PPE and critical medical supplies. A few commenters stated that other forms of PPE suffered shortages during the pandemic similar to surgical N95 respirators and therefore investing in domestic production for these products was also important for future emergency preparedness. We stated that we will consider these comments for future rulemaking if appropriate as we gain more experience with our policy. We seek comment on other PPE types and medical devices that could be appropriate for a similar payment adjustment.

G. Payment for HIV Pre-Exposure Prophylaxis (PrEP) in Hospital Outpatient Departments

On July 12, 2023, CMS proposed to cover Pre-Exposure Prophylaxis (PrEP) to prevent Human Immunodeficiency Virus (HIV) under Medicare Part B. This proposed coverage would include coverage for the HIV PrEP drugs, drug administration, HIV and hepatitis B screening, and individual counseling performed by either physicians or certain other health care practitioners. If finalized as proposed, all of the components would be covered as an additional preventive service without Part B cost-sharing (*i.e.*, deductibles or co-pays). The final National Coverage Determination (NCD) has not been issued as of the issuance of this proposed rule.⁹⁸

The HCPCS codes that describe these services are described in Table 72.

BILLING CODE 4120-01-P

⁹⁸ <https://www.cms.gov/files/document/faq-prep-hiv-06242024.pdf>.

TABLE 72: HCPCS Coding and Long Descriptors for HIV PrEP Drugs and Services

HCPCS Code	Long Descriptor
J0739	Injection, cabotegravir, 1mg, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment for hiv)
J0750	Emtricitabine 200mg and tenofovir disoproxil fumarate 300mg, oral, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv)
J0751	Emtricitabine 200mg and tenofovir alafenamide 25mg, oral, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv)
G0011	Individual counseling for pre-exposure prophylaxis (prep) by physician or qualified health care professional (qhp) to prevent human immunodeficiency virus (hiv), includes hiv risk assessment (initial or continued assessment of risk), hiv risk reduction and medication adherence, 15-30 minutes
G0012	Injection of pre-exposure prophylaxis (prep) drug for hiv prevention, under skin or into muscle
G0013	Individual counseling for pre-exposure prophylaxis (prep) by clinical staff to prevent human immunodeficiency virus (hiv), includes: hiv risk assessment (initial or continued assessment of risk), hiv risk reduction and medication adherence
J0799	Fda approved prescription drug, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv), not otherwise classified

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For CY 2025, we propose to pay for HIV PrEP drugs and related services as additional preventive services under the OPPS, if covered in the final NCD. We believe the resource costs for HCPCS codes listed in Table 72 would be similar across different settings of care, including the HOPD and physician office, and therefore the proposed policies for determining the payment amounts for these services in the CY 2025 PFS proposed rule would be appropriate for use under the OPPS as well. Therefore, we propose to pay for the HCPCS codes listed in Table 72 that are furnished in HOPDs in a similar manner as when these codes are furnished in the physician office.

HCPCS code G0012 (Injection of pre-exposure prophylaxis (prep) drug for hiv prevention, under skin or into muscle) may be used to describe the injection of a PrEP drug for HIV prevention. For CY 2025, if covered as an additional preventative service, we

propose to assign this HCPCS code to APC 5692 (Level 2 Drug Administration) based on the crosswalk to HCPCS code 96372 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular) based on the anticipated similarity in resource use. For the HIV PrEP counseling services performed by hospital staff, specifically HCPCS code G0013, if covered as an additional preventative service, we are proposing to assign this service to a clinical APC with a payment rate that approximates the payment rate in the physician office setting. The proposed CY 2025 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. We are not proposing to pay for HIV PrEP counseling performed by physicians under the OPPS as this is a physician-only service.

To determine the OPPS payment amount for HIV PrEP drugs we propose to utilize the ASP methodology under section 1847A of the Act when ASP data

is available. As discussed in the CY 2025 PFS proposed rule, we believe the use of ASP data would be preferable for determining the payment amount for HIV PrEP, for two reasons. First, this approach would determine the payment amount for these drugs in the same way as the payment amount is usually determined for most other drugs that are separately payable under Part B, when possible. This would include the application of payment limit calculations for multiple source drugs, single source drugs and biologicals, and biosimilar biological products, as is done products under section 1847A of the Act, for each applicable billing and payment code. Second, because section 1847A(c)(3) of the Act requires that calculation of the manufacturer's ASP for an NDC must include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid drug rebate

program, discounts under the 340B Program, and rebates under the Part B and Part D Medicare inflation rebate program), this would set a payment amount that would likely better reflect acquisition cost of the drug than list prices in available compendia (such as Wholesale Acquisition Cost (WAC)).

Specifically, for HIV PrEP drugs, if ASP data is not available for a particular drug, the PFS proposal describes the use of alternative pricing sources. As previously stated, we believe the resource costs should be similar regardless of whether HIV PrEP drugs are furnished in the HOPD or the physician office, and we propose to use the same method of utilizing alternative pricing sources for drugs paid under the OPPS as additional preventive services as is proposed under the PFS.

If ASP data for HIV PrEP is not available, we propose to determine the payment amount for the applicable billing and payment code using the most recently published amount for the drug in Medicaid's National Average Drug Acquisition Cost (NADAC) survey (OMB control number 0938–1041).⁹⁹ When using NADAC data, we propose to determine the payment amount per billing unit, which would be an average of NADAC prices for all NDCs for the drug. If a drug is available in generic and brand formulations, we propose all NDCs will be averaged together to determine the payment amount.

Most recently published for purposes of this policy means the most recently updated NADAC survey available 30 days after the close of the quarter for which ASP data would have been reported if it were available.¹⁰⁰ For example, if NADAC is used to determine the payment amount effective for dates of service in the third calendar quarter, CMS would use the most recent NADAC survey update available on the 30th day after the close of the first calendar quarter. This survey provides a national drug pricing benchmark for certain drugs that is adequately comprehensive to serve as the first alternative pricing source in the case that ASP data is not available. CMS conducts surveys of retail community pharmacy prices to develop the NADAC pricing benchmark in the annual NADAC pricing file. The pricing benchmark is reflective of the prices paid by retail community pharmacies to acquire prescription and over-the-counter covered outpatient drugs. NADAC data is publicly available and it

can be accessed at <https://data.medicaid.gov/nadac>.

Since NADAC pricing is only available for drugs typically dispensed through retail community pharmacies, there could be circumstances in which ASP and NADAC are not available for HIV PrEP. Therefore, if both ASP and NADAC pricing data are not available for a DCAPS drug, we propose to use the most recently published and listed prices for pharmaceutical products in the Federal Supply Schedule (FSS) to calculate the payment amount for the applicable billing and payment code. Most recently published for purposes of this policy means the most recently updated FSS survey available 30 days after the close of the quarter for which ASP data would have been reported if it were available.¹⁰¹ For example, if FSS is used to determine the payment amount effective for dates of service in the third calendar quarter, CMS would use the most recent FSS update available on the 30th day after the close of the first calendar quarter. When using the FSS, we would calculate the average price per billing unit (as described in the billing and payment code for the drug) for all NDCs listed for a drug. Drug pricing information, including FSS pricing, from the Veteran Affairs' (VA's) pharmaceutical pricing database is publicly available at the NDC level and published at <https://www.va.gov/opal/nac/fss/pharmPrices.asp>.

We propose to use FSS data when ASP and NADAC data are not available because FSS data is one of the few existing options for drug pricing that includes a wide variety of drug formulations, including both self-administered drugs typically dispensed through retail community pharmacies and drugs administered incident to a physician's service. For more details on this pricing methodology for the physician office setting, please see the CY 2025 PFS proposed rule.

We note that the PFS proposal includes a final step of invoice pricing; however, invoice pricing is not currently available under the OPPS, so we are not proposing to adopt that portion of the PFS proposal. However, please see our Invoice Drug Pricing Proposal for CY 2026 in section V.B.2.d. of this proposed rule. Because invoice pricing is not available in the OPPS currently, we propose that if ASP, NADAC, and FSS pricing are not available for a particular drug covered as an additional preventive service, we will use WAC plus 6 percent, or 3 percent if in an initial sales period, consistent with payment for separately

payable drugs paid under the OPPS. This would result in different pricing between the OPPS and PFS if ASP, NADAC, and FSS pricing are not available, but we believe it is appropriate because invoice pricing is not an option under the OPPS and this pricing metric should only apply to a small subset of drugs covered as additional preventive services until one of the other pricing metrics becomes available. We are proposing to treat other drugs covered as additional preventative services under this same methodology.

If the HIV PrEP drugs are covered as additional preventative services, we propose to update the payment rates determined using the methodologies previously summarized on January 1, 2025 or the date of coverage, whichever is later, which would be further updated on the same schedule as the ASP pricing file, which is updated each calendar quarter. We propose to assign the drug products covered as additional preventive services to status indicator K (Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals; Paid under OPPS; separate APC payment), as this status indicator identifies drugs and biologicals that are separately paid under the OPPS and therefore would allow us to operationalize separate payment for PrEP drugs. If the HIV PrEP drugs are covered as additional preventative services, on January 1, 2025 or the date of coverage, whichever is later, we propose that we would assign each HIV PrEP drug covered as an additional preventative to its own APC, which will have a payment rate assigned according to the previously defined methodology.

HCPCS code J0799 (Hiv prep, fda approved, noc) was created effective January 2, 2024, and may be used to describe an HIV PrEP drug that is FDA approved but is not otherwise classified. We propose to pay 95 percent of AWP for HCPCS code J0799, which is consistent with how unlisted drugs and biologicals are paid under the OPPS when they are reported with HCPCS code C9399 (Unclassified drugs or biologicals). As HCPCS code J0799 and HCPCS code C9399 both describe drugs that are unclassified or not otherwise classified, we believe the payment methodologies should be similarly aligned. Section 1833(t)(15) of the Act, as added by section 621(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), provides for payment under the OPPS for new drugs and biologicals until HCPCS codes are assigned. Under this provision, we are

⁹⁹ <https://www.medicaid.gov/medicaid/prescription-drugs/retail-price-survey/index.html>.

¹⁰⁰ 42 CFR 414.804(a)(5).

¹⁰¹ 42 CFR 414.804(a)(5).

required to make payment for a covered outpatient drug or biological that is furnished as part of covered outpatient department services but for which a HCPCS code has not yet been assigned in an amount equal to 95 percent of AWP for the drug or biological.

In the CY 2005 OPPS/ASC final rule with comment period (69 FR 65805), we implemented section 1833(t)(15) of the Act by instructing hospitals to bill for a drug or biological that is newly approved by the FDA and that does not yet have a HCPCS code by reporting the NDC for the product along with the newly created HCPCS code C9399 (Unclassified drugs or biologicals). We explained that when HCPCS code C9399 appears on a claim, the Shared Systems suspends the claim for manual pricing by the Medicare Administrative Contractor (MAC). The MAC prices the claim at 95 percent of the drug or biological's AWP, using Red Book or an equivalent recognized compendium, and processes the claim for payment. We emphasized that this approach enables hospitals to bill and receive payment for a new drug or biological concurrent with its approval by the FDA. The hospital does not have to wait for the next quarterly release or for approval of a product-specific HCPCS code to receive payment for a newly approved drug or biological or to resubmit claims for adjustment. We instructed that hospitals would discontinue billing HCPCS code C9399 and the NDC upon implementation of a product specific HCPCS code, status indicator, and appropriate payment amount with the next quarterly update. While the statute does not require drugs that are covered as additional preventive services to be paid at 95 percent of AWP when not assigned to a product specific HCPCS code, we believe it would be appropriate to create a parallel policy given that HCPCS code J0799 and HCPCS code C9399 both describe drugs that are unclassified or not otherwise classified. As the payment amount for HCPCS code C9399 is statutorily mandated at 95 percent of AWP, we believe that the payment amount for HCPCS code J0799 should also be 95 percent of AWP.

Therefore, we propose to establish an identical payment policy for HCPCS code J0799, which may be used to describe drugs that are FDA-approved for PrEP and are covered as additional preventive services. In order to effectuate payment at 95 percent of AWP, we propose to require hospitals to bill for a drug that is newly FDA approved for HIV PrEP, and covered as an additional preventive service, and that does not yet have a HCPCS code,

by reporting the NDC for the product along with the newly created HCPCS code J0799. Similar to HCPCS code C9399, when HCPCS code J0799 appears on a claim, the Shared Systems will suspend the claim for manual pricing by the MAC. The MAC would price the claim at 95 percent of the drug or biological's AWP, using Red Book or an equivalent recognized compendium, and process the claim for payment. This approach would enable hospitals to bill and receive payment for a drug that is newly FDA approved for HIV PrEP and covered as an additional preventive service concurrent with its approval by the FDA. The hospital would not have to wait for the next quarterly release or for approval of a product-specific HCPCS code to receive payment for a newly approved drug or to resubmit claims for adjustment. We would instruct hospitals to discontinue billing HCPCS code C9399 and the NDC upon implementation of a product specific HCPCS code, status indicator, and appropriate payment amount with the next quarterly update.

Finally, if covered as an additional preventive service, we propose to assign all HCPCS codes describing pharmacy supply fees for HIV PrEP to an OPPS status indicator of "B". This follows the longstanding OPPS practice of assigning HCPCS codes that describe a pharmacy supply or dispensing fee to status indicator "B" (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x); Not paid under OPPS), such as HCPCS code Q0512 (Pharmacy supply fee for oral anti-cancer, oral anti-emetic or immunosuppressive drug(s); for a subsequent prescription in a 30-day period) and HCPCS code Q0513 (Pharmacy dispensing fee for inhalation drug(s); per 30 days).

H. Payment Policy for Devices in Category B Investigational Device Exemption (IDE) Clinical Trials Policy and Drugs/Devices With a Medicare Coverage With Evidence Development (CED) Designation

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72027), and as authorized by section 1833(w) of the Act, we finalized a policy to make a single blended payment for devices and services in Category B IDE studies in order to preserve the scientific validity of these studies by avoiding differences in Medicare payment methods that would otherwise reveal the group (treatment or control) to which a patient has been assigned. Specifically, we codified our process of utilizing a single packaged payment for Category B IDE studies, including the

cost of the device and routine care items and services, in the regulation text for payment to hospitals in a new § 419.47. We provided in new § 419.47(a) and (b) that CMS will create a new HCPCS code, or revise an existing HCPCS code, to describe a Category B IDE study, which will include both the treatment and control arms, related device(s) of the study, as well as routine care items and services, as specified under 42 CFR 405.201, when CMS determines that the Medicare coverage IDE study criteria at § 405.212 are met, and a new or revised code is necessary to preserve the scientific validity of the IDE study, such as by preventing the unblinding of the study. We finalized that the single blended payment rate would be dependent on the specific trial protocol and would account for the frequency with which the investigational device is used compared to the control where the investigational device is not used. For example, in a study for which CMS determines the Medicare coverage IDE study criteria in § 405.212 are met and where there is a 1:1 assignment of the device to control (no device), Medicare's payment rate would prospectively average the payment for the device with the zero payment for the control in a 1:1 ratio. Furthermore, costs for routine care items and services in the study, as specified under § 405.201, would be included in the single blended payment (87 FR 72026 through 72027).

Since implementing this policy, we have heard from interested parties that our regulation at § 419.47(a) and (b) excluded clinical trials for which there is no control arm. We appreciate the input. Category B IDE studies with no control arm would be paid normally because an alternative payment methodology would not be necessary to preserve their scientific validity. Our policy at § 419.47 applies only to IDE studies with a control arm and where a payment adjustment is necessary to preserve the scientific validity of such a study. The rule was not intended to suggest that CMS will not pay for Category B IDEs with no control arm, provided the studies meet the coverage criteria. In those circumstances, Medicare payments would be made using the usual Medicare payment methodologies.

In many instances, requests for coding and payment for devices in Category B IDE studies are submitted through our New Technology APC application process and include the submission of cost information. However, we have encountered difficulties determining accurate payment rates for Category B IDE studies in the absence of New Technology APC applications such as

when coding for Category B IDE studies is developed through the CPT Editorial Panel process. We encourage interested parties to use the New Technology APC application process where applicable to submit cost information to CMS. Absent information on the resource costs associated with the services and devices in a Category B IDE study, we may assign a SI of E2 to indicate an item, code or service for which pricing information and claims data are not available, and, therefore, the item, code or service is not paid by Medicare when submitted by an outpatient claim.

For CY 2025, we are proposing to utilize a payment methodology similar to the one developed for Category B IDE clinical trials for drugs and devices covered under a national coverage determination (NCD) that uses the Coverage with Evidence Development (CED) paradigm and a payment adjustment is necessary to preserve the scientific validity of such a study. Specifically, we propose to use our authority at section 1833(w) of the Act to develop alternative methods of payment under Medicare Part B for drugs and devices being studied in clinical trials under a CED NCD. These CED NCDs will be listed on the CMS CED website.¹⁰²

Similar to our policy on devices in Category B IDE trials, for devices under a CED NCD, we propose to make a single blended payment rate that would be dependent on the specific trial protocol and would account for the frequency with which the investigational device is used compared to the control where the investigational device is not used. For example, in a study for which there is a 1:1 assignment of the device to control (no device), Medicare's payment rate would prospectively average the payment for the device with the zero payment for the control in a 1:1 ratio.

As described previously and when necessary to preserve the scientific validity of the study, we propose to make payment using an adjusted payment level representing the frequency with which the study drug and placebo, or comparator drug, is furnished. A placebo, or comparator drug, could represent what a beneficiary would typically receive in order to serve as a comparator to assess the effectiveness, or therapeutic benefit, of the study drug. These adjusted payments would protect the scientific validity of the trial by avoiding differences in Medicare payment methods that could otherwise invalidate

the scientific validity of the trial, such as by revealing the group (treatment or control) to which a patient has been assigned. We propose to base the payment amount for the study drug, or active comparator drug, on the ASP methodology, that is ASP plus 6 percent if ASP data is available. If ASP data is not available, then we propose to pay the wholesale acquisition cost (WAC). During an initial sales period, we propose to base the payment on WAC plus 3 percent, otherwise, we propose to base payment on WAC plus 6 percent. If WAC is not available, then we propose to pay 95 percent of average wholesale price (AWP). This payment hierarchy is consistent with CMS payment for non-passthrough separately payable drugs in the OPDS as discussed in section V.B. of this proposed rule.

These payment amounts would be used to calculate the adjusted payment level representing the frequency with which the study drug and placebo, or comparator drug, is furnished. For purposes of setting this adjusted payment level, we propose to use a zero dollar amount for a placebo or comparator. A new, or revised, HCPCS code would be created for the drug and placebo or comparator in the CED study. We propose that we would assign this HCPCS code to its own APC reflecting the payment amount determined appropriate based on available pricing information and the frequency with which the study drug and placebo, or comparator drug, is used.

For example, as most drugs are currently paid per dosage unit, such as per 1 mg, a payment rate, potentially priced per 1 mg of drug, placebo, or active comparator, might be based on the average sales price methodology for the drug averaged with a zero-dollar payment for the placebo, or the applicable payment rate of the comparator drug. A single averaged payment would be made regardless of whether 1 mg of study drug, 1 mg of placebo, or 1 mg of comparator drug is used. If the trial is a 1:1 (treatment: placebo) then the payment rate would be the same for every trial participant and would represent half of the total payment for the drug. In a simplified example, if the ASP plus 6 percent payment rate for Drug X was \$1 per 1 mg then in this example, the payment rate for the blended code of Drug X and placebo would be \$0.50 per 1 mg. If a beneficiary received 100 mg of the study drug, then a \$50 payment would be made. If a beneficiary received 100 mg of the placebo, then a \$50 payment would be made. The same HCPCS code would be billed in both the study drug and placebo examples. The same

payment methodology would apply if the study design was 1:2 (treatment: placebos, which equals payment at $\frac{1}{3}$ the cost of the study drug) or 1:3 (treatment: placebos, which equals payment at $\frac{1}{4}$ the cost of the study drug). In situations where there are multi-arm, or single-arm, cross over trials where participants receive placebo, or sham, for the first half of the trial and then the study drug for the second half of the trial, the payment would be reflective of this, and set in the same manner as a 1:1 trial, since half of the time the beneficiary would receive the placebo and the other half they would receive the study drug. No matter the trial design, CMS payment would be reflective of the expected frequency with which the study treatment, control, active comparator, or placebo is provided. We note that we propose to assign payment rates based on an adjusted payment level representing the frequency with which the study drug and placebo, or comparator drug, is projected to be furnished for the trial as a whole, and not necessarily the exact frequency with which the study drug and placebo, or comparator drug, is furnished to a particular hospital enrolled as a clinical trial site. Clinical trial sponsors should work with CMS to ensure timely establishment of payment and coding for drugs being studied under a CED designation requiring an adjusted level of payment.

While the items and services furnished as placebo controls may not be considered reasonable and necessary under section 1862(a)(1)(A) of the Act because they have no health benefit, these items and services can be necessary in order to conduct a scientifically valid clinical study. As such, these items can be covered under section 1862(a)(1)(E) of the Act when furnished in the context of a qualifying clinical study.¹⁰³

CMS may cover and pay for routine costs of an approved clinical trial in both the treatment arm and the control (standard of care or placebo). Routine costs include all items and services that are otherwise generally available to Medicare beneficiaries (*i.e.*, there exists a benefit category for the item or service, coverage is not statutorily excluded for the item or service, and there is not a national non-coverage decision for the item or service) that are provided in either the experimental or the control arms of a clinical trial. Although CMS

¹⁰² <https://www.cms.gov/medicare/coverage/evidence>.

¹⁰³ Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development. November 20, 2014. <https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?MCDId=27>.

may cover and pay for routine costs of an CED approved clinical trial in both the treatment arm and the control (standard of care or placebo), there may be circumstances, such as single arm studies, where no unique coding or unique payment would be required to preserve the scientific validity of such a study created for routine costs associated with clinical trials. Similarly, if the routine costs are the exact same between different arms of a trial, and routine billing and payment of those routine costs would not unblind a study, then no unique coding or payment would be required for those costs. There would be no need to include these routine costs in the HCPCS code assigned to a blended payment rate. If covered, these routine costs would be paid according to existing coding and Medicare payment mechanisms. Under the proposed rule an alternate method of payment would be established only when necessary to maintain the scientific validity of the trial, such as to prevent the billing and payment of routine costs from unblinding the trial. These determinations will be made based on the clinical trial protocol communicated to CMS by the clinical trial sponsor, before CMS would establish an appropriate code with an adjusted payment level for routine costs for CED trials. CMS’s determination will be different in CED trials from our policy regarding devices and procedures in Category B IDE trials, where the provision of an investigational device usually requires a combination of

procedures or services to implant, or administer, the device to a patient. In contrast, the infusion of a drug is typically a more straightforward process, and associated routine costs may not be provided at the same time that the drug is administered, making it impractical to create a single code to describe the study drug and all associated routine costs.

Finally, we want to be sure there are no other instances where Medicare payment methodologies might interfere with the scientific validity of a trial. We are seeking comment on these possible alternative scenarios, such as Medicare payment interfering with clinical trial recruitment in such a way that could compromise the scientific integrity of a clinical trial and would consider adjustments to our payment policy for devices in Category B IDE clinical trials and devices/drugs in clinical trials with a CED designation in future rulemaking.

We propose to codify our coding and payment policy to Category B IDE clinical trials with control arms through revisions to § 419.47(a) to specify that these are placebo control arms. We also propose to codify our proposed process for developing coding and payment for devices/drugs in CED-designated clinical trials by adding new paragraphs (c) and (d) to § 419.47. Specifically, we propose to provide in new § 419.47(c) that CMS would create a new HCPCS code, or revise an existing HCPCS code, to describe a device/drug studied in a clinical trial with the Medicare CED designation, which would include the study device/drug and control arm, when CMS determines it is necessary to

establish a CED designation for a device/drug subsequent to a CED NCD. Additionally, in new § 419.47(d) we propose that when we create a new HCPCS code or revise an existing HCPCS code under proposed paragraph (c), we would make a single payment for the HCPCS code that includes payment for the investigational device/drug and any control.

XI. Proposed CY 2025 OPPS Payment Status and Comment Indicators

A. Proposed CY 2025 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and whether particular OPPS policies apply to the code.

For CY 2025 and subsequent years, we propose to create two new status indicators, “K1” and “H1.” We propose these two new status indicators to identify the products that qualify for separate payment under our new payment policy for non-opioid post-surgical pain management drugs, biologicals, and devices, as authorized by section 4135 of the Consolidated Appropriations Act, 2023. This policy is discussed further in section XIII.E of this proposed rule. The proposed definitions and payment status of proposed status indicators “K1” and “H1” can be found in Table 73.

TABLE 73: PROPOSED DEFINITIONS AND PAYMENT STATUS OF PROPOSED STATUS INDICATORS K1 AND H1

Proposed Status Indicator	Proposed Descriptor	Proposed OPPS Payment Status
K1	Non-Opioid Drugs and Biologicals For Post-Surgical Pain Relief	Paid under OPPS; separate APC payment. Subject to criteria and payment limitation under Section 4135 of the CAA, 2023.
H1	Non-Opioid Medical Devices For Post-Surgical Pain Relief	Separate payment based on hospital’s charges adjusted to cost. Subject to criteria and payment limitation under Section 4135 of the CAA, 2023.

For CY 2025 and subsequent years, we propose to modify the definition of status indicator “K” to remove the word “therapeutic” from the phrase “therapeutic radiopharmaceuticals” to

indicate that both diagnostic and therapeutic radiopharmaceuticals may be assigned to status indicator “K” in accordance with our policy proposal in section II.A.3.a. of this proposed rule.

The proposed definition and payment status of status indicator “K” can be found in Table 74.

TABLE 74: PROPOSED DEFINITIONS AND PAYMENT STATUS OF STATUS INDICATOR K

Proposed Status Indicator	Proposed Descriptor	Proposed OPPS Payment Status
K	Nonpass-Through Drugs and Nonimplantable Biologicals, Including Radiopharmaceuticals	Paid under OPPS; separate APC payment.

We do not propose to make any other changes to the existing definitions of status indicators that are listed in Addendum D1 to this proposed rule, which is available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>.

The complete list of proposed CY 2025 payment status indicators and their definitions is displayed in Addendum D1 to this proposed rule, which is available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>.

The proposed CY 2025 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule, which are available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>.

B. Proposed CY 2025 Comment Indicator Definitions

We propose to use four comment indicators for the CY 2025 OPPS. These comment indicators, “CH,” “NC,” “NI,” and “NP,” are in effect for CY 2024; and we propose to continue their use in CY 2025. The proposed CY 2025 OPPS comment indicators are as follows:

- “CH”—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.

- “NC”—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year for

which we requested comments in the CY 2024 OPPS/ASC proposed rule, final APC assignment; comments will not be accepted on the final APC assignment for the new code.

- “NI”—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.

- “NP”—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

The definitions of the proposed OPPS comment indicators for CY 2025 are listed in Addendum D2 to this proposed rule, which is available on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>.

We solicit public comments on our proposed definitions of the OPPS comment indicators for 2025.

XII. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) was established under section 1805 of the Act in large part to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to the Congress no later than March and June of each year that present its Medicare payment policy recommendations. The March report typically provides discussion of Medicare payment policy across

different payment systems and the June report typically discusses selected Medicare issues. We are including this section to make stakeholders aware of certain MedPAC recommendations for the OPPS and ASC payment systems as discussed in its March 2024 report.

A. OPPS Payment Rates Update

The March 2024 MedPAC “Report to the Congress: Medicare Payment Policy,” recommended that Congress update Medicare OPPS payment rates by the amount specified in current law plus 1.5 percent. We refer readers to the March 2024 report for a complete discussion of this recommendation.¹⁰⁴ We appreciate MedPAC’s recommendation and, as discussed further in section II.B of this proposed rule, we propose to increase the OPPS payment rates by the amount specified in current law.

B. Medicare Safety Net Index

In the March 2024 MedPAC “Report to the Congress: Medicare Payment Policy,” MedPAC stated that their recommended update to IPPS and OPPS payment rates of current law plus 1.5 percent may not be sufficient to ensure the financial viability of some Medicare safety-net hospitals with a poor payer mix. MedPAC recommends redistributing the current Medicare safety-net payments (disproportionate share hospital and uncompensated care payments) using the MedPAC-developed Medicare Safety-Net Index (MSNI) for hospitals. In addition, MedPAC recommends adding \$4 billion to this MSNI pool of funds to help

¹⁰⁴ Medicare Payment Advisory Committee. March 2024 Report to the Congress. Chapter 3: Hospital inpatient and outpatient services, p.49. Available at: <https://www.medpac.gov>.

maintain the financial viability of Medicare safety-net hospitals and recommended to the Congress transitional approaches for a MSNI policy.

We appreciate MedPAC's recommendation and, as discussed further in section II.B of this proposed rule, we propose to increase the OPPS payment rates by the amount specified in current law.

C. ASC Cost Data

In the March 2024 MedPAC "Report to the Congress: Medicare Payment Policy," MedPAC reiterated its longstanding recommendation that Congress require ASCs to report cost data to enable the Commission to examine the growth of ASCs' costs over time and analyze Medicare payments relative to the costs of efficient providers. MedPAC suggested that such cost data would enable policymakers to establish payment rates that accurately reflect ASC costs and are also necessary to determine whether an existing Medicare market basket is an appropriate proxy for ASC costs or whether an ASC-specific market basket should be developed, stating both the CPI-U and hospital market basket update likely do not reflect an ASC's cost structure. MedPAC contended that it is feasible for small facilities, such as ASCs, to provide cost information since other small facilities, such as home health agencies, hospices, and rural health clinics, currently furnish cost data to CMS. Further, ASCs in Pennsylvania submit cost and revenue data annually to a state agency to estimate margins for those ASCs, and that, as businesses, ASCs keep records of their costs for filing taxes and other purposes.¹⁰⁵

While we recognize that the submission of cost data could place additional administrative burden on most ASCs, and we do not propose any cost reporting requirements for ASCs in this proposed rule, as in previous years, we continue to seek public comment on methods that would mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use such data in the determination of ASC costs. Such cost data would be beneficial in establishing an ASC-specific market basket for updating payment rates under the ASC payment system.

XIII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background, Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CYs 2012 to 2024 OPPS/ASC final rules with comment period (76 FR 74378 through 74379; 77 FR 68434 through 68467; 78 FR 75064 through 75090; 79 FR 66915 through 66940; 80 FR 70474 through 70502; 81 FR 79732 through 79753; 82 FR 59401 through 59424; 83 FR 59028 through 59080; 84 FR 61370 through 61410; 85 FR 86121 through 86179; 86 FR 63761 through 63815; 87 FR 72054 through 72096; and 88 FR 81900 through 81961).

B. Proposed ASC Treatment of New and Revised Codes

1. Background on Process for New and Revised HCPCS Codes

We update the lists and payment rates for covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment systems (§ 416.173; 72 FR 42535). We base ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies and we use quarterly change requests (CRs) to update services paid for under the OPPS. We also provide quarterly update CRs for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). We release new and revised Level II HCPCS codes and recognize the release of new and revised CPT codes by the American Medical Association (AMA) and make these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. We recognize the release of new and revised Category III CPT codes in the July and January CRs. These updates implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payments and update the payment rates for separately paid drugs and biologicals based on the most recently

submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for an example of how this process is used to update HCPCS and CPT codes, which we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 42291; 76 FR 74380 through 74384).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures, new codes, and codes with revised descriptors, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle, is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

Payment for ASC procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on ASC claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system maintained by the AMA, and includes Category I, II, and III CPT codes. Level II of the HCPCS, which is maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging

¹⁰⁵ Medicare Payment Advisory Committee. March 2024 Report to the Congress. Chapter 10: Ambulatory surgical center services: Status report, p. 297. Available at: https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_MedPAC_Report_To_Congress_SEC.pdf.

technologies, services, and procedures; and

- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPI/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes. However, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in this CY 2025 OPPI/ASC proposed rule.

We have separated our discussion below based on when the codes are released and whether we propose to solicit public comments in this proposed rule (and respond to those

comments in the CY 2025 OPPI/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2025 OPPI/ASC final rule with comment period (and responding to those comments in the CY 2026 OPPI/ASC final rule with comment period).

1. April 2024 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2024 update, there were no new CPT codes; however, there were several new Level II HCPCS codes. In the April 2024 ASC quarterly update (Transmittal 12559, dated March 28, 2024, CR 13577), we added several new Level II HCPCS codes to the list of covered ancillary services. Table 75 (New Level II HCPCS Codes for Ancillary Services Effective April 1, 2024) of this proposed rule, lists the new Level II HCPCS codes that were implemented April 1, 2024. The proposed comment indicators, payment indicators and payment rates, where applicable, for these April codes can be found in Addendum BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective April 1, 2024, are assigned to comment indicator “NP” in Addendum BB to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this

proposed rule. We note that the following ASC addenda are available via the internet on the CMS website.

- *ASC Addendum AA*: Proposed ASC Covered Surgical Procedures for CY 2025 (Including Surgical Procedures for Which Payment is Packaged),

- *ASC Addendum BB*: Proposed ASC Covered Ancillary Services Integral to Covered Surgical Procedures for CY 2025 (Including Ancillary Services for Which Payment is Packaged),

- *ASC Addendum DD1*: Proposed ASC Payment Indicators (PI) for CY 2025,

- *ASC Addendum DD2*: Proposed ASC Comment Indicators (CI) for CY 2025,

- *ASC Addendum EE*: Proposed Surgical Procedures to be Excluded from Payment in ASC for CY 2025, and

- *ASC Addendum FF*: Proposed ASC Device Offset Percentages for CY 2025,

- *Addendum O*: Long Descriptors for New Category I CPT Codes, Category III CPT Codes, C-codes, and G-Codes Effective January 1, 2025.

We invite public comments on the proposed payment indicators for the new HCPCS codes that were recognized as ASC covered ancillary services in April 2024 through the quarterly update CRs, as listed in Table 75 (New Level II HCPCS Codes for Ancillary Services Effective April 1, 2024) of this proposed rule. We propose to finalize their payment indicators in the CY 2025 OPPI/ASC final rule with comment period.

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TABLE 75: NEW LEVEL II HCPCS CODES FOR ASC COVERED ANCILLARY SERVICES EFFECTIVE APRIL 1, 2024

CY 2024 HCPCS Code	CY 2024 Long Descriptor
C9166	Injection, secukinumab, intravenous, 1 mg
C9167	Injection, adams13, recombinant-krhn, 10 iu
C9168	Injection, mirikizumab-mrkz, 1 mg
J0177	Injection, aflibercept hd, 1 mg
J0577	Injection, buprenorphine extended-release (brixadi), less than or equal to 7 days of therapy
J0578	Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit
J0651	Injection, levothyroxine sodium (fresenius kabi) not therapeutically equivalent to J0650, 10 mcg
J0652	Injection, levothyroxine sodium (hikma) not therapeutically equivalent to J0650, 10 mcg
J1203	Injection, cipaglucosidase alfa-atga, 5 mg
J1323	Injection, elranatamab-bcmm, 1 mg
J2277	Injection, motixafortide, 0.25 mg
J2782	Injection, avacincaptad pegol, 0.1 mg
J2801	Injection, risperidone (rykindo), 0.5 mg
J3055	Injection, talquetamab-tgvs, 0.25 mg
J3424	Injection, hydroxocobalamin, intravenous, 10 grams
J7165	Injection, prothrombin complexconcentrate, human-lans, per i.u. of factor ix activity
J7354	Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg)
J9073	Injection, cyclophosphamide (ingenus), 5 mg
J9075	Injection, cyclophosphamide, not otherwise specified, 5 mg
J9248	Injection, melphalan (hepzato), 1 mg
Q4305	American amnion ac tri-layer, per square centimeter
Q4306	American amnion ac, per square centimeter
Q4307	American amnion, per square centimeter
Q4308	Sanopellis, per square centimeter
Q4309	Via matrix, per square centimeter
Q4310	Procenta, per 100 mg

2. July 2024 HCPCS Codes Proposed Rule Comment Solicitation

In the July 2024 ASC quarterly update (Transmittal 12673, Change Request 13656, dated June 13, 2024), we added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and covered ancillary services. Table 76 (New HCPCS Codes for Covered Surgical Procedures and Covered Ancillary Services Effective July 1,

2024) of this proposed rule, lists the new HCPCS codes that are effective July 1, 2024. The proposed comment indicators, payment indicators, and payment rates for the codes can be found in Addendum AA and Addendum BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective July 1, 2024, are assigned to comment

indicator “NP” in Addendum AA and BB to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

TABLE 76: NEW LEVEL II HCPCS CODES FOR ASC COVERED ANCILLARY SERVICES EFFECTIVE JULY 1, 2024

CY 2024 HCPCS Code	CY 2024 Long Descriptor
A9506	Graphite crucible for preparation of technetium Tc 99m-labeled carbon aerosol, each
C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation
C1606	Adapter, single-use (i.e. disposable), for attaching ultrasound system to upper gastrointestinal endoscope
J0211	Injection, sodium nitrite 3 mg and sodium thiosulfate 125 mg (nithiodote)
J0687	Injection, cefazolin sodium (wg critical care), not therapeutically equivalent to j0690, 500 mg
J0872	Injection, daptomycin (xellia), unrefrigerated, not therapeutically equivalent to j0878 or j0873, 1 mg
J0911	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for esrd on dialysis adult patients receiving chronic hemodialysis)
J3247	Injection, secukinumab, intravenous, 1 mg
J3263	Injection, toripalimab-tpzi, 1 mg
J3393	Injection, betibeglogene autotemcel, per treatment
J3394	Injection, lovotibeglogene autotemcel, per treatment
J7171	Injection, adamts13, recombinant-krhn, 10 iu
J7355	Injection, travoprost, intracameral implant, 1 microgram
J8611	Methotrexate (jylamvo), oral, 2.5 mg
J8612	Methotrexate (xatmep), oral, 2.5 mg
0621T	Trabeculectomy ab interno by laser;
0867T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume greater than or equal to 50 mL
0869T	Injection(s), bone-substitute material for bone and/or soft tissue hardware fixation augmentation, including intraoperative imaging guidance, when performed
0884T	Esophagoscopy, flexible, transoral, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for esophageal stricture, including fluoroscopic guidance, when performed
0885T	Colonoscopy, flexible, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed
0886T	Sigmoidoscopy, flexible, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed
0888T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including imaging guidance

covered ancillary services effective April 1, 2024 and July 1, 2024, through the quarterly update CRs, as listed in Tables 75 and 76. We propose to finalize the payment indicators in the CY 2025 OPPS/ASC final rule with comment period.

3. October 2024 HCPCS Codes Final Rule Comment Solicitation

For CY 2025, consistent with our established policy, we propose that the Level II HCPCS codes that will be effective October 1, 2024, would be flagged with comment indicator “NI” in Addendum BB to the CY 2025 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim ASC payment status for CY 2024. We will invite public comments in the CY 2025 OPPS/ASC final rule with comment period on the interim payment indicators, which would then be finalized in the CY 2026 OPPS/ASC final rule with comment period.

5. January 2025 HCPCS Codes

a. Level II HCPCS Codes Final Rule Comment Solicitation

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the ASC payment system for the calendar year. We note that unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the G-codes listed in Addendum O to this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Therefore, these Level II HCPCS codes will be released to the public through the CY 2025 OPPS/ASC final rule with comment period, January 2025 ASC Update CR, and the CMS HCPCS website.

In addition, for CY 2025, we propose to continue our established policy of assigning comment indicator “NI” in Addendum AA and Addendum BB to the OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2025, to indicate that we are assigning them an interim payment indicator, which is subject to public comment. We will be inviting public comments in the CY 2025 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2026 OPPS/ASC final rule with comment period.

b. CPT Codes Proposed Rule Comment Solicitation

For the CY 2025 ASC update, we received the CPT codes that will be effective January 1, 2025, from the AMA in time to be included in this proposed rule. The new, revised, and deleted CPT codes can be found in ASC Addendum AA and Addendum BB to this proposed rule (which are available via the internet on the CMS website). We note that the new and revised CPT codes are assigned to comment indicator “NP” in ASC Addendum AA and Addendum BB of this proposed rule to indicate that the code is new for the next calendar year, or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed payment indicator assignment. We will accept comments and finalize the payment indicators in the CY 2025 OPPS/ASC final rule with comment period. Further, we remind readers that the CPT code descriptors that appear in Addendum AA and Addendum BB are short descriptors and do not describe the complete procedure, service, or item described by the CPT code. Therefore, we include the 5-digit placeholder codes and their long descriptors for the new CY 2025 CPT codes in Addendum O to this proposed rule (which is available via the internet

on the CMS website) so that the public can comment on our proposed payment indicator assignments. The 5-digit placeholder codes can be found in Addendum O to this proposed rule, specifically under the column labeled “CY 2025 OPPS/ASC Proposed Rule 5-Digit AMA/CMS Placeholder Code.” We intend to include the final CPT code numbers the CY 2025 OPPS/ASC final rule with comment period.

In summary, we solicit public comments on the proposed CY 2025 payment indicators for the new Category I and III CPT codes that will be effective January 1, 2025. Because these codes are listed in Addendum AA and Addendum BB with short descriptors only, we are listing them again in Addendum O with the long descriptors. We also propose to finalize the payment indicator for these codes (with their final CPT code numbers) in the CY 2025 OPPS/ASC final rule with comment period. The proposed payment indicators and comment indicators for these codes can be found in Addendum AA and BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. The new CPT codes that will be effective January 1, 2025, are assigned to comment indicator “NP” in Addendum AA and BB to this proposed rule to indicate that the codes are assigned to an interim payment indicator and that comments will be accepted on their interim ASC payment assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

Finally, in Table 77, we summarize our process for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the ASC payment system.

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**TABLE 77: COMMENT AND FINALIZATION TIMEFRAMES FOR
NEW AND REVISED ASC-RELATED HCPCS CODES**

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2024	HCPCS (CPT and Level II codes)	April 1, 2024	CY 2025 OPPS/ASC proposed rule	CY 2025 OPPS/ASC final rule with comment period
July 2024	HCPCS (CPT and Level II codes)	July 1, 2024	CY 2025 OPPS/ASC proposed rule	CY 2025 OPPS/ASC final rule with comment period
October 2024	HCPCS (CPT and Level II codes)	October 1, 2024	CY 2025 OPPS/ASC final rule with comment period	CY 2026 OPPS/ASC final rule with comment period
January 2025	CPT Codes	January 1, 2025	CY 2025 OPPS/ASC proposed rule	CY 2025 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2025	CY 2025 OPPS/ASC final rule with comment period	CY 2026 OPPS/ASC final rule with comment period

BILLING CODE 4120-01-C**6. ASC Payment and Comment
Indicators****a. Background**

In addition to the payment indicators that we introduced in the August 2, 2007 ASC final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy-relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC CPL prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services,

brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators included in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator “NI” is used in the OPPS/ASC final rule with comment period to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator “NI” also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, and the interim payment indicator assigned is subject to comment, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622).

The comment indicator “NP” is used in the OPPS/ASC proposed rule to

indicate new codes for the next calendar year for which the proposed payment indicator assigned is subject to comment. The comment indicator “NP” also is assigned to existing codes with substantial revisions to their descriptors, such that we consider them to be describing new services, and the proposed payment indicator assigned is subject to comment, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497).

The “CH” comment indicator is used in Addenda AA and BB to the proposed rule (these addenda are available via the internet on the CMS website) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year, for example, if an active HCPCS code is newly recognized as payable in ASCs or an active HCPCS code is discontinued at the end of the current calendar year. The “CH” comment indicators that are published in the final rule are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

In the CY 2021 OPPS/ASC final rule with comment period, we finalized the addition of ASC payment indicator “K5”—Items, Codes, and Services for which pricing information and claims data are not available. No payment made.—to ASC Addendum DD1 (which is available via the internet on the CMS website) to indicate those services and procedures that CMS anticipates will become payable when claims data or payment information becomes available.

In CY 2024 OPPS/ASC final rule with comment period, we finalized the addition of two ASC payment indicators, “D1”—“Ancillary dental service/item; no separate payment made” and “D2”—“Non office-based dental procedure added in CY 2024 or later”, for new dental codes for CY 2024 and subsequent calendar years to indicate potentially payable dental services and procedures in the ASC setting (88 FR 81907). We added these two codes to Addendum DD1 (which is available via the internet on the CMS website).

b. Proposed ASC Payment and Comment Indicators for CY 2025

For CY 2025, we propose new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. Proposed Category I and III CPT codes that are new and revised for CY 2025 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2025, compared to the CY 2024 descriptors, are included in ASC Addenda AA and BB to this proposed rule and labeled with comment indicator “NP” to indicate that these CPT and Level II HCPCS codes are open for comment as part of the CY 2025 OPPS/ASC proposed rule.

We propose to modify the descriptor of ASC payment indicator “L6”—“New Technology Intraocular Lens (NTIOL); special payment” to “Special payment; New Technology Intraocular Lens (NTIOL) or qualifying non-opioid devices”, to account for non-opioid devices paid for under the ASC payment system pursuant to section 4135 of the CAA, 2023. More information about this non-opioid policy can be found in section XIII.E of this proposed rule.

We refer readers to Addenda DD1 and DD2 of this proposed rule (these addenda are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators proposed for the CY 2025 update.

C. Proposed Payment Policies Under the ASC Payment System

1. Proposed ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with payment indicators “G2” and “A2.” Payment indicator “A2” was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator “A2” is no longer required to identify surgical procedures subject to transitional payment, we have retained payment indicator “A2” because it is used to identify procedures that are exempted from the application of the office-based designation.

Payment rates for office-based procedures (payment indicators “P2,” “P3,” and “R2”) are the lower of the PFS nonfacility PE RVU-based amount or the amount calculated using the ASC standard rate setting methodology for the procedure. As detailed in section XIII.C.3.b of this proposed rule, we update the payment amounts for office-based procedures (payment indicators “P2,” “P3,” and “R2”) using the most recent available MPFS and OPPS data. We compare the estimated current year rate for each of the office-based procedures, calculated according to the ASC standard rate setting methodology, to the PFS nonfacility PE RVU-based amount to determine which is lower and, therefore, would be the current year payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

The rate calculation established for device-intensive procedures (payment indicator “J8”) is structured so only the service (non-device) portion of the rate is subject to the ASC conversion factor. We update the payment rates for device-intensive procedures to incorporate the most recent device offset percentages calculated under the ASC standard ratesetting methodology, as discussed in section XIII.C.4 of this proposed rule.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal procedures under the OPPS. Under the OPPS, a conditionally packaged procedure (status indicators “Q1” and “Q2”) describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator “N1”) under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There is no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To ensure that the ASC payment system provides separate payment for surgical procedures that only involve device removal—conditionally packaged in the OPPS (status indicator “Q2”)—we have continued to provide separate payment since CY 2014 and assign the current ASC payment indicators associated with these procedures.

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2025

We propose to update ASC payment rates for CY 2025 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XIII.C.4 of this proposed rule. As the proposed OPPS relative payment weights are generally based on geometric mean costs, we propose that the ASC payment system will generally use the geometric mean cost to determine proposed relative payment weights under the ASC standard methodology. We propose to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators “A2” and “G2.”

We propose to calculate payment rates for office-based procedures (payment indicators “P2,” “P3,” and “R2”) and device-intensive procedures

(payment indicator “J8”) according to our established policies and to identify device-intensive procedures using the methodology discussed in section XIII.C.4 of this proposed rule. Therefore, we propose to update the payment amount for the service portion (the non-device portion) of the device-intensive procedures using the standard ASC ratesetting methodology and the payment amount for the device portion based on the proposed CY 2025 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. We propose that payment for office-based procedures would be at the lesser of the proposed CY 2025 MPFS nonfacility PE RVU-based amount or the proposed CY 2025 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2024, for CY 2025, we propose to continue our policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators “Q1” and “Q2”) will be assigned the current ASC payment indicators associated with those procedures and will continue to be paid separately under the ASC payment system.

c. Proposed Payment for ASC Add-On Procedures Eligible for Complexity Adjustments Under the OPPS

In this section, we discuss the policy to provide increased payment under the ASC payment system for combinations of certain “J1” service codes and add-on procedure codes that are eligible for a complexity adjustment under the OPPS.

(1) OPPS C–APC Complexity Adjustment Policy

Under the OPPS, complexity adjustments are utilized to provide increased payment for certain comprehensive services. As discussed in section II.A.2.b of this proposed rule, we apply a complexity adjustment by promoting qualifying paired “J1” service code combinations or paired code combinations of “J1” services and add-on codes from the originating Comprehensive APC (C–APC) (the C–APC to which the designated primary service is first assigned) to the next higher paying C–APC in the same clinical family of C–APCs. A “J1” status indicator refers to a hospital outpatient service paid through a C–APC. We package payment for all add-on codes, which are codes that describe a procedure or service always performed in addition to a primary service or procedure, into the payment for the C–APC. However, certain combinations of

primary service codes and add-on codes may qualify for a complexity adjustment.

We apply complexity adjustments when the paired code combination represents a complex, costly form or version of the primary service when the frequency and cost thresholds are met. The frequency threshold is met when there are 25 or more claims reporting the code combination, and the cost threshold is met when there is a violation of the 2 times rule, as specified in section 1833(t)(2) of the Act and described in section III.A.2.b of this proposed rule, in the originating C–APC. These paired code combinations that meet the frequency and cost threshold criteria represent those that exhibit materially greater resource requirements than the primary service. After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim that are either assigned to status indicator “J1” or add-on codes to determine if there are paired code combinations that meet the complexity adjustment criteria. Once we have determined that a particular combination of “J1” services, or combinations of a “J1” service and add-on code, represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described previously, we promote the claim to the next higher cost C–APC within the clinical family unless the primary service is already assigned to the highest cost APC within the C–APC clinical family or assigned to the only C–APC in a clinical family. We do not create new C–APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802).

As previously stated, we package payment for add-on codes into the C–APC payment rate. If any add-on code reported in conjunction with the “J1” primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and the primary service code reported with the add-on code is not reassigned to the next higher cost C–APC. We list the proposed complexity adjustments for “J1” and add-on code

combinations for CY 2025, along with all of the other proposed complexity adjustments, in Addendum J to this proposed rule (which is available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>).

(2) CY 2025 ASC Special Payment Policy Proposal for OPPS Complexity-Adjusted C–APCs

For CY 2025, we propose to continue the special payment policy and methodology for OPPS complexity-adjusted C–APCs that was finalized in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72078 through 72080).

For those ASC complexity adjustment codes for which we have claims data, we propose to use the claims data to calculate the code combination utilization and estimated payments for the ASC payment system budget neutrality calculations for CY 2025. The ASC complexity adjustment budget neutrality calculations are discussed further in section XIII.H.2.a of this proposed rule. The full list of the proposed ASC complexity adjustment codes for CY 2025 can be found in the ASC addenda and the supplemental policy file, which also includes both the existing ASC complexity adjustment codes and proposed additions, is published with the proposed rule on the CMS website at <https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/asc-regulations-and-notice>. Since the complexity adjustment assignments change each year under the OPPS, the proposed list of ASC complexity adjustment codes eligible for this proposed payment policy has changed slightly from the previous year.

d. Proposed Low Volume APCs and Limit on ASC Payment Rates for Procedures Assigned to Low Volume APCs

As stated in section XIII.D.1.b of this proposed rule, the ASC payment system generally uses OPPS geometric mean costs under the standard methodology to determine proposed relative payment weights under the standard ASC ratesetting methodology.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a universal Low Volume APC policy for CY 2022 and subsequent calendar years. Under our policy, we expanded the low volume adjustment policy that is applied to procedures assigned to New Technology APCs to also apply to clinical and brachytherapy APCs.

Specifically, a clinical APC or brachytherapy APC with fewer than 100 claims per year would be designated as a Low Volume APC. For items or services assigned to a Low Volume APC, we use up to 4 years of claims data to establish a payment rate for the APC as we currently do for low volume services assigned to New Technology APCs. The payment rate for a Low Volume APC or a low volume New Technology procedure would be based on the highest of the median cost, arithmetic mean cost, or geometric mean cost calculated using multiple years of claims data.

Based on claims data available for this proposed rule, we propose to designate six brachytherapy APCs and four clinical APCs as Low Volume APCs under the ASC payment system and

shown in Table 78. The four clinical APCs and six brachytherapy APCs meet our criteria of having fewer than 100 single claims in the relevant claims year (CY 2023 for this CY 2025 OPPS/ASC proposed rule) and therefore, we propose that they would be subject to our universal Low Volume APC policy and the APC cost metric would be based on the greater of the median cost, arithmetic mean cost, or geometric mean cost using up to 4 years of claims data. Nine of the ten APCs were designated as low volume APCs in CY 2024. Based on data for the CY 2025 OPPS/ASC proposed rule, APC 2645 (Brachytx, non-stranded, hold-198) now meets our criteria to be designated a low volume APC; and we propose to designate it as such for CY 2025.

Table 78 includes the CY 2023 claims available for ratesetting for each of the APCs we propose be designated as low volume APCs for CY 2025. The cost statistics for our proposed low volume APCs, such as the median, arithmetic mean, and geometric mean cost are available for download with this proposed rule on the CMS website. We refer readers to our website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices>; click on the relevant regulation to download the low volume APC cost statistics under the standard (ASC) ratesetting methodology in the downloads section of the web page.

TABLE 78: PROPOSED LOW VOLUME APCS USING STANDARD (ASC) RATESETTING METHODOLOGY FOR CY 2025

APC	APC Description	CY 2023 Claims Available for Ratesetting
2632	Iodine I-125 sodium iodide	0*
2635	Brachytx, non-str, HA, P-103	13
2636	Brachy linear, non-str, P-103	1
2642	Brachytx, stranded, C-131	90
2645	Brachytx, non-str, gold-198	86
2647	Brachytx, NS, Non-HDRIr-192	2
5244	Level 4 Blood Product Exchanges and Related Services	2
5494	Level 4 Intraocular Procedures	15
5495	Level 5 Intraocular Procedures	37
5496	Level 6 Intraocular Procedures	14

* For the CY 2025 OPPS/ASC proposed rule, there were no CY 2023 claims that contain the HCPCS code assigned to APC 2632 (HCPCS code A9527) available for ratesetting.

2. Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services generally vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status

indicators “N,” “Q1,” and “Q2”) under the OPPS.

In the CY 2013 OPPS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment for procedures that are conditionally packaged in the OPPS (status indicators “Q1” and “Q2”). Under the OPPS, a conditionally packaged procedure describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical

procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indicator “N1”) under the ASC payment system (except for device removal procedures, as discussed in the CY 2022 OPPS/ASC proposed rule (86 FR 42083)). Thus, our policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for ancillary items and services also to be paid, the ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies generally provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates and package payment for drugs and biologicals for which payment is packaged under the OPPS. However, as discussed in the CY 2022 OPPS/ASC final rule with comment period, for CY 2022, we finalized a policy to unpackage and pay separately at ASP plus 6 percent for the cost of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174 (86 FR 63483).

We generally pay for separately payable radiology services at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to “Z2” so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount (“Z3”), regardless of which is lower (§ 416.171(d)(1)).

Similarly, we also finalized our policy to set the payment indicator to “Z2” for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (§ 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not

have prospectively established ASC payment rates according to ASC payment system policies (72 FR 42502 and 42508 through 42509; § 416.164(b)). Under the ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure’s OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a “device offset” to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator “Z2” and revised the definition of payment indicator “Z2” to include a reference to diagnostic

services and those for which the payment is based on the PFS nonfacility PE RVU-based amount be assigned payment indicator “Z3,” and revised the definition of payment indicator “Z3” to include a reference to diagnostic services.

b. Proposed Payment for Covered Ancillary Services for CY 2025

We propose to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2025 OPPS and ASC payment rates and subsequent years’ payment rates. We also propose to continue to set the CY 2025 ASC payment rates and subsequent years’ payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2025 and subsequent years’ payment rates.

Covered ancillary services and their proposed payment indicators for CY 2025 are listed in Addendum BB of this proposed rule (which is available via the internet on the CMS website). For those covered ancillary services where the payment rate is the lower of the rate under the ASC standard rate setting methodology and the PFS final rates (similar to our office-based payment policy), the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed PFS rates effective January 1, 2025. For a discussion of the PFS rates, we refer readers to the CY 2025 PFS proposed rule, which is available on the CMS website at: <https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notice>.

3. Covered Surgical Procedures Designated as Office-Based Procedures

a. Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as “office-based” those procedures that are added to the ASC Covered Procedures List (CPL) in CY 2008 or later years that we determine are furnished predominantly (more than 50 percent of the time) in physicians’ offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that final rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list

from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC CPL beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that final rule with payment indicator “P2” (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); “P3” (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or “R2” (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the ASC standard ratesetting methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the ASC CPL to include all covered surgical procedures eligible for payment in

ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or nonoffice-based, after taking into account updated volume and utilization data.

b. CY 2025 Proposed Office-Based Procedures

In developing this proposed rule, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment (described in detail in section XIII.C.1.d of this proposed rule), including their potential designation as office-based. Historically, we would also review the most recent claims volume and utilization data (CY 2023 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2024 of “G2” (Non office-based

surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) as well as for those procedures assigned one of the temporary office-based payment indicators, specifically “P2,” “P3,” or “R2” in the CY 2023 OPPS/ASC final rule with comment period (86 FR 63769 through 63773).

Our review of the CY 2023 volume and utilization data of covered surgical procedures currently assigned a payment indicator of “G2” (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) resulted in the identification of two surgical procedures that we believed met the criteria for designation as permanently office-based. The data indicate that these procedures are performed more than 50 percent of the time in physicians’ offices, and the services are of a level of complexity consistent with other procedures performed routinely in physicians’ offices. The CPT codes that we propose to permanently designate as office-based for CY 2025 are listed in Table 79.

TABLE 79: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2025

CY 2024 CPT/HCPCS Code	Long Descriptor	Final CY 2024 ASC Payment Indicator	Proposed CY 2025 ASC Payment Indicator*
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision	G2	P3*
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)	G2	P2*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2025 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2025 PFS proposed rule.

As discussed in the August 2, 2007 ASC final rule (72 FR 42533 through 42535), we finalized our policy to designate certain new surgical procedures as temporarily office-based until adequate claims data are available to assess their predominant sites of service, whereupon if we confirm their office-based nature, the procedures are permanently assigned to the list of office-based procedures. In the absence of claims data, we use other available information, including our clinical

advisors’ judgment, predecessor CPT and Level II HCPCS codes, information submitted by representatives of specialty societies and professional associations, and information submitted by commenters during the public comment period.

We reviewed CY 2023 volume and utilization data for nine surgical procedures designated as temporarily office-based in the CY 2023 OPPS/ASC final rule with comment period and temporarily assigned one of the office-

based payment indicators, specifically “P2,” “P3,” or “R2.” In Table 122 of the CY 2024 OPPS/ASC final rule with comment period, we finalized assigning temporary office-based designations to seven surgical procedures for CY 2024 (88 FR 81919). As shown in Table 80, for one of the seven surgical procedures, there was greater than 50 claims available and the volume and utilization data indicated this procedure was performed predominantly in the office setting. Therefore, we propose to no

longer designate this procedure as temporarily office-based and to

permanently designate this procedure as office-based and assign one of the office-

based payment indicators, specifically “P2,” “P3,” or “R2.”

TABLE 80: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NO LONGER DESIGNATED AS TEMPORARILY OFFICE-BASED FOR CY 2025

CY 2024 CPT/HCPCS Code	Long Descriptor	Final CY 2024 ASC Payment Indicator	Proposed CY 2025 ASC Payment Indicator*
67516	Suprachoroidal space injection of pharmacologic agent (separate procedure)	P3	P3*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2025 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2025 PFS proposed rule.

For six of the seven procedures that were designated as temporarily office-based in the CY 2023 OPPS/ASC final rule with comment period and temporarily assigned one of the office-based payment indicators, specifically “P2,” “P3,” or “R2,” there were fewer than 50 claims; therefore, there was an insufficient amount to determine if the office setting was the predominant setting of care for these procedures. Therefore, as shown in Table 81, we propose to continue to designate such procedures as temporarily office-based for CY 2025 and assign one of the office-based payment indicators.

For CY 2025, we propose to designate three new CY 2025 CPT codes for ASC

covered surgical procedures as temporarily office-based—CPT codes XX34T (Removal of integrated neurostimulation system, vagus nerve), 15XX3 (Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin), and 5XX06 (Catheterization with removal of temporary device for ischemic remodeling (*i.e.*, pressure necrosis) of bladder neck and prostate). After reviewing the clinical characteristics, utilization, and volume of related procedure codes, we determined that CPT code XX34T is most similar to

0588T, which is temporarily designated as an office-based surgical procedure. Additionally, CPT code 15XX3 is most similar to CPT code 11310 (Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.5 cm or less), which is designated as an office-based surgical procedure. Lastly, CPT code 5XX06 is most similar to CPT code 51705 (Change of bladder tube) which is also designated as an office-based surgical procedure. Therefore, as shown in Table 81, we propose to also designate these three new CPT codes as temporarily office-based for CY 2025.

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TABLE 81: PROPOSED CY 2025 PAYMENT INDICATORS FOR NEW AND EXISTING ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2024 CPT/HCPCS Code / CY 2025 Placeholder Code	Long Descriptor	Final CY 2024 ASC Payment Indicator	Proposed CY 2025 ASC Payment Indicator*
0581T	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral	R2	J8*
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	R2	R2*
0864T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy	R2	R2*
XX34T	Removal of integrated neurostimulation system, vagus nerve	NA	R2*
15XX3	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin	NA	R2*
5XX06	Catheterization with removal of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate	NA	P3*
64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator	R2	R2*
65785	Implantation of intrastromal corneal ring segments	P3	P3*
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2025 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2025 PFS proposed rule.

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The procedures for which the proposed office-based designation for CY 2025 is temporary are indicated by an asterisk in Addendum AA to this proposed rule (which is available via

the internet on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices>).

4. Device-Intensive ASC Covered Surgical Procedures

a. Background

We refer readers to the CY 2019 OPPS/ASC final rule with comment

period (83 FR 59040 through 59041), for a summary of our existing policies regarding ASC covered surgical procedures that are designated as device-intensive.

b. CY 2025 Proposed Device Intensive Procedures

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59043), for CY 2019, we modified our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. The device offset percentage is the percentage of device costs within a procedure's total costs. Specifically, for CY 2019 and subsequent years, we adopted a policy that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable or insertable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. Corresponding to this change in the cost criterion, we adopted a policy that the default device offset for new codes that describe procedures that involve the implantation of medical devices will be 31 percent beginning in CY 2019. For new codes describing procedures that are payable when furnished in an ASC and involve the implantation of a medical device, we adopted a policy that the default device offset would be applied in the same manner as the policy we adopted in section IV.B.2 of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948). We amended § 416.171(b)(2) of the regulations to reflect these new device criteria.

In addition, as also adopted in section IV.B.2 of the CY 2019 OPPS/ASC final rule with comment period, to further align the device-intensive policy with the criteria used for device pass-through status, we specified, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B

device by FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;

- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:
 - ++ Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or
 - ++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63773 through 63775), we modified our approach to assigning device-intensive status to surgical procedures under the ASC payment system. First, we adopted a policy of assigning device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices if their device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPPS. Second, we adopted a policy that if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC ratesetting methodology, the procedure will be assigned device-intensive status under the ASC payment system with a default device offset percentage of 31 percent. The policies were adopted to provide consistency between the OPPS and ASC payment system and provide a more appropriate payment rate for surgical procedures with significant device costs under the ASC payment system.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72078 through 72080), we finalized our policy to create certain C-codes, or ASC complexity adjustment codes that describe certain combinations of a primary covered surgical procedure as well as a packaged (payment indicator = “N1”) procedure that are otherwise eligible for a complexity adjustment under the OPPS (as listed in Addendum J). Each ASC complexity adjustment code's APC assignment is based on its

corresponding OPPS complexity adjustment code's APC assignment. In the CY 2023 OPPS/ASC final rule with comment period, we stated our belief that it would be appropriate for these ASC complexity adjustment codes to qualify for device-intensive status under the ASC payment system if the primary procedure of the code was also designated as device-intensive. Under our current policy, the ASC complexity adjustment code retains the device portion of the primary procedure (also called the “device offset amount”) and not the device offset percentage. Therefore, for device-intensive ASC complexity adjustment codes, we set the device portion of the combined procedure equal to the device portion of the primary procedure and calculate the device offset percentage by dividing the device portion by the ASC complexity adjustment code's APC payment rate. Further, we apply our standard ASC payment system ratesetting methodology to the non-device portion of the ASC complexity adjustment code's APC payment rate; that is, we multiply the OPPS relative weight by the ASC budget neutrality adjustment and the ASC conversion factor and sum that amount with the device portion to calculate the ASC payment rate.

As discussed in section IV.B of this proposed rule, the purpose of applying the default device offset percentage to new codes that describe procedures that implant or insert devices is to ensure access in the ASC setting for new procedures until claims data become available. Our ratesetting methodology sets the ASC device offset amount constant at the OPPS device offset amount. Device offset amounts under the OPPS and ASC Payment System are the device offset percentages of a procedure multiplied by the OPPS or ASC Payment System payment rate, respectively, for that procedure. While the ASC ratesetting methodology relies on the ASC conversion factor and the scaled OPPS APC relative weights to construct ASC payment rates, for device-intensive procedures, the device offset percentage of the procedure relies on the higher OPPS conversion factor while the non device portion relies on the lower ASC conversion factor. For non device-intensive procedures for which the payment is based on OPPS relative payment weight, one hundred percent of the procedure's payment rate relies on the ASC conversion factor. Therefore, the greater the device offset percentage under the ASC Payment System, the greater the ASC payment rate.

Device offset percentages, which represent the device cost portion of a

procedure's total cost, are determined using the most recent claims data for that procedure. For newer procedures that describe procedures which implant or insert single-use devices that meet our definition of a device and for which the device costs are estimated to be greater than 30 percent of the total procedure cost and lack claims data, we have relied on several policies to determine an appropriate device offset percentage until such claims data becomes available. First, if the new procedure has claims data from a predecessor code, as described by CPT coding guidance, we rely on claims data from the predecessor code in assigning the device offset percentage for the new HCPCS code (88 FR 81919 through 81922). Second, in limited instances where a new device-intensive procedure does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we may use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and use the claims data of the clinically related or similar code(s) for purposes of determining whether to use the device offset percentage of the clinically related or similar code(s) or to apply the default device offset to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have few or no clinical differences and use the same device(s). If the new device-intensive procedure does not have claims data from a predecessor code or a clinically similar code that uses the same device, we have assigned a default device offset percentage of 31 percent. While we do allow for additional information in our consideration of a higher offset percentage than the default device offset, our payment policies under both the OPPI and ASC Payment System are meant to encourage efficiencies and promote savings to the Medicare program and we believe relying on claims data rather than external pricing data helps put downward pressure on changes in medical device prices. Therefore, it would be extremely rare that the appropriate determination of a device offset percentage would rely on pricing data or invoices from a device manufacturer rather than the default device offset percentage.

However, we are aware that there may be certain situations where newer device-intensive procedures lack claims data from a predecessor code and a clinically similar code that uses the

same device, but the default device offset percentage would not adequately reflect the existing device portion of the procedure's costs when compared to the cost of similar devices. The difference in the default device portion and the potential device cost could possibly limit access to newer, more complex, device-intensive procedures in the ASC setting if the cost of the new device does indeed reflect a cost equivalent to that of the similar existing devices. As HOPDs and ASCs perform new procedures with significant device costs, we believe it is appropriate to modify our default device offset methodology to pay HOPDs and ASCs more appropriately when we lack claims data for these newer procedures. Therefore, for this proposed rule and subsequent calendar years, we propose to modify our default device offset percentage for new device-intensive procedures. Specifically, for all new covered surgical HCPCS codes that describe procedures which implant or insert single-use devices that meet our definition of a device and for which the device costs are estimated to be greater than 30 percent of the total procedure cost and lack claims data, we would apply a default device offset percentage that is the greater of: 31 percent or the device offset percentage of the APC to which the procedure has been assigned. We propose this methodological change for both the OPPI and ASC Payment System for CY 2025 and subsequent calendar years.

We still believe that a HCPCS code-level device offset is, in most cases, a more accurate representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all the procedures assigned to an APC. However, because newer device-intensive procedures lack claims data and therefore a HCPCS code-level device offset may not be possible, we believe the APC-wide average device offset percentage is, in most cases, a better reflection of the estimated device costs of the procedure than a default 31 percent offset. Additionally, there can be instances where the typical device costs of procedures in an APC can be significantly greater than the 31 percent default device offset. For these reasons, we propose to modify our methodology for determining the device offset percentage for new procedures that describe the implantation or insertion of a single-use device that meet our definition of a device and for which the device cost is projected to be greater than 30 percent of the total procedure cost that do not yet have associated

claims data to apply a device offset percentage that is the greater of 31 percent or the device offset percentage of the APC to which the procedure has been assigned. This proposal would apply to new device-intensive procedures assigned to clinical APCs and would not apply to new procedures assigned to New Technology APCs.

Under our proposal, we would continue to first rely on the associated claims data for the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. If there is no claims data from the new HCPCS or any predecessor code, we may continue to use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining a device offset percentage to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have few or no clinical differences and use the same devices. For new device-intensive procedures that describe the implantation or insertion of a single-use device that meet our definition of a device and for which the device cost is significant, projected to be greater than 30 percent of the total procedure cost, and lack claims data, we would then rely on our proposed device offset policy and apply the greater of 31 percent or the device offset percentage of the APC to which the procedure has been assigned.

We solicit comments on our proposed changes to our default device offset policy for CY 2025 and subsequent calendar years under the OPPI and ASC payment system. The listing of proposed payment indicators for covered surgical procedures as well as their respective proposed device offset percentages and device offset amounts, which incorporates our proposed changes to the default device offset policy, can be found in Addendum FF to this proposed rule (which is available via the internet on the CMS website).

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted or inserted in ASCs at no cost/full credit or partial credit is set forth in § 416.179 of our regulations and is consistent with the OPPI policy that was in effect until CY 2014. We refer readers to the CY 2008 OPPI/ASC final rule with comment period (72 FR 66845 through 66848) for a full

discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices. ASC payment is reduced by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device.

Effective CY 2014, under the OPPI, we finalized our proposal to reduce OPPI payment for applicable APCs by the full or partial credit a provider receives for a device, capped at the device offset amount. Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPI, in the CY 2014 OPPI/ASC final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPI, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the amount of the actual credit received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

Under current ASC policy, all ASC device-intensive covered surgical procedures are subject to the no cost/full credit and partial credit device adjustment policy. Specifically, when a device-intensive procedure is performed to implant or insert a device that is furnished at no cost or with full credit from the manufacturer, the ASC appends the HCPCS “FB” modifier on the line in the claim with the procedure to implant or insert the device. The contractor reduces payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure furnished by the ASC.

In the CY 2019 OPPI/ASC final rule with comment period (83 FR 59043 through 59044) we adopted a policy to reduce the payment for a device-

intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC will append the HCPCS “FC” modifier to the HCPCS code for the device-intensive surgical procedure when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs have the option of either: (1) submitting the claim for the device-intensive procedure to their Medicare contractor after the procedure’s performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the “FC” modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 OPPI/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost or receive full credit or partial credit for the device, we apply our “FB”/“FC” modifier policy to all device-intensive procedures.

In the CY 2019 OPPI/ASC final rule with comment period (83 FR 59043 through 59044) we stated we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. In the CY 2020 OPPI/ASC final rule with comment period, we finalized continuing our existing policies for CY 2020. We note that we inadvertently omitted language that this policy would apply not just in CY 2019 but also in subsequent calendar years. We intended to apply this policy in CY 2019 and subsequent calendar years. Therefore, we finalized our proposal to apply our

policy for partial credits specified in the CY 2019 OPPI/ASC final rule with comment period (83 FR 59043 through 59044) in CY 2022 and subsequent calendar years (86 FR 63775 through 63776). Specifically, for CY 2022 and subsequent calendar years, we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device, ASCs have the option of either: (1) submitting the claim for the device-intensive procedure to their Medicare contractor after the procedure’s performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the “FC” modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount.

We are not proposing any changes to our policies related to no cost/full credit or partial credit devices for CY 2025.

5. Requirement in the Physician Fee Schedule CY 2025 Proposed Rule for HOPDs and ASCs To Report Discarded Amounts of Certain Single-Dose or Single-Use Package Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) (“the Infrastructure Act”) amended section 1847A of the Act to re-designate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The CY 2025 PFS proposed rule includes proposals related to the discarded drug refund policy, including proposals that may impact hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs). Similar to our CY 2023 and CY 2024 notice in the OPPI/ASC proposed rules (87 FR 71988 and 88 FR 49760), we wanted to ensure interested parties were

aware of these proposals and knew to refer to the CY 2025 Physician Fee Schedule proposed rule for a full description of the proposed policy. Interested parties are asked to submit comments on any proposals to implement Section 90004 of the Infrastructure Act to the CY 2025 PFS proposed rule. Public comments on these proposals will be addressed in the CY 2025 PFS final rule with comment period. We note that this same notice appears in section V.B.6 of this proposed rule with respect to the OPPTS.

D. Proposed Additions to ASC Covered Surgical Procedures and Covered Ancillary Services Lists

1. Proposed Additions to the List of ASC Covered Surgical Procedures

Section 1833(i)(1) of the Act requires us, in part, to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can also be safely performed in an ASC, a CAH, or an HOPD, and to review and update the list of ASC covered surgical procedures at least every 2 years. We evaluate the ASC covered procedures list (ASC CPL) each year to determine whether procedures should be added to or removed from the list, and changes to the list are often made in response to specific concerns raised by stakeholders.

Under our regulations at §§ 416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2022, are surgical procedures that meet the general standards specified in § 416.166(b) and are not excluded under the general exclusion criteria specified in § 416.166(c). Specifically, under § 416.166(b), the general standards provide that covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that are separately paid under the OPPTS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

Section 416.166(c) sets out the general exclusion criteria used under the ASC payment system to evaluate the safety of procedures for performance in an ASC. The general exclusion criteria provide that covered surgical procedures do not include those surgical procedures that: (1) generally result in extensive blood

loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life-threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under § 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under § 411.15.

In the CY 2019 OPPTS/ASC final rule with comment period (83 FR 59029 through 59030), we defined a surgical procedure under the ASC payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as “surgery” (CPT codes 10000 through 69999) (72 FR 42476), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we determined met the general standards established in previous years for addition to the ASC CPL.

In the CY 2024 OPPTS/ASC final rule with comment period, we finalized adding several dental surgical procedures to the ASC CPL that met our regulatory criteria at §§ 416.166. We note that there are statutory and regulatory limitations regarding Medicare coverage and payment for dental services. Section 1862(a)(12) of the Act generally precludes Medicare Part A or Part B payment for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth (collectively referred to in this section as “dental services”). The regulation at § 411.15(i) similarly prohibits payment for dental services. In the CY 2023 PFS final rule (87 FR 69663), we explained that there are certain instances where dental services are so integral to other medically necessary services that they are not in connection with dental services within the meaning of section 1862(a)(12) of the Act. Rather, such dental services are inextricably linked to, and substantially related to the clinical success of, other covered services (hereafter in this section, “inextricably linked”). To provide greater clarity to current policies, the CY 2023 PFS final rule finalized: (1) a clarification of our interpretation of section 1862(a)(12) of the Act to permit payment for dental services that are inextricably linked to other covered services; (2) clarification and codification of certain longstanding Medicare FFS payment policies for dental services that are inextricably

linked to other covered services; (3) that, beginning for CY 2023, Medicare Parts A and B payment can be made for certain dental services inextricably linked to Medicare-covered organ transplant, cardiac valve replacement, or valvuloplasty procedures; and, (4) beginning for CY 2024, that Medicare Parts A and B payment can be made for certain dental services inextricably linked to Medicare-covered services for treatment of head and neck cancers (87 FR 69670 through 69671).

For the ASC setting, services must meet all applicable Medicare conditions for coverage and payment to be paid by Medicare, including those as specified under the CY 2023 PFS final rule (87 FR 69687 through 69688) and § 411.15(i)(3). Medicare payment may be made in the ASC setting for dental services for which payment may be made under Medicare Part B, paid under the OPPTS, and that meet the ASC CPL criteria. The fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate under the ASC payment system indicates only how the product, procedure, or service may be paid if covered by the program. MACs will be involved in the final decision regarding whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment. Therefore, even if a code describing a dental service has an associated payment rate on the ASC CPL, Medicare will only make payment for the service if it meets applicable requirements. We also clarify that adding dental procedures to the ASC CPL does not serve as a coverage determination for dental services under general anesthesia. We direct readers to the CY 2025 PFS proposed rule for additional discussion of Medicare coverage and payment for dental services, which is available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

For a detailed discussion of the history of our policies for adding surgical procedures to the ASC CPL, we refer readers to the CY 2021 through CY 2024 OPPTS/ASC final rules with comment period (85 FR 86143 through 86145; 86 FR 63777 through 63805; 87 FR 72068 through 72076; and 88 FR 81923 through 81945).

2. Proposed Changes to the List of ASC Covered Surgical Procedures for CY 2025

Our current policy, which includes consideration of the general standards and exclusion criteria we have historically used to determine whether

a surgical procedure should be added to the ASC CPL, is intended to ensure that surgical procedures added to the ASC CPL can be performed safely in the ASC setting on the typical Medicare beneficiary.

As part of our evaluation process to add procedures to the CPL, we assess potential procedures against the specific list of ASC CPL criteria at § 416.166. We also examine clinical data on these procedures from multiple sites of services, review literature and experiential data, and analyze claims data trends to ensure that these procedures meet all our criteria and are not expected to pose a significant risk to beneficiary safety when performed in an ASC. For CY 2025, we also reviewed supporting evidence received in the pre-proposed rule nominations process to inform our procedure evaluations. Based upon this review, we propose to update the ASC CPL by adding 20 medical and dental surgical procedures to the list for CY 2025, as shown in Table 82.

After reviewing the clinical characteristics of these twenty

procedures and consulting with stakeholders and multiple clinical advisors, we determined that these procedures are separately paid under the OPPI, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. These procedures are surgical or surgery-like, clinically similar to procedures in the CPT surgical range that we determined met the general standards for addition to the ASC CPL. These procedures are not excluded from being included on the ASC CPL because they do not generally result in extensive blood loss, require major or prolonged invasion of body cavities, commonly require systemic thrombolytic therapy, or directly involve major blood vessels; are not generally emergent or life-threatening in nature or designated as requiring inpatient care; or can only be reported using a CPT unlisted surgical procedure code or are otherwise excluded under

Medicare. Therefore, we believe these procedures may all be appropriately performed in an ASC and propose to include them on the ASC CPL for CY 2025.

We continue to focus on maximizing patient access to care by adding procedures to the ASC CPL when appropriate. While expanding the ASC CPL offers benefits, such as preserving the capacity of hospitals to treat more acute patients and promoting site neutrality, we also believe that any additions to the CPL should be added in a carefully calibrated fashion to ensure that the procedure is safe to be performed in the ASC setting. We encourage interested parties to submit procedure recommendations to be added to the ASC CPL, particularly if there is evidence that these procedures meet our criteria and can be safely performed in the ASC setting. We expect to continue to gradually expand the ASC CPL, as medical practice and technology continue to evolve and advance in future years.

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TABLE 82: CY 2025 PROPOSED SURGICAL PROCEDURES FOR THE ASC CPL

CY 2025 CPT/HCPCS/CDT Code	CY 2025 Long Descriptor
0717T	Autologous adipose-derived regenerative cell (adrc) therapy for partial thickness rotator cuff tear; adipose tissue harvesting, isolation and preparation of harvested cells, including incubation with cell dissociation enzymes, filtration, washing, and concentration of adrcs
0718T	Autologous adipose-derived regenerative cell (adrc) therapy for partial thickness rotator cuff tear; injection into supraspinatus tendon including ultrasound guidance, unilateral
0795T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; complete system (ie, right atrial and right ventricular pacemaker components)
0801T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; dual-chamber system (ie, right atrial and right ventricular pacemaker components)
D7251	Coronectomy - intentional partial tooth removal, impacted teeth only
D7280	Exposure of an unerupted tooth
D7410	Excision of benign lesion up to 1.25 cm
D7411	Excision of benign lesion greater than 1.25 cm
D7412	Excision of benign lesion, complicated
D7413	Excision of malignant lesion up to 1.25 cm
D7414	Excision of malignant lesion greater than 1.25 cm
D7415	Excision of malignant lesion, complicated
D7450	Removal of benign odontogenic cyst or tumor-lesion diameter up to 1.25 cm
D7451	Removal of benign odontogenic cyst or tumor-lesion diameter greater than 1.25 cm
D7460	Removal of benign nonodontogenic cyst or tumor-lesion diameter up to 1.25 cm
D7461	Removal of benign nonodontogenic cyst or tumor-lesion diameter greater than 1.25 cm
D7485	Reduction of osseous tuberosity
D7521	Incision and drainage of abscess - extraoral soft tissue - complicated (includes drainage of multiple fascial spaces)
D7530	Removal of foreign body from mucosa, skin, or subcutaneous alveolar tissue
D7540	Removal of reaction-producing foreign bodies-musculoskeletal system

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3. Covered Ancillary Services

Covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment. As provided at § 416.164(b), we make separate ASC payments for ancillary items and services when they are provided integral to ASC covered surgical procedures that include the following: (1) brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPI; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPI; (5) certain radiology services for which separate payment is allowed under the OPPI; and (6) non-opioid pain management drugs that function as a supply when used in a surgical procedure. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

In the CY 2019 OPPI/ASC final rule with comment period (83 FR 59062 through 59063), consistent with the established ASC payment system policy (72 FR 42497), we finalized the policy to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPI and to continue this reconciliation of packaged status for subsequent calendar years. As discussed in prior rulemaking, maintaining consistency with the OPPI may result in changes to ASC payment indicators for some covered ancillary services. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2024, but will be packaged under the CY 2025 OPPI, we would also package the ancillary service under the ASC payment system for CY 2025 to maintain consistency with the OPPI. Comment indicator “CH” is used in Addendum BB (which is available via the internet on the CMS website) to indicate covered ancillary services for which we propose a change in the ASC payment indicator to reflect a proposed change in the OPPI treatment of the service for CY 2025.

In the CY 2022 OPPI/ASC final rule with comment period, we finalized our proposal to revise 42 CFR 416.164(b)(6) to include, as ancillary items that are integral to a covered surgical procedure and for which separate payment is allowed, non-opioid pain management drugs and biologicals that function as a supply when used in a surgical

procedure as determined by CMS (86 FR 63490).

New CPT and HCPCS codes for covered ancillary services for CY 2025 can be found in section XIII.B of this proposed rule. All ASC covered ancillary services and their final payment indicators for CY 2025 are also included in Addendum BB to this proposed rule (which is available via the internet on the CMS website). *Claims Processing Limitations for Covered Ancillary Procedures Performed with G0330.*

We finalized adding HCPCS code G0330 (*Facility services for dental rehabilitation procedure(s) performed on a patient who requires monitored anesthesia (e.g., general, intravenous sedation (monitored anesthesia care) and use of an operating room)*) to the ASC CPL in the CY 2024 OPPI/ASC final rule (88 FR 81924). In ASC Addendum BB, there is a specific and definitive list of covered ancillary dental services with payment indicator of “D1,” indicating an ancillary dental service or item with no separate payment made. In the CY 2024 OPPI/ASC final rule with comment period (88 FR 81945 through 46), we finalized that code G0330 could only be billed when accompanied by a covered ancillary procedure that has the payment indicator of “D1.” Performance of at least one of these covered ancillary services is integral to each of the surgical procedures that correspond to G0330. This limitation ensures that only covered ancillary services we evaluated for safety in the ASC setting could be performed with code G0330.

While HCPCS code G0330 must be billed with a covered ancillary procedure with a payment indicator of “D1,” these covered ancillary procedures with a payment indicator of “D1” can be billed with surgical procedures other than G0330. When billed with procedures other than code G0330, these ancillary procedures would be packaged in accordance with our policy for covered ancillary procedures. Additionally, other than HCPCS code G0330, procedures assigned to payment indicator “D2,” indicating non office-based dental procedure added in CY 2024 or later, are not required to be billed with a covered ancillary procedure assigned to payment indicator “D1” to receive payment for the procedure.

The fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate under the ASC payment system indicates only how the product, procedure, or service may be paid if covered by the program. MACs will be involved in the final

decision regarding whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment. Therefore, even if a code describing a dental service has an associated payment rate on the ASC CPL, Medicare will only make payment for the service if it meets applicable requirements.

E. ASC Payment Policy for Non-Opioid Post-Surgery Pain Management Drugs, Biologicals, and Devices

1. Background on OPPI/ASC Non-Opioid Pain Management Packaging Policies

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Pub. L. 115–271) was enacted. Section 1833(t)(22)(A)(i) of the Act, as added by section 6082(a) of the SUPPORT Act, states that the Secretary must review payments under the OPPI for opioids and evidence based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. As part of this review, under section 1833(t)(22)(A)(iii) of the Act, the Secretary must consider the extent to which revisions to such payments (such as the creation of additional groups of covered outpatient department (OPD) services to separately classify those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce the payment incentives for using opioids instead of non-opioid alternatives for pain management. In conducting this review and considering any revisions, the Secretary must focus on covered OPD services (or groups of services) assigned to C–APCs, APCs that include surgical services, or services determined by the Secretary that generally involve treatment for pain management. If the Secretary identifies revisions to payments pursuant to section 1833(t)(22)(A)(iii) of the Act, section 1833(t)(22)(C) of the Act requires the Secretary to, as determined appropriate, begin making revisions for services furnished on or after January 1, 2020. Revisions under this paragraph are required to be treated as adjustments for purposes of paragraph (9)(B) of the Act, which requires any adjustments to be made in a budget neutral manner. Section 1833(i)(8) of the Act, as added by section 6082(b) of the SUPPORT Act, requires the Secretary to conduct a similar type of review as required for

the OPPTS and to make revisions to the ASC payment system in an appropriate manner, as determined by the Secretary.

For a detailed discussion of rulemaking on non-opioid alternatives prior to CY 2020, we refer readers to the CYs 2018 and 2019 OPPTS/ASC final rules with comment period (82 FR 59345; 83 FR 58855 through 58860).

For the CY 2020 OPPTS/ASC proposed rule (84 FR 39423 through 39427), as required by section 1833(t)(22)(A)(i) of the Act, we reviewed payments under the OPPTS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. For the CY 2020 OPPTS/ASC proposed rule (84 FR 39423 through 39427), we proposed to continue our policy to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting.

In the CY 2020 OPPTS/ASC final rule with comment period (84 FR 61173 through 61180), after reviewing data from stakeholders and Medicare claims data, we did not find compelling evidence to suggest that revisions to our OPPTS payment policies for non-opioid pain management alternatives were necessary for CY 2020. We finalized our proposal to continue to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2020. Under this policy, for CY 2020,

the only drug that qualified for separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply was Exparel.

In the CY 2021 OPPTS/ASC final rule with comment period (85 FR 85896 through 85899), we continued the policy to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they were furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021. For CY 2021, only Exparel and Omidria met the criteria as non-opioid pain management drugs that function as surgical supplies in the ASC setting and received separate payment under the ASC payment system.

In the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63483), we finalized a policy to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting, are FDA-approved, have an FDA-approved indication for pain management or as an analgesic, and have a per-day cost above the OPPTS/ASC drug packaging threshold; and we finalized our proposed regulation text changes at 42 CFR 416.164(a)(4) and (b)(6), 416.171(b)(1), and 416.174 as proposed.

In the CY 2023 OPPTS/ASC final rule with comment period (87 FR 72089), we determined that five products were eligible for separate payment in the ASC setting under our final policy for CY 2022. We noted that future products, or products not discussed in that rulemaking that may be eligible for separate payment under this policy, would be evaluated in future

rulemaking (86 FR 63496). In the CY 2023 final rule with comment period, we finalized that five drugs would receive separate payment in the ASC setting for CY 2023 under the policy for non-opioid pain management drugs and biologicals that function as surgical supplies (86 FR 63496).

In the CY 2023 OPPTS/ASC final rule with comment period, we finalized a clarification of our policy by codifying the two additional criteria for separate payment for non-opioid pain management drugs and biologicals that function as surgical supplies in the regulatory text at § 416.174 as a technical change. First, we finalized at new § 416.174(a)(3) that non-opioid pain management drugs or biologicals that function as a supply in a surgical procedure are eligible for separate payment if the drug or biological does not have transitional pass-through payment status under § 419.64. In the case where a drug or biological otherwise meets the requirements under § 416.174 and has transitional pass-through payment status that will expire during the calendar year, the drug or biological would qualify for separate payment under § 416.174 during such calendar year on the first day of the next calendar year quarter after its pass-through status expires. Second, we finalized that new § 416.174(a)(4) would reflect that the drug or biological must not already be separately payable in the OPPTS or ASC payment system under a policy other than the one specified in § 416.174.

In the CY 2024 OPPTS/ASC final rule with comment period, we finalized four drugs as eligible to receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system and which met the criteria at § 416.174(a) for CY 2024. (See Table 83.)

TABLE 83: SUMMARY OF PRODUCTS FINALIZED UNDER THE NON-OPIOID PAIN MANAGEMENT POLICY FOR CY 2024

HCPSC Code	Brand Name	Long Descriptor	CY 2024 OPPS Status Indicator (SI)*	CY 2024 ASC Payment Indicator (PI)*
C9290	Exparel	Injection, bupivacaine liposome, 1 mg	N	K2
J1097	Omidria	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	N	K2
J1096	Dextenza	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	N	K2
C9089	Xaracoll	Bupivacaine, collagen-matrix implant, 1 mg	N	K2

*Please see ASC Addenda BB for applicable payment rates, OPPS Addenda D1 for SI definitions, and ASC Addenda DD1 for PI definitions. All are available via the internet on the CMS website for the CY 2024 OPPS/ASC rule.

F. Proposed CY 2025 Non-Opioid Policy for Pain Relief Under the OPPS and ASC Payment System

1. Background on Access to Non-Opioid Treatments for Pain Relief

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA, 2023, titled Access to Non-Opioid Treatments for Pain Relief, amended section 1833(t)(16) and section 1833(i) of the Social Security Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief (as that term is defined in section 1833(t)(16)(G)(i) of the Act). In particular, section 1833(t)(16)(G) provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025 and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount.

Paragraph (10) of section 1833(i) of the Act cross-references the OPPS provisions about the additional payment amount and payment limitation for non-

opioid treatments for pain relief and applies them to payment under the ASC payment system. In particular, subparagraph (A) of paragraph (10) of section 1833(i) of the Act, as added by section 4135(b) of the CAA, 2023, provides that in the case of surgical services furnished on or after January 1, 2025, and before January 1, 2028, additional payments shall be made under the ASC payment system for non-opioid treatments for pain relief in the same amount provided in clause (ii) and subject to the limitation in clause (iii) of section 1833(t)(16)(G) of the Act for the OPPS. Subparagraph (B) of section 1833(i)(10) of the Act provides that a drug or biological that meets the requirements of 42 CFR 416.174 and is a non-opioid treatment for pain relief shall also receive additional payment in the amount provided in clause (ii) and subject to the limitation in clause (iii) of section 1833(t)(16)(G) of the Act. Additional payments are required to begin on January 1, 2025. The statute directs CMS to provide “additional payment”, and for purposes of this proposal, we interrupt this language to be equivalent to “separate payment,” since CMS provides an additional payment by unpackaging the product and then making a separate payment. “Separate payment” is the more commonly used terminology in the OPPS rule and likely more familiar with readers, therefore, to avoid confusion

we will be using “separate payment” throughout the rest of this section, which we believe to be synonymous with “additional payment.”

Our proposals to implement the amendments to sections 1833(t)(16) and section 1833(i) of the Act required by section 4135 of the CAA, 2023 are discussed below.

2. Proposed CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

a. Statutory Authority for OPPS/ASC Non-Opioid Policy

Prior to CY 2025, the statutory authority for the ASC non-opioid policy is section 1833(i)(8) of the Act, as added by section 6082(b) of the SUPPORT Act. Section 1833(i)(8) of the Act refers to paragraph (t)(22), which states that the Secretary shall conduct a similar type of review as the one required for the OPPS for opioids and evidence based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives and make such revisions as the Secretary determines appropriate. As discussed in the previous section, CMS’s policy for CY 2024 is to provide separate payment in the ASC setting for certain qualifying non-opioid pain management drugs that

function as a supply in a surgical procedure.

As noted previously, section 4135 of the CAA, 2023, provides for temporary separate payments for certain non-opioid treatments for pain relief in both the hospital outpatient department and ambulatory surgical center settings from January 1, 2025 through December 31, 2027. Specifically, these separate payments are for qualifying drugs, biologicals, and devices that, among other requirements, have their payment packaged into payment for a covered OPD service (or group of services). Pursuant to section 1833(t)(2)(E) of the Act, the temporary separate payments must be made in a budget neutral manner.

(1) Drugs and Biologicals Subject to the ASC Non-Opioid Policy (42 CFR 416.174)

Section 1833(i)(10)(B), titled “Transition,” provides that a drug or biological that meets the requirements of the regulation at 42 CFR 416.174 (the current ASC non-opioid policy) and that meets the definition of a non-opioid treatment for pain relief at section 1833(t)(16)(G)(iv) shall receive separate payments under section 4135 of the CAA, 2023, subject to the payment limitation. In light of this requirement, we propose that drugs and biologicals that meet the definition of a non-opioid treatment for pain relief for purposes of section 4135 that are currently subject to the ASC policy for non-opioid treatments authorized by section 6082 of the SUPPORT Act, would instead receive separate payments, subject to the limitation, for the duration of the payment period for section 4135. These drugs and biologicals are described in the discussions that follow.

(2) Definition of Non-Opioid Treatment for Pain Relief

Section 1833(t)(16)(G)(iv) of the Act defines a non-opioid treatment for pain relief. In order for a drug or biological product to qualify as a non-opioid treatment for pain relief, pursuant to section 1833(t)(16)(G)(iv)(I), the product must have “a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body’s opioid receptors.” In order for a medical device to qualify as a non-opioid treatment for pain relief, pursuant to section 1833(t)(16)(G)(iv)(II)(bb), the medical devices must be “used to deliver a therapy to reduce postoperative pain, or produce post-surgical or regional analgesia.” This subparagraph also defines such a device as having “an

application under section 515 of the Federal Food, Drug, and Cosmetic Act that has been approved with respect to the device, been cleared for market under section 510(k) of such Act, or is exempt from the requirements of section 510(k) of such Act pursuant to subsection (l) or (m) or section 510 of such Act or section 520(g) of such Act” and “demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal.”

(3) Evidence Requirement for Medical Devices

To determine whether a medical device fulfills the requirement that it has demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal, we propose to review all data submitted during the public comment period to determine if the device demonstrates the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids. When interested parties submit non-opioid device recommendations for CY 2025, we encourage them to also submit with their public comments any relevant literature that demonstrates that the named medical device replaces, reduces, or avoids opioid use per this statutory provision. We propose that CMS will review any literature submitted and determine whether it meets this evidence criterion. We are not requiring that commenters submit any data or literature with their device recommendations. If there is no data or literature submitted for a medical device, or if the materials submitted do not demonstrate any ability of the medical device to replace, reduce, or avoid opioids, the medical device will not meet this evidence criterion and will therefore not qualify for separate payment under section 4135.

c. Non-Opioid Product Indications

(1) FDA-Approved Indications for Drugs and Biologicals

Section 1833(t)(16)(G)(iv)(I) of the Act specifies that to meet the definition of a non-opioid treatment for pain relief and to be eligible for separate payment, a drug or biological product must have a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia,

without acting upon the body’s opioid receptors.

Given these statutory requirements, we propose only to approve separate payment for drug or biological products with an FDA-approved indication that closely aligns with the statutorily required indication language to reduce post-operative pain or produce post-surgical or regional analgesia. Products with an indication that does not meet the statutory requirement will not qualify. Table 84 includes citations to the indications of the drugs and biologicals that we propose meet the statutory requirements and should qualify for separate payment for CY 2025.

(2) Indications for Medical Devices

With respect to medical devices, section 1833(t)(16)(G)(iv)(II) of the Act specifies that such a device must be used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia to qualify for separate payment under section 4135. It also must have an application approved under section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA), have been cleared for market under section 510(k) of the FDCA, or be exempt from the requirements of section 510(k) of the FDCA pursuant to section 510(l) or (m) or 520(g) of the FDCA. For medical devices, we propose to only approve medical devices with an indication that specifies that the device is used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia and which also have FDA approval, market clearance, or an appropriate exemption from the requirements of section 510(k). Table 84 includes citations to the indication of one device that we propose meets the statutory requirements and should qualify for separate payment for CY 2025.

d. Amount of Payment

Section 1833(t)(16)(G)(ii)(I) of the Act provides that, for a non-opioid treatment for pain relief that is a drug or biological product, the amount of separate payment is the amount of payment for such product determined under section 1847A of the Act that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological, subject to a limitation, as described in the next section. Section 1833(t)(16)(G)(ii)(II) of the Act provides that, for a non-opioid treatment for pain relief that is a medical device, the amount of separate payment is the amount of the hospital’s charges for the

device, adjusted to cost, that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the device, subject to a limitation, as described in the next section. As the language in Section 1833(t)(16)(G)(ii)(II) of the Act is very similar to the transitional pass-through language at section 1833(t)(6)(D)(i) and (ii) of the Act, we propose implementing a similar payment methodology for non-opioid products. A payment offset is the amount reflecting the portion of the non-opioid product in the procedure payment rate. We propose to assign a payment offset of zero dollars for the qualifying drugs, biologicals, and devices for CY 2025. A zero offset means that we would not offset or remove the amount that the non-opioid product represents from the procedure payment rate when setting payment rates. We propose this would apply for CY 2025 for all non-opioid drugs, biologicals, and devices that qualify for separate payment. We believe it makes sense to propose a zero dollar offset for the initial year of the policy as some of these products are new products or newly separately paid in the OPPS setting and their costs may not be fully reflected yet in the cost of procedures in which they may be used. Therefore, the separate payment for a drug or biological will be determined by subtracting from the amount calculated using the methodology outlined in section 1847A of the Act the portion of the otherwise applicable Medicare OPD fee schedule associated with the drug or biological, which as previously discussed, we propose to be zero dollars for CY 2025. For the amount of payment for a medical device, the separate payment amount will be determined by subtracting from the hospital's charges for the device, adjusted to cost, the portion of the otherwise applicable Medicare OPD fee schedule amount associated with the medical device, which as previously discussed, we propose to be zero dollars for CY 2025. These separate payment amounts will all be subject to the payment limitation described in the subsequent section.

Section 1833(i)(10) of the Act establishes the same separate payment for the ASC setting as for hospital outpatient departments, as described in section 1833(t)(16)(G)(ii) of the Act. Both separate payments are subject to the limitation in section 1833(t)(16)(G)(iii) of the Act, which specifies that the separate payment amount shall not exceed the estimated average of 18 percent of the OPD fee schedule amount for the OPD service (or

group of services) with which the non-opioid treatment for pain relief is furnished. Our proposed implementation of this payment limitation is discussed in further detail below. Given this statutory requirement, we propose to pay the same separate payment amount for qualifying non-opioid products in both the HOPD and ASC settings.

As the statute requires separate payment for these non-opioid treatments for pain relief, these products cannot be packaged into the procedure payment. Under our current threshold packaging policy, if the estimated per day cost for a drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we package payment for the drug or biological into the payment for the associated procedure. Similarly, under our comprehensive APC (C-APC) policy, we package all payments for services integral, ancillary, supportive, dependent, and adjunctive to the primary service into a single payment for the primary comprehensive service. For more information on the drug packaging threshold, see section V.B.1.a of this proposed rule, and section II.A.b of this proposed rule for further information on C-APC packaging. We propose that non-opioid treatments for pain relief would not be subject to the threshold packaging policy in section V.B.1.a. of the proposed rule (88 FR 49676) and would also be separately paid when used during a comprehensive APC (C-APC) procedure in the HOPD setting.

e. Payment Limitation

Section 1833(t)(16)(G)(iii) of the Act states that the separate payment amount specified in clause (ii), (which is described in the previous section) shall not exceed the estimated average of 18 percent of the OPD fee schedule amount for the OPD service (or group of services) with which the non-opioid treatment for pain relief is furnished, as determined by the Secretary.

For the non-opioid products that are currently billed under the OPPS, we conducted a claims analysis of CY 2023 OPPS claims, which are the claims available for CY 2025 rulemaking, and found that approximately 90 percent of the utilization, on average, for these non-opioid products is focused in the top five most frequently performed services for each product. Given this, we believe that using the top five services would provide a representative estimate for purposes of the payment limitation. As illustrated in Table 85, we propose to use the top five services by volume associated with a drug, biological, or

medical device, to determine the volume-weighted payment rate per claim and the 18 percent payment limitation specified by statute, based on the most recent claims data available. This payment limitation approach is also generally consistent with the comments received in response to the comment solicitation in the CY 2024 OPPS/ASC proposed rule (88 FR 49767 through 49769). For example, in response to the CY 2024 comment solicitation, several commenters supported CMS establishing a payment limitation for each non-opioid treatment item based on a volume-weighted OPPS payment rate for the top five services that package the item into their payment rate.

We propose to apply the 18 percent payment limitation per date of service billed, rather than per HCPCS dosage unit. This is due to the fact that there are typically multiple HCPCS dosage units (also called billing units) of each drug or biological billed per claim. Thus, the total units of a drug billed on a date of service is more reflective of the cost of the drug in that encounter. The amount of drug or biological used during an encounter, represented by a date of service for purposes of this proposal, will impact whether the separate payment for the drug or biological exceeds the payment limitation required by statute. Meaning, the same drug or biological may or may not be subject to the payment limitation depending on the amount of drug used. For example, a drug is paid \$1 per 1 mg (per billing unit) and has a payment limitation set at \$100 based on 18 percent of the volume weighted average of the payment of the top 5 services associated with the use of the drug. If 50 mg (50 billing units) of this drug were to be billed during one patient encounter or one date of service, then \$50 would be paid. The payment limitation would not apply as the payment for the drug did not exceed the payment limitation of \$100. If 200 mg (200 billing units) of that same drug were to be billed during one patient encounter or one date of service, then the \$200 payment would be limited to \$100. In this case the payment limitation would apply as the payment for the drug exceeded the payment limitation of \$100. We propose to apply this payment limitation to the date of service billed as the payment limitation applies to the total amount of separate payment, rather than the HCPCS dosage unit payment, which may only represent a small fraction of the total amount of payment.

We propose to create new status indicators for non-opioid drugs and

devices to implement this payment limitation. Under the OPPS, non-opioid drugs and biologicals under this policy would be assigned a status indicator of K1, while non-opioid devices would be assigned a status indicator of H1. Further discussion of these new status indicators can be found in section X1.A of this proposed rule.

As discussed in section XIII.B.6.b. of this proposed rule, we propose to modify the descriptor of ASC payment indicator “L6”—“New Technology Intraocular Lens (NTIOL); special payment” to “Special payment; New Technology Intraocular Lens (NTIOL) or qualifying non-opioid devices” and propose to assign qualifying non-opioid medical devices to this payment indicator to operationalize payment of these devices. We propose to assign qualifying drugs and biologicals to existing payment indicator “K2.” We refer readers to Addenda DD1 and DD2 of this proposed rule (these addenda are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators proposed for the CY 2025 update.

We have presented our proposed payment limitation calculations for qualifying non-opioid products in Table 85. We welcome public comment on the methodology used to determine the payment limitation.

d. Payment Limitation With No Claims Data

For drugs, biologicals, and devices with no claims data, such as for newly FDA-approved and marketed products or products that did not previously have their own product-specific HCPCS code by which to track payment and utilization data, we are soliciting comment on the best approach for determining a payment limitation, as required by section 1833(t)(16)(G)(iii) of the Act. As discussed in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81953), CMS could utilize the services with which a product would be expected to be furnished and would typically be packaged absent this policy, based on expected clinical use

patterns. Determining the service, or group of services, to use to calculate the payment limitation could be accomplished through engagement with interested parties and a review by CMS Medical Officers and clinical staff. Absent engagement from interested parties, CMS could determine the service, or group of services, to use to calculate the payment limitation based on expected clinical use patterns. CMS could then adjust the services that are used to calculate the payment limitation as claims data becomes available in subsequent years. We welcome comments on how to set a payment limitation for a product for which we do not have claims data on which to base a payment limitation. The product is described by HCPCS code C98X4 (ON—Q Pump). We solicit comment on the top 5 procedures performed with this product, and the HCPCS code that describes the procedure, in order to calculate a volume weighted payment limitation for this device for CY 2025.

We anticipate that we may update the payment limitation amount in future rulemaking as we gather additional claims data on the utilization of and payment for this product.

e. Qualifying Products

The following tables (Tables 84 and 85) list the non-opioid alternatives of which we are aware that we propose would receive separate payment as a non-opioid pain management drug or device under section 4135 criteria for CY 2025. With respect to one medical device, Table 84 also includes references to literature previously submitted to CMS, which CMS has reviewed and based on that review, has determined that the device shows the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal. Based on this determination, we propose the device listed in Table 84 is eligible for separate payment.

In general, CMS routinely receives comments from readers of the proposed

rule with detailed rationale as to why and how a particular drug, biological, medical device, or other item or service should be paid in their view. We are soliciting comment on whether there are any additional drugs, biologicals, or medical devices that meet the statutory requirements outlined in 1833(t)(16)(G) and 1833(i)(10). As discussed in this section, there are specific requirements with respect to FDA approval that must be met in order for the product to qualify for separate payment. For medical devices, the statute also requires that the device has demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal. Interested parties that believe that a product not addressed in this proposed rule meets the statutory requirements should submit information during the comment period that indicates that such product meets the statutory eligibility requirements. If CMS determines that such product(s) does in fact meet the statutory eligibility requirements, we would finalize separate payment for that product in the CY 2025 OPPS/ASC final rule with comment period. For drugs and biological products not addressed in this proposed rule, if no comment is submitted that outlines how that drug or biological meets the statutory criteria, then CMS will not finalize separate payment for such product for CY 2025. For medical devices not addressed in this proposed rule, unless a comment is submitted that both outlines how that device meets the statutory criteria and includes literature that demonstrates that the device has the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal, then CMS will not finalize separate payment for such device for CY 2025.

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TABLE 84: PROPOSED LIST OF QUALIFYING PRODUCTS FOR SEPARATE PAYMENT UNDER SECTION 4135 OF THE CAA, 2023

Brand Name	HCPCS Code	Long Descriptor	Meets Requirements
Exparel	C9290	Injection, bupivacaine liposome, 1mg	Yes ¹⁰⁶
Omidria	J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	Yes ¹⁰⁷
Dextenza	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	Yes ¹⁰⁸
Xaracoll	C9089	Bupivacaine, collagen-matrix implant, 1 mg	Yes ¹⁰⁹
Zynrelef	C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	Yes. ¹¹⁰ Effective April 1, 2025
Ketorolac tromethamine Injection	J1885	Injection, ketorolac tromethamine, per 15 mg	Yes ¹¹¹
ON-Q Pump	C98X4	Elastomeric infusion pump, non-opioid pain management delivery system, including catheter and other system component(s)	Yes ^{112,113}

¹⁰⁶ Exparel. FDA Package Insert. November 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022496s051lbl.pdf.

¹⁰⁷ Omidria. FDA Package Insert. December 2017. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205388s006lbl.pdf.

¹⁰⁸ Dextenza. FDA Package Insert. October 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208742s007lbl.pdf.

¹⁰⁹ Xaracoll. FDA Package Insert. August 2020. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209511s000lbl.pdf.

¹¹⁰ Zynrelef. FDA Package Insert. January 2024. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/211988s013lbl.pdf.

¹¹¹ Ketorolac tromethamine Injection. FDA Package Insert. May 2014. https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/074802s038lbl.pdf.

¹¹² On-Q Pump. FDA 510K. February 2019. https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181360.pdf.

¹¹³ Ding DY, Manoli A 3rd, Galos DK, Jain S, Tejwani NC. Continuous Popliteal Sciatic Nerve Block Versus Single Injection Nerve Block for Ankle Fracture Surgery: A Prospective Randomized Comparative Trial. J Orthop Trauma. 2015;29(9):393–398. <https://pubmed.ncbi.nlm.nih.gov/2616525>.

**TABLE 85: PROPOSED LIST OF QUALIFYING PRODUCTS AND PROPOSED
PAYMENT LIMITATION DETERMINATIONS UNDER SECTION 4135 OF THE CAA,
2023**

Non-Opioid Drug	HCPCS Code for Primary Procedure	Total Units in CY 2025 data (CY 2023 claims)	Proportion of Top 5	CY 2025 Procedure Payment Rate	18% of the CY 2025 Procedure Payment Rate	Payment Limitation Applied Per Date of Service Volume Weighted Average of 18% of Procedure Payment Rate	Separate Payment Rate (Per Billing Unit)*
Zynrelef (C9088)	27447	9,385	36.25%	\$13,048.08	2,348.65	\$1,206.16	\$0.73
	73560	6,471	24.99%	\$86.88	15.64		
	27130	3,831	14.80%	\$13,048.08	2,348.65		
	96361	3,256	12.58%	\$42.37	7.63		
	86900	2,947	11.38%	\$116.11	20.90		
Xaracoll (C9089)	49505	347	47.02%	\$3,541.93	637.55	\$388.53	\$0.85
	88307	106	14.36%	\$324.11	58.34		
	88302	99	13.41%	\$24.96	4.49		
	88304	95	12.87%	\$50.14	9.03		
	49507	91	12.33%	\$3,541.93	637.55		
Exparel (C9290)	27447	33,513	24.01%	\$13,048.08	2,348.65	\$583.29	\$1.41
	96361	27,739	19.88%	\$42.37	7.63		
	88307	26,224	18.79%	\$324.11	58.34		
	86900	26,117	18.71%	\$116.11	20.90		
	73560	25,968	18.61%	\$86.88	15.64		
Dextenza (J1096)	66984	4,553	46.57%	\$2,159.44	388.70	\$386.39	\$117.01
	68841	4,349	44.48%	\$2,114.22	380.56		
	66982	564	5.77%	\$2,159.44	388.70		
	66991	174	1.78%	\$4,250.50	765.09		
	92499	137	1.40%	\$24.96	4.49		
Omidria (J1097)	66984	8,885	79.76%	\$2,159.44	388.70	\$383.59	\$97.12
	66982	1,256	11.28%	\$2,159.44	388.70		
	68841	393	3.53%	\$2,114.22	380.56		
	92499	370	3.32%	\$24.96	4.49		
	66991	235	2.11%	\$4,250.50	765.09		
Ketorolac tromethamine Injection (J1885)	96375	659,685	28.34%	\$42.37	7.63	\$22.82	\$0.702
	96361	489,948	21.05%	\$42.37	7.63		
	96374	451,076	19.38%	\$206.57	37.18		
	96372	395,425	16.99%	\$67.47	12.14		
	99284	331,342	14.24%	\$381.61	68.69		

*We note the payment rates for drugs and biologicals are subject to our standard quarterly drug pricing updates; therefore, the payment rate is the payment rate available as of April 1, 2024, and may not be the same payment rate available throughout CY 2025.

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Conforming proposed regulation text changes can be found at 42 CFR 416.174 for the ASC payment system and § 419.43 for the OPPIs. We propose revisions to § 419.174(a) to establish the eligibility for non-opioid pain

management drugs and biologicals, and by adding modifications to subparagraphs (1), (2), and (3) to outline drug and biological FDA approval requirements, the exclusion of drugs and biologicals with pass-through

status, and the requirement that the drug or biological has payment that is packaged. We propose new § 419.174(b) to establish the eligibility for non-opioid pain management medical devices, which includes new subparagraphs (1),

(2), (3), and (4). These new subparagraphs describe medical device FDA requirements, medical device clinical trial or peer-reviewed journal requirements, the exclusion of medical devices with pass-through status, and the requirement that the medical device has payment that is packaged. New paragraph (c) describes the payment amounts for qualifying drugs and biologicals in subparagraph (1) and medical devices in subparagraph (2), as well as the payment limitation for drugs, biologicals, and medical devices in subparagraph (3). Similarly, we also propose new 419.43(k), which contains payment for non-opioid pain management drugs and biologicals. Specifically, new paragraph (1) outlines the eligibility for separate payment for non-opioid pain management drugs and biologicals, with new subparagraphs outlining (i) the drug or biological's required FDA status, (ii) the drug or biological's pass-through status, and (iii) the drug or biological's packaged status. We also propose to add new paragraph 419.43(k)(2), which contains payment for non-opioid pain management medical devices. Specifically, new paragraph (2) outlines the eligibility for separate payment for non-opioid pain management medical devices, with new subparagraphs outlining (i) the medical device's required FDA status, (ii) the medical device clinical trial or peer-reviewed journal requirements, (iii) the medical device's pass-through status, and (iv) the medical device's packaged status. New 419.43(k)(3) describes the separate payment amount for qualifying non-opioid treatments for pain relief. Specifically, subparagraph (i) sets the separate payment amount for a qualifying drug or biological, subparagraph (ii) sets the separate payment amount for a qualifying medical device, and subparagraph (iii) sets the payment limitation for drugs, biologicals, and medical devices.

G. Proposed New Technology Intraocular Lenses (NTIOLs)

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in § 416.195.

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of NTIOLs is as follows:

- Applicants submit their NTIOL requests for review to CMS by the annual deadline which is announced in the annual OPPS/ASC final rule with comment period. For a request to be

considered complete, we require submission of the information requested in the guidance document titled “Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lenses (NTIOLs) or Inclusion of an IOL in an Existing NTIOL Class” posted on the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/new-technology-intraocular-lenses-ntiols>.

- We announce annually, in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Public Law 103–432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.

- In the final rule with comment period updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments.

++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests To Establish New NTIOL Classes for CY 2025

We did not receive any requests for review to establish a new NTIOL class for CY 2025 by March 1, 2024, the due date published in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81956).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is \$50 per lens. Since implementation of the process for adjustment of payment

amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we do not propose to revise the payment adjustment amount for CY 2025.

H. Proposed Calculation of the ASC Payment Rates and the ASC Conversion Factor

1. Background

In the August 2, 2007, ASC final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007, as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; § 416.171(e)).

We note that we consider the term “expenditures” in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-

step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007, ASC final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of \$41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XIII.D.2 of the CY 2023 OPPS/ASC proposed rule (87 FR 44715 through 44716)), and certain diagnostic tests within the medicine range that are covered ancillary services, the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 ASC final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor costs when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d)(10) of the Act is specific to acute care hospitals. We believe that using the most recently available pre-

floor and pre-reclassified IPPS hospital wage indexes results in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the pre-floor, pre-reclassified hospital wage indexes, which are updated yearly and are used by several other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs (89 FR 23424). Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index for the fiscal year under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

On July 21, 2023, OMB issued OMB Bulletin No. 23–01, which provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on July 16, 2021, in the **Federal Register** (86 FR 37770) and 2020 Census Bureau data. (A copy of this bulletin may be obtained at: <https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf>). The pre-floor pre-reclassified IPPS hospital wage indexes for CY 2024 do not reflect OMB's new area delineations and, because the ASC wage indexes are the pre-floor and pre-reclassified IPPS hospital wages indexes, the CY 2024 ASC wage indexes do not reflect the most recent OMB changes. As discussed in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36139 through 36150), we proposed to use the new CBSAs delineations issued by OMB in OMB Bulletin 23–01 for the IPPS hospital wage index beginning in CY 2025. Therefore, because the ASC wage indexes for the calendar year are the pre-floor and pre-reclassified IPPS hospital wage indexes for the fiscal year, we propose to incorporate the new OMB delineations into CY 2025 ASC wage indexes. We believe that using the revised delineations based on OMB Bulletin No. 23–01 will increase the integrity of the ASC wage index system by creating a more accurate representation of current geographic variations in wage levels.

In adopting the revised CBSA delineations from the 2010 Census data which were issued by OMB on July 15, 2015 through OMB Bulletin No. 15–01, for ASCs in counties that would see a decline in their ASC wage index for CY 2015, we adopted a blended wage index of 50 percent of the CY 2014 wage index value and 50 percent of the CY 2015 wage index value (79 FR 66937). However, we note that other Medicare payment systems incorporate a policy of

capping year-to-year wage index decreases for each facility at 5 percent of the previous year's wage index value (89 FR 23431 through 23433). We believe such a policy would also be appropriate for the ASC payment system as we transition to the CBSA delineations based on the 2020 Census data. As discussed in the IPPS/LTCH FY 2025 proposed rule, the 5-percent cap mitigates any large negative impacts of adopting the new delineations and prevents large year-to-year declines in wage index values as a means to reduce volatility (89 FR 36150). Therefore, for CY 2025, we propose to incorporate the new OMB delineations into the CY 2025 ASC wage indexes and propose to apply a 5-percent cap on wage index decreases at the county level (or county-equivalent level) and the ASC wage index of that county would apply to all ASCs physically located in that county. We note that this 5-percent cap is applied in a budget neutral manner. The 5-percent cap reduces the wage index scalar for a calendar year which, in turn, will reduce the ASC conversion factor and the payment rates for covered ASC services in counties that are not affected by the 5-percent cap on wage index decreases. Further, we are soliciting comments on whether we should extend this policy after CY 2025 and permanently adopt a budget-neutral 5-percent cap on year-to-year wage index decreases.

The proposed CY 2025 ASC wage indexes fully reflect the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed previously, as set forth in OMB Bulletin Nos. 23–01) including replacing the eight counties with the county-equivalent planning regions of Connecticut. We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. When all of the areas contiguous to the urban CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, our policy has been to determine the ASC wage index by calculating the average of all wage indexes for urban areas in the State (75 FR 72058 through 72059). In other situations, where there are no IPPS hospitals located in a relevant labor market area, we apply our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the

area with no wage index. For example, for CY 2025, we are applying a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville, GA) and in CBSA 35 (Rural North Dakota).

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2025 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and PFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). The OPPS relative payment weights are scaled to maintain budget neutrality for the OPPS. We then scale the OPPS relative payment weights again to establish the ASC relative payment weights. To accomplish this, we hold estimated total ASC payment levels constant between calendar years for purposes of maintaining budget neutrality in the ASC payment system. That is, we apply the weight scalar to ensure that projected expenditures from the updated ASC payment weights in the ASC payment system are equal to what would be the current expenditures based on the scaled ASC payment weights. In this way, we ensure budget neutrality and that the only changes to total payments to ASCs result from increases or decreases in the ASC payment update factor.

Where the estimated ASC expenditures for an upcoming year are higher than the estimated ASC expenditures for the current year, the ASC weight scalar is reduced, in order to bring the estimated ASC expenditures in line with the expenditures for the baseline year. This frequently results in ASC relative payment weights for surgical procedures that are lower than the OPPS relative payment weights for the same procedures for the upcoming year. Therefore, over time, even if procedures performed in the HOPD and ASC receive the same update factor under the OPPS and ASC payment system, payment rates under the ASC payment system would increase at a lower rate than payment for the same procedures performed in the HOPD as a result of applying the ASC weight scalar to ensure budget neutrality.

As discussed in section II.A.1.a of this proposed rule, we are using the CY 2023 claims data to be consistent with the OPPS claims data for this proposed rule. Consistent with our established policy, we propose to scale the CY 2025 relative

payment weights for ASCs according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2023, we propose to compare the estimated total payment using the CY 2024 ASC relative payment weights with the estimated total payment using the CY 2025 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2024 and CY 2025.

In consideration of our policy to provide a higher ASC payment rate with ASC complexity adjustment codes for certain primary procedures when performed with add-on packaged services, we incorporated estimated total spending and estimated utilization for these codes in our budget neutrality calculation for CYs 2023 and 2024. We estimated in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72094) that the impact on CY 2023 estimated total payments from our finalized CY 2023 ASC complexity adjustment codes would be \$5 million in spending and we finalized our proposal to incorporate this \$5 million in estimated CY 2023 total payments for the budget neutrality calculation. Based on CY 2023 utilization data, we now estimate that the actual amount of spending on the new CY 2023 ASC complexity adjustment codes for CY 2023 was \$24 million. We estimate that there will not be an additional increase in ASC spending related to our newly proposed ASC complexity adjustment codes for CY 2025.

Additionally, as discussed in Section XIII.E of this proposed rule, section 4135(a) and (b) of the CAA, 2023, titled Access to Non-Opioid Treatments for Pain Relief, amended section 1833(t)(16) and section 1833(i) of the Act, respectively, to provide for temporary separate payments for non-opioid treatments for pain relief. As discussed in further detail in Section XIII.E.e of this proposed rule, for qualifying nonopioid products, we propose to apply the 18 percent payment limitation on the volume weighted payment average of the top 5 services associated with the use of the qualifying nonopioid product. Currently, four of these qualifying nonopioid products are separately payable without the 18 percent payment limitation—HCPCS Codes C9089 (Bupivacaine implant, 1 mg), C9290 (Inj, bupivacaine liposome), J1096 (Dexametha oph insert 0.1 mg), and J1097 (Phenylep ketorolac oph soln). Therefore, to maintain budget neutrality, we must estimate the total anticipated reduction as a result of the 18 percent payment limitation required by Section 4135 of the CAA, 2023.

Using CY 2023 utilization for these four drugs and CY 2024 ASC payment rates, we anticipate that the 18 percent payment limitation will reduce CY 2025 ASC expenditures by approximately \$9 million. Therefore, we are reducing estimated CY 2025 total payments by \$9 million in our weight scalar calculation as a result of Section 4135 of the CAA, 2023.

We propose to use the ratio of estimated CY 2024 to estimated CY 2025 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2025. The proposed CY 2025 ASC weight scalar is 0.876. We note that we have historically displayed this figure rounded to the nearest ten thousandth; however, we believe this level of specificity is unnecessarily burdensome for an ASC payment system that is less than one-tenth the size of the OPPS (in which the weight scalar is rounded to the nearest ten-thousandth). An ASC weight scalar rounded to the nearest ten thousandth is highly sensitive to spending changes and can require the costly reissuance of new ASC payment rates from only very minor payment rate changes within the ASC Payment System, such as a revised PFS conversion factor as a result of Congressional action. Therefore, for CY 2025 and subsequent calendar years, we propose to set the ASC weight scalar rounded to the nearest thousandth. Consistent with historical practice, we propose to scale, using this method, the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

We propose that we would not scale ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the

total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. We propose to use the CY 2023 claims data to model our budget neutrality adjustment for CY 2025.

b. Updating the ASC Conversion Factor

Under the OPPTS, we typically apply a budget neutrality adjustment for provider-level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2017 ASC payment system and subsequent years, in the CY 2017 OPPTS/ASC final rule with comment period (81 FR 79751 through 79753), we finalized our policy to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier-level changes in wage index values for the upcoming year, just as the OPPTS wage index budget neutrality adjustment is calculated and applied to the OPPTS conversion factor. For CY 2025, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2023 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2025 ASC wage indexes. Specifically, holding CY 2023 ASC utilization, service-mix, and the proposed CY 2025 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2024 ASC wage indexes and the total adjusted payment using the proposed CY 2025 ASC wage indexes which included our proposed 5-percent cap on wage index declines. We used the 50 percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2024 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2025 ASC wage indexes and applied the resulting ratio of 0.9958 (the proposed CY 2025 ASC wage index budget neutrality adjustment) to the CY 2024 ASC conversion factor to calculate the proposed CY 2025 ASC conversion factor.

Section 1833(i)(2)(D)(v) of the Act requires that the ASC conversion factor be reduced by a productivity adjustment in each calendar year. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of

changes in annual economy-wide private nonfarm business multifactor productivity (MFP). We finalized the methodology for calculating the productivity adjustment in the CY 2011 PFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 PFS final rule with comment period (76 FR 73300 through 73301) and the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70500 through 70501). The proposed productivity adjustment for CY 2025 was projected to be 0.4 percentage point, as published in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36204) based on IGI's 2023 fourth quarter forecast.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (CPI-U), U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI-U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at § 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI-U for CY 2010 and subsequent calendar years.

In the CY 2019 OPPTS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized a policy to apply the productivity-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we would assess whether there is a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a productivity-adjusted hospital market basket update, as well as whether there are any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. The most recent available full year of claims data to assess the expected migration applying the productivity-adjusted hospital market basket update during the interim period would fall within the period from CY 2019 through CY 2022. However, the impact of the COVID-19 PHE on health care utilization, in particular in CY 2020, was

tremendously profound, particularly for elective surgeries, because many beneficiaries avoided healthcare settings, when possible, to avoid possible infection from the SARS-CoV-2 virus. As a result, it is nearly impossible to disentangle the effects from the COVID-19 PHE in our analysis of whether the higher update factor for the ASC payment system caused increased migration to the ASC setting. To analyze whether procedures migrated from the hospital setting to the ASC setting, we need to use claims data from a period during which the COVID-19 PHE had less of an impact on health care utilization. Therefore, for CY 2024, we finalized our proposal to extend the 5-year interim period an additional 2 years, that is, through CY 2024 and CY 2025. We believed hospital outpatient and ASC utilization data from CYs 2023 and 2024 will enable us to more accurately analyze whether the application of the productivity-adjusted hospital market basket update to the ASC payment system had an effect on the migration of services from the hospital setting to the ASC setting. We revised our regulations at 42 CFR 416.171(a)(2)(iii) and (iv), which establish the annual update to the ASC conversion factor, to reflect this 2-year extension. We also revised our regulations at § 416.171(a)(2)(vi) and (vii), which establish the 2.0 percentage point reduction for ASCs that fail to meet the standards for reporting ASC quality measures, and § 416.171(a)(2)(viii)(B) and (C), which establish the productivity adjustment, to reflect this 2-year extension.

For CY 2025, we propose to utilize the proposed hospital market basket percentage increase of 3.0 percent reduced by the proposed productivity adjustment of 0.4 percentage point, resulting in a proposed productivity-adjusted hospital market basket update of 2.6 percent for ASCs meeting the quality reporting requirements. Therefore, we propose to apply a proposed 2.6 percent productivity-adjusted hospital market basket update factor to the CY 2024 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2025 ASC payment amounts. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the productivity-adjusted hospital market basket update factor for ASCs that fail to meet the ASCQR Program requirements.

We refer readers to section XIV.E of the CY 2019 OPPS/ASC final rule with comment period (83 FR 59138 through 59139) and section XIV.E of this proposed rule for a detailed discussion of our policies regarding payment reduction for ASCs that fail to meet ASCQR Program requirements. We propose to utilize the proposed inpatient hospital market basket percentage increase of 3.0 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then reduced by the proposed 0.4 percentage point productivity adjustment. Therefore, we propose to apply a 0.6 percent productivity-adjusted hospital market basket update factor to the CY 2024 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also propose that if more recent data are subsequently available (for example, a more recent estimate of the inpatient hospital market basket percentage increase or productivity adjustment), we would use such data, if appropriate, to determine the CY 2025 ASC update for the CY 2025 OPPS/ASC final rule with comment period.

For CY 2025, we propose to adjust the CY 2024 ASC conversion factor (\$53.514) by the proposed wage index budget neutrality factor of 0.9958 in addition to the proposed productivity-adjusted hospital market basket update of 2.6 percent discussed previously, which results in a proposed CY 2025 ASC conversion factor of \$54.675 (a 2.2 percent increase) for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we propose to adjust the CY 2024 ASC conversion factor (\$53.514) by the proposed wage index budget neutrality factor of 0.9958 in addition to the proposed quality reporting/productivity-adjusted hospital market basket update of 0.2 percent discussed previously, which results in a proposed CY 2025 ASC conversion factor of \$53.609 for ASCs not meeting the quality reporting requirements.

3. Display of the Proposed CY 2025 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available on the CMS website) display the proposed ASC payment rates for CY 2025 for covered surgical procedures and covered ancillary services, respectively. The proposed payment rates included in Addenda AA and BB to this proposed rule reflect the full ASC proposed payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the

quality reporting requirements under the ASCQR Program.

These Addenda contain several types of information related to the proposed CY 2025 payment rates. Specifically, in Addendum AA, a “Y” in the column titled “To be Subject to Multiple Procedure Discounting” indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50 percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

For CY 2021, we finalized adding a new column to ASC Addendum BB titled “Drug Pass-Through Expiration during Calendar Year” where we flag through the use of an asterisk each drug for which pass-through payment is expiring during the calendar year (that is, on a date other than December 31st).

The values displayed in the column titled “Proposed CY 2025 Payment Weight” are the proposed relative payment weights for each of the listed services for CY 2025. The proposed relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures; services that are paid at the MPFS nonfacility PE RVU-based amount; separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS; or services that are contractor-priced or paid at reasonable cost in ASCs. This includes separate payment for non-opioid pain management drugs.

To derive the proposed CY 2025 payment rate displayed in the “Proposed CY 2025 Payment Rate” column, each ASC payment weight in the “Proposed CY 2025 Payment Weight” column was multiplied by the proposed CY 2025 conversion factor. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update as reduced by the productivity adjustment. The proposed CY 2025 ASC conversion factor uses the proposed CY 2025 productivity-adjusted hospital market basket update factor of 2.6 percent (which is equal to the proposed inpatient hospital market basket

percentage increase of 3.0 percent reduced by the proposed productivity adjustment of 0.4 percentage point).

In Addendum BB, there are no relative payment weights displayed in the “Proposed CY 2025 Payment Weight” column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The “Proposed CY 2025 Payment” column displays the proposed CY 2025 national unadjusted ASC payment rates for all items and services. The proposed CY 2025 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on the most recently available data used for payment in physicians’ offices.

Addendum EE to this proposed rule provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2025.

Addendum FF to this proposed rule displays the OPPS payment rate (based on the standard ratesetting methodology), the APC device offset percentage, the device offset percentage for determining device-intensive status (based on the standard ratesetting methodology), and the device portion of the ASC payment rate for CY 2025 for covered surgical procedures.

XIV. Cross-Program Proposals for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs

A. Background

We refer readers to sections XV, XVI, and XVII of this proposed rule for program-specific background information, including the statutory authorities and previously finalized and newly proposed measure sets, for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs, respectively.

B. CMS Commitment To Advancing Health Equity Using Quality Measurement

We are committed to advancing health equity and improving health outcomes through our quality reporting programs. The CMS Framework for Health Equity acknowledges that “addressing health and healthcare disparities and achieving health equity should underpin efforts to focus attention and drive action on our nation’s top health priorities.” CMS

defines health equity as “the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.”¹¹⁴

Significant and persistent disparities in health care outcomes exist in the United States (U.S.). Belonging to a racial or ethnic minority group, living with a disability, being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community, living in a rural area, or being near or below the poverty level are often associated with worse health outcomes.^{115 116 117} Health disparities manifest primarily as worse health outcomes in populations where access to care is inequitable.^{118 119} Such differences persist across geography and healthcare settings irrespective of improvements in quality of care over time.^{120 121} Inequities in the social determinants of health affecting these groups are interrelated and influence a wide range of health and quality of life outcomes and risks.¹²²

Inequities related to the social determinants of health may affect health-related social needs (HRSNs). HRSNs are individual-level, adverse social conditions that negatively impact an individual's health or healthcare and are associated with worse health outcomes and increased healthcare utilization.¹²³ While HRSNs account for 50 to 70 percent of health outcomes, the mechanisms by which this connection emerges are complex and multifaceted.^{124 125} Growing evidence demonstrates that specific HRSNs are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality-based payment programs.^{126 127} The persistent interactions among individuals' HRSNs, medical providers' practices and behaviors, and community resources significantly impact healthcare access, quality, and costs, as described in the CMS Equity Plan for Improving Quality in Medicare.^{128 129} Assessment of HRSNs is an essential mechanism for capturing the interaction between social, community, and environmental factors associated with health status and health outcomes.^{130 131}

[it.org/5774/2020414003754/https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities](https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities).

¹²³ Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. Available at: <https://www.cms.gov/priorities/innovation/media/document/ahcm-screeningtool-companion>.

¹²⁴ Kaiser Family Foundation. (2021). Racial and Ethnic Health Inequities and Medicare. Available at: <https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/>.

¹²⁵ The Physicians Foundation. (2021). Viewpoints: Social Determinants of Health. Available at: <https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf>.

¹²⁶ Zhang Y, Li J, Yu J, Braun RT, Casalino LP. (2021). Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. *JAMA Network Open*, 4(6), e2113212. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780864>.

¹²⁷ Khullar D, Schpero WL, Bond AM, Qian Y, Casalino LP (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. *JAMA*, 324(10), 975–983. <https://doi.org/10.1001/jama.2020.13129>.

¹²⁸ Centers for Medicare & Medicaid Services. (2021). Paving the Way to Equity: A Progress Report. Available at: <https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf>.

¹²⁹ Centers for Medicare & Medicaid Services Office of Minority Health. (2021). The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMSEquityPlanforMedicare_090615.pdf.

¹³⁰ Alley DE, Asomugha CN, Conway PH, Sanghavi DM. (2016). Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. *New England Journal of*

Studies indicate that healthcare facility leadership can positively influence culture for better quality, patient outcomes, and experience of care.^{132 133 134}

We are committed to supporting healthcare facility leadership in building a culture of equity that focuses on eliminating health disparities to provide patients with high quality healthcare through the collection and public reporting of health equity focused measures, including in outpatient care settings.¹³⁵

Health equity quality measurement supports the Meaningful Measures 2.0 goal to “Leverage Quality Measures to Promote Equity and Close Gaps in Care” as well as the objective to “commit to a patient-centered approach in quality measure and value-based incentives programs.” Additionally, under the CMS National Quality Strategy, adoption of health equity quality measures would support addressing the quality priority to “advance health equity and whole-person care” by employing a uniform approach for gathering, reporting, and analyzing health equity data across CMS quality programs.¹³⁶

Medicine, 374(1), 8–11. Available at: <https://www.nejm.org/doi/10.1056/NEJMp1512532>.

¹³¹ Centers for Disease Control and Prevention. (July 2020). CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/downloads/community/CDC-Strategy.pdf>.

¹³² We use the term “healthcare facility” to refer to hospital outpatient departments (HOPDs), rural emergency hospitals (REHs), and ambulatory surgical centers (ASCs) collectively.

¹³³ Smith SA, Yount N, Sorra J. (2017). Exploring Relationships Between Hospital Patient Safety Culture and Consumer Reports Safety Scores. *BMC Health Services Research*, 17(1), 143. <https://doi.org/10.1186/s12913-017-2078-6>.

¹³⁴ Bradley EH, Brewster AL, McNatt Z, et al. (2018). How Guiding Coalitions Promote Positive Culture Change in Hospitals: A Longitudinal Mixed Methods Interventional Study. *BMJ Quality & Safety*, 27(3), 218–225. <https://qualitysafety.bmj.com/content/27/3/218>.

¹³⁵ Smith SA, Yount N, Sorra J. (2017). Exploring Relationships Between Hospital Patient Safety Culture and Consumer Reports Safety Scores. *BMC Health Services Research*, 17(1), 143. <https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-017-2078-6>.

¹³⁶ Centers for Medicare & Medicaid Services. (2024). CMS National Quality Strategy. Centers for Medicare and Medicaid Services. Available at: <https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy>.

¹¹⁴ Centers for Medicare & Medicaid Services. (2022). CMS Framework for Health Equity 2022–2032. Available at: <https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf>.

¹¹⁵ Polyakova M, Udalova V, Kocks G, Genadek K, Finlay K, Finkelstein AN. (2021). Racial Disparities in Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. *Health Affairs*, 40(2), 307–316. <https://doi.org/10.1377/hlthaff.2020.02142>.

¹¹⁶ Rural Health Research Gateway. (2018). Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. Available at: <https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf>.

¹¹⁷ Heslin KC, Hall JE. (2021). Sexual Orientation Disparities in Risk Factors for Adverse COVID–19–Related Outcomes, by Race/Ethnicity—Behavioral Risk Factor Surveillance System, United States, 2017–2019. *MMWR Morbidity Mortality Weekly Report*, 70(5), 149. <http://dx.doi.org/10.15585/mmwr.mm7005a1>.

¹¹⁸ The Physicians Foundation. (2020). Survey of America's Patients, Part Three. Available at: <https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf>.

¹¹⁹ Office of the Assistant Secretary for Planning and Evaluation. (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: <https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress>.

¹²⁰ Ibid.

¹²¹ Khullar D, Schpero WL, Bond AM, Qian Y, Casalino LP. (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. *JAMA*, 324(10), 975–983. <https://jamanetwork.com/journals/jama/fullarticle/2770410>.

¹²² Office of Disease Prevention and Health Promotion. (2021). Healthy People 2020: Disparities. Available at: <https://wayback.archive->

1. Proposal To Adopt the Hospital Commitment to Health Equity (HCHE) Measure for the Hospital Outpatient Quality Reporting (OQR) and Rural Emergency Hospital Quality Reporting (REHQR) Programs and the Facility Commitment to Health Equity (FCHE) Measure for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination or Program Determination.¹³⁷

a. Background

Strong and committed leadership from healthcare facility management is essential in shifting organizational culture to reduce health disparities and reach health equity goals.¹³⁸ The Agency for Healthcare Research and Quality and The Joint Commission identified that healthcare facility leadership plays an important role in promoting a culture of quality and safety.^{139 140} The Institute of Healthcare Improvement's research shows that health equity must be a priority championed by leadership teams to improve both patient access to needed healthcare services and outcomes among disadvantaged populations.¹⁴¹ Based upon these findings, we believe that healthcare facility leadership is instrumental in setting specific, measurable, attainable, realistic, and time-based (SMART) goals to assess progress towards achieving equity priorities and ensuring high-quality care is equally accessible to all individuals.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25592 and 25593),

we sought public comment on potential future efforts to address health equity in the Hospital Inpatient Quality Reporting (IQR) Program, particularly the inclusion of a structural measure to assess the degree of hospital leadership commitment to collecting and monitoring health equity performance data. We specifically sought feedback on (1) conceptual and measurement priorities to facilitate organizational efforts to improve health equity; and (2) an appropriate measure regarding organizational commitment to health equity and accessibility for individuals with intellectual and developmental disabilities. In response, we received support for the development and implementation of a health equity structural measure. We also received comments expressing concerns about such a health equity structural measure. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45414 through 45416) for summaries of the comments we received related to this solicitation.

We considered this feedback with the intent that future health equity measures would align across the Medicare quality reporting programs, including the Hospital OQR, REHQR, and ASCQR Programs, to ensure equitable care across both inpatient and outpatient settings to the greatest extent possible within facilities and hospitals participating in Medicare. In addition, we believe that measuring leadership commitment to health equity should not be limited to the inpatient hospital setting but should cover the continuum of care as patients seek and receive care at various care settings.

We initially developed the HCHE and FCHE measures for use in the Hospital IQR and Inpatient Psychiatric Facility Quality Reporting (IPFQR) Programs, respectively, with the expectation of expansion into other Medicare quality reporting programs. The HCHE and FCHE measures are attestation-based structural measures that assess hospitals' and facilities' commitment to health equity across the following five domains adapted from the CMS Office of Minority Health's "Building an Organizational Response to Health Disparities" framework: equity as a strategic priority, data calculation, data analysis, quality improvement, and leadership engagement.¹⁴² These measures are intended to encourage hospitals and facilities to analyze their

data to understand how factors, including race, ethnicity, and the social determinants of health can contribute to the delivery of more equitable care.¹⁴³

We believe these domains provide actionable focus areas for the assessment of healthcare facility leadership commitment because they are foundational to incentivizing hospitals and facilities to collect and utilize data to identify critical equity gaps, implement plans to address those gaps, and ensure that resources are dedicated toward healthcare equity initiatives. We also believe these measures support hospitals and facilities in quality improvement, promote efficient and effective use of resources, and leverage available data.

Adoption of these measures in the Hospital OQR, REHQR, and ASCQR Programs would support our efforts to align measures across CMS programs, including the Hospital Inpatient Quality Reporting (IQR) Program (87 FR 49191 through 49201), Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program (88 FR 51100 through 51107), PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program (88 FR 59204 through 59210), and End-Stage Renal Disease Quality Incentive Program (ESRD QIP) (88 FR 76437 through 76446). We believe that alignment across the quality reporting programs is important to ensure that health equity, which impacts patients regardless of where they receive their care, is addressed in every healthcare delivery setting. Adopting these measures across quality reporting programs would incentivize quality reporting entities to collect and utilize data to identify critical equity gaps, implement plans to address said gaps, and ensure that resources are dedicated toward addressing health equity initiatives.

b. Overview of the Measures

The HCHE and FCHE measures assess a hospital's or facility's commitment to health equity by using equity-focused organizational domains aimed at advancing health equity for all patients, including but not limited to those in racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. Table 86 and Table 87 describe the five attestation domains and their elements

¹³⁷ We use the phrase "payment determination" for the Hospital OQR and ASCQR Programs to represent our assessment of whether the 2-percentage point reduction in payment for failing to meet program requirements is warranted. We use the phrase "program determination" for the REHQR Program to represent our assessment of compliance with program requirements for an applicable year because the REHQR Program does not include an associated payment adjustment.

¹³⁸ Bradley EH, Brewster AL, McNatt Z, Linnander EL, Cherlin E, Fosburgh H, Ting HH, Curry LA. (2018). How Guiding Coalitions Promote Positive Culture Change in Hospitals: A Longitudinal Mixed Methods Interventional Study. *BMJ Quality & Safety*, 27(3), 218–225. <https://pubmed.ncbi.nlm.nih.gov/29101290/>.

¹³⁹ Agency for Healthcare Research and Quality. (September 2019). Leadership Role in Improving Patient Safety. Patient Safety Network. Available at: <https://psnet.ahrq.gov/primer/leadership-role-improving-safety>.

¹⁴⁰ Joint Commission on Accreditation of Healthcare Organizations. (June 2021). The essential role of leadership in developing a safety of culture. *Sentinel Event Alert*. (57), 1–8. <https://www.jointcommission.org/-/media/tjc/newsletters/sea-57-safety-culture-and-leadership-final3.pdf>.

¹⁴¹ Mate KS, Wyatt R. (2017). Health Equity Must Be a Strategic Priority. *NEJM Catalyst*. Available at: <https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556>.

¹⁴² Centers for Medicare & Medicaid Services. (2021). Building an Organizational Response to Health Disparities [Fact Sheet]. U.S. Department of Health and Human Services. Available at: <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf>.

¹⁴³ We note that the term "hospital" includes HOPDs and REHs for the purposes of this measure.

for the HCHE and FCHE measures, respectively.

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TABLE 86: HOSPITAL COMMITMENT TO HEALTH EQUITY MEASURE

ATTESTATION DOMAINS

Attestation	Elements: Select all that apply (Note: Affirmative attestation of all elements within a domain would be required for the hospital to receive a point for the domain in the numerator)
Domain 1: Equity is a Strategic Priority	
Hospital commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority. Please attest that your hospital has a strategic plan for advancing health equity and that it includes all the following elements.	(A) Our hospital strategic plan identifies priority populations who currently experience health disparities. (B) Our hospital strategic plan identifies health equity goals and discrete action steps to achieving these goals. (C) Our hospital strategic plan outlines specific resources which have been dedicated to achieving our equity goals. (D) Our hospital strategic plan describes our approach for engaging key stakeholders, such as community-based organizations.
Domain 2: Data Collection	
Collecting valid and reliable demographic and social determinant of health data on patients served in a hospital is an important step in identifying and eliminating health disparities. Please attest that your hospital engages in the following activities.	(A) Our hospital collects demographic information (such as self-reported race, national origin, primary language, and ethnicity data), and/or social determinant of health information on the majority of our patients. (B) Our hospital has training for staff in culturally sensitive collection of demographic and/or social determinant of health information. (C) Our hospital inputs demographic and/or social determinant of health information collected from patients into structured, interoperable data elements using a certified EHR technology.
Domain 3: Data Analysis	
Effective data analysis can provide insights into which factors contribute to health disparities and how to respond. Please attest that your hospital engages in the following activities.	(A) Our hospital stratifies key performance indicators by demographic and/or social determinants of health variables to identify equity gaps and includes this information on hospital performance dashboards.
Domain 4: Quality Improvement	
Health disparities are evidence that high-quality care has not been delivered equitably to all patients. Engagement in quality improvement activities can improve quality of care for all patients.	(A) Our hospital participates in local, regional, or national quality improvement activities focused on reducing health disparities.
Domain 5: Leadership Engagement	
Leaders and staff can improve their capacity to address disparities by demonstrating routine and thorough attention to equity and setting an organizational culture of equity. Please attest that your hospital engages in the following activities.	(A) Our senior leadership, including chief executives and the entire board of trustees, annually reviews our strategic plan for achieving health equity. (B) Our senior leadership, including chief executives and the entire board of trustees, annually reviews key performance indicators stratified by demographic and/or social factors.

TABLE 87: FACILITY COMMITMENT TO HEALTH EQUITY MEASURE**ATTESTATION DOMAINS**

Attestation	Elements: Select all that apply (Note: Affirmative attestation of all elements within a domain would be required for the facility to receive a point for the domain in the numerator)
Domain 1: Equity is a Strategic Priority	
Facility commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority. Please attest that your facility has a strategic plan for advancing health equity and that it includes all the following elements.	(A) Our facility strategic plan identifies priority populations who currently experience health disparities. (B) Our facility strategic plan identifies health equity goals and discrete action steps to achieving these goals. (C) Our facility strategic plan outlines specific resources which have been dedicated to achieving our equity goals. (D) Our facility strategic plan describes our approach for engaging key stakeholders, such as community-based organizations.
Domain 2: Data Collection	
Collecting valid and reliable demographic and social determinant of health data on patients served in a facility is an important step in identifying and eliminating health disparities. Please attest that your facility engages in the following activities.	(A) Our facility collects demographic information (such as self-reported race, national origin primary language and ethnicity data), and/or social determinant of health information on the majority of our patients. (B) Our facility has training for staff in culturally sensitive collection of demographic and/or social determinant of health information. (C) Our facility inputs demographic and/or social determinant of health information collected from patients into structured, interoperable data elements using an EHR technology.
Domain 3: Data Analysis	
Effective data analysis can provide insights into which factors contribute to health disparities and how to respond. Please attest that your facility engages in the following activities.	(A) Our facility stratifies key performance indicators by demographic and/or social determinants of health variables to identify equity gaps and includes this information on facility performance dashboards.
Domain 4: Quality Improvement	
Health disparities are evidence that high-quality care has not been delivered equitably to all patients. Engagement in quality improvement activities can improve quality of care for all patients.	(A) Our facility participates in local, regional, or national quality improvement activities focused on reducing health disparities.
Domain 5: Leadership Engagement	
Leaders and staff can improve their capacity to address disparities by demonstrating routine and thorough attention to equity and setting an organizational culture of equity. Please attest that your facility engages in the following activities.	(A) Our facility senior leadership, such as chief executives and the entire facility board of trustees, annually reviews our strategic plan for achieving health equity. (B) Our facility senior leadership, such as chief executives and the entire facility board of trustees, annually reviews key performance indicators stratified by demographic and/or social factors.

The HCHE measure is currently used in the Hospital IQR and PCHQR Programs. As further discussed below, we propose to adopt the HCHE measure for the Hospital OQR and REHQR Programs. The FCHE measure is currently used in the IPFQR Program and ESRD QIP. As further discussed below, we propose to adopt the FCHE measure for the ASCQR Program.

We note that there are two measure specification variations between the HCHE and FCHE measures, as reflected in Tables 86 and 87. First, Table 86 references hospitals (such as HOPDs and REHs) in connection with HCHE; Table 87 references facilities (such as ASCs, which are not hospitals) in connection with FCHE. Second, Domain 2C of the HCHE measure requires hospitals to use a certified electronic health record (EHR) technology (CEHRT)¹⁴⁴ in order to attest “yes”; Domain 2C of the FCHE measure requires facilities to use EHR technology, but does not require the use of CEHRT, in order to attest “yes.” We recognize that ASCs have governance structures and operational circumstances that are distinct from hospitals. We also recognize that many non-hospital facilities, including ASCs, have not adopted CEHRT, but may use some EHR technology,¹⁴⁵ justifying this variation in Domain 2C between the HCHE and FCHE measures.¹⁴⁶

c. Pre-Rulemaking Measure Review

As required under section 1890A of the Act, the Consensus-Based Entity (CBE), currently Battelle, established the Partnership for Quality Measurement

(PQM), comprised of clinicians, patients, measure experts, and health information technology specialists, to participate in the pre-rulemaking process and the measure endorsement process and provide input on the selection of quality and efficiency measures. The pre-rulemaking process, which we refer to as the Pre-Rulemaking Measure Review (PRMR), includes a review of measures published on the publicly available list of Measures Under Consideration (MUC List) by one of several committees convened by the PQM for the purpose of providing multi-stakeholder input to the Secretary on the selection of quality and efficiency measures under consideration for use in certain Medicare quality programs, including the Hospital OQR, REHQR, and ASCQR Programs. More details regarding the PRMR process may be found in the PQM Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review, including details of the measure review processes in Chapter 3.¹⁴⁷

As part of the PRMR process, the Hospital Recommendation Group reviewed and voted on the HCHE and FCHE measures during their meeting on January 18 and 19, 2024.^{148 149} The voting results of the HCHE measure for the Hospital OQR and REHQR Programs were “recommend with conditions,” and the voting results of the FCHE measure were “recommended without conditions” for the ASCQR Program. The conditions for the HCHE measure for the Hospital OQR and REHQR Programs were: (1) obtaining CBE endorsement; (2) additional specificity around attestation requirements; and (3) ongoing data collection for further measure testing, particularly with regard to smaller entities.¹⁵⁰ We have taken these conditions into account, as follows, and are proposing both of these measures for adoption. We discuss CBE

endorsement in section XIV.B.1.d below.

Regarding the condition to provide additional specificity around attestation requirements, we note that these domains were developed based on the recommendations from a technical expert panel (TEP) that informed our initial selection and development of this measure.¹⁵¹ We also addressed this concern during the January 18–19, 2024 PRMR meeting by sharing that there are accompanying guidance documents available to provide information and examples of qualifying activities for the HCHE measure (which can also be applied to the FCHE measure).^{152 153}

With respect to the condition related to ongoing data collection for further measure testing due to concerns that smaller entities may face challenges regarding data collection and analysis, we reiterate that HCHE is an attestation measure only in Hospital OQR, a pay-for-reporting program, and REHQR, a program with no associated payment adjustment.¹⁵⁴ While we acknowledge the limitations in testing structural measures, we believe this measure captures useful information regarding providers’ commitment to promoting health equity to inform patient choice. We have therefore considered the Hospital Recommendation Group’s concerns and determined that they are adequately addressed.

d. CBE Endorsement

Section 1833(t)(17)(C)(i) of the Act provides that the Hospital OQR Program, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities (not necessarily the CBE). Under section 1833(i)(7)(B) of the Act, this requirement at section 1833(t)(17)(C) applies to the ASCQR Program except as the Secretary may otherwise provide. For the Hospital OQR Program and ASCQR Program, we

¹⁴⁴ CEHRT refers to the certified health IT requirements established by CMS and the Office of the National Coordinator for Health Information Technology (ONC). ONC health IT certification criteria referenced in the CEHRT definition can be found at 45 CFR 170.315. Please refer to the following for more details on CEHRT requirements: <https://www.cms.gov/medicare/regulations-guidance/promoting-interoperability-programs/certified-ehr-technology>. Please refer to the Measure Calculation section for more details on CEHRT and the HCHE Measure.

¹⁴⁵ We define the term “EHR technology” as ONC’s definition for Electronic Health Record, “a real-time patient health record with access to evidence-based decision support tools that can be used to aid clinicians in decision making. The EHR can automate and streamline a clinician’s workflow, ensuring that all clinical information is communicated. It can also prevent delays in response that result in gaps in care. The EHR can also support the collection of data for uses other than clinical care, such as billing, quality management, outcome reporting, and public health disease surveillance and reporting.” at <https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/glossary>.

¹⁴⁶ Taira A. (June 2021). ASCA Survey Shows Mixed Usage of EHR among ASCs. ASC Focus. Available at: <https://www.ascfocus.org/ascfocus/content/articles-content/articles/2021/digital-debut/asca-survey-shows-mixed-usage-of-ehr-among-asc>.

¹⁴⁷ Partnership for Quality Measurement. (September 2023). Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review. Available at: https://p4qm.org/sites/default/files/2023-09/Guidebook-of-Policies-and-Procedures-for-Pre-Rulemaking-Measure-Review-%28PRMR%29-and-Measure-Set-Review-%28MSR%29-Final_0.pdf.

¹⁴⁸ Partnership for Quality Measurement. 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: <https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf>.

¹⁴⁹ Partnership for Quality Measurement. Pre-Rulemaking Measure Review Measures Under Consideration: 2023 Recommendations Report. Available at: <https://p4qm.org/sites/default/files/2024-02/PRMR-2023-MUC-Recommendations-Report-Final.pdf>.

¹⁵⁰ Ibid.

¹⁵¹ Centers for Medicare & Medicaid Services. (February 2022). Summary of Technical Expert Panel (TEP) Meeting #1, November 16, 2021: Health Equity Quality Measurement, Hospital Commitment to Health Equity Measure. Available at: <https://mmshub.cms.gov/sites/default/files/HealthEquityQualityMeasurementTEP1SumReport.pdf>.

¹⁵² Centers for Medicare & Medicaid Services (January 2024). Attestation Guidance for the Hospital Commitment to Health Equity Measure (v 1.2). Available at: https://qualitynet.cms.gov/files/659c609eca7fd3001b35edab?filename=AttstGdnceHCHEMeas_v1.2.pdf.

¹⁵³ Centers for Medicare & Medicaid Services (January 2024). Frequently Asked Questions Hospital Commitment to Health Equity, HIQR. Available at: https://qualitynet.cms.gov/files/659c60afd4b704001df0af51?filename=FAQ_HCHE_HIQR.pdf.

¹⁵⁴ Partnership for Quality Measurement. (2023). 2023 PRMR Final MUC Recommendation Spreadsheet. Available at: <https://p4qm.org/PRMR>.

note that section 1833(t)(17) of the Act does not require that each measure we adopt for these programs be CBE-endorsed (75 FR 72064 and 72065 for the Hospital OQR Program and 76 FR 74494 for the ASCQR Program).

Section 1833(t)(17)(C)(i) of the Act also requires measures developed for the Hospital OQR Program to reflect consensus among affected parties. Under section 1833(i)(7)(B) of the Act, this requirement also applies to the ASCQR Program except as the Secretary may otherwise provide. As we have noted in previous rulemaking, consensus among affected parties can be reflected in ways other than CBE endorsement, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment (75 FR 72064 and 72065 for the Hospital OQR Program and 76 FR 74494 for the ASCQR Program).

For the REHQR Program, section 1861(kkk)(7)(C)(i) of the Act generally requires that quality measures specified by the Secretary for the REHQR Program be endorsed by a CBE; however, section 1861(kkk)(7)(C)(ii) of the Act provides an exception to the general CBE-endorsement requirement, stating that in the case of a specified area or medical topic determined appropriate by the Secretary for which a measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and therefore we believe the exception in section 1861(kkk)(7)(C)(ii) of the Act applies for purposes of this measure for the REHQR Program.

At this time, we find no other feasible and practicable measures set forth by a national consensus building entity on the topic of a hospital's or facility's leadership commitment to health equity. While we recognize the value of measures undergoing CBE endorsement review and prefer to use endorsed measures, there are currently no CBE-endorsed measures that address hospital or facility commitment to health equity. Given the urgency of achieving health equity, it is important to implement this measure as soon as possible. As previously noted, the HCHE measure was developed based on the consensus of a TEP whose recommendations informed the initial selection, development, and emphasis of the

importance of this measure and subsequently the FCHE measure, which, as noted in section XIV.B.1.b above, is a similar measure with only two measure specification variations to accommodate setting-specific realities with regards to CEHRT adoption.¹⁵⁵ We will consider submitting the HCHE and FCHE measures to the CBE for endorsement in the future.

e. Measure Calculation

The proposed HCHE and FCHE measures each consist of the same five attestation-based domains as shown in Table 86 and Table 87, respectively, subject to variations noted above.

The numerator of both the HCHE and FCHE measures would capture the total number of domains to which the hospital or facility is able to attest affirmatively, up to a maximum of five domains. We propose that a hospital or facility would only receive a point for a domain if it attested "yes" to all of the elements within that domain. We would not accept an attestation whereby a hospital or facility attests "yes" to some, but not all, of the elements; in the event a hospital or facility would not be able to attest "yes" to one or more elements within a domain, or the entirety of a domain, they would respond "no." For example, for Domain 1, if the hospital or facility's strategic plan meets elements (A) and (B), but not (C) and (D) of Domain 1, then the hospital or facility would not be able to affirmatively attest "yes" and would receive zero points for Domain 1.

The denominator of both the HCHE and FCHE measures would constitute a total of five points (that is, one point per domain).

We also refer readers to the measure specifications, available on our QualityNet website.¹⁵⁶

As noted above, Domain 2C of the HCHE measure requires the use of CEHRT, while Domain 2C of the FCHE measure requires the use of EHR technology, which is not required to be certified by ONC in accordance with ONC's requirements. We made this distinction because we recognize that many non-hospital facilities, including ASCs, currently have not adopted

CEHRT and instead use non-certified EHR technology,¹⁵⁷ while a majority of hospitals have adopted CEHRT.¹⁵⁸ Although REHs are a new Medicare provider type, the majority of REH-eligible facilities, as noted in the CY 2024 OPPTS/ASC final rule (88 FR 82069), have met requirements for the reporting of electronic clinical quality measures (eCQMs), which require CEHRT, under the Medicare Promoting Interoperability Program.

f. Data Submission Requirements

We propose to require hospitals and ASCs to submit their yes/no attestation responses on these structural measures in all three programs by an annual deadline using the CMS-designated information system (currently, the Hospital Quality Reporting (HQR) system) consistent with the data submission requirements of these measures in the Hospital IQR, IPFQR and PCHQR Programs. We refer readers to sections XV.E.2.a, XVI.E.3.b, and XVII.E.2.a of this proposed rule for additional details regarding data submission deadlines for web-based measure reporting such as the HCHE and FCHE measures for the Hospital OQR, REHQR, and ASCQR Programs, respectively.

We invite public comment on our proposal to adopt the HCHE measure for the Hospital OQR Program beginning with the CY 2025 reporting period/CY 2027 payment determination, to adopt the HCHE measure for the REHQR Program beginning with the CY 2025 reporting period/CY 2027 program determination, and to adopt the FCHE measure for the ASCQR Program beginning with the CY 2025 reporting period/CY 2027 payment determination.

2. Proposal To Adopt the Screening for Social Drivers of Health (SDOH) Measure for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting for the CY 2026 Reporting Period/CY 2028 Payment or Program Determination

¹⁵⁵ Centers for Medicare & Medicaid Services. (February, 2022). Summary of Technical Expert Panel (TEP) Meeting #1 November 16, 2021: Health Equity Quality Measurement Hospital Commitment to Health Equity Measure. Available at: <https://mmshub.cms.gov/sites/default/files/HealthEquityQualityMeasurementTEP1SumReport.pdf>.

¹⁵⁶ The proposed Hospital OQR and REHQR Program measure specifications can be found at <https://qualitynet.cms.gov/outpatient/oqr/proposedmeasures>. The proposed ASCQR Program measure specifications can be found at <https://qualitynet.cms.gov/asc/ascqr/proposedmeasures>.

¹⁵⁷ Taira A. (June 2021). ASCA Survey Shows Mixed Usage of EHR among ASCs. ASC Focus. Available at: <https://www.ascfocus.org/ascfocus/content/articles-content/articles/2021/digital-debut/asca-survey-shows-mixed-usage-of-ehr-among-asc>.

¹⁵⁸ Office of the National Coordinator for Health Information Technology. (2023). National Trends in Hospital and Physician Adoption of Electronic Health Records. Available at: <https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records>.

a. Background

SDOH is an umbrella term that refers to community-level factors that impact health and well-being, while HRSNs are social and economic needs that individuals experience that affect their ability to maintain their health and well-being.¹⁵⁹ Consistent screening of patients for potential HRSNs helps healthcare facilities identify individuals who have historically been underserved by the healthcare system and could support ongoing quality improvement initiatives at the population level by providing data to stratify patient risk and organizational performance to address SDOH.¹⁶⁰ ¹⁶¹ While widespread interest exists in addressing SDOH at community, state, and national levels and in supporting HRSNs for patients who experience one or more HRSNs, action is inconsistent, with 92 percent of hospitals screening for one or more of the five HRSNs listed in Table 88 but only 24 percent of hospitals screening for all five of these HRSNs.¹⁶²

Additionally, pilot studies screening for HRSNs have been conducted in the HOPD and ASC settings, with clinicians and staff agreeing that HRSN data are important and relevant to collect in these settings to improve patient care and communication as well as to connect patients with social-related services.¹⁶³ ¹⁶⁴ We believe that it is essential for healthcare facilities to screen for patient-level HRSN data to support the improvement of patient outcomes and their identified social needs.

In 2017, the CMS Center for Medicare and Medicaid Innovation (CMMI) launched the Accountable Health Communities (AHC) Model, which tested whether systematically identifying and addressing the HRSNs of Medicare and Medicaid beneficiaries through screening, referral, and community navigation services impacted their health outcomes and related healthcare utilization and costs.¹⁶⁵ ¹⁶⁶ Evaluation of the AHC Model's standard 10-item AHC Health-Related Social Needs Screening Tool

(AHC HRSN Screening Tool) found a reduction in emergency department (ED) visits among Medicaid and Medicare fee-for-service (FFS) beneficiaries.¹⁶⁷

Under the AHC Model, the following five core domains were selected to screen for HRSNs among Medicare and Medicaid beneficiaries: (1) food insecurity; (2) housing instability; (3) transportation needs; (4) utility difficulties; and (5) interpersonal safety. These domains were chosen based upon literature review and expert consensus utilizing the following criteria: (1) availability of high-quality scientific evidence linking a given HRSN to adverse health outcomes and increased healthcare utilization, including hospitalizations and associated costs; (2) ability for a given HRSN to be screened and identified prior to discharge, be addressed by community-based services, and potentially improve healthcare outcomes, including reduced readmissions; and (3) evidence that a given HRSN is not systematically addressed by healthcare providers.¹⁶⁸ In addition to established evidence of their association with health status, risk, and outcomes, these five domains were selected for the AHC Model because they can be assessed across the broadest spectrum of individuals in a variety of settings.¹⁶⁹

¹⁵⁹ Assistant Secretary for Planning and Evaluation. (November 2023). Call to Action: Addressing Health-Related Social Needs in Communities Across the Nation. Available at: <https://aspe.hhs.gov/sites/default/files/documents/3e2f6140d0087435cc6832bf8cf32618/hhs-call-to-action-health-related-social-needs.pdf>.

¹⁶⁰ Assistant Secretary for Planning and Evaluation. (September 2022). Reflections Accompanying a Report on Addressing Social Drivers of Health: Evaluating Area-level Indices. Available at: <https://aspe.hhs.gov/sites/default/files/documents/474a62378abf941f20b3eaa74ca5721c/Area-level-Indices-ASPE-Reflections.pdf>.

¹⁶¹ American Hospital Association. (December 2020). Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. Available at: https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf.

¹⁶² Frazee TK, Brewster AL, Lewis VA, Beidler LB, Murray GF, Colla, CH. (2019). Prevalence of Screening for Food Insecurity, Housing Instability, Utility Needs, Transportation Needs, and Interpersonal Violence by US Physician Practices and Hospitals. *JAMA Network Open*, 2(9),

e1911514. <https://doi.org/10.1001/jamanetworkopen.2019.11514>.

¹⁶³ Berkowitz RL, Bui L, Shen Z, Pressman A, Moreno M, Brown S, Nilon, A Miller-Rosales, Azar KM. (2021). Evaluation of a social determinants of health screening questionnaire and workflow pilot within an adult ambulatory clinic. *BMC Family Practice*, 22(1), 256. <https://doi.org/10.1186/s12875-021-01598->.

¹⁶⁴ Schickedanz A, Hamity C, Rogers A, Sharp AL, Jackson A. (2019). Clinician Experiences and Attitudes Regarding Screening for Social Determinants of Health in a Large Integrated Health System. *Medical Care*, 57, S197–S201. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6721844/>.

¹⁶⁵ Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. Available at: <https://innovation.cms.gov/media/document/ahcm-screeningtool-companion>.

¹⁶⁶ Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model. Available at: <https://www.cms.gov/priorities/innovation/innovation-models/ahcm>.

¹⁶⁷ Centers for Medicare & Medicaid Services. (2023). Accountable Health Communities (AHC) Model Evaluation: Second Evaluation Report. CMS Innovation Center. Available at: <https://www.cms.gov/priorities/innovation/data-and-reports/2023/ahc-second-eval-rpt>.

¹⁶⁸ Billieux A, Verlander, K, Anthony S, Alley D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). <https://doi.org/10.31478/201705b>.

¹⁶⁹ Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model. Available at: <https://innovation.cms.gov/innovation-models/ahcm>.

TABLE 88: THE FIVE CORE HRSN DOMAINS SCREENED UNDER THE AHC MODEL

Domain	Description
Food Insecurity	Food insecurity is defined as limited or uncertain access to adequate quality and quantity of food at the household level. It is associated with diminished mental and physical health and increased risk for chronic conditions. ¹⁷⁰ Individuals experiencing food insecurity often have inadequate access to healthier food options which can impede self-management of chronic diseases like diabetes and heart disease, and require individuals to make personal trade-offs between food purchases and medical needs, including prescription medication refills and preventive health services. ^{171,172} Food insecurity is associated with high-cost healthcare utilization including emergency department (ED) visits and outpatient visits. ^{173,174}
Housing Instability	Housing instability encompasses multiple conditions ranging from inability to pay rent or mortgage, frequent changes in residence including temporary stays with friends and relatives, living in crowded conditions, and actual lack of sheltered housing in which an individual does not have a personal residence. ¹⁷⁵ Population surveys consistently show that people from some racial and ethnic minority groups constitute the largest proportion of the U.S. population experiencing housing instability. ¹⁷⁶ Housing instability is associated with higher rates of chronic illnesses, injuries, and complications and more frequent utilization of high-cost healthcare services. ¹⁷⁷
Transportation Needs	Unmet transportation needs include limitations that impede transportation to destinations required for all aspects of daily living. ¹⁷⁸ Groups disproportionately affected include older adults (aged >65 years), people with lower incomes, people with impaired mobility, residents of rural areas, and people from some racial and ethnic minority
	groups. Transportation needs contribute to postponement of routine medical care and preventive services which ultimately lead to chronic illness exacerbation and more frequent utilization of high-cost healthcare services. ^{179,180} Patients with serious mental illness often lack access to transportation with many Medicaid eligible patients relying on Medicaid's non-emergency medical transportation (NEMT) to access needed healthcare, though this does not provide access to transportation to other aspects of daily living. ¹⁸¹
Utility Difficulties	Inconsistent availability of electricity, water, oil, and gas services is directly associated with housing instability and food insecurity. ¹⁸² Specifically, interventions that increase or maintain access to such services have been associated with individual and population-level health improvements. ¹⁸³
Interpersonal Safety	Interpersonal safety affects individuals across the lifespan, from birth to old age, and is directly linked to mental and physical health. Assessment for this domain includes screening for exposure to intimate partner violence, child abuse, and elder abuse. ¹⁸⁴ Exposure to violence and social isolation are reflective of individual-level social relations and living conditions that are directly associated with injury, psychological distress, and death in all age groups. ¹⁸⁵

These five evidence-based HRSN domains described in Table 88 informed

¹⁷⁰ Berkowitz SA, Seligman HK, Meigs JB, Basu S. (2018). Food Insecurity, Healthcare Utilization, and High Cost: A Longitudinal Cohort Study. *The American Journal of Managed Care*, 24(9), 399–404. <http://www.ncbi.nlm.nih.gov/pmc/articles/pmc6426124/>.

¹⁷¹ Seligman HK, Berkowitz, SA. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. *Annual Review of Public Health*, 40(1), 319–337. <https://www.annualreviews.org/doi/10.1146/annurev-publhealth-040218-044132>.

¹⁷² National Academies of Sciences, Engineering, and Medicine. (2006). Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The

National Academies Press. Available at: <https://nap.nationalacademies.org/catalog/23285/executive-summary-cost-benefit-analysis-of-providing-non-emergency-medical-transportation>.

¹⁷³ Berkowitz SA, Seligman HK, Meigs JB, Basu S. (2018). Food Insecurity, Healthcare Utilization, and High Cost: A Longitudinal Cohort Study. *The American Journal of Managed Care*, 24(9), 399–404. <http://www.ncbi.nlm.nih.gov/pmc/articles/pmc6426124/>.

¹⁷⁴ Dean EB, French MT, Mortensen, K. (2020). Food insecurity, health care utilization, and health care expenditures. *Health Services Research*, 55(S2), 883–893. Available at: <https://doi.org/10.1111/1475-6773.13283>.

¹⁷⁵ Hill-Briggs, F. (2020). Social Determinants of Health and Diabetes: A Scientific Review. *Diabetes Care*, 44(1), 258–279. <https://pubmed.ncbi.nlm.nih.gov/33139407/>.

our development of the Screening for SDOH and Screen Positive Rate for

¹⁷⁶ Henry M, de Sousa T, Roddey C, Gayen S, Bednar T, Abt Associates. (January 2021). The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness. U.S. Department of Housing and Urban Development. Available at: <https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf>.

¹⁷⁷ Baxter A, Tweed E, Katikireddi S, Thomson H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. *Journal of Epidemiology and Community Health*, 73; 379–387. <https://doi.org/10.1136/jech-2018-210981>.

SDOH measures. We used these five HRSN domains to inform the development of the SDOH measure we propose to adopt in this proposed rule because the AHC Model's HRSN Screening Tool allows healthcare facilities to quickly screen for patients' core health-related social needs and was designed to work in a variety of clinical settings, making it ideal for implementing across quality reporting programs, including the Hospital OQR, REHQR, and ASCQR Programs, with minimal burden to healthcare facilities.¹⁸⁶

We recognize that patient interaction with the healthcare system may be limited by setting. For example, a patient receiving care in an HOPD, REH, or ASC may not have recently received

¹⁷⁸ Centers for Medicare and Medicaid Services. (2023) Addressing Transportation Barriers: A User Case in Leveraging the Value-Based Insurance Design (VBID) Model. Available at: <https://www.cms.gov/priorities/innovation/innovation-models/vbid>.

¹⁷⁹ Billioux A, Verlander, K, Anthony S, Alley D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). <https://doi.org/10.31478/201705b>.

¹⁸⁰ Shier G, Ginsburg M, Howell J, Volland P, Golden R. (2013). Strong Social Support Services, Such as Transportation And Help For Caregivers, Can Lead To Lower Health Care Use And Costs. *Health Affairs*, 32(3), 544–551. <https://www.healthaffairs.org/doi/10.1377/hlthaff.2012.0170>.

¹⁸¹ National Alliance on Mental Illness. Medicaid: Non-Emergency Medical Transportation (NEMT). Available at: <https://www.nami.org/Advocacy/Policy-Priorities/Supporting-Community-Inclusion-and-Non-Discrimination/Medicaid-Non-Emergency-Medical-Transportation>.

¹⁸² Baxter A, Tweed E, Katikireddi S, Thomson H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. *Journal of Epidemiology and Community Health*, 73; 379–387. <https://doi.org/10.1136/jech-2018-210981>.

¹⁸³ Wright BJ, Vartanian KB, Li HF, Royal N, Matson JK (2016). Formerly Homeless People Had Lower Overall Health Care Expenditures After Moving into Supportive Housing. *Health Affairs*, 35(1), 20–27. <https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.0393>.

¹⁸⁴ Billioux A, Verlander K, Anthony S, Alley D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). <https://doi.org/10.31478/201705b>.

¹⁸⁵ Henry M, de Sousa T, Roddey C, Gayen S, Bednar T, Abt Associates. (January 2021). The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness. U.S. Department of Housing and Urban Development. Available at: <https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf>.

¹⁸⁶ Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. Available at: <https://innovation.cms.gov/media/document/ahcm-screeningtool-companion>.

care in an acute care hospital paid under IPPS, inpatient psychiatric facility cancer hospital, or dialysis facility, and therefore would not have the opportunity to benefit from being screened for SDOHs despite this measure's prior adoption in other quality programs. By adopting aligned Screening for SDOH measures within the Hospital OQR, REHQR, and ASCQR Programs, we expect to increase the likelihood that these settings will screen patients and provide contextualized care and any necessary relevant referrals to address their patient's needs.

Screening for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety in HOPDs, REHs, and ASCs can help identify and provide appropriate referrals for patients who may benefit from greater support in one or more of those areas. Adoption of the Screening for SDOH measure in the Hospital OQR, REHQR, and ASCQR Programs would continue to support our priority of identifying risk factors for inadequate health care access and adverse health outcomes among patients.

b. Measure Overview

The Screening for SDOH measure is a process measure that assesses the total number of patients, who were 18 years or older on the date of service, screened for social risk factors (specifically, the five HRSNs of food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) as they receive care from a HOPD, REH, or ASC.

c. Pre-Rulemaking Measure Review

As part of the PRMR process, the Hospital Recommendation Group reviewed and voted on the Screening for SDOH measure during their meeting on January 18 and 19, 2024.¹⁸⁷ The Hospital Recommendation Group “recommended with conditions” the Screening for SDOH measure for all three programs (that is, the Hospital OQR, REHQR, and ASCQR Programs).

The committee recommended a condition specific to the Hospital OQR Program, which was to allow hospitals to report this measure one time each year for both the Hospital IQR Program and Hospital OQR Program if applicable.¹⁸⁸ We note that we considered allowing hospitals to report

this measure jointly for the Hospital IQR and Hospital OQR Programs (if applicable); however, as the patient populations represented by the programs are different, as is the measure calculation due to this difference in the denominator, we propose to require a separate data submission for each program. More importantly, patients and consumers would likely find useful Compare tool information on screening rates separated for inpatient and outpatient departments of the same hospital.

d. CBE Endorsement

Section 1833(t)(17)(C)(i) of the Act provides that the Hospital OQR Program, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities (not necessarily the CBE). Under section 1833(i)(7)(B) of the Act, this requirement at section 1833(t)(17)(C) applies to the ASCQR Program except as the Secretary may otherwise provide. For the Hospital OQR Program and ASCQR Program, we note that section 1833(t)(17) of the Act does not require that each measure we adopt for these programs be CBE-endorsed (75 FR 72064 and 72065 for the Hospital OQR Program and 76 FR 74494 for the ASCQR Program).

Section 1833(t)(17)(C)(i) of the Act also requires measures developed for the Hospital OQR Program to reflect consensus among affected parties. Under section 1833(i)(7)(B), this requirement also applies to the ASCQR Program except as the Secretary may otherwise provide. As we have noted in previous rulemaking, consensus among affected parties can be reflected in ways other than CBE endorsement, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment (75 FR 72064 and 72065 for the Hospital OQR Program and 76 FR 74494 for the ASCQR Program).

For the REHQR Program, section 1861(kkk)(7)(C)(i) of the Act generally requires that quality measures specified by the Secretary for the REHQR Program be endorsed by a CBE; however, section 1861(kkk)(7)(C)(ii) of the Act provides an exception to the general CBE-endorsement requirement, stating that in the case of a specified area or medical topic determined appropriate by the Secretary for which a measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not endorsed as long as due consideration is given to measures that have been endorsed or adopted by

¹⁸⁷ The Screening for SDOH measure is identified on the MUC List as MUC2023–156.

¹⁸⁸ Partnership for Quality Measurement. 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: <https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf>.

a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and therefore we believe the exception in section 1861(kk)(7)(C)(ii) of the Act applies for purposes of this measure for the REHQR Program.

At this time, we find no other feasible and practicable measures set forth by a national consensus building entity on the topic of screening for SDOH. While we recognize the value of measures undergoing CBE endorsement review and prefer to use endorsed measures, there are currently no CBE-endorsed measures that address screening for SDOH in the outpatient setting. Given the urgency of achieving health equity, it is important to implement this measure as soon as possible. We note that the five domains for which patients would be screened were chosen based upon literature review and expert consensus, and that these five domains informed development of the Screening for SDOH measure. We will consider submitting the Screening for SDOH measure to the CBE for endorsement in the future.

e. Data Sources

For data collection of the Screening for SDOH measure, we propose that healthcare facilities would use a self-selected screening tool to collect these data. We propose to allow healthcare facilities to select their screening tool to reduce burden and in recognition of the fact that some healthcare facilities may already be screening their patients for HRSNs. If a healthcare facility is not already doing so, many screening tools for HRSNs already exist. While we acknowledge the potential benefits of requiring all healthcare facilities to use the same screening instrument or a prescribed set of standards around the number or types of screening questions used, we also recognize the benefits of providing healthcare facilities with flexibility to customize screening and data collection to their patient populations and individual needs.

One example of a screening tool that healthcare facilities could consider using is the AHC HRSN Screening Tool, which providers used in the AHC Model to screen for HRSNs in their Medicare, Medicaid, and dually eligible beneficiary populations.¹⁸⁹ We have tested the AHC HRSN Screening Tool across many care delivery sites in

diverse geographic locations and determined that it demonstrates evidence of both reliability and validity.¹⁹⁰ The AHC HRSN Screening Tool can be implemented in a variety of healthcare settings, including HOPDs, REHs, and ASCs. While the AHC Model focused on HRSNs among community-dwelling Medicare and Medicaid beneficiaries, the AHC HRSN Screening Tool can be used to screen patients with any insurance status or type, including commercially insured and uninsured individuals. The AHC HRSN Screening Tool has broad applicability in settings outside of the AHC Model as it screens for a range of five HRSN domains while also being concise, limited to only ten questions. We believe this promotes manageable integration into clinical workflow settings and provides greater accessibility and application to diverse patient populations.^{191 192}

For additional screening tools for healthcare facilities to consider using to collect data for this proposed Screening for SDOH measure, we refer readers to evidence-based resources like the Social Interventions Research and Evaluation Network (SIREN) website, for example, which provides comprehensive information about the most widely used HRSN screening tools.^{193 194} SIREN contains descriptions of the content and characteristics of various tools, including information about intended populations, completion time, and number of questions.

We also encourage healthcare facilities to consider digital standardized screening tools. We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49207 through 49208), where we discuss how the use of certified health information technology (IT), including but not limited to

¹⁹⁰ Centers for Medicare and Medicaid Services. (2023). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. Available at: <https://www.cms.gov/priorities/innovation/media/document/ahcm-screeningtool-companion>.

¹⁹¹ Ibid.

¹⁹² Billioux A, Verlander, K, Anthony S, Alley D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). <https://doi.org/10.31478/201705b>.

¹⁹³ Social Interventions Research & Evaluation Network. (2019). Social Needs Screening Tool Comparison Table. Available at: <https://sirennetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison>.

¹⁹⁴ The Social Interventions Research and Evaluation Network (SIREN) at University of California San Francisco was launched in the spring of 2016 to synthesize, disseminate, and catalyze research on SDOH and healthcare delivery.

CEHRT,¹⁹⁵ can support capture of HRSN information in a standardized, interoperable fashion. We also encourage healthcare facilities to learn about the United States Core Data for Interoperability (USCDI) standard used in certified health IT and how this standard can support interoperable exchange of health and HRSN assessment data.¹⁹⁶

In alignment with the Hospital IQR Program, we propose that HOPDs, REHs, and ASCs could confirm the current status of any previously reported HRSNs in another care setting and inquire about others not previously reported, in lieu of re-screening a patient within the reporting period. In addition, if this information has been captured in the EHR in another outpatient setting or the inpatient setting during the same reporting period, we propose that the HOPD, REH, and ASC could use that information for purposes of reporting the measure in lieu of screening the patient. We intend to monitor and evaluate the measure screening requirements, including frequency, in these outpatient settings to ensure balance between quality of care for patients and facility burden.

f. Measure Calculation

The Screening for SDOH measure is calculated as a percentage equal to the numerator over the denominator. The numerator is defined as the number of patients admitted to an HOPD, REH, or ASC, who are 18 years or older on the date of admission and are screened for all five HRSNs described in Table 88 during their receipt of services in the HOPD, REH, or ASC, as applicable.¹⁹⁷ The denominator is defined as the number of patients who are admitted to a HOPD, REH, or ASC, as applicable, and who are 18 years or older.

The measure excludes patients who: (1) opt-out of screening; or (2) are themselves unable to complete the screening and have no legal guardian or caregiver able to do so on the patient's behalf.

¹⁹⁵ CEHRT refers to certified health IT requirements defined by CMS for certain programs which incorporate health IT certification criteria established by the Office of the National Coordinator for Health Information Technology (ONC) at 45 CFR 170.315.

¹⁹⁶ Office of the National Coordinator for Health IT (ONC). United States Core Data for Interoperability. Available at: <https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>.

¹⁹⁷ The term "admitted patients" appears in the measure specifications and MUC documentation and is intended to refer to a person who receives ambulatory care in these designated settings.

¹⁸⁹ Centers for Medicare and Medicaid Services. The Accountable Health Communities Health-Related Social Needs Screening Tool. Available at: <https://www.cms.gov/priorities/innovation/files/worksheets/ahcm-screeningtool.pdf>.

g. Data Submission and Reporting

We propose to allow healthcare facilities to voluntarily submit to CMS aggregate data for this measure for the CY 2025 reporting period and then to require mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination. Specifically, we propose that healthcare facilities would aggregate data they collect for the numerator and the denominator to CMS (as described in section XIV.B.2.f of this proposed rule), and that they would not be required to submit patient-level data. We propose to require aggregate data because we believe patient-level reporting is unnecessary and would cause undue burden due to the transfer of large quantities of data. However, in the future, we may consider requiring the reporting of patient-level information. This measure aims to encourage healthcare facilities to screen for and identify HRSNs in order to identify and address social needs among their patient populations.

We also propose that healthcare facilities would be required to submit data on this measure annually using the CMS-designated information system (currently, the HQR system) consistent with the data submission requirements for this measure in the Hospital IQR, IPFQR and PCHQR Programs. We refer readers to sections XV.E.2.a, XVI.E.3.b, and XVII.E.2.a of this proposed rule for additional details regarding data submission using the CMS-designated information system in the Hospital OQR, REHQR, and ASC Programs, respectively.

We propose to adopt this measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination. We propose to begin with one year of voluntary reporting to provide a transition period for healthcare facilities to select and integrate screening tools into their clinical workflow processes.

We invite public comment on our proposal to adopt the Screening for SDOH measure for the Hospital OQR, REHQR, and ASCQR Programs beginning with voluntary reporting for the CY 2025 reporting period, and to require mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination, as described above.

3. Proposal To Adopt the Screen Positive Rate for Social Drivers of Health (SDOH) Measure for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment or Program Determination

a. Background

In the outpatient setting, we encourage systematic screening of patients' HRSNs to identify patient needs and support improvements in health outcomes. While the Screening for SDOH measure (discussed previously in section XIV.B.2 of this proposed rule) identifies individuals with HRSNs, the Screen Positive Rate for SDOH measure estimates the magnitude of these needs for a healthcare facility's patient population served. We believe the adoption of the Screen Positive Rate for SDOH measure would encourage healthcare facilities to track the prevalence of specific HRSNs among patients over time and use the data to stratify risk as part of quality performance improvement efforts.

We propose that healthcare facilities would be required to report the Screen Positive Rate for SDOH measure as the rate of patients who screened positive for each of the five core HRSNs domains discussed in Table 88: food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.¹⁹⁸

b. Measure Overview

While the Screening for SDOH measure (discussed in section XIV.B.2) enables identification of individuals with HRSNs, the Screen Positive Rate for SDOH measure would allow healthcare facilities to capture the magnitude of these needs by requiring healthcare facilities to report the rates of patients who screened positive for each of the five core HRSNs. The Screen Positive Rate for SDOH is a process measure that provides information on the percent of patients receiving care at an HOPD, REH, or ASC, who were 18 years or older on the date of service, who were screened for all five HRSNs described in Table 88, and who screened positive for one or more of

those HRSNs. Healthcare facilities would report this measure as five separate rates, one for each of the HRSNs: food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. This measure is not intended for comparison of screen positive rates of HRSNs between healthcare facilities but is rather to provide transparency in the delivery of care and actionable information to healthcare facilities on the unmet needs among their patients.

c. Pre-Rulemaking Measure Review

As part of the PRMR process, the Hospital Recommendation Group reviewed and voted on the Screen Positive Rate for SDOH measure¹⁹⁹ during their meeting on January 18 and 19, 2024.^{200 201} The committee did not reach the 75 percent vote required to reach a consensus as to its recommendation for the Screen Positive Rate for SDOH measure for the Hospital OQR, REHQR, or ASCQR Programs. The committee expressed a concern about ambiguity in the interpretation of data from the Screen Positive Rate for SDOH measure as well as expectations regarding healthcare facilities. We acknowledge that a high score could be interpreted in different ways but that the objective of this measure is to incentivize collection of these data to help identify patient needs and where resources constraints exist. The committee also discussed a condition specific to the Hospital OQR Program, which was to allow hospitals to report this measure one time each year for both the Hospital IQR Program and Hospital OQR Program.²⁰² We note that we considered allowing hospitals to report this measure jointly for the Hospital IQR and Hospital OQR Programs (if applicable); however, as the patient populations represented by the programs are different, as is the measure calculation due to this difference in the denominator, we propose to require a

¹⁹⁹ The Screen Positive Rate for SDOH measure is identified on the MUC List as MUC2023–171.

²⁰⁰ Centers for Medicare & Medicaid Services. List of Measures Under Consideration for December 1, 2023. Available at: <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>.

²⁰¹ Centers for Medicare & Medicaid Services. (December 2023). Overview of the List of Measures Under Consideration. Available at: <https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf>.

²⁰² Partnership for Quality Measurement. (2023). 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: <https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf>.

¹⁹⁸ Billioux A, Verlander, K, Anthony S, Alley D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives*, 7(5). <https://doi.org/10.31478/201705b>.

separate data submission for each program.

Further, we have identified the implementation of this measure in the Hospital OQR, REHQR, and ASCQR Programs as an important way to address the health equity measurement gap. We also believe that the information collected from this measure can help HOPDs, REHs, and ASCs understand SDOH needs in their patient population and to devise appropriate interventions. On this basis, we propose this measure for adoption for all three of our programs.

d. CBE Endorsement

As discussed in section XIV.B.2.d, we find no other feasible and practicable measures set forth by a national consensus building entity on the topic of screening for SDOH. While we recognize the value of measures undergoing CBE endorsement review and prefer to use endorsed measures, there are currently no CBE-endorsed measures that address screening for SDOH in the outpatient setting. Given the urgency of achieving health equity, it is important to implement this measure as soon as possible. We note that the five domains for which patients would be screened were chosen based upon literature review and expert consensus, and that these five domains informed development of the Screen Positive Rate for SDOH measure. We will consider submitting the Screen Positive Rate for SDOH measure to the CBE for endorsement in the future.

e. Data Sources

The data sources for this measure are as described for the Screening for SDOH measure found in section XIV.B.2.e of this proposed rule.

f. Measure Calculation

The Screen Positive Rate for SDOH measure is calculated with a numerator and denominator. The numerator is defined as the number of patients receiving care at an HOPD, REH, or ASC who are 18 years or older on the date of admission, who were screened for all five HRSNs described in Table 88, and who screen positive for having a need in one or more of those HRSNs (calculated separately). The denominator is defined as the number of patients receiving care at the HOPD, REH, or ASC who are 18 years or older on the date of admission and are screened for all five HRSNs during their care.

The results of this measure are calculated and reported as five separate rates—one for each HRSN, each calculated with the same denominator.

The measure excludes patients who: (1) opt-out of screening; or (2) are themselves unable to complete the screening and have no legal guardian or caregiver able to do so on the patient's behalf.

g. Data Submission and Reporting

While this measure would require healthcare facilities to collect patient-level data on their patients' SDOH screening results, consistent with the Screening for SDOH measure, we propose to adopt this measure as an aggregate measure. Specifically, we propose that healthcare facilities would be required to submit aggregated data representing the total numerator results for each of the five screening areas and the total number of patients screened for all five of the HRSNs. We propose to require aggregate data because we believe it is unnecessary for healthcare facilities to submit data collected at the patient level as this would cause undue burden due to the transfer of large quantities of data. However, in the future, we may consider the reporting of patient-level information. This measure aims to encourage healthcare facilities to screen for and identify HRSNs as it is most important for healthcare facilities to collect this HRSN data to address social needs among their patient populations.

Healthcare facilities would be required to submit information via a CMS-designated information system (currently the HQR system) consistent with the prior adoption of this measure in the Hospital IQR, IPFQR and PCHQR Programs. We refer readers to sections XV.E.2.a, XVI.E.3.b, and XVII.E.2.a of this proposed rule for additional details regarding data submission using the CMS-designated information system in the Hospital OQR, REHQR, and ASC Programs, respectively.

We note that we considered requiring hospitals to report this measure jointly for the Hospital IQR and Hospital OQR Programs; that is, requiring hospitals to submit once under both programs rather than submitting data twice in the HQR system. However, as the populations represented by the programs are different, resulting in different calculations of the measure denominator under each program, we propose to require a separate data submission for each program.

We propose to adopt this Screen Positive Rate for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination to be consistent with the Screening for SDOH

measure. Similar to the Screening for SDOH measure, a voluntary period would allow time for healthcare facilities to select and integrate screening tools into their clinical workflow processes and gain experience with both measures before measure results are publicly displayed on the Compare tool.

We invite public comment on our proposal to adopt the Screen Positive Rate for SDOH measure for the Hospital OQR, REHQR, and ASCQR Programs beginning with voluntary reporting on this measure for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment or program determination, as described above.

C. Proposal To Modify the Immediate Measure Removal Policy for the Hospital Outpatient Quality Reporting (OQR) and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs Beginning With CY 2025

In the CY 2010 OPPI/ASC final rule with comment period (74 FR 60634 through 60635) and the CY 2015 OPPI/ASC final rule with comment period (79 FR 66967 through 66968), we finalized a process for immediate removal of Hospital OQR and ASCQR Program measures, respectively, based on evidence that the continued use of a measure as specified raises patient safety concerns. We refer readers to our regulations at 42 CFR 419.46(i)(2) for the Hospital OQR Program and 42 CFR 416.320(b) for the ASCQR Program for the codification of these immediate measure removal policies.

When there is evidence that continued use of a measure potentially raises patient safety concerns, we believe that immediate action should be taken to discontinue collection of the measure to not encourage potentially harmful practices. We also believe that seeking public input on the removal of such measures increases the public's voice in decision-making and increases transparency. We noted this in the CY 2024 OPPI/ASC final rule (88 FR 82052), where we finalized an immediate measure suspension policy for the REHQR Program in lieu of an immediate measure removal policy. The REHQR Program's immediate measure suspension policy more appropriately provides that, in cases where we believe that a measure raises patient safety concerns, we will suspend the measure's use in the program, instead of immediately removing the measure, until its potential removal undergoes the standard rulemaking process (88 FR 82052).

We believe that our rationale for finalizing the immediate measure suspension policy in the REHQR Program (88 FR 82052) also applies to the Hospital OQR and ASCQR Programs. On this basis, we propose to modify the immediate measure removal policies in the Hospital OQR and ASCQR Programs so that they are more appropriately referred to as immediate measure suspension policies beginning with CY 2025.

Under this proposed immediate measure suspension policy in the Hospital OQR or ASCQR Programs, in cases where we determine there is evidence that the collection and reporting of a measure raises potential patient safety concerns, we would suspend the measure from the program (as applicable) until potential removal can be proposed through the rulemaking process. We will notify the healthcare facility (HOPDs or ASCs, as applicable) and the public of the decision to suspend the measure through standard communication channels, including, but not limited to, program-specific listservs and program guidance currently housed on a CMS-designated website. We would then address the suspension and

propose policies regarding any such suspended measure in the next feasible rulemaking cycle.

We also propose to revise the Hospital OQR Program regulatory text at § 419.46(i)(2) and the ASCQR Program regulatory text at § 416.320(b) to codify the immediate measure suspension policy. We further propose to clarify the standard for immediate measure suspension in these regulatory texts by revising references to patient safety concerns raised by “continued use of a measure as specified” to patient safety concerns raised by “collection and reporting activities related to a quality measure”.

We invite public comment on these proposals.

XV. Hospital Outpatient Quality Reporting (OQR) Program

A. Background and Statutory Authority

The Hospital Outpatient Quality Reporting (OQR) Program is a pay-for-reporting program intended to improve the quality of care provided to Medicare beneficiaries, facilitate public transparency, and ensure accountability of hospital outpatient departments

(HOPDs). Section 1833(t)(17)(A) of the Social Security Act (the Act) states that subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act) that do not submit data required for measures selected with respect to such a year, in the form and manner required by the Secretary, will incur a 2.0 percentage point reduction to their annual Outpatient Department (OPD) fee schedule increase factor.

We refer readers to the CY 2011 OPPTS/ASC Payment System final rule (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program, as well as program requirements codified at 42 CFR 419.46, and to the CY 2024 OPPTS/ASC final rule for information regarding the program’s regulatory history (88 FR 81961 through 82012).

1. Previously Finalized Program Measure Set Beginning With the CY 2027 Payment Determination

Table 89 summarizes the previously finalized Hospital OQR Program measures beginning with the CY 2027 payment determination:

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**TABLE 89: PREVIOUSLY FINALIZED HOSPITAL OQR PROGRAM MEASURE
SET BEGINNING WITH THE CY 2027 PAYMENT DETERMINATION**

CBE #	Measure Name
None	Abdomen Computed Tomography (CT) – Use of Contrast Material
3490	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
0658	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
None	Breast Cancer Screening Recall Rates
None†	Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
None†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
3636	COVID–19 Vaccination Coverage Among Health Care Personnel (HCP)
3663e	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Excessive Radiation eCQM)**
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
0661	Head CT or Magnetic Resonance Imaging (MRI) Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
None†	Left Without Being Seen
None†	MRI Lumbar Spine for Low Back Pain
None†	Median Time from ED Arrival to ED Departure for Discharged ED Patients
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) • About Facilities and Staff • Communication About Procedure • Preparation for Discharge and Recovery • Overall Rating of Facility • Recommendation of Facility
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM)***
None	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM

†Measure is no longer endorsed by the Consensus Based Entity (CBE) but was endorsed previously.

*This measure is voluntary.

**This measure begins with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination, as discussed in the CY 2024 OPPI/ASC final rule (88 FR 81988 through 81992).

***This measure begins with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2031 payment determination, as discussed in the CY 2024 OPPI/ASC final rule (88 FR 81984 through 81986).

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B. Program Measure Set Policies

1. Measure Retention

We refer readers to § 419.46(i)(1) and the CY 2013 OPPI/ASC final rule (77 FR 68471) for our policies regarding measure retention.

We are not proposing any changes to these policies in this proposed rule.

2. Measure Suspension or Removal

We refer readers to §§ 419.46(i)(2) and (3) and the CY 2013 OPPI/ASC final

rule (77 FR 68472 and 68473) for our program policies regarding: (1) general measure removal, suspension, and replacement; and (2) immediate measure removal.

We refer readers to section XIV.C of this proposed rule for our cross-program proposal to modify the immediate removal policy for adopted Hospital OQR Program measures.

3. Measure Adoption

We refer readers to the CY 2024 OPPI/ASC final rule (88 FR 81973) for

a discussion of the statutory requirements and our considerations for adopting quality measures under the Hospital OQR Program.

We are not proposing any changes to these policies in this proposed rule.

C. Program Measure Proposals

1. Proposed New Measures for the Hospital OQR Program Measure Set

a. Proposals To Adopt Health Equity Measures in the Hospital OQR Program

We refer readers to sections XIV.B.1, XIV.B.2, and XIV.B.3, respectively, of

this proposed rule for our cross-program proposals to adopt the following measures in the Hospital OQR Program: (1) the Hospital Commitment to Health Equity (HCHE) measure, beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

b. Proposal To Adopt the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM) Beginning With Voluntary Reporting For the CY 2026 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2027 Reporting Period/CY 2029 Payment Determination

(1) Background

Recent studies have shown that compared to inpatient settings, outpatient settings are associated with worse patient understanding and lower patient activation (that is, an individual's understanding, competence, and willingness to participate in care decisions during their recovery), indicating an area for quality of care improvement.^{203 204 205} One study found that providers in the inpatient setting provided more complete discharge instructions and end-of-visit summaries to patients when compared to providers in the ambulatory setting, including continuing medication names and instructions (96 percent vs. 40 percent), new medication names and instructions

(99 percent vs. 29 percent), and pending diagnostic test names and instructions (90 percent vs. 61 percent).²⁰⁶ A lack of understanding of recovery information²⁰⁷ and other aspects of health literacy have been linked to poor adherence to treatment, decreased patient safety, increased return to the emergency department (ED), lower levels of patient satisfaction, and disproportionate effects on patients with limited English proficiency and patients over age 65, who face additional barriers and recovery issues after their receipt of a hospital outpatient service.^{208 209} Reduced patient engagement and a deficiency in detailed discharge information in the inpatient setting were also associated with a higher risk of readmissions to an inpatient setting.²¹⁰ Research indicates that information that is simpler to read and more complete has been associated with fewer follow-up calls to providers as well as less frequent hospital readmissions.^{211 212}

(2) Measure Overview

The Information Transfer PRO-PM aims to assess the level of clear, personalized recovery information provided to patients aged 18-years or older who had surgery or a procedure at an HOPD. The measure reports the average score of a patient's ratings on a three-domain, 9-item survey²¹³ to evaluate the clarity of the clinical information patients are given before, during, and after an outpatient surgery or procedure. The survey covers three

domains for patients or their caregivers to rate the clarity of information received regarding their post-discharge²¹⁴ recovery: applicability to patient needs, medication, and daily activities. The applicability to patient needs domain assesses whether the recovery information considered a patient's health needs and personal circumstances. The medications domain examines the clarity of medication information provided, specifically guidance on taking new medications, potential side effects, and discontinuing medication. The daily activities domain assesses the clarity of guidelines around diet, physical activity, returning to work, and driving. Results from the survey provide hospitals with patient reported outcome (PRO) data designed to assess communication efforts and enable hospitals to reduce the risk of patient harm that may occur if the patient does not fully understand the recovery information.

This measure addresses the priority area stated in our Meaningful Measures Framework of adopting high-quality measures that focus on person-centered care.²¹⁵ Additionally, the Information Transfer PRO-PM supports the National Quality Strategy goal of equity and engagement by engaging individuals to become partners in their care and ensuring that individuals and caregivers have the information needed to make the best choices for their health.²¹⁶

Pilot testing conducted by the measure developer in 26 HOPDs in five states demonstrated that the measure is reliable and meaningful.^{217 218} The measure developer assessed reliability of the measure using the Cronbach alpha score²¹⁹ to determine whether the nine survey questions reliably measured

²⁰⁶ Ibid.

²⁰⁷ We use the term "recovery information" to mean the clinical care instructions provided to patients or their caregivers after the completion of surgery or a non-surgical procedure.

²⁰⁸ DeSai C, Janowiak K, Secheli B, et al. (2021). Empowering patients: simplifying discharge instructions. *BMJ Open Quality*;10(3)001419. <http://doi.org/10.1136/bmjopen-2021-001419>.

²⁰⁹ Malevanchik L., Wheeler M., Gagliardi K., Karliner L., Shah S.J. (2021). Disparities After Discharge: The Association of Limited English Proficiency and Postdischarge Patient-Reported Issues, The Issues, The Joint Commission Journal on Quality and Patient Safety, 47(12):775–782. <https://doi.org/10.1016/j.jcjq.2021.08.013>.

²¹⁰ Erlang AS, Schjødt K, Linde JKS, Jensen AL. (2021). An observational study of older patients' experiences of involvement in discharge planning. *Geriatr Nurs* 42(4):855–862. <http://doi.org/10.1016/j.gerinurse.2021.04.002>

²¹¹ Choudhry AJ, Younis M, Ray-Zack MD, et al. (2019). Enhanced readability of discharge summaries decreases provider telephone calls and patient readmissions in the posthospital setting. *Surgery*. 165(4):789–794. <https://doi.org/10.1016/j.surg.2018.10.014>.

²¹² Mitchell JP. (2015). Association of provider communication and discharge instructions on lower readmissions. *J Healthc Qual.*, 37(1):33–40. <https://doi.org/10.1097/01.JHQ.0000460126.88382.13>.

²¹³ A copy of the survey instrument is available at: <https://www.cms.gov/files/document/patient-understanding-key-information-related-recovery-after-facility-based-outpatient-procedure-or.pdf>.

²¹⁴ The term "discharge" appears in the measure specifications and is intended to refer to the transition of a patient from the outpatient hospital setting to home or next level of care.

²¹⁵ Centers for Medicare & Medicaid Services. (2024). Meaningful Measures 2.0. Available at: <https://www.cms.gov/medicare/quality/meaningful-measures-initiative/meaningful-measures-20>.

²¹⁶ Centers for Medicare & Medicaid Services. (2024). CMS Quality Strategy. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy>.

²¹⁷ Partnership for Quality Measurement. (2024). 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: <https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf>.

²¹⁸ Partnership for Quality Measurement. Submission Tool and Repository Measure Database. <https://p4qm.org/measures/4210>.

²¹⁹ For more information on what the Cronbach alpha score determines and how it is used, we refer readers to: Tavakol M & Dennick R. (2011). Making sense of Cronbach's alpha. *Int J Med Educ.* 27;2: 53–55. [www.doi.org/10.5116/ijme.4dfb.8dfd](https://doi.org/10.5116/ijme.4dfb.8dfd).

²⁰³ Kang E, Gillespie BM, Tobiano G, et al. (2018). Discharge education delivered to general surgical patients in their management of recovery post discharge: A systematic mixed studies review. *Int J Nurs Stud.* 87:1–13. <https://doi.org/10.1016/j.ijnurstu.2018.07.004>.

²⁰⁴ Hoek AE, Anker SCP, van Beeck EF, et al. (2020). Patient Discharge Instructions in the Emergency Department and Their Effects on Comprehension and Recall of Discharge Instructions: A Systematic Review and Meta-analysis. *Ann Emerg Med.* 75(3):435–444. <https://doi.org/10.1016/j.annemergmed.2019.06.008>.

²⁰⁵ Downey E, Olds DM. (2021). Comparison of Documentation on Inpatient Discharge and Ambulatory End-of-Visit Summaries. *J Healthc Qual.* 43(3):e43–e52. <https://doi.org/10.1097/JHQ.000000000000269>.

the same underlying characteristic; that is, the clarity and applicability of recovery instructions. The Cronbach alpha score, which compares the amount of shared variance, or covariance, among the instrument items to the total variance, indicated that the survey items are reliable because they reflect a high level of covariance relative to the total variance.²²⁰ Additionally, the measure developer found the performance scores among facilities in the pilot study to be moderately reliable using a signal-to-noise ratio, which estimated variance among facilities and facility specific errors to determine the extent to which variance in facility scores can be attributed to variance in actual performance.²²¹ To assess meaningfulness, the measure developer asked members of a Patient and Family Engagement (PFE) Work Group and a Technical Expert Panel (TEP) to vote on the measure's ability to distinguish between good and poor quality of care at measured facilities.^{222 223} All of the patients from the PFE Work Group and 80% of the TEP panel members who participated in the vote agreed that the measure could distinguish between good and poor quality of care.²²⁴ We refer readers to <https://p4qm.org/measures/4210> for more information about the feasibility, scientific acceptability, meaningfulness, and validity of the Information Transfer PRO–PM.

As previously stated in the CY 2024 OPPS/ASC final rule (88 FR 81985), while we acknowledge that PRO–PMs require providers to integrate data collection into clinical information systems, this integration provides an important opportunity for patient-reported outcomes to inform clinical decision-making and benefits patients by engaging them in discussions about potential outcomes. The testing of this measure by the measure developer, which included interviews with clinicians, nurses, quality improvement officers, and data administrators in HOPDs, indicated that the increased burden on HOPDs would be minimal because the data would be collected and reported electronically by

administrative staff and quality officers engaged in data sharing activities, outside of the clinical workflow, before being integrated into a clinical information system. Additionally, testing indicated that the increased burden on respondents would be minimal and contribute minimally to patient survey fatigue because the survey is easily understood and consists of only nine questions administered electronically,²²⁵ presenting a low burden for completion.

(3) Pre-Rulemaking Measure Review

Under the PRMR process, the Hospital Recommendation Group reviewed and voted on the Information Transfer PRO–PM²²⁶ during their meeting on January 18–19, 2024.²²⁷ The voting results for the Information Transfer PRO–PM measure for the Hospital OQR Program were “recommend with conditions”. The condition was that the survey be administered at the time of the surgery or procedure so there is no conflict with other measured pain and function outcomes to improve response rates.²²⁸ We have taken into account the condition to administer the survey at the time of the surgery or procedure; however, we have determined that allowing time after the surgery or procedure before administration of the survey is important to limit the possibility that the patient's responses are influenced by time-dependent variables related to proximity to the surgery or procedure, such as medications that could affect comprehension, fatigue, or acute pain. In addition, administering the survey more than one day but less than seven days post-procedure mitigates overlap of the initial administration and survey reminder of the OAS CAHPS, which is administered on the first day post-procedure and then followed up at 14 days.²²⁹

²²⁵ Examples of survey administration and collection include email, text, and patient information portals. These examples are not exhaustive. By leaving the method of survey administration and collection to the HOPD, we allow facilities the flexibility to choose the most appropriate method for their current infrastructure and patient base.

²²⁶ The Information Transfer PRO–PM is identified on the MUC List as MUC2023–17.

²²⁷ Partnership for Quality Measurement. (2024). 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: <https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf>.

²²⁸ *Ibid.*

²²⁹ Centers for Medicare and Medicaid Services. Schedule of OAS CAHPS Contact Attempts by Survey Mode. Available at: https://oascahps.org/ScheduleOASCAHPSContactAttempts_7–20–21.pdf.

(4) CBE Endorsement

We submitted the Information Transfer PRO–PM to the CBE for endorsement review in the Fall 2023 cycle (CBE #4210), and the CBE endorsed the measure on March 18, 2024.²³⁰

(5) Data Collection, Submission, and Reporting

(a) Data Collection

(i) Data Sources

We propose that the Information Transfer PRO–PM would be calculated based on PRO data collected by HOPDs directly or through their authorized third-party vendors through a web-based survey instrument distributed to patients or their caregivers.

We also propose that the survey would be administered two-to-seven days post-procedure or surgery, based on evidence that the most common time period for patients to be delivered a survey is within 0–48 hours post-procedure or surgery at a HOPD (n=6),^{231 232 233 234 235 236} while other time periods include within two weeks post-procedure or surgery (n=4).^{237 238 239 240}

²³⁰ Partnership for Quality Measurement. Submission Tool and Repository Measure Database. <https://p4qm.org/measures/4210>.

²³¹ Engel KG, Buckley BA, Forth VE, et al. (2012). Patient understanding of emergency department discharge instructions: where are knowledge deficits greatest? *Acad Emerg Med*. 19(9):E1035–1044.

²³² Engel KG, Heisler M, Smith DM, Robinson CH, Forman JH, Ubel PA. (2009). Patient comprehension of emergency department care and instructions: are patients aware of when they do not understand? *Ann Emerg Med*. 53(4):454–461 e415.

²³³ Erlang AS, Schjodt K, Linde JKS, Jensen AL. (2021). An observational study of older patients' experiences of involvement in discharge planning. *Geriatr Nurs*. 42(4):855–862.

²³⁴ Lin MJ, Tirosh AG, Landry A. (2015). Examining patient comprehension of emergency department discharge instructions: Who says they understand when they do not? *Intern Emerg Med*. 10(8):993–1002.

²³⁵ Makaryus AN, Friedman EA. (2005). Patients' understanding of their treatment plans and diagnosis at discharge. *Mayo Clin Proc*. 80(8):991–994.

²³⁶ Hastings S, Stechuchak K, Oddone E, et al. (2012). Older veterans and emergency department discharge information. *BMJ Qual Saf*. 21(10):835–842.

²³⁷ Clarke C, Friedman SM, Shi K, Arenovich T, Monzon J, Culligan C. (2005). Emergency department discharge instructions comprehension and compliance study. *CJEM*. 7(1):5–11.

²³⁸ Henderson A, Zernike W. A study of the impact of discharge information for surgical patients. (2001). *J Adv Nurs*. 35(3):435–441.

²³⁹ Karliner LS, Auerbach A, Napoles A, Schillinger D, Nickleach D, Perez-Stable EJ. (2012). Language barriers and understanding of hospital discharge instructions. *Med Care*. 50(4):283–289.

²⁴⁰ Makaryus AN, Friedman EA. (2005). Patients' understanding of their treatment plans and diagnosis at discharge. *Mayo Clin PRac*. 80(8):991–994.

²²⁰ *Ibid.*

²²¹ Partnership for Quality Measurement. Submission Tool and Repository Measure Database. <https://p4qm.org/measures/4210>.

²²² Partnership for Quality Measurement. 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: <https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf>.

²²³ See also <https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/measure-methodology>.

²²⁴ *Ibid.*

one week post-procedure or surgery, (n=3)^{241 242 243} or 90 days post-procedure or surgery (n=1).²⁴⁴ We propose that the survey would be administered not less than two days post-procedure or surgery because we have determined, as discussed above, that allowing time after the surgery or procedure before administration of the survey will limit the possibility that the patient's responses are influenced by time-dependent variables related to proximity to the surgery or procedure, such as medications that could affect comprehension, fatigue, or acute pain. We propose that the survey would be administered no later than seven days post-procedure or surgery because this timeframe may be more appropriate for patient reporting of specific events than longer time periods.^{245 246} In pilot testing, patients were sent a reminder to complete the survey seven days after receipt. The survey remained open until pilot testing was completed, with the mean length of time between the procedure date to the survey response date being 65 days, or approximately two months. We are therefore proposing a 65-day window for patient response.

The survey has been tested and reliability determined in English and Spanish, and the survey can be completed using a translator, proxy, or caregiver.

(ii) Measure Specifications

The measure numerator is the sum of all individual scores a HOPD receives from eligible respondents, which could be patients or caregivers. Individual scores are calculated using a top-box approach; each individual score is calculated for each respondent by taking the sum of items for which the respondent gave the most positive

response ("Yes" or "Very Clear") and dividing by the number of items the respondent deemed applicable to their procedure or surgery. Applicable items are calculated by subtracting the sum of items for which the respondent selected "Does not apply" from the total number of survey items (nine).²⁴⁷

The measure denominator is the total number of patients 18-years or older who had a procedure or surgery in an HOPD, left the HOPD alive, and responded to the survey.^{248 249} Only fully completed surveys are included in the measure calculation.

The intent of the measure is to encourage HOPDs to provide individualized recovery instructions regardless of the patient's unique characteristics; therefore, there is no need for risk-adjustment. For additional details regarding the measure specifications, we refer readers to our QualityNet website.²⁵⁰

(b) Data Submission and Reporting

We propose to adopt the Information Transfer PRO-PM as a voluntary measure for the CY 2026 reporting period followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination. We would utilize the voluntary period to monitor the implementation and operationalization of the measure.

We refer readers to section XV.E.2.c of this proposed rule for a discussion of the Information Transfer PRO-PM form, manner, and timing of data submission and reporting requirements.

We invite public comment on this proposal.

2. Proposed Measure Removals From the Hospital OQR Program Measure Set

a. Proposal To Remove the MRI Lumbar Spine for Low Back Pain Measure Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination

In the CY 2009 OPPI/ASC final rule (73 FR 68766), we adopted the MRI Lumbar Spine for Low Back Pain measure beginning with the CY 2010 payment determination. This claims-based measure evaluates the percentage of magnetic resonance imaging (MRI) of the lumbar spine studies for low back

pain performed in the outpatient setting where conservative therapy was not attempted prior to the MRI. The MRI Lumbar Spine for Low Back Pain measure was initially endorsed by a consensus-based entity (CBE) in 2008, but endorsement of this measure was removed in 2017 because the measure developer did not submit the measure for review during its designated measure endorsement maintenance cycle.

When we adopted this measure for the Hospital OQR Program, we cited growing concerns about the overuse of imaging services and evidence that a substantial portion of MRIs for low back pain does not lead to any modification of therapy based on MRI results, especially when performed on the first visit prior to any attempt to diagnose or treat the patient through more conservative means (73 FR 68764). Since then, our internal analyses have shown that the measure has maintained stable national performance (excluding the CY 2022 performance period impacted by our COVID-19 exception policies) and low average volumes, indicating limited reliability and capacity to improve the quality of care for patients with reported low back pain. A study in the *Journal of the American College of Radiology* found that documentation of conditions that fall into the exclusion criteria of the measure increased after implementation, resulting in smaller patient populations and indicating that the measure may not translate to improvement of imaging appropriateness.²⁵¹ Other studies have shown that the MRI Lumbar Spine for Low Back Pain measure has not correlated with improved outcomes.^{252 253 254} The latest findings are consistent with responses to a 2020 request for public comment where commenters expressed concerns regarding measure exclusion conditions,

²⁵¹ Flug JA and Lind KE. (2017). Public Reporting of MRI of the Lumbar Spine for Low Back Pain and Changes in Clinical Documentation, *Journal of the American College of Radiology* (14)12: 1545–1551. <https://doi.org/10.1016/j.jacr.2017.07.012>.

²⁵² Blackmore CC. (2019). The Relationship Between Medicare Outpatient Efficiency Measure OP8 and Lumbar MRI Utilization, *Journal of the American College of Radiology* 16(3): 276–281. <https://doi.org/10.1016/j.jacr.2018.10.026>.

²⁵³ Lind KE and Flug JA. (2019). Sociodemographic Variation in the Use of Conservative Therapy Before MRI of the Lumbar Spine for Low Back Pain in the Era of Public Reporting, *Journal of the American College of Radiology* 16(4): 560–569. <https://doi.org/10.1016/j.jacr.2018.12.047>.

²⁵⁴ Martin BI and Jarvik JG. (2015). The Medicare Outpatient Imaging Efficiency Measure for Low Back Pain ("OP-8"), *Radiology* 276(1). <https://doi.org/10.1148/radiol.2015150648>.

²⁴¹ Albrecht JS, Gruber-Baldini AL, Hirshon JM, et al. (2014). Hospital discharge instructions: comprehension and compliance among older adults. *J Gen Intern Med*. 29(11):1491–1498.

²⁴² Coleman EA, Chugh A, Williams MV, et al. (2013). Understanding and execution of discharge instructions. *AM J Med Qual*. 28(5):383–391.

²⁴³ Flacker J, Park W, Sims A. (2007). Hospital discharge information and older patients; do they get what they need? *J Hosp Med*. 2(5):291–296.

²⁴⁴ Hastings SN, Barrett A, Weinberger M, et al. (2011). Older patients' understanding of emergency department discharge information and its relationship with adverse outcomes. *J Patient Saf*. 7(1):19–25.

²⁴⁵ Stull, D, Leidy, N, Parasuraman, B, et al. (2009). Optimal recall periods for patient-reported outcomes: Challenges and potential solutions. Current medical research and opinion. 25. 929–42. www.doi.org/10.1185/03007990902774765.

²⁴⁶ Peasgood T, Caruana JM, Mukuria C. (2023). Systematic Review of the Effect of a One-Day Versus Seven-Day Recall Duration on Patient Reported Outcome Measures (PROMs). *Patient*. 16(3):201–221. www.doi.org/10.1007/s40271-022-00611-w.

²⁴⁷ Partnership for Quality Measurement. Submission Tool and Repository Measure Database. <https://p4qm.org/measures/4210>.

²⁴⁸ Surveys could be completed by patient or a caregiver.

²⁴⁹ Partnership for Quality Measurement. Submission Tool and Repository Measure Database. <https://p4qm.org/measures/4210>.

²⁵⁰ The proposed OQR Program measure specifications can be found at <https://qualitynet.cms.gov/outpatient/oqr/proposedmeasures>.

imaging modalities, measure validity, and measure usability. In response to that request for public comments, commenters also stated that an unintended consequence of using this measure may be delayed diagnoses.²⁵⁵

Based on these findings, this measure meets the criteria that we have adopted for measure removal Factor 2 (that is, performance or improvement on a measure does not result in better patient outcomes), as codified under § 419.46(i)(3)(i)(B). Therefore, we propose to remove the MRI Lumbar Spine for Low Back Pain measure from the Hospital OQR Program beginning with the CY 2025 reporting period/CY 2027 payment determination.

We invite public comment on this proposal, including feedback on other potential measures that may better address unnecessary imaging, which we will consider for adoption into the Hospital OQR Program in future rulemaking.

b. Proposal To Remove the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery Measure Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination

In the CY 2011 OPPI/ASC final rule (75 FR 72079 and 72080), we adopted the claims-based Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure beginning with the CY 2012 payment determination. This measure calculates the percentage of stress echocardiography, single photon emission computed tomography myocardial perfusion imaging (SPECT MPI), stress magnetic resonance imaging (MRI), or computed coronary tomography angiography (CCTA) performed at each facility in the 30 days prior to an ambulatory non-cardiac, low-

risk surgery performed at any location, and was endorsed by a CBE in 2011. Endorsement was removed in 2021 after the measure developer did not submit the measure for review during its designated measure endorsement maintenance cycle.

We adopted the measure for the Hospital OQR measure set, in part, to address an area of patient safety related to one of the most common imaging services in the Medicare population at the time, as we believed inappropriate use could increase the patient's risk of cancer, contribute no benefit to the quality of care, and result in the unnecessary waste of services (75 FR 72076). In response to commenter concerns regarding the infrequent occurrence of low-risk non-cardiac surgeries, and whether this measure may assess significant differences in the provision of imaging tests and their impact on the quality of care provided, we stated our belief at the time that the measure could identify outlier practice patterns and encourage HOPDs to improve their quality of care.

Our routine monitoring and evaluation shows that the range of cases per HOPD varies greatly (that is, from one to over 1,300 cases), posing limitations when assessing and interpreting comparative performance trends over time.²⁵⁶ In addition, while there was a slight average performance score improvement from payment determination years CY 2020 to 2024 (despite the COVID-19 pandemic and

the larger pool of reporters) of about one percent (4.7 percent and 3.6, respectively), the variation between the 10th and 25th percentiles of performance is not statistically distinguishable, indicating the measure may not provide meaningful data for informing consumers about quality of care for this service in HOPDs. Furthermore, at a 3.5 percent average overall rate for this measure for the CY 2024 payment determination year, there is little room for national performance on this measure to show significant improvement as lower rates are better for this measure.

Based on these findings, this measure meets the criteria for measure removal Factor 2 (that is, performance or improvement on a measure does not result in better patient outcomes), as codified under § 419.46(i)(3)(i)(B). Therefore, we propose to remove the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure beginning with the CY 2025 reporting period/CY 2027 payment determination.

We invite public comment on this proposal, including feedback on other potential measures that may better address unnecessary imaging, which we will consider for adoption into the Hospital OQR Program in future rulemaking.

3. Summary of Proposed Program Measure Set Updates

a. Proposed Program Measure Set Beginning With the CY 2027 Payment Determination

Table 90 summarizes the newly proposed Hospital OQR Program measure set beginning with the CY 2027 payment determination, which would remove the two imaging efficiency measures discussed above and add the three cross-program health equity measures discussed in sections XV.C.2.a, XV.C.2.b, and XIV.B, respectively, of this proposed rule.

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²⁵¹ Flug JA and Lind KE. (2017). Public Reporting of MRI of the Lumbar Spine for Low Back Pain and Changes in Clinical Documentation, *Journal of the American College of Radiology* (14)12: 1545–1551. <https://doi.org/10.1016/j.jacr.2017.07.012>.

²⁵² Blackmore CC. (2019). The Relationship Between Medicare Outpatient Efficiency Measure OP8 and Lumbar MRI Utilization, *Journal of the American College of Radiology* 16(3): 276–281. <https://doi.org/10.1016/j.jacr.2018.10.026>.

²⁵³ Lind KE and Flug JA. (2019). Sociodemographic Variation in the Use of Conservative Therapy Before MRI of the Lumbar Spine for Low Back Pain in the Era of Public Reporting, *Journal of the American College of Radiology* 16(4): 560–569. <https://doi.org/10.1016/j.jacr.2018.12.047>.

²⁵⁴ Martin BI and Jarvik JG. (2015). The Medicare Outpatient Imaging Efficiency Measure for Low Back Pain (“OP-8”), *Radiology* 276(1). <https://doi.org/10.1148/radiol.2015150648>.

TABLE 90: PROPOSED UPDATED HOSPITAL OQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2027 PAYMENT DETERMINATION

CBE #	Measure Name
None	Abdomen CT – Use of Contrast Material
3490	Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy
0658	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
None	Breast Cancer Screening Recall Rates
None†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
3636	COVID-19 Vaccination Coverage Among HCP
3663e	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults**
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
0661	Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
None	Hospital Commitment to Health Equity***
None†	Left Without Being Seen
None†	Median Time from ED Arrival to ED Departure for Discharged ED Patients
None	OAS CAHPS • About Facilities and Staff • Communication About Procedure • Preparation for Discharge and Recovery • Overall Rating of Facility • Recommendation of Facility
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO-PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO-PM)****
None	Screening for Social Drivers of Health*****
None	Screen Positive Rate for Social Drivers of Health*****
None	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM

†Measure is no longer endorsed by the CBE but was endorsed previously.

*This measure is voluntary.

**This measure begins with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination, as discussed in the CY 2024 OPPI/ASC final rule (81988 FR through 81992).

***In this proposed rule, we propose to adopt this measure beginning with the CY 2025 reporting period/ CY 2027 payment determination, as discussed in section XIV.B.1 of this proposed rule.

****This measure begins with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2031 payment determination, as discussed in the CY 2024 OPPI/ASC final rule (88 FR 81984 through 81986).

*****In this proposed rule, we propose to adopt this measure beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination, as discussed in sections XIV.B.2 and XIV.B.3 of this proposed rule.

b. Proposed Program Measure Set Updates Beginning With the CY 2031 Payment Determination

Table 91 summarizes the newly proposed Hospital OQR Program

measure set for the CY 2031 payment determination, which would remove the two imaging efficiency measures, discussed in sections XV.C.2.a and XV.C.2.b of this proposed rule; add the Information Transfer PRO-PM,

discussed in section XV.C.1.b of this proposed rule; and add the three cross-program health equity measures, discussed in sections XIV.B.1, XIV.B.2, and XIV.B.3 of this proposed rule.

TABLE 91: PROPOSED UPDATED HOSPITAL OQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2031 PAYMENT DETERMINATION

CBE #	Measure Name
None	Abdomen CT – Use of Contrast Material
3490	Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy
0658	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
None	Breast Cancer Screening Recall Rates
None†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
3636	COVID–19 Vaccination Coverage Among HCP
3663e	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
0661	Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
None	Hospital Commitment to Health Equity**
None†	Left Without Being Seen
None†	Median Time from ED Arrival to ED Departure for Discharged ED Patients
None	OAS CAHPS • About Facilities and Staff • Communication About Procedure • Preparation for Discharge and Recovery • Overall Rating of Facility • Recommendation of Facility
4210	Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM)
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM)
None	Screening for Social Drivers of Health***
None	Screen Positive Rate for Social Drivers of Health***
None	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM

†Measure is no longer endorsed by the CBE but was endorsed previously.

*This measure is voluntary.

**In this proposed rule, we propose to adopt this measure beginning with the CY 2025 reporting period/ CY 2027 payment determination, as discussed in section XIV.B.1 of this proposed rule.

***In this proposed rule, we propose to adopt this measure beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination, as discussed in sections XIV.B.2 and XIV.B.3 of this proposed rule.

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D. Administrative Requirements

We refer readers to § 419.46(b) and (c) and the CYs 2014, 2016, and 2019 OPPS/ASC final rules (78 FR 75108 through 75109, 80 FR 70519, and 83 FR 59103 through 59104, respectively) for our policies regarding program participation requirements and withdrawal from the program.

We are not proposing any changes to these policies in this proposed rule.

E. Form, Manner, and Timing of Data Submission

1. General Data Submission Policy

We refer readers to § 419.46(d) and the CY 2023 OPPS/ASC final rule (87 FR 72110 through 72112) for our general program policies regarding: (1) submission of data under the Hospital OQR Program generally; (2) review and correction of submitted data; and (3) extraordinary circumstance exception requests (ECE) for data submission.

We also refer readers to the CYs 2019 and 2022 OPPS/ASC final rules (83 FR 59104 through 59105 and 86 FR 63861,

respectively) for details regarding our maintenance of technical specifications. We maintain measure technical specification manuals (referred to as Specifications Manuals) that can be found on the CMS website at: <https://qualitynet.cms.gov/outpatient/specifications-manuals>.

We are not proposing any changes to these policies in this proposed rule.

2. Measure Specific Data Submission and Reporting Requirements

We refer readers to the CYs 2014, 2016, 2022, 2023, and 2024 OPPS/ASC final rules (77 FR 68484; 80 FR 70521, 87 FR 72110 through 72112; 78 FR

75097 through 75100; and 88 FR 82004 through 82006, respectively) for information regarding our claims-based, web-based, eCQM, chart-abstracted, PRO-PM, and survey-based data submission and reporting requirements.

a. Web-Based Measures

(1) CMS-Designated Information System and Proposal for Data Submission for the Hospital Commitment to Health Equity (HCHE), Screening for Social Drivers of Health (SDOH), and Screen Positive Rate for SDOH Measures

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75112 through 75115), the CY 2016 OPPS/ASC final rule (80 FR 70521), and the CMS website, currently available at <https://qualitynet.cms.gov>, for a discussion of the requirements for measure data submitted via the Hospital Quality Reporting (HQR) System (formerly referred to as the QualityNet Secure Portal). The HQR System safeguards protected health information in compliance with the HIPAA Privacy and Security Rules (45 CFR part 160 and 45 CFR part 164, subparts A, C, and E).

In section XIV.B.1, XIV.B.2, and XIV.B.3 of this proposed rule, we proposed adoption of:

(1) the Hospital Commitment to Health Equity measure, beginning with the CY 2025 reporting period/CY 2027 payment determination;

(2) the Screening for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and

(3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

Consistent with our established data submission requirements (80 FR 70521 and 70522), we propose that HOPDs would be required to submit all of the data required to calculate each of these three measures annually using a CMS-approved, web-based, data collection tool available within the HQR System starting January 1 through and including May 15 in the year prior to the applicable payment determination year. For the Hospital OQR Program, the performance period (which we refer to as the CY reporting period) for each of these measures on which data is submitted using a web-based tool would be January 1 through and including December 31 of the year that is 2 years prior to the applicable payment determination year; and the data

submission period would be January 1 through and including May 15 in the calendar year immediately following the CY reporting period and immediately prior to applicable payment determination year. For example, for the CY 2025 reporting period/2027 payment determination, the data submission period would be January 1, 2026, through and including May 15, 2026, covering the performance period of January 1, 2025, through and including December 31, 2025. Pursuant to § 419.46(d)(4), a review and corrections period runs concurrently with the data submission period. During this timeframe, HOPDs would be able to enter, review, and correct data submitted for these measures.

We invite public comment on this proposal.

(2) National Healthcare Safety Network (NHSN)

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75097 through 75100) for a discussion of the previously finalized requirements for measure data submitted via the Centers for Disease Control and Prevention NHSN website.

We are not proposing any changes to these policies in this proposed rule.

b. Electronic Clinical Quality Measures (eCQMs) and Proposal To Require Electronic Health Record (EHR) Technology To Be Certified to All eCQMs Available To Report Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination

In the CY 2024 Medicare Physician Fee Schedule (PFS) final rule (88 FR 79307 through 79312), we finalized revisions to the definition of certified electronic health record technology (CEHRT) for the Medicare Promoting Interoperability Program at 42 CFR 495.4 and for the Quality Payment Program at 42 CFR 414.1305. Specifically, we added a reference to the “Base EHR definition,” which ONC proposed in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) proposed rule (88 FR 23759, 23905). We finalized these revisions to ensure, if the HTI-1 proposals were finalized, the “Base EHR definition” would be applicable for the CEHRT definitions going forward (88 FR 79309 through 79312).²⁵⁷ ONC subsequently finalized a definition of “Base EHR” in the Health Data, Technology, and Interoperability: Certification Program Updates,

Algorithm Transparency, and Information Sharing final rule (89 FR 1192, 1298).

We also finalized the replacement of references to the “2015 Edition health IT certification criteria” with “ONC health IT certification criteria,” and the addition of the regulatory citation for ONC health IT certification criteria in 45 CFR 170.315. We finalized the proposal to specify that EHR technology must meet ONC’s health IT certification criteria “as adopted and updated in 45 CFR 170.315” to qualify as CEHRT (88 FR 79553). These revisions, finalized in the CY 2024 PFS final rule, are consistent with the policy subsequently finalized in ONC’s HTI-1 final rule, which appeared in the **Federal Register** on January 9, 2024 (89 FR 1205 through 1210). For additional background and information on this update, we refer readers to the discussion in the CY 2024 PFS final rule on this topic (88 FR 79307 through 79312).

In the CY 2022 OPPS/ASC final rule (86 FR 63868 and 63869), we adopted a requirement for hospitals to utilize certified technology updated to be consistent with the 2015 Edition Cures Update for reporting eCQMs under the Hospital OQR Program, beginning with the CY 2023 reporting period/CY 2025 payment determination. However, we did not finalize a requirement that the EHR technology used for eCQM reporting must be certified to all eCQMs (that is, tested and validated on each individual eCQM) in the Hospital OQR Program.

The Hospital IQR Program and the Medicare Promoting Interoperability Program require EHRs to be certified to all available eCQMs in the programs. We finalized this policy for the Hospital IQR Program in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38393) for the FY 2019 and FY 2020 payment determination years, and we finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42505 through 42506) that this policy would continue beginning with the CY 2020 reporting period/FY 2022 payment determination. For the Medicare Promoting Interoperability Program, we finalized this policy in the FY 2018 and FY 2019 IPPS/LTCH PPS final rules for CYs 2018 and 2019, respectively (82 FR 38483 through 38485 and 83 FR 41671 through 41672, respectively). We also finalized the continuation of this requirement in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42600 and 42601) for CY 2020 and subsequent years. When EHRs are certified to all available eCQMs in a program measure set, hospitals are able to accurately capture and report data for these measures. For this reason, and to

²⁵⁵ *Ibid.*

align the Hospital OQR Program's eCQM certification requirements with the Hospital IQR Program and Medicare Promoting Interoperability Program clinical quality measure electronic submission requirements for eligible hospitals, we propose that beginning with the CY 2025 reporting period/CY 2027 payment determination, a HOPD using EHR technology certified to the ONC health IT certification criteria would be required to have its EHR technology certified to all eCQMs that are available to report under the Hospital OQR Program to meet reporting requirements for the Hospital OQR Program.

We further propose that for the CY 2025 reporting period/CY 2027 payment determination and subsequent years, HOPDs would additionally be required to use the most recent version of the eCQM electronic measure specifications for the designated reporting period available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: <https://ecqi.healthit.gov/>. We noted in the CY 2021 OPPS/ASC final rule (86 FR 63861) that we would generally update the measure specifications on an annual basis to align with current clinical guidelines and code systems.

Our proposal to require that EHRs be certified to all available eCQMs would promote more accurate electronic quality reporting by incentivizing HOPDs to have their EHR and other health information technology (IT) vendors test all available eCQMs and offer reporting modules with certified eCQMs. Through this requirement, we expect greater certainty for hospitals that their EHR systems are capable of accurately calculating the eCQMs reported to CMS under the Hospital OQR Program because the EHR technology would be up to date and tested on each eCQM. Additionally, we anticipate this requirement would help reduce burden for hospitals by potentially reducing the frequency of needing to consult with their EHR and other health IT vendors to troubleshoot implementation or reporting issues.

Finally, we propose to revise regulatory text at § 419.46 to add a new section (j) to codify submission requirements for eCQMs under the Hospital OQR Program. Under this proposal, we would codify in § 419.46(j)(1) the requirement for hospitals to utilize certified technology updated to be consistent with ONC's health IT certification criteria, as adopted and updated in 45 CFR 170.315, for reporting eCQMs under the Hospital OQR Program. We propose to codify in § 419.46(j)(2) the requirement

that the EHR technology used for eCQM reporting must be certified to all eCQMs (that is, tested and validated on each individual eCQM) available to report under the Hospital OQR Program. We also propose to codify in § 419.46(j)(3) the requirement that hospitals use the most recent version of the eCQM electronic measure specifications for the applicable reporting period available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: <https://ecqi.healthit.gov/> or another website as designated by CMS.

We invite public comment on these proposals.

c. Patient-Reported Outcome-Based Performance Measures (PRO-PMs)

(1) Proposal for Data Submission of PRO-PM Data

In the CY 2024 OPPS/ASC final rule (88 FR 82006) we finalized that for the Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA) PRO-PM, hospitals must use the HQR system for data submission for a PRO-PM. In this proposed rule, we propose to apply this submission method to PRO-PMs generally, including the Information Transfer PRO-PM. We propose that hospitals must use the HQR system for data submission for any PRO-PM that we adopt for the Hospital OQR Program measure set. HOPDs may choose to: (1) directly submit their PRO-PM data to CMS using the HQR system; or (2) utilize a third-party entity, such as a vendor or registry, to submit their data using the HQR system. The HQR system allows for data submission using multiple file formats (such as CSV, XML) and a manual data entry option, allowing HOPDs additional flexibility in data submission.

We invite public comment on this proposal.

(2) Proposal for Data Submission and Reporting Requirements for the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM)

In section XV.C.1.b of this proposed rule, we discuss the proposed adoption of the Information Transfer PRO-PM beginning with voluntary reporting for the CY 2026 reporting period followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination. We propose that the performance period on which data is submitted would be January 1 through and including December 31 of the year that is two years prior to the

applicable payment determination year. We propose to require HOPDs to submit their Information Transfer PRO-PM data between the period starting January 1st though and including May 15 of the year prior to the applicable payment determination year. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a non-workday for federal employees by statute or Executive Order would be extended to the first day thereafter. We propose to require HOPDs to offer all patients meeting the measure's denominator specifications the opportunity to complete the survey. Additionally, we propose a minimum random sample size of 300 completed surveys to ensure the reliability of the measure, as this is a recommended minimum sample size for a population of 1,500 to provide a 95 percent confidence interval and a 90 percent confidence interval for a population of over 10,000; this is also generally accepted as a minimum sample size for stable population estimates.^{258 259} HOPDs that are unable to collect 300 completed surveys will not be able to perform random sampling, and would instead be required to submit data on survey responses from all completed surveys received.

We invite public comment on these proposals.

F. Public Reporting of Measure Data

1. General Policy

We refer readers to the CY 2024 OPPS/ASC final rules (88 FR 81995 and 81996) for our previously finalized policies regarding public display of quality measures.

2. Proposal To Publicly Report the Median Time From Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients—Psychiatric/Mental Health Patients Strata on Care Compare

We refer readers to the CY 2011 OPPS/ASC final rule (75 FR 72086) where we adopted the Median Time from ED Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) measure beginning with CY 2013 payment determination. The Median Time for

²⁵⁸ Ahmad, H., & Halim, H. (2017). Determining Sample Size for Research Activities. *Selangor Business Review*, 2(1), 20–34. Retrieved from <https://sbr-journals.unisel.edu.my/ojs/index.php/sbr/article/view/12>.

²⁵⁹ Voorhis, C. & Morgan, B. (2007). Understanding Power and Rules of Thumb for Determining Sample Size. *Tutorials in Quantitative Methods for Psychology*, 3 (2), 43–50. [www.doi.org/10.20982/tqmp.03.2.p043](https://doi.org/10.20982/tqmp.03.2.p043).

Discharged ED Patients measure is a chart-abstracted measure that evaluates the time from ED arrival to departure, also known as ED throughput time. The measure data are stratified into four separate calculations: (a) Median Time for Discharged ED Patients—Overall Rate; (b) Median Time for Discharged ED Patients—Reporting Measure, which excludes psychiatric/mental health and transfer patients; (c) Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients, which includes information only for psychiatric/mental health patients; and (d) Median Time for Discharged ED Patients—Transfer Patients, which includes information only for patients transferred from the ED.

In the CY 2024 OPPS/ASC final rule (88 FR 81995 and 81996), we finalized that data for three measure strata (that is, the Overall Rate, Reporting Measure, and Transfer Patients strata) would be publicly reported both on data.medicare.gov in downloadable data files and on Care Compare (or subsequent CMS-designated websites). Data for the Psychiatric/Mental Health Patients stratum are not currently publicly reported on the Care Compare site, though these data are published on data.medicare.gov in downloadable data files (82 FR 59438). In the CY 2018 OPPS/ASC final rule (82 FR 52576 through 52578), we summarized commenters' concerns that delays in ED discharge of mental health patients may be influenced, in part, by the availability of community resources. In response, we stated that we would take additional time for further consideration prior to displaying this subset of data on Care Compare. We have considered commenters' concern that factors outside of an HOPD's control may influence ED throughput for psychiatric/mental health patients; however, it is our understanding that many hospitals face such concerns, and that timely care is a critical aspect of quality of care. We also stated in the CY 2024 OPPS/ASC final rule (88 FR 82061) in the context of adopting this measure for the REHQR Program that the public reporting of these data on Care Compare could help patients and their caregivers identify which facilities are performing better than others despite potential challenges, and drive quality improvement efforts.

Our routine monitoring and evaluation of the CY 2024 performance period for this measure has shown a median ED throughput time of 4.7 hours for psychiatric/mental health patients compared to 2.6 hours for non-psychiatric/mental health patients, suggesting this is an area that may

benefit from additional quality improvement efforts. Data from the Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients will be useful for patients choosing a care location, as well as researchers and hospital staff as they attempt to address health disparities and improve the timeliness of care for mental health patients. Since the data required for public reporting are already collected and submitted by participating HOPDs, publicly reporting this stratification would not create additional hospital burden.

For these reasons, we propose to make data for the Psychiatric/Mental Health Patients stratification available on Care Compare, including data that were previously published on data.medicare.gov but not displayed on the Care Compare site, beginning in CY 2025.

We invite public comment on this proposal.

G. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2025 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to the proposed rule, which is available via the internet on the CMS website): “J1,” “J2,” “P,” “Q1,” “Q2,” “Q3,” “R,” “S,” “T,” “V,” or “U.” Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements, with the exception of services assigned to New Technology APCs with assigned status indicator “S” or “T.” We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79796), we clarified that the reporting ratio does not apply to codes with status indicator “Q4” because services and procedures coded with status indicator “Q4” are either packaged or paid through the Clinical Laboratory Fee Schedule and are never paid separately through the OPPS.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the “reporting ratio” to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the

CY 2010 OPPI/ASC final rule with comment period, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPI/ASC final rule with comment period by the CY 2010 OPPI final rule with comment period reporting ratio of 0.980 (74 FR 60642).

We note that the only difference in the calculation for the full conversion factor and the calculation for the reduced conversion factor is that the full conversion factor uses the full OPD update, and the reduced conversion factor uses the reduced OPD update. The baseline OPPI conversion factor calculation is the same since all other adjustments would be applied to both conversion factor calculations. Therefore, our standard approach of calculating the reporting ratio as described earlier in this section is equivalent to dividing the reduced OPD update factor by that of the full OPD update factor. In other words:

Full Conversion Factor = Baseline OPPI conversion factor * (1 + OPD update factor)

Reduced Conversion Factor = Baseline OPPI conversion factor * (1 + OPD update factor - 0.02)

Reporting Ratio = Reduced Conversion Factor/Full Conversion Factor

Which is equivalent to:

Reporting Ratio = (1 + OPD Update factor - 0.02)/(1 + OPD update factor)

In the CY 2009 OPPI/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPI/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPI national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment, the multiple procedure adjustment, the interrupted procedure adjustment, the rural sole community hospital adjustment, and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPI outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPI beginning in the CY 2010 OPPI/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPI outlier calculation and eligibility criteria, we refer readers to section II.G of the CY 2023 OPPI/ASC proposed rule (87 FR 44533 through 44534).

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2025

We propose to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2025 annual payment update factor. For the CY 2025 OPPI/ASC proposed rule, the proposed reporting ratio is 0.9805, which, when multiplied by the proposed full conversion factor of \$89.379, equals a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of \$87.636. We propose to continue to apply the reporting ratio to all services calculated using the OPPI conversion factor. We propose to continue to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of "J1," "J2," "P," "Q1," "Q2," "Q3," "R," "S," "T," "V," and "U" (other than New Technology APCs to which we have proposed status indicator assignments of "S" and "T"). We propose to continue to exclude services paid under New Technology

APCs. We propose to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also propose to continue to apply all other applicable standard adjustments to the OPPI national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we propose to continue to calculate OPPI outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. In addition to our proposal to implement the policy through the use of a reporting ratio, we also propose to calculate the reporting ratio to four decimals (rather than the previously used three decimals) to more precisely calculate the reduced adjusted payment and copayment rates.

For CY 2025, the proposed reporting ratio is 0.9805, which, when multiplied by the proposed full conversion factor of \$89.379, equaled a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of \$87.636.

XVI. Rural Emergency Hospital Quality Reporting (REHQR) Program

A. Background and Statutory Authority

The Rural Emergency Hospital Quality Reporting (REHQR) Program's overarching goals are to improve the quality of care provided to Medicare beneficiaries, facilitate public transparency, ensure accountability, and safeguard the accessibility of hospitals in rural settings.

Section 1861(kkk)(7)(A) of the Social Security Act (the Act) provides that the Secretary shall establish quality measurement reporting requirements for Rural Emergency Hospitals (REHs), which may include the use of a small number of claims-based outcomes measures or surveys of patients with respect to their experience in the REH. In selecting measures for quality reporting, section 1861(kkk)(7)(C)(iii) provides that the Secretary shall take into consideration ways to account for REHs that lack sufficient case volume to ensure that the performance rates for such measures are reliable. Although section 1861(kkk)(7)(C)(i) of the Act requires that measures specified by the Secretary for use in the REHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, section 1861(kkk)(7)(C)(ii) of the

Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

In addition, section 1861(kkk)(7)(D) of the Act provides that the Secretary shall establish procedures for making data submitted by REHs for the REHQR Program available to the public, following the opportunity for the REH to

review and submit corrections on such data, with such data to be posted on a CMS website as determined appropriate by the Secretary. Beginning with 2023 (or each year beginning on or after the date that is one year after one or more measures are first specified), section 1861(kkk)(7)(B)(ii) of the Act requires REHs to submit quality measure data to the Secretary “in a form and manner, and at a time, specified by the Secretary.”

We refer readers to section XVI of the CY 2024 OPPI/ASC final rule (88 FR 82046 through 82076) for an overview of the REHQR Program, which includes a more detailed discussion of the

statutory history and program requirements codified at 42 CFR 419.95.

1. Previously Finalized Program Measure Sets

We refer readers to the CY 2024 OPPI/ASC final rule (88 FR 82066 through 82067) for more information regarding the previously finalized REHQR Program measure set beginning with the CY 2024 reporting period.

Table 92 below summarizes the previously finalized REHQR Program measure set and initial reporting periods with program determinations beginning with the CY 2026 program determination.²⁶⁰

TABLE 92: PREVIOUSLY FINALIZED REHQR PROGRAM MEASURE SET AND INITIAL REPORTING PERIODS BEGINNING WITH THE CY 2026 PROGRAM DETERMINATION

CBE #	Measure Name	Initial Reporting Periods	Initial Program Determination Affected
None	Abdomen Computed Tomography (CT) – Use of Contrast Material	January 1, 2024 – December 31, 2024	CY 2026
None	Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients		
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery		
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	January 1, 2024 – December 31, 2026	CY 2028

B. Program Measure Set Policies: Retention, Suspension or Removal, Modification, and Adoption

We refer readers to § 419.95(e) and the CY 2024 OPPI/ASC final rule (88 FR 82051 through 82053) for our program policies regarding measure retention, and immediate and general measure suspension and removal, and to § 419.95(d) and the CY 2024 OPPI/ASC final rule (88 FR 82054) for our program policies regarding modifications to previously adopted measures.

We further refer readers to the CY 2024 OPPI/ASC final rule (88 FR 82047 through 82051) for a discussion of our considerations for adopting quality measures under the REHQR Program, and to section XIV.B.1.c of this

proposed rule for information regarding the pre-rulemaking process.

We are not proposing any changes to these policies in this proposed rule.

C. Program Measure Proposals

1. Proposal To Adopt Health Equity Quality Measures in the REHQR Program

We refer readers to sections XIV.B.1, XIV.B.2, and XIV.B.3 of this proposed rule for our cross-program proposals to adopt the following measures in the REHQR Program: (1) the Hospital Commitment to Health Equity (HCHE) measure, beginning with the CY 2025 reporting period/CY 2027 program determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary

represent our assessment of compliance with program requirements for an applicable year

reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination; and (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination.

Under the REHQR Program’s statutory requirement under section 1861(kkk)(7)(C)(iii) of the Act to consider the impact of low case volumes, we note that once mandatory reporting begins, the measure specifications require all patients to be screened and thus we do not believe the Screening for SDOH measure or the

because the REHQR Program does not include an associated payment adjustment.

²⁶⁰ We are using the phrase “Program Determination” for the REHQR Program to

Screen Positive Rate for SDOH measure would suffer from low case volumes. In addition, as stated in the CY 2024 OPPI/ASC final rule (88 FR 82066), CMS does not report measures publicly unless it achieves sufficient case volumes to allow for public reporting of the collected data.

2. Proposal To Modify the Reporting Period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery Measure Beginning With the CY 2027 Program Determination

In the CY 2024 OPPI/ASC final rule, we adopted the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure in the REHQR Program with a one-year reporting period beginning with the CY 2024 reporting period (88 FR 82064 through 82066).

This measure is calculated from Part A and Part B Medicare administrative claims data for Medicare FFS beneficiaries with an outpatient same-day surgical procedure excluding eye surgeries and colonoscopies (except colonoscopy with biopsy). Colonoscopies are excluded from this measure as these procedures are

examined separately on their own. Eye surgeries are excluded because they are performed in high volume and are generally perceived as being “low risk.” As stated in the CY 2024 OPPI/ASC final rule (88 FR 82064), this measure makes unplanned patient hospital visits (ED visits, observation stays, or unplanned inpatient admissions) after surgery more visible to providers and patients through publicly reporting scores.

As we noted in the CY 2024 OPPI/ASC final rule (88 FR 82064), we believe this measure could also encourage providers to engage in quality improvement activities to reduce these visits by providing feedback to hospitals and providers. This measure meets the National Quality Strategy goals of embedding quality into the care journey and promoting safety,²⁶¹ and we expect that the measure would promote improvement in patient care over time (88 FR 82064 through 82065).

We have continued to monitor and evaluate the reporting patterns of hospitals that have converted to REH status and have found that under the Hospital OQR Program, a limited number of current REHs are able to

publicly report on this measure as specified based on case threshold minimums. Therefore, in consideration of our statutory obligation to consider ways to account for low case volumes and to publicly report on quality-of-care metrics for REHs, we propose to increase the reporting period from one year to two years beginning with the CY 2027 program determination.

Under this proposal, the previously finalized one-year data collection period for the CY 2026 program determination would remain the same (that is, encounters from January 1, 2024 through December 31, 2024), and then beginning with the CY 2027 program determination, the reporting period would be supplemented with data from the prior calendar year. For example, for the CY 2027 program determination, the reporting period would comprise data from CYs 2024 and 2025 (that is, encounters from January 1, 2024 through December 31, 2025). We note that, as stated in the CY 2024 OPPI/ASC final rule (88 FR 82066), CMS does not report measures publicly unless it achieves sufficient case volumes to allow for public reporting of the collected data.

TABLE 93: COMPARISON OF 1-YEAR AND 2-YEAR REPORTING PERIODS FOR THE RISK-STANDARDIZED HOSPITAL VISITS WITHIN 7 DAYS AFTER OUTPATIENT SURGERY MEASURE FOR REHS

Data Time Period	REHs with at least 1 Denominator Case	REHs Meeting the Threshold for Public Reporting*	Total Eligible Surgical Cases	Total Number Patients with Visits
Risk-Standardized Hospital Visits Within 7 Days After Outpatient Surgery Measure				
One-Year Reporting Period				
Jan 1, 2020 - Dec 31, 2020	6	1	120	7
Jan 1, 2021 - Dec 31, 2021	7	1	207	14
Jan 1, 2022 - Dec 31, 2022	8	1	225	19
Proposed Two-Year Reporting Period				
Jan 1, 2020 - Dec 31, 2021	7	4	327	21
Jan 1, 2021 - Dec 31, 2022	8	3	432	33
Jan 1, 2022 - Dec 31, 2023	8	4	552	40

*30 or more eligible surgical cases are required to meet the Risk-Standardized Hospital Visits Within 7 Days After Outpatient Surgery measure's threshold to establish reliability for public reporting.

As seen in Table 93, the longer reporting period of two years would facilitate greater case volumes for this measure and, subsequently, a larger

portion of REHs would have data that could be reported publicly as more REHs attain the Risk-Standardized Hospital Visits Within 7 Days After

Outpatient Surgery measure's minimum case threshold for reliability of 30 surgical cases. In addition, REHs reporting on the measure with two years

²⁶¹ CMS, What is the CMS National Quality Strategy?. Available at: <https://www.cms.gov/>

[medicare/quality/meaningful-measures-initiative/cms-quality-strategy](https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy).

of data would have more eligible patients to assess; this increase in eligible cases would reduce the error estimate, making the confidence interval narrower, that is, increasing the reliability of the calculated measure. We refer readers to the CY 2019 OPPTS/ASC final rule (83 FR 59106 through 59107) where we finalized a similar policy to extend the reporting period of the Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure in the Hospital OQR Program from two to three years.

Under this proposal, there would be no gap in public reporting nor delay in

providing REHs with data for quality improvement efforts. As this is a claims-based measure, REHs would not have any additional reporting burden associated with a longer reporting period.

We invite public comment on this proposal.

3. Summary of Proposed Program Measure Set Updates

a. Proposed Program Measure Set Beginning With the CY 2027 Program Determination

Table 94 summarizes the proposed updated REHQR Program measure set

and reporting periods beginning with the CY 2027 program determination.

Specifically, Table 94 includes the previously finalized measure set with updates to reflect the proposed extension of the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure beginning with the CY 2027 program determination, and the three proposed new cross-program health equity measures as detailed in sections XIV.B.1, XIV.B.2, and XIV.B.3, respectively, of this proposed rule:

TABLE 94: PROPOSED UPDATED REHQR PROGRAM MEASURE SET AND REPORTING PERIODS BEGINNING WITH THE CY 2027 PROGRAM DETERMINATION

CBE #	Measure Name	Reporting Period	Program Determination
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	January 1, 2024 – December 31, 2026	CY 2028
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery*	January 1, 2024 – December 31, 2025	CY 2027
None	Abdomen Computed Tomography (CT) – Use of Contrast Material	January 1, 2025 – December 31, 2025	
None	Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients		
None	Hospital Commitment to Health Equity (HCHE)**		
None	Screening for Social Drivers of Health (SDOH)***		
None	Screen Positive Rate for SDOH***		

*We propose that this measure would have an extended reporting period beginning with the CY 2027 program determination, as discussed in section XVI.C.2 of this proposed rule.

**We propose that this measure would be mandatory beginning with the CY 2025 reporting period/CY 2027 program determination, as discussed in section XIV.B.1 of this proposed rule.

***We propose that this measure would begin with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination, as discussed in sections XIV.B.2 and XIV.B.3 of this proposed rule.

b. Proposed Program Measure Set Beginning With the CY 2028 Program Determination

Table 95 summarizes the proposed updated REHQR Program measure set

and reporting periods beginning with the CY 2028 program determination.

Specifically, Table 95 includes the previously finalized measure set with updates to reflect the proposed extension of the reporting period for the Risk-Standardized Hospital Visits

Within 7 Days After Hospital Outpatient Surgery measure beginning with the CY 2028 program determination, and the three proposed new cross-program health equity measures as detailed in sections XIV.B.1, XIV.B.2, and XIV.B.3, respectively, of this proposed rule:

TABLE 95: PROPOSED UPDATED REHQR PROGRAM MEASURE SET AND REPORTING PERIODS BEGINNING WITH THE CY 2028 PROGRAM DETERMINATION

CBE #	Measure Name	Reporting Period	Program Determination
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	January 1, 2024 – December 31, 2026	CY 2028
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery*	January 1, 2025 – December 31, 2026	
None	Abdomen Computed Tomography (CT) – Use of Contrast Material	January 1, 2026 – December 31, 2026	
None	Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients		
None	Hospital Commitment to Health Equity (HCHE)**		
None	Screening for Social Drivers of Health (SDOH)***		
None	Screen Positive Rate for SDOH***		

*We propose that this measure would have an extended reporting period beginning with the CY 2027 program determination, as discussed in section XVI.C.2 of this proposed rule.

**We propose that this measure would be mandatory beginning with the CY 2025 reporting period/CY 2027 program determination, as discussed in section XIV.B.1 of this proposed rule.

***We propose that this measure would begin with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination, as discussed in sections XIV.B.2 and XIV.B.3 of this proposed rule.

D. Administrative Requirements

We refer readers to § 419.95(b) and the CY 2024 OPPI/ASC final rule (88 FR 82074) for our policies regarding administrative requirements previously finalized for the REHQR Program.

We are not proposing any changes to these policies in this proposed rule.

E. Form, Manner, and Timing of Data Submission

1. General Policy

We refer readers to § 419.95(c) and § 419.95(g) and the CY 2024 OPPI/ASC final rule (88 FR 82074 through 82076) for our general policies regarding: (1) submission of data under the REHQR Program generally; (2) review and correction of submitted data; and (3) extraordinary circumstance exception (ECE) requests for data submission.

We are not proposing any changes to these policies in this proposed rule.

2. Proposed Data Submission Policy Following Conversion to REH Status

As we have implemented these general policies and some hospitals have converted to REH status, we believe that it is necessary to specify when a hospital that converts to REH status is required to report data to the REHQR Program. Thus, we propose that an REH must begin submitting data to the REHQR Program on the first day of the quarter following the date that a hospital has been designated as

converted to an REH in accordance with the process outlined in section 1861(kkk) of the Act.

We invite public comment on this proposal.

3. Measure-Specific Data Submission and Reporting Requirements

a. Data Submission Requirements for Chart-Abstracted Measures

We refer readers to the CY 2024 OPPI/ASC final rule (88 FR 82074 through 82075) for information regarding chart-abstracted data submission and reporting requirements.

We are not proposing any changes to these policies in this proposed rule.

b. Proposal for the HCHE, Screening for SDOH, and Screen Positive Rate for SDOH Measures' Data Submission Requirements and Reporting Requirements

To align with the Hospital OQR (80 FR 70521 through 70522) and ASCQR (81 FR 79821 through 79822) Programs, we propose a web-based submission policy where REHs would submit data for applicable measures once annually using a CMS-approved, web-based, data collection tool available within the Hospital Quality Reporting (HQR) System. In alignment with the Hospital OQR and ASCQR Programs, REHs would submit data during the period of January 1 to May 15 in the year prior to the affected program determination year. For example, for the CY 2025

reporting period/CY 2027 program determination, the data submission period would be January 1, 2026, to May 15, 2026, covering the performance period of January 1, 2025, to December 31, 2025. Under the review and corrections period provided at § 419.95(c)(3), REHs would be able to enter, review, and correct data submitted during the data submission period.

These policies would apply to web-based measures adopted by the REHQR program, including the following three measures proposed for adoption in this year's rule:

- The HCHE measure, beginning with the CY 2025 reporting period/CY 2027 program determination;

- The Screening for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination; and

- The Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination.

We refer readers to sections XIV.B.1, XIV.B.2, and XIV.B.3 for additional information on the HCHE, Screening for SDOH, and Screen Positive Rate for SDOH measures.

We invite public comment on this proposal.

c. Data Submission Requirements for Claims-Based Measure Data

In addition, we refer readers to section XVI.C.2 of this proposed rule where we discuss our proposal to modify the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery Measure beginning with the CY 2027 program determination. This claims-based measure would continue to be reported in accordance with other claims-based measures, as previously finalized in the CY 2024 OPPS/ASC final rule (88 FR 85075).

We are not proposing any changes to these policies in this proposed rule.

F. Public Reporting of Measure Data

We refer readers to § 419.95(f) and the CY 2024 OPPS/ASC final rule (88 FR 82071 through 82074) for our program policy regarding the public reporting of quality data.

We are not proposing any changes to these policies in this proposed rule.

XVII. Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background and Statutory Authority

The Ambulatory Surgical Center Quality Reporting (ASCQR) Program is a pay-for-reporting program intended to improve the quality of care provided to Medicare beneficiaries, facilitate public transparency, and ensure accountability of ambulatory surgical centers (ASCs).

Section 1833(i)(7)(A) of the Act authorizes the Secretary to reduce any annual increase under the revised ambulatory surgical center (ASC) payment system by 2.0 percentage points for such year that an ASC that fails to submit required data on quality measures specified by the Secretary in accordance with section 1833(i)(7)(B) of the Act. Section 1833(i)(7)(B) of the Act states that, except as the Secretary may otherwise provide, several of the statutory provisions governing the Hospital Outpatient Quality Reporting (OQR) Program, specifically sections 1833(t)(17)(B) through (E) of the Act, also apply to the services of ASCs under the ASCQR Program in a similar manner to the manner in which they apply to the services of hospital outpatient departments under the Hospital OQR Program. Sections 1833(t)(17)(B) through (E) of the Act generally govern

the development and replacement of quality measures, the form and manner of submission of data to CMS, and procedures for making the data submitted to CMS available to the public.

We refer readers to the CY 2012 OPPS/ASC final rule (76 FR 74492 through 74494) for a detailed discussion of the program's statutory authority, as well as program requirements codified at 42 CFR part 416, subpart H (§ 416.300 through § 416.330), and the CY 2024 OPPS/ASC final rule (88 FR 82012) for information regarding the program's regulatory history.

1. Previously Finalized Program Measure Sets

We refer readers to the CY 2024 OPPS/ASC final rule (88 FR 82038) for additional information regarding the previously finalized ASCQR Program measure set beginning with the CY 2027 payment determination.

a. Previously Finalized Measure Set Beginning With the CY 2027 Payment Determination

Table 96 summarizes the previously finalized ASCQR Program measures beginning with the CY 2027 payment determination.

TABLE 96: PREVIOUSLY FINALIZED ASCQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2027 PAYMENT DETERMINATION

CBE #	Measure Name
None†	All-Cause Hospital Transfer/Admission
None†	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery)*
3636	COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)
0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
3357	Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at ASCs
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
3470	Hospital Visits After Orthopedic Ambulatory Surgical Center (ASC) Procedures
3366	Hospital Visits After Urology ASC Procedures
None	Normothermia Outcome
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)
	• About Facilities and Staff
	• Communication About Procedure
	• Overall Rating of Facility
	• Preparation for Discharge and Recovery
	• Recommendation of Facility
None†	Patient Burn
None†	Patient Fall
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA PRO-PM) in the ASC Setting**
None	Unplanned Anterior Vitrectomy
None†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

†Measure is no longer endorsed by Consensus Based Entity (CBE) but was endorsed previously.

*This measure is voluntary.

**This measure begins with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2031 payment determination, as discussed in the CY 2024 OPPS/ASC final rule (88 FR 82033 through 82036).

b. Previously Finalized Measure Set Beginning With the CY 2031 Payment Determination

beginning with the CY 2031 payment determination.

Table 97 summarizes the previously finalized ASCQR Program measures

**TABLE 97: PREVIOUSLY FINALIZED ASCQR PROGRAM MEASURE SET
BEGINNING WITH THE CY 2031 PAYMENT DETERMINATION**

CBE #	Measure Name
None†	All-Cause Hospital Transfer/Admission
None†	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery)*
3636	COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)
0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
3357	Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at ASCs
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
3470	Hospital Visits After Orthopedic ASC Procedures
3366	Hospital Visits After Urology ASC Procedures
None	Normothermia Outcome
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)
	• About Facilities and Staff
	• Communication About Procedure
	• Overall Rating of Facility
	• Preparation for Discharge and Recovery
	• Recommendation of Facility
None†	Patient Burn
None†	Patient Fall
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA PRO-PM) in the ASC Setting
None	Unplanned Anterior Vitrectomy
None†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

†Measure is no longer endorsed by the CBE but was endorsed previously.

*This measure is voluntary.

B. Program Measure Set Policies

1. Measure Retention

We refer readers to § 416.320 and the CY 2012 OPPS/ASC final rule (76 FR 74504) for our policies regarding measure retention.

We are not proposing any changes to these policies in this proposed rule.

2. Measure Suspension or Removal

We refer readers to § 416.320 and the CY 2019 OPPS/ASC final rule (83 FR 59111 through 59115) for our program policies regarding: (1) general measure removal, suspension, or replacement; and (2) immediate measure removal.

We refer readers to section XIV.C of this proposed rule for our cross-program proposal to modify the immediate measure removal policy for quality measures for the ASCQR Program.

3. Measure Modification

We refer readers to § 416.325 and the CY 2016 OPPS/ASC final rule (80 FR 70531) for our program policies

regarding modifications to previously adopted measures.

We are not proposing any changes to these policies in this proposed rule.

4. Measure Adoption

We refer readers to the CY 2013 OPPS/ASC final rule (77 FR 68493 and 68494) for details regarding program priorities we consider for quality measure selection.

We are not proposing any changes to these policies in this proposed rule.

C. Program Measure Proposals

1. Proposal To Adopt Health Equity Quality Measures in the ASCQR Program

We refer readers to sections XIV.B.1, XIV.B.2, and XIV.B.3 of this proposed rule for our cross-program proposals to adopt the following measures in the ASCQR Program: (1) the Facility Commitment to Health Equity (FCHE) measure, beginning with the CY 2025 reporting period/CY 2027 payment

determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

2. Summary of Proposed Program Measure Set Updates

a. Proposed Program Measure Set Beginning With the CY 2027 Payment Determination

Table 98 summarizes the proposed updated ASCQR Program measure set beginning with the CY 2027 payment determination.

Specifically, Table 98 includes the previously finalized measure set and the

three proposed new cross-program health equity measures, as detailed in

sections XIV.B.1, XIV.B.2, and XIV.B.3, respectively, of this proposed rule.

TABLE 98: PROPOSED UPDATED ASCQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2027 PAYMENT DETERMINATION

CBE #	Measure Name
None†	All-Cause Hospital Transfer/Admission
None†	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery)*
3636	COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)
0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
None	Facility Commitment to Health Equity (FCHE)***
3357	Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at ASCs
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
3470	Hospital Visits After Orthopedic Ambulatory Surgical Center (ASC) Procedures
3366	Hospital Visits After Urology ASC Procedures
None	Normothermia Outcome
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)
	• About Facilities and Staff
	• Communication About Procedure
	• Overall Rating of Facility
	• Preparation for Discharge and Recovery
	• Recommendation of Facility
None†	Patient Burn
None†	Patient Fall
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA PRO-PM) in the ASC Setting**
None	Screening for Social Drivers of Health (SDOH)****
None	Screen Positive for Social Drivers of Health (SDOH)****
None	Unplanned Anterior Vitrectomy
None†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

†Measure is no longer endorsed by the CBE but was endorsed previously.

*This measure is voluntary.

**This measure begins with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2031 payment determination, as discussed in the CY 2024 OPPI/ASC final rule (88 FR 82033 through 82036).

***We propose that this measure would be mandatory beginning with the CY 2025 Reporting Period/CY 2027 payment determination, as discussed in section XIV.B.1 of this proposed rule.

****We propose that this measure would begin with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination, as discussed in sections XIV.B.2 and XIV.B.3 of this proposed rule.

b. Proposed Program Measure Set Beginning With the CY 2031 Payment Determination

Table 99 summarizes the proposed updated ASCQR Program measure set

beginning with the CY 2031 payment determination.

Specifically, Table 99 includes the previously finalized measure set and the three proposed new cross-program

health equity measures, as detailed in sections XIV.B.1, XIV.B.2, and XIV.B.3, respectively, of this proposed rule.

TABLE 99: PROPOSED UPDATED ASCQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2031 PAYMENT DETERMINATIONP

CBE #	Measure Name
None†	All-Cause Hospital Transfer/Admission
None†	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery)*
3636	COVID–19 Vaccination Coverage Among Health Care Personnel (HCP)
0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
None	Facility Commitment to Health Equity (FCHE)**
3357	Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers (ASCs)
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy
3470	Hospital Visits After Orthopedic ASC Procedures
3366	Hospital Visits After Urology ASC Procedures
None	Normothermia Outcome
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)
	• About Facilities and Staff • Communication About Procedure • Overall Rating of Facility • Preparation for Discharge and Recovery • Recommendation of Facility
	None†
	Patient Burn
	Patient Fall
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA PRO-PM) in the ASC Setting
None	Screening for Social Drivers of Health (SDOH)***
None	Screen Positive for Social Drivers of Health (SDOH)***
None	Unplanned Anterior Vitrectomy
None†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

†Measure is no longer endorsed by the CBE but was endorsed previously.

*We note that this measure is voluntary.

**We propose that this measure would be mandatory beginning with the CY 2025 Reporting Period/CY 2027 payment determination, as discussed in section XIV.B.1 of this proposed rule.

***We propose that this measure would begin with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination, as discussed in sections XIV.B.2 and XIV.B.3 of this proposed rule.

D. Administrative Requirements

We refer readers to § 416.305 and the CY 2016 OPPS/ASC final rule (80 FR 70533 and 70534) for our program policies regarding participation and withdrawal requirements.

We are not proposing any changes to these policies in this proposed rule.

E. Form, Manner, and Timing of Data Submission

1. General Policy

We refer readers to § 416.310 and the CYs 2017, 2018, and 2021 OPPS/ASC final rules (81 FR 79824 and 79825; 82 FR 59472 through 59475; and 85 FR

86191 and 86192, respectively) for our general program policies regarding: (1) submission of data under the ASCQR Program generally; (2) review and correction of submitted data; and (3) extraordinary circumstance exception (ECE) requests for data submission.

We are not proposing any changes to these policies in this proposed rule.

We also refer readers to the CY 2016 OPPS/ASC final rule (80 FR 70531) for details regarding submission requirements for previously adopted ASCQR Program measures in the ASCQR Program Specifications Manual.

2. Measure-Specific Data Submission and Reporting Requirements

We refer readers to § 416.310 and the CYs 2016, 2022, and 2024 OPPS/ASC final rules (80 FR 70534 through 70536; 86 FR 63905 through 63909; and 88 FR 82041 through 82045, respectively) for information regarding our claims-based, survey-based, and PRO–PM data submission and reporting requirements.

a. Web-Based Measures

(1) CMS-Designated Information System and Proposal for Data Submission for the Facility Commitment to Health Equity (FCHE), Screening for Social Drivers of Health (SDOH), and Screen Positive Rate for SDOH Measures

We refer readers to § 416.310(c)(1), the CY 2017 OPPS/ASC final rule (81 FR 79821 and 79822), the CY 2018 OPPS/ASC final rule (82 FR 59473), and the CY 2024 final rule (88 FR 82039 and 82040) for details regarding submission of web-based data via a CMS-designated information system (currently the Hospital Quality Reporting (HQR) System).

In sections XIV.B.1, XIV.B.2, and XIV.B.3 of this proposed rule, we propose the adoption of:

(1) the FCHE measure, beginning with the CY 2025 reporting period/CY 2027 payment determination;

(2) the Screening for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and

(3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

Consistent with our established data submission requirements (81 FR 79821 and 79822; 82 FR 59473; 88 FR 82039 and 82040), we propose that ASCs would be required to submit all of the data required to calculate each of these three measures annually using a CMS-approved, web-based, data collection tool available within the HQR System starting January 1 through and including May 15 in the year prior to the applicable payment determination year. For the ASCQR Program, the performance period (which we refer to as the CY reporting period) for each measure on which data is submitted using a web-based tool would be January 1 through and including December 31 of the year that is two years prior to the applicable payment determination year; and the data submission period would be January 1 through and including May 15 in the calendar year immediately following the CY reporting period and immediately prior to applicable payment determination year. For example, for the CY 2025 reporting period/2027 payment determination, the data submission period would be January 1, 2026, through and including May 15, 2026, covering the performance period of January 1, 2025, through and including December 31, 2025. Pursuant to

§ 416.310(c)(1)(iii), a review and corrections period runs concurrently with the data submission period. During this timeframe, ASCs would be able to enter, review, and correct data submitted during the data submission period.

We invite public comment on this proposal.

(2) National Health Safety Network (NHSN)

We refer readers to § 416.310(c)(2) and the CY 2014 OPPS/ASC final rule (78 FR 75139 and 75140) for our policies regarding submission of web-based data via the Center for Disease Control and Prevention's NHSN.

We are not proposing any changes to these policies in this proposed rule.

F. Public Reporting of Measure Data

We refer readers to § 416.315 and the CY 2018 OPPS/ASC final rule (82 FR 59472) for our program policies regarding public reporting of quality data.

We are not proposing any changes to these policies in this proposed rule.

G. Request for Information (RFI)—Development of Frameworks for Specialty Focused Reporting and Minimum Case Number for Required Reporting

The ASCQR Program promotes informed patient decision-making regarding clinical care across ASC procedures through a robust set of quality measures, data on which the ASCQR Program publicly reports as discussed in section XVII.F of this proposed rule. The ASCQR Program's current measure set captures clinical quality across all ASCs, including specialty clinical procedures performed only by a subset of ASCs. Thus, a portion of the ASCQR Program measure set only applies to an ASC if it performs those specialty procedures. Currently, ASCs are required to attest if they do not have cases for a given measure, increasing reporting burden.

We seek to ensure the most meaningful measures apply to each facility, as requiring an ASC to report on measures minimally relevant to their patient population increases burden with minimum benefit. Therefore, we are seeking comment on two potential future frameworks which would achieve the following outcomes: (1) the addition of case minimums for specialty measure reporting; (2) the removal of the zero case attestation requirement for specialty measures to decrease reporting burden; and (3) the verification of individual measure case counts using claims data to determine which

specialty measures would potentially be required for reporting for individual ASCs. Verifying case counts using claims data would allow us to confirm that individual ASCs are reporting on measures meeting or surpassing case minimums.

Under these potential frameworks, we are considering revising the data reporting requirements for the ASCQR Program to only require that ASCs report data to CMS on quality measures that are related to their medical interventions, policies, processes, and procedures, or can be abstracted from claims. These potential frameworks would require ASCs to report measures generally applicable to all ASCQR Program participants and relevant specialty-specific measures, defined as those which evaluate performance on certain specialty clinical procedures performed only by a subset of ASCs.

The current ASCQR Program measure set has seven generally applicable measures for which reporting would be required in both frameworks for all ASCs: four patient safety measures (Patient Burn; Patient Fall; Wrong Site, Wrong Patient, Wrong Procedure, Wrong Implant; All-Cause Hospital Transfer Admission), one general surgery measure (Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers), one vaccination measure (COVID-19 Vaccination Coverage Among Health Care Personnel), and one patient experience of care survey measure (OAS CAHPS). In addition, we have proposed in this proposed rule to adopt three new generally applicable measures (FCHE, Screening for SDOH, and Screen Positive Rate for SDOH), which ASCs would also be required to report if finalized.

The specialties addressed by the current ASCQR Program measure set, and the related specialty-specific measures, are described in Table 100. Under our first potential framework, the "Specialty-Select" framework, all ASCs would be required to report all specialty-specific, claims-based measures (currently, four) because these measures are not administratively burdensome to ASCs. Additionally, ASCs would also be required to select a specified number of the remaining non-claims-based specialty-specific measures (currently, four) to report if those measures are applicable to that ASC. We would define the number of non-claims-based specialty-specific measures that ASCs would be required to report in future rulemaking.

To determine if a non-claims-based specialty-specific measure is applicable

to an ASC, we are considering the implementation of a case threshold minimum which we would specify in future rulemaking, for each measure. We would determine if case threshold minimums, defined as the number of cases for a specific measure that must be met or exceeded to potentially require reporting, have been met using claims data. Once an ASC met the measure's case threshold minimum, that measure would become available for that ASC to select to meet reporting requirements. We note that reporting claims-based specialty-specific measures would be required regardless of whether the case threshold minimum is met. In this RFI we are seeking comment on the number of non-claims-based specialty-specific measures that ASCs should be required to report and what the appropriate threshold for the case threshold minimum should be.

We are considering the use of Medicare Fee-for-Service (FFS) and

Medicare Advantage claim volume data to determine which non-claims-based specialty-specific measures have met the specified case threshold minimum (that is, claims information would indicate an ASC was performing sufficient case volumes in a specialty area). We note that this threshold would be independent from our "Minimum case volume for program participation" policy, which exempts ASCs with fewer than 240 total Medicare claims per year from participating in the ASCQR Program, in the manner specified at § 416.305(c). The case threshold minimum discussed in this RFI would be applied to individual non-claims-based specialty-specific measures for ASCs required to participate in the ASCQR Program.

For example, if we decide that each ASC must select three out of the four available non-claims-based specialty-specific measures to report, and an ASC surpasses the specified case threshold

minimum for all four non-claims-based specialty-specific measures, the ASC would then choose three out of the four non-claims-based specialty-specific measures to report. If an ASC surpasses the specified case threshold minimum for only one or two non-claims-based specialty-specific measures, the ASC will no longer have a choice, and must report all measures meeting the case threshold minimum. If an ASC does not meet the case threshold minimum for any non-claims-based specialty-specific measures, reporting for any of these measures would be voluntary. Under such a framework, ASCs could not utilize the claims-based measures to meet Specialty-Select reporting requirements nor could ASCs opt-out of reporting these measures. ASCs which do not have one or more cases for a given measure would no longer be required to provide an attestation of having zero cases.

TABLE 100: CURRENT SPECIALTY-SPECIFIC ASCQR PROGRAM MEASURES

Specialty	Measure	Current Reporting Requirement	Data Source
Ophthalmology	Unplanned Anterior Vitrectomy	Mandatory	Patient Medical Records
Ophthalmology	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery)	Voluntary	Patient Reported Data and Surveys
Surgical	Normothermia Outcome	Mandatory	Patient Medical Records
Surgical	Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO- PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO-PM)	Voluntary through CY 2027 reporting period; Mandatory beginning with CY 2028 reporting period	Patient Reported Data and Surveys
Surgical	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures	Mandatory	Medicare Claims
Gastroenterology	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	Mandatory	Medicare Claims
Gastroenterology	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy	Mandatory	Medicare Claims
Urology	Hospital Visits after Urology Ambulatory Surgical Center Procedures	Mandatory	Medicare Claims

Four of these measures are not claims-based and, under this potential framework, would not be applicable or required for all ASCs to report, but would rather be available for selection upon meeting a specified case threshold minimum:

- Unplanned Anterior Vitrectomy;
- Cataracts Visual Function

(Previously referred to as Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery) (voluntary);

- Normothermia Outcome; and
- Risk-Standardized Patient-Reported

Outcome-Based Performance Measure (PRO-PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO-PM).

We acknowledge that currently there are few non-claims-based specialty-specific measures from which to choose to report. However, we are interested to learn if such a framework with both mandatory measures applicable to all ASCs and selectable, specialty-specific measures could lay the groundwork for providing higher quality data to patients while ensuring ASCs are not reporting data on measures that are minimally relevant, if not irrelevant, to their patient population.

Regarding this Specialty-Select framework, we are requesting comment on the following questions:

- Given that ASCs would still be required to report claims-based specialty-specific measures, as these measures are not administratively burdensome to ASCs, and there are currently only four non-claims-based specialty-specific quality measures in the ASCQR Program data set, how many non-claims-based specialty-specific measures should we require ASCs select to report?

- Are there specialty-specific measures that commenters would recommend for development and adoption in the ASCQR Program measure set to create a more robust selection?

- How should we determine what non-claims-based specialty-specific measures would be eligible for a given ASC to select toward meeting reporting requirements? In other words, how can we determine if an ASC meets the minimum case number for a given measure, which would allow the ASC to choose that measure to meet reporting requirements?

As an alternative to the Specialty-Select framework discussed previously, we are considering requiring reporting for all non-claims-based specialty-specific measures for which case counts reach a specified case threshold

minimum. This case threshold minimum would not apply to claims-based specialty-specific measures, as their reporting would be mandatory since these measures are not administratively burdensome to ASCs. Under this alternative framework, mandatory data reporting for non-claims-based specialty-specific measures would occur only if an ASC met established case threshold minimums. For example, if an ASC has 30 or more qualifying patients for the measure during the applicable reporting period, which is the current minimum case threshold required for public reporting for some measures, the ASC would be required to submit data for these measures. Likewise, if an ASC has fewer than 30 patients for the measure, data reporting on the measure would be voluntary. This framework could be termed a Specialty Threshold framework and would differ from the previously discussed Specialty-Select framework as an ASC would be required to report on all non-claims-based specialty-specific measures for which the ASC reaches the case threshold minimum.

Regarding both the Specialty Threshold framework and the Specialty-Select framework, we are requesting comment on the following questions:

- Would use of Medicare Fee-for-Service (FFS) claim volume be sufficient for determining minimum case volumes?

- Should Medicare Advantage claim volume or service data be included when determining case volume thresholds for reporting a measure?

- Do commenters recommend any processes that could be followed or analyses we could conduct to determine case minimums?

We invite public comment on both the Specialty-Select framework and the alternative Specialty Threshold framework for potential inclusion in the ASCQR Program.

H. Payment Reduction for ASCs That Fail to Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to the CY 2012 OPPI/ASC final rule with comment period (76 FR 74492 through 74493) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Policy Regarding Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system are equal to the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. For CY 2025, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the productivity-adjusted hospital market basket update factor. The productivity adjustment is set forth in section 1833(i)(2)(D)(v) of the Act. The productivity-adjusted hospital market basket update is the annual update for the ASC payment system for a 5-year period (CY 2019 through CY 2023), which was extended an additional two years (through CY 2025) in the CY 2024 OPPI/ASC final rule with comment period (88 FR 81960). Under the ASCQR Program, in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPI/ASC final rule with comment period (77 FR 68499), any annual increase in certain payment rates under the ASC payment system shall be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates (77 FR 68500). For a complete discussion of the calculation of the ASC conversion factor and our finalized proposal to update the ASC payment rates using the inpatient hospital market basket update for CYs 2019 through 2023, we refer readers to the CY 2019 OPPI/ASC final rule with comment period (83 FR 59073 through 59080).

In the CY 2013 OPPI/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized the following policies: (1) to calculate a full update conversion factor and an ASCQR Program reduced update conversion factor; (2) to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination; and (3) that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the

productivity adjustment. The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to the proposed rule, which are available via the internet on the CMS website): “A2,” “G2,” “P2,” “R2” and “Z2,” as well as the service portion of device-intensive procedures identified by “J8” (77 FR 68500). We finalized our proposal that payment for all services assigned the payment indicators listed would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor (77 FR 68500).

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators “A2,” “D2,” “G2,” “J8,” “P2,” “R2” and “Z2.” These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures, radiology services and diagnostic tests where payment is based on the PFS nonfacility PE RVU-based amount, and a few other specific services that receive cost-based payment (77 FR 68500). As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, are not affected by reductions to the annual update (77 FR 68500).

Office-based surgical procedures (generally those performed more than 50 percent of the time in physicians’ offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents) are paid at the lesser of the PFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS will be at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the standard ASC ratesetting methodology when provided integral to covered ASC surgical procedures. In the CY 2013 OPPS/ASC final rule with comment

period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code, regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we have noted our belief that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced coinsurance liability for beneficiaries (77 FR 68500). Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary’s national unadjusted coinsurance for a service to which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost (77 FR 68500). We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements (77 FR 68500).

In the CY 2015 through CY 2024 OPPS/ASC final rules with comment period, we did not make any other changes to these policies. We propose to continue applying these policies for the CY 2025 reporting period/CY 2027 payment determination and for subsequent years.

XVIII. Medicaid Clinic Services Four Walls Exceptions

A. Background

Under section 1902(a)(10) of the Act, States may offer certain Medicaid benefits, at State option, to categorically

needy and medically needy Medicaid beneficiaries, as described in that section of the statute. Clinic services are one of these optional benefit categories. Section 1905(a)(9) of the Act, as amended by section 4105 of part 1 of subtitle B of title IV of the Omnibus Budget Reconciliation Act of 1987 (OBRA ’87, Pub. L. 110–203), defines clinic services as services furnished by or under the direction of a physician, without regard to whether the clinic itself is administered by a physician, including such services furnished outside the clinic by clinic personnel to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address (hereinafter referred to as “individuals who are unhoused”).^{262 263}

The regulation implementing section 1905(a)(9) of the Act, 42 CFR 440.90, includes certain conditions and limitations on Medicaid coverage of clinic services. Specifically, § 440.90 defines clinic services as preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients.²⁶⁴ Section 440.90 further provides that clinic services include two types of services furnished to outpatients, listed at § 440.90(a) and (b). The first type of services included in the benefit, under § 440.90(a), is services furnished at the clinic (hereinafter referred to as the “four walls” requirement) by or under the direction of a physician or dentist. Section 440.90(b) implements the statutory language providing that clinic services also include services furnished outside the clinic, by clinic personnel under the direction of a physician, to an

²⁶² Public Law 100–203, enacted December 22, 1987, 100 Stat. 1330, 1330–147, <https://www.congress.gov/100/statute/STATUTE-101/STATUTE-101-Pg1330.pdf>.

²⁶³ This document contains links to non-United States Government websites. We are providing these links because they contain additional information relevant to the topic(s) discussed in this document or that otherwise may be useful to the reader. We cannot attest to the accuracy of information provided on the cited third-party websites or any other linked third-party site. We are providing these links for reference only; linking to a non-United States Government website does not constitute an endorsement by CMS, HHS, or any of their employees of the sponsors or the information and/or any products presented on the website. Also, please be aware that the privacy protections generally provided by United States Government websites do not apply to third-party sites.

²⁶⁴ An outpatient is defined at 42 CFR 440.2 as a patient of an organized medical facility, or distinct part of that facility who is expected by the facility to receive and who does receive professional services for less than a 24-hour period regardless of the hour of admission, whether or not a bed is used, or whether or not the patient remains in the facility past midnight.

eligible individual who is unhoused. In section 4320 of the State Medicaid Manual, we explained that if a State elects to cover clinic services, the State may choose the type of clinics or clinic services that are covered.²⁶⁵

We added § 440.90(b) in 1991, after Congress added the language about services furnished outside the clinic to individuals who are unhoused to section 1905(a)(9) of the Act in OBRA '87.²⁶⁶ In the preamble to that rule, we explained that clinic services have always been limited to people who go to the clinic (or a satellite location) and get the services onsite, and that the exception added by OBRA '87 represents an exception to the general coverage requirement for services to be furnished on the premises of the clinic. Further, we explained our view that Congress ratified the requirement that other clinic services must be furnished onsite by establishing an explicit exception to the requirement that clinic services be furnished onsite in order to be covered. CMS has long interpreted the exception to the four walls requirement at § 440.90(b) to be mandatory for States that opt to cover the clinic services benefit. We reiterated CMS's longstanding interpretation that section 1905(a)(9) of the Act and § 440.90 establish a four walls requirement in a frequently asked questions document that we published on January 18, 2017 (hereinafter referred to as "the January 18, 2017 FAQ"), to supplement State Health Official letter number 16-002, Federal Funding for Services "Received Through" an IHS/Tribal Facility and Furnished to Medicaid-Eligible American Indians and Alaska Natives.^{267 268}

The Medicaid clinic services benefit is distinct from the Medicaid federally qualified health center (FQHC) services benefit and the Medicaid rural health

clinic (RHC) services benefit. The Medicaid FQHC services benefit is defined at section 1905(a)(2)(C) of the Act, and FQHCs and FQHC services are further defined at section 1905(l)(2) of the Act. The Medicaid RHC services benefit is defined at section 1905(a)(2)(B) of the Act, and RHCs and RHC services are further defined at section 1905(l)(1) of the Act. Unlike the clinic services benefit, which is an optional benefit for States, the FQHC and RHC benefits are mandatory for categorically needy Medicaid beneficiaries under section 1902(a)(10) of the Act. In addition, there is no Federal four walls requirement under the Medicaid FQHC or RHC services benefits, unlike the clinic services benefit. Federal Medicaid law does not prevent States from covering Medicaid FQHC and RHC services provided outside of the four walls of an FQHC or RHC.²⁶⁹

On January 28, 2021, the President signed Executive Order (E.O.) 14009, "Strengthening Medicaid and the Affordable Care Act," which established the policy objective to protect and strengthen Medicaid and the Affordable Care Act and to make high-quality health care accessible and affordable for every American, and directed executive departments and agencies to review existing regulations, orders, guidance documents, and policies to determine whether such agency actions are inconsistent with this policy.²⁷⁰ As part of this review of existing policies, E.O. 14009 directed Federal agencies to consider whether to suspend, revise, or rescind agency actions considered inconsistent with this objective. On April 5, 2022, E.O. 14070, "Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage," directed Federal agencies with responsibilities related to Americans' access to health coverage to review agency actions to identify ways to continue to expand the availability of affordable health coverage, to improve the quality of coverage, to strengthen benefits, and to help more Americans enroll in quality health coverage.²⁷¹

²⁶⁹ We note that the Consolidated Appropriations Act, 2024, Division G, Title I, Section 209 (P.L. 118-42) amended section 1905 of the Act to establish a certified community behavioral health clinic (CCBHC) services benefit effective March 9, 2024. The CCBHC services benefit is distinct from the clinic services benefit and there is no four walls requirement for the CCBHC services benefit under Federal Medicaid law.

²⁷⁰ Exec. Order No. 14009, 86 FR 7793 (Jan. 28, 2021). See, <https://www.Federalregister.gov/documents/2021/02/02/2021-02252/strengthening-medicare-and-the-affordable-care-act>.

²⁷¹ Exec. Order No. 14070, 87 FR 20689 (Apr. 8, 2021). See, <https://www.Federalregister.gov/>

On November 6, 2000, President Clinton signed E.O. 13175, "Consultation and Coordination With Indian Tribal Governments," which recognizes the unique legal relationship between the United States and Indian Tribal governments and, to strengthen this government-to-government relationship and support tribal sovereignty and self-determination, charges all executive departments and agencies with engaging in meaningful and timely consultation with Tribal officials in the development of Federal policies that have Tribal implications.²⁷² On January 26, 2021, President Biden issued a "Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships," which reaffirms E.O. 13175's directive to engage in regular, meaningful, and robust consultation with Tribal officials in the development of Federal policies that have Tribal implications.²⁷³

Consistent with E.O. 13175, CMS issued a Tribal Consultation policy in 2011 and updated it in 2015 for the purpose of building meaningful relationships with Indian Tribes and to establish a clear, concise and mutually acceptable process through which consultation can take place between CMS and Tribes.^{274 275} As one of its core principles, the policy provides that, because Congress amended titles XVIII and XIX of the Act to authorize Indian Health Service (IHS) and Tribal health programs to bill Medicare and Medicaid, "[t]he involvement of Indian tribes in the development of CMS policy is crucial for mutual understanding and development of culturally appropriate approaches to improve greater access to CMS programs for American Indians and Alaska Natives (AI/ANs), to enhance health care resources to IHS

[documents/2022/04/08/2022-07716/continuing-to-strengthen-americans-access-to-affordable-quality-health-coverage](https://www.Federalregister.gov/documents/2022/04/08/2022-07716/continuing-to-strengthen-americans-access-to-affordable-quality-health-coverage).

²⁷² Exec. Order No. 13175, 65 FR 67249 (Nov. 6, 2000). See, <https://www.Federalregister.gov/documents/2000/11/09/00-29003/consultation-and-coordination-with-indian-tribal-governments>.

²⁷³ President Joseph R. Biden to Heads of Executive Departments and Agencies, memorandum, "Tribal Consultation and Strengthening Nation-to-Nation Relationships," January 26, 2021, Presidential Actions, <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/26/memorandum-on-tribal-consultation-and-strengthening-nation-to-nation-relationships/>.

²⁷⁴ CMS, "Tribal Consultation," CMS.gov, September 6, 2023, <https://www.cms.gov/training-education/partner-outreach-resources/american-indian-alaska-native/tribal-consultation>.

²⁷⁵ CMS, Tribal Consultation Policy, Policy, (Washington, DC, 2015), <https://www.cms.gov/outreach-and-education/american-indian-alaska-native/aian/downloads/cmtribalconsultationpolicy2015.pdf>.

²⁶⁵ U.S. Department of Health and Human Services, Health Care Financing Administration (HCFA), *The State Medicaid Manual*, Manual, (Baltimore, MD, 1985), Section 4320, <https://www.cms.gov/regulations-and-guidance/guidance/manuals/paper-based-manuals-items/cms021927>.

²⁶⁶ Medicare and Medicaid Programs; OBRA '87 Conforming Amendments, 56 FR 8832, 8835 (March 1, 1991) (hereinafter referred to as the 1991 rule). https://archives.Federalregister.gov/issue_slice/1991/3/1/8829-8854.pdf.

²⁶⁷ CMS, *Federal Funding for Services "Received Through" an IHS/Tribal Facility and Furnished to Medicaid-Eligible American Indians and Alaska Natives*, State Health Official Letter (SHO) #16-002, (Baltimore, MD, 2016), <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/sho022616.pdf>.

²⁶⁸ CMS, *Frequently-Asked Questions (FAQs) Federal Funding for Services "Received Through" an IHS/Tribal Facility and Furnished to Medicaid-Eligible American Indians and Alaska Natives (SHO #16-002)*, FAQ, (Baltimore, MD, 2017), <https://www.medicaid.gov/media/40241>.

and tribal health programs, and to contribute to overall improved health outcomes for American Indians.” As part of its government-to-government relationship with the Tribes, CMS has engaged in meaningful consultation with Tribes and Tribal leaders, the CMS Tribal Technical Advisory Group (TTAG), and the HHS Secretary’s Tribal Advisory Committee (STAC) regarding concerns about the impact that the four walls requirement could have on IHS/Tribal clinics and AI/AN beneficiaries’ access to health care when a grace period currently in place for IHS/Tribal clinics (as discussed below) ends. As part of this consultation, Tribes requested a permanent exemption from the four walls requirement for IHS/Tribal clinics. In the development of this proposed rule, we have taken into consideration comments and feedback received during Tribal consultation.

IHS, a Federal agency within the Department of Health and Human Services, is responsible for furnishing comprehensive, culturally appropriate health services to, as of April 2024, almost 2.8 million AI/ANs who are eligible for services from IHS, per regulations at 42 CFR part 136, as well as other individuals whom IHS or Tribes are authorized to serve under 25 U.S.C. 1680c.²⁷⁶ IHS’s provision of health services to its beneficiaries stems from the special government-to-government relationship between the Federal government and Indian Tribes. The Federal government’s relationship with Tribes is based on Article I, section 8 of the Constitution, and has been given form and substance by numerous treaties, statutes, Supreme Court decisions, and Executive Orders. The IHS delivery system includes hospitals and clinics that are owned and operated by IHS, owned by IHS and Tribally-operated as authorized by the Indian Self-Determination and Education Assistance Act (ISDEAA, Pub. L. 93–638 (as amended)), or owned and operated by Tribes and Tribal organizations as authorized by the ISDEAA.²⁷⁷ We refer to these three kinds of facilities in our discussions of the proposed amendments to § 440.90 as “IHS/Tribal facilities” or, when referring to circumstances where these facilities

operate as Medicaid clinic services providers, “IHS/Tribal clinics.”²⁷⁸ Section 1911 of the Act and implementing regulations at § 431.110 provide that a facility of IHS, whether operated by IHS or by a Tribe or Tribal organization (CMS has interpreted similar language in section 1905(b) of the Act to refer to all three kinds of IHS/Tribal facilities described above),²⁷⁹ may participate in the Medicaid program subject to the conditions and requirements generally applicable under Title XIX of the Act. Many IHS/Tribal facilities are covered and paid as clinic services providers in the Medicaid program. Under section 1903(a)(1) of the Act, the Federal government is required to match State expenditures for medical assistance at the Federal Medical Assistance Percentage (FMAP), which is defined at section 1905(b) of the Act to be 100 percent for State expenditures for Medicaid-covered services received through an IHS facility whether operated by IHS or by a Tribe or Tribal organization (which, again, CMS has interpreted to refer to all three kinds of IHS/Tribal facilities described above). Under CMS’s longstanding interpretation of section 1905(b) of the Act, this 100 percent FMAP is available only for State expenditures on services received through an IHS/Tribal facility (such as a clinic) by AI/AN Medicaid beneficiaries. State expenditures on services furnished by an IHS/Tribal facility to other individuals are not matched by the Federal government at 100 percent, but rather at the State’s regularly applicable FMAP rate.

As part of our Center for Medicaid & CHIP Services (CMCS) Mental Health and Substance Use Disorder Action Plan published in July 2023, we are pursuing strategies to increase access to prevention and treatment, engagement in care, and improve quality of care for beneficiaries with behavioral health disorders.²⁸⁰ Behavioral health disorders include both substance use disorders and mental health disorders. Medicaid plays a crucial role in financing health care for individuals with behavioral health disorders and is the largest payer of behavioral health

services.²⁸¹ There are no Federal requirements for States to cover services furnished by behavioral health clinics or any specific types of behavioral health clinics under the clinic services benefit. However, we are aware that approximately 16 States cover services provided by behavioral health clinics of varying types under the clinic services benefit, such as Community Mental Health Centers certified under the Medicare Conditions of Participation at 42 CFR part 485 Subpart J, substance use disorder clinics, or mental health clinics.

We released a framework for advancing health care in rural, Tribal, and geographically isolated communities in November 2022.²⁸² Our framework focuses on six priorities, including expanding access to comprehensive health care coverage, benefits, and services and supports to individuals who live in these communities. Medicaid plays an important role in financing health care in rural areas, as nearly a quarter of individuals under age 65 who live in rural areas are covered by Medicaid. Importantly, Medicaid also provides critical access to care for individuals in rural areas who are older or disabled, as more than one in five residents of rural areas (approximately 22 percent) are dually enrolled in Medicaid and Medicare.²⁸³ There are no Federal requirements under the clinic services benefit governing how States should provide coverage of services furnished specifically by clinics located in rural areas under that benefit—the Federal requirements that apply generally to that benefit, including the four walls requirement, also apply to services furnished by clinics in rural areas. A State may cover Medicaid clinic services provided by various types of clinics located in rural areas, such as primary care clinics, behavioral health clinics, surgical clinics, and other types of clinics. As noted earlier in this

²⁸¹ Guth, Madeline, Heather Saunders, Lauren Niles, Angela Bergefurd, Kathleen Gifford, and Roxanne Kennedy Published. 2023. “How Do States Deliver, Administer, and Integrate Behavioral Health Care? Findings from a Survey of State Medicaid Programs.” KFF, May 25, 2023. <https://www.kff.org/mental-health/issue-brief/how-do-states-deliver-administer-and-integrate-behavioral-health-care-findings-from-a-survey-of-state-medicare-programs/>.

²⁸² CMS, *CMS Framework for Advancing Health Care in Rural, Tribal, and Geographically Isolated Communities*, (2022), Framework, <https://www.cms.gov/files/document/cms-geographic-framework.pdf>.

²⁸³ Medicaid and CHIP Payment and Access Commission (MACPAC), *Medicaid and Rural Health*, Issue Brief, (Washington, DC, 2021), 1, <https://www.macpac.gov/wp-content/uploads/2021/04/Medicaid-and-Rural-Health.pdf>.

²⁷⁶ IHS, *Indian Health Service Health Equity Report*, Fact Sheet, (2024), https://www.ihs.gov/sites/newsroom/themes/responsive2017/display_objects/documents/factsheets/IHS_Health_Equity_Report_FactSheet_2024.pdf.

²⁷⁷ HCFA and IHS, “Memorandum of Agreement Between the Indian Health Services and the Health Care Financing Administration,” Memorandum of Agreement, December 19, 1996, <https://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/ALAN/LTSS-TA-Center/pdf/memorandum-of-agreement.pdf>.

²⁷⁸ Although Urban Indian Organizations that operate under Title V of the Indian Health Care Improvement Act are also part of the IHS delivery system, for purposes of our discussions of the proposed amendments to § 440.90, the terms IHS/Tribal facility and IHS/Tribal clinic do not include a facility operated by an Urban Indian Organization.

²⁷⁹ HCFA and IHS, Memorandum of Agreement.

²⁸⁰ CMS, *Mental Health and Substance Use Disorder Action Plan*, (2023), Action Plan, <https://www.medicaid.gov/medicaid/benefits/downloads/cmcs-mntl-helth-substnce-disrdr-actn-plan.pdf>.

section of the proposed rule, the Medicaid RHC services benefit is different from the Medicaid clinic services benefit and does not include a four walls requirement under Federal Medicaid law; thus, facilities that qualify as RHCs under Federal Medicaid law could provide Medicaid services under the RHC services benefit, including outside of the four walls.

Section 1902(a)(30)(A) of the Act requires that Medicaid payments for services be consistent with efficiency, economy, and quality of care, and be sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Under this requirement, States generally have significant latitude in setting payment methodologies and rates for covered services, and there is no specific payment methodology required for clinic services, although regulations at § 447.321 require the application of upper payment limits for clinics that are not IHS/Tribal clinics. States generally pay for clinic services via a facility rate. They typically adopt, as the payment rate for Medicaid clinic services furnished by IHS/Tribal clinics, the Outpatient per Visit Rate (excluding Medicare) that IHS establishes for services provided by IHS facilities to Medicaid beneficiaries and for certain other Federal programs. This rate, and a set of three other rates for Medicare outpatient visits and certain inpatient services, are frequently referred to collectively as the IHS all-inclusive rates (AIRs), and therefore this IHS Outpatient per Visit Rate (excluding Medicare) is hereinafter referred to as the “AIR.”²⁸⁴ In contrast, States generally pay for Medicaid benefits provided by individual practitioners, such as the physician services benefit, at a professional fee schedule rate under the Medicaid State plan.

²⁸⁴ IHS establishes the AIRs under the authority in sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248 and 249(b)), Public Law 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*). IHS calculates AIRs on an annual basis and the rates are then published in the **Federal Register**. The AIRs are based on annual cost report analysis prepared by IHS’s contractor. IHS reviews the cost report analysis and upon completion of the review, IHS submits recommended rates to the Office of Management and Budget (OMB) for final approval through HHS and CMS. Upon approval by OMB, the approved rates are published in the **Federal Register**. See <https://www.ihs.gov/BusinessOffice/reimbursement-rates/>. Calendar year 2024 rates and additional information can be found in the **Federal Register** published December 19, 2023 (88 FR 87779): <https://www.federalregister.gov/documents/2023/12/19/2023-27815/reimbursement-rates-for-calendar-year-2024>.

As we noted in the January 18, 2017 FAQ, CMS recognized in 2017 that IHS/Tribal clinics were providing services outside of the four walls, including to individuals to whom the existing statutory and regulatory exception does not apply, and that States were paying for these services at the clinic services rate (which in all or nearly all cases is the AIR). In the January 18, 2017 FAQ, we announced a 4-year grace period to January 30, 2021, to allow States time to come into compliance with the four walls requirement for IHS/Tribal clinics. On January 15, 2021, due to the COVID–19 Public Health Emergency (PHE), CMS issued a CMCS Informational Bulletin (CIB) announcing an extension of the four walls grace period to October 31, 2021. CMS issued subsequent CIBs on October 4, 2021 and September 8, 2023, announcing further extensions of the grace period to nine months from when the COVID–19 PHE ended, and February 11, 2025, respectively.²⁸⁵

Since the release of the January 18, 2017 FAQ and throughout the grace period, we have heard from Tribes, the CMS TTAG, and the HHS STAC, that the four walls requirement will create barriers in access to care for Medicaid beneficiaries who receive care from IHS/Tribal clinics after the grace period expires. Tribes, the TTAG, and the STAC have asked CMS to eliminate the four walls requirement for IHS/Tribal clinics. In addition to these requests, CMS has received a handful of other requests from States to allow exceptions to the four walls requirements for clinics that serve vulnerable populations. For example, we received one section 1115 demonstration request to cover clinic services outside of the four walls for behavioral health clinics, under which the State sought to use the requested section 1115 demonstration authority to improve access to and retention in behavioral health treatment. In addition, we received inquiries from States seeking to cover, under the clinic services benefit, mobile crisis services provided by behavioral health clinics to individuals experiencing a behavioral health crisis, but we advised those States that we could not approve coverage of mobile crisis services under the clinic services benefit due to the four walls requirement.

This proposed rule aims to address the concerns we have heard from Tribes, the TTAG, the STAC, States, and other

interested parties. It aims to fulfill E.O.s 14009 and 14070 by helping States to strengthen and improve access to clinic services. It also helps to fulfill E.O. 13175 by recognizing the United States’ unique legal relationship with Tribes and by responding to advice and input received from Tribes through consultation. In addition, we believe this proposed rule is consistent with our strategies, goals, and objectives to advance health equity and improve health care access for Tribal, behavioral health, and rural populations as described in our CMCS Mental Health and Substance Use Disorder Action Plan and CMS Framework for Advancing Health Care in Rural, Tribal, and Geographically Isolated Communities.

Consistent with our statutory authority at section 1905(a)(9) of the Act, we propose to add three exceptions to the four walls requirement at § 440.90, for the reasons set forth in section XVIII.B of this proposed rule. First, we propose to add an exception for clinic services furnished by IHS/Tribal clinics. Second, we propose to add an exception for clinic services furnished by a clinic that is primarily organized for the care and treatment of outpatients with behavioral health disorders, including mental health and substance-use disorders. Third, we propose to add an exception for clinic services furnished by a clinic located in a rural area (and that is not an RHC, which could already provide services covered under a separate Medicaid benefit). We propose to make the exception for clinic services furnished by IHS/Tribal clinics a mandatory component of the clinic benefit and to make the exceptions for clinic services furnished by behavioral health clinics and clinics located in rural areas optional for States.

B. Provisions of the Proposed Regulations

As explained in section XVIII.A of this proposed rule, we previously interpreted section 1905(a)(9) of the Act to limit Medicaid clinic services to services furnished within the four walls of the clinic, except only for services furnished by clinic personnel to individuals who are unhoused. We continue to believe that because Congress added only one specific reference to services furnished outside the clinic to the statute in OBRA ‘87, it generally ratified our prior interpretation of the four walls requirement. Thus, we continue to believe that the statute authorizes neither broad exceptions to the four walls requirement that have no relationship to the current exception nor

²⁸⁵ CMS, *Further Extension of Grace Period Related to the “Four Walls” Requirement under 42 CFR 440.90 for Indian Health Service and Tribal Facilities to February 11, 2025*, CMCS Informational Bulletin, (Baltimore, MD, 2023), <https://www.medicaid.gov/sites/default/files/2023-09/cib090823.pdf>.

a complete elimination of the four walls requirement. However, we are now reinterpreting section 1905(a)(9) of the Act as permitting additional exceptions to the four walls requirements for populations served by clinics if those populations have similar health care access issues to individuals who are unhoused. When Congress added the exception to the statute, it introduced the exception with the word “including” (OBRA ’87). We interpret the word “including” in the statute as not precluding additional exceptions to the four walls requirement, so long as any additional exception is similar to the exception for individuals who are unhoused. Had Congress wanted to limit the clinic benefit to only services provided within the four walls and services provided outside the four walls to the unhoused, it could have written a narrower exception instead of using “including” as it did when adding the exception to section 1905(a)(9) of the Act. As discussed in the Congressional record for OBRA ’87 in H.R. Rep. 100–391, Congress amended section 1905(a)(9) of the Act to create an exception to the four walls requirement for individuals who are unhoused to address access concerns for a population that has unmet health needs, distrusts mainstream providers, and has difficulty accessing care when providers are unable to meet them where they are located.²⁸⁶ We believe that adding exceptions to the four walls requirement for populations with similar needs and barriers to access as individuals who are unhoused is consistent with the statutory text and purpose of the initial exception.

In developing the proposed exceptions, we considered the characteristics of the unhoused population that is targeted by the current statutory and regulatory exception. According to data from the Department of Housing and Urban Development (HUD), 21 percent of individuals who are unhoused reported having a serious mental illness while 16 percent reported having a substance use disorder.²⁸⁷ Individuals who are unhoused often lack transportation to access health care and cite this lack of transportation as a barrier to managing their health.^{288 289} In many cases,

individuals who are unhoused distrust providers due to perceptions of disrespect and discrimination.²⁹⁰ Individuals who are unhoused also experience much poorer health outcomes than those who are housed; for example, nearly two thirds of individuals who are unhoused experience clinically significant dental problems and are four times as likely to visit an emergency department.^{291 292} A recent study found that when controlling for demographic and geographic differences, an individual who is unhoused is three and one half times more likely to experience early mortality than an individual who is housed.²⁹³ As indicated earlier in this section of the proposed rule, we believe that providing additional exceptions to the clinic services four walls requirement for populations with similar needs and barriers to access as individuals who are unhoused is consistent with the statute.

The exceptions outlined in this proposed rule follow four criteria that mirror the needs and barriers to access experienced by individuals who are unhoused:

- The population experiences high rates of behavioral health diagnoses or difficulty accessing behavioral health services;
- The population experiences issues accessing services due to lack of transportation;
- The population experiences a historical mistrust of the health care system; and
- The population experiences high rates of poor health outcomes and mortality.

Yale, accessed March 15, 2024, <https://happy.sites.yale.edu/barriers-care>.

²⁸⁹ Murphy, Erin Roark. 2019. “Transportation and Homelessness: A Systematic Review.” *Journal of Social Distress and the Homeless* 28 (2): 1–10. <https://doi.org/10.1080/10530789.2019.1582202>.

²⁹⁰ Becker, Jenna N., and Karen J. Foli. 2021. “Health-Seeking Behaviours in the Homeless Population: A Concept Analysis.” *Health & Social Care in the Community* 30 (2). <https://doi.org/10.1111/hsc.13499>.

²⁹¹ Baggett, Travis P., James J. O’Connell, Daniel E. Singer, and Nancy A. Rigotti. 2010. “The Unmet Health Care Needs of Homeless Adults: A National Study.” *American Journal of Public Health* 100 (7): 1326–33. <https://doi.org/10.2105/ajph.2009.180109>.

²⁹² Lin, Wen-Chieh, Monica Bharel, Jianying Zhang, Elizabeth O’Connell, and Robin E. Clark. 2015. “Frequent Emergency Department Visits and Hospitalizations among Homeless People with Medicaid: Implications for Medicaid Expansion.” *American Journal of Public Health* 105 (S5): S716–22. <https://doi.org/10.2105/ajph.2015.302693>.

²⁹³ Logani, Ilina, Bruce Meyer, and Angela Wyse. 2023. *The Mortality of the US Homeless Population*. BF Becker Friedman Institute for Economics at UChicago. The University of Chicago. March 27, 2023. <https://bfi.uchicago.edu/insight/research-summary/the-mortality-of-the-us-homeless-population/>.

By authorizing additional clinic services to be furnished outside of the four walls, the proposed exceptions are expected to improve access to care for the populations targeted by the exceptions. The exceptions would authorize States to pay the facility-based clinic services payment rates (such as the AIR for IHS/Tribal clinics) for the excepted services. Currently, due to the four walls requirement, States can cover and pay for services that are provided by clinic personnel outside the four walls—but that do not fit within the exception at § 440.90(b)—only under Medicaid practitioner services benefits, such as physician services, rehabilitative services, or other licensed practitioner services—not under the clinic services benefit.

It is CMS’s understanding that State payment rates for these Medicaid practitioner services benefits are generally lower than the facility-based payment rates that States establish or adopt for Medicaid clinic services (such as the facility-based payment rate under the AIR, in the case of IHS/Tribal clinics), because the facility-based payment rates typically account for more overhead costs. While it is CMS’s understanding that States generally pay lower rates for Medicaid practitioner services than they do for Medicaid facility-based services, it should be noted that States generally have the flexibility to increase practitioner services payment rates. States must also comply with section 1902(a)(30)(A) of the Act, which requires States to assure that payments are consistent with efficiency, economy, and quality of care, and are sufficient to enlist enough providers so that care and services are available under the Medicaid State plan at least to the extent that such care and services are available to the general population in the geographic area.

Creating the exceptions could thus result in higher payments to providers for the excepted services. Studies of Medicaid payment rates have found that provider willingness to furnish services may be greater in States that pay providers at higher rates.^{294 295} Further, practitioners may be reluctant to

²⁹⁴ Candon, Molly, Stephen Zuckerman, Douglas Wissoker, Brendan Saloner, Genevieve M. Kenney, Karin Rhodes, and Daniel Polsky. 2018. “Declining Medicaid Fees and Primary Care Appointment Availability for New Medicaid Patients.” *JAMA Internal Medicine* 178 (1): 145. <https://doi.org/10.1001/jamainternmed.2017.6302>.

²⁹⁵ Holgash, Kayla, and Martha Heberlein. 2019. *Physician Acceptance of New Medicaid Patients: What Matters and What Doesn’t*. Health Affairs Blog (blog). April 19, 2019. <https://www.healthaffairs.org/content/forefront/physician-acceptance-new-medicare-patients-matters-and-doesn-t>.

²⁸⁶ H.R. Rep. No. 100–391, at 523 (1987), reprinted in 1987 U.S.C.C.A.N. 2313–1, 2313–343.

²⁸⁷ U.S. Department of Housing and Urban Development (HUD), *HUD 2022 Continuum of Care Homeless Assistance Programs Homeless Populations and Subpopulations*, Summary Report, (Washington, DC, 2022), https://files.hudexchange.info/reports/published/CoC_PopSub_NatTerrDC_2022.pdf.

²⁸⁸ Yale University, “Barrier to Care,” Hypertension Awareness & Prevention Program at

provide home-based care when paid under a professional fee schedule rate, since travel expenses and time are often not factored into the payment rate.²⁹⁶ As this evidence suggests, higher payment rates for services are more likely to incentivize providers to furnish those services. Because the proposal would authorize payment at the generally higher facility-based clinic services payment rates for the excepted services, we believe that it would incentivize providers to provide these services, and thereby meet these beneficiaries where they are located, which for reasons further discussed below, will help to ensure access to necessary care.

We considered whether this change in interpretation could burden States, beneficiaries, providers, or others who have relied on our current interpretation. Based on our current awareness of how States implement the Medicaid clinic services benefit, we do not anticipate that our proposal would create burdens for Medicaid clinic services providers or Medicaid beneficiaries, and we have considered the possible burden for State Medicaid programs in developing the proposal. We invite comments on whether our proposal might create any burdens for States, beneficiaries, providers, or other interested parties.

1. IHS/Tribal Clinics

In response to advice and input received through Tribal consultation, we propose to add a new paragraph (c) to § 440.90 to add an exception to the four walls requirement for IHS/Tribal clinics, to authorize payment for clinic services provided outside the four walls by IHS/Tribal clinic personnel. This exception would be mandatory for all States that opt to cover the Medicaid clinic services benefit. We refer in the proposed regulation text to clinics that are facilities of the IHS, whether operated by IHS or by a Tribe or Tribal organization as authorized by the ISDEAA, to make clear that this exception applies only to IHS/Tribal clinics. The proposed regulatory language identifying the facilities that would be subject to the exception is consistent with our longstanding interpretation of the language used in sections 1905(b) and 1911 of the Act, and would mean clinics that are owned and operated by IHS, clinics that are owned by IHS and Tribally-operated as

authorized by the ISDEAA, or clinics that are owned and operated by Tribes and Tribal organizations as authorized by the ISDEAA.²⁹⁷

Under section 1903(a)(1) of the Act, as discussed earlier, the Federal government is required to match State expenditures for medical assistance at the Federal Medical Assistance Percentage (FMAP), which is defined at section 1905(b) of the Act to be 100 percent for State expenditures for Medicaid-covered services received through an IHS facility whether operated by IHS or by a Tribe or Tribal organization (which, again, CMS has interpreted to refer to all three kinds of IHS/Tribal facilities described above). Under CMS's longstanding interpretation of section 1905(b) of the Act, this 100 percent FMAP is available only for State expenditures on services received through an IHS/Tribal facility (such as a clinic) by AI/AN Medicaid beneficiaries. State expenditures on services furnished by an IHS/Tribal facility to other Medicaid beneficiaries are not matched by the Federal government at 100 percent, but rather at the otherwise applicable FMAP, and this would continue to apply for services provided outside the four walls of a clinic.

We are not proposing to include facilities operated by urban Indian organizations (UIOs) in this proposed exception, because it is our understanding that many of those facilities currently participate in Medicaid as providers of the Medicaid FQHC services benefit, not as providers of the clinic services benefit. Because Medicaid FQHC services are not subject to a four walls requirement under Federal Medicaid law, we believe that UIOs are unlikely to need the proposed exception. UIO facilities that provide Medicaid clinic services might qualify as behavioral health clinics or clinics in rural areas and be exempt from the four walls requirement under one of the two optional exceptions discussed below.

This exception would apply to any Medicaid beneficiary who receives services from the IHS/Tribal clinic. Under IHS authorities, these clinics serve Medicaid beneficiaries who are eligible to receive services from the IHS/Tribal clinic under IHS regulations at 42 CFR part 136, and also may serve other Medicaid beneficiaries under 25 U.S.C. 1680c. As mentioned in section XVIII.A of this proposed rule, all services covered under the clinic services benefit must be furnished by or under the direction of a physician, so we propose to include language in this exception

specifying that services subject to the exception would have to be furnished under the direction of a physician to make that requirement clear.

We propose this exception based on advice and input received through Tribal consultation and because the population served by IHS/Tribal clinics, which is predominately AI/AN, tends to meet the criteria CMS has identified that warrant an exception from the four walls requirement (for example, high rates of behavioral health needs, lack of accessible transportation, mistrust of the health care system, and high rates of morbidity and poor health outcomes).

AI/ANs experience high rates of behavioral health diagnoses. In particular, the opioid crisis plaguing many communities is especially acute in Tribal communities.²⁹⁸ As reported by the Centers for Disease Control and Prevention (CDC), AI/ANs have the highest rate of drug overdose compared to other U.S. populations, and they experienced a 39 percent increase in overdoses between 2019 and 2020.²⁹⁹

Many AI/ANs also experience difficulties accessing services due to lack of transportation. Tribal lands encompass about 56 million acres nationwide, including 145,000 miles of roads.³⁰⁰ Roads in Tribal communities are typically rudimentary and in poor condition. For example, about 70 percent of Tribal roads across the country are unpaved compared to 45 percent of all rural roads.^{301 302} Because Tribal communities are often located in rural or remote areas covering vast distances, providers can be extremely far away from their patients. For example, it is common for AI/ANs to have to travel between 60 and 90 miles one-way for health care appointments.³⁰³ Many AI/ANs also do

²⁹⁸ Tipps, Robin T., Gregory T. Buzzard, and John A. McDougall. 2018. "The Opioid Epidemic in Indian Country." *The Journal of Law, Medicine & Ethics* 46 (2): 422–36. <https://doi.org/10.1177/1073110518782950>.

²⁹⁹ Centers for Disease Control and Prevention (CDC), "Drug Overdose Prevention in Tribal Communities," CDC, May 2, 2024, https://www.cdc.gov/overdose-prevention/health-equity/tribal-communities.html?CDC_AAref_Val=https://www.cdc.gov/drugoverdose/health-equity/tribal.html.

³⁰⁰ Congressional Research Service (CRS), *Highways and Highway Safety on Indian Lands*, CRS Report, (Washington, DC, 2016), https://www.everycrsreport.com/files/20160202_R44359_38af583fdef681edc7b5d4daeeeb5bc506a4f919.pdf.

³⁰¹ Id.

³⁰² CRS, *Rural Highways*, CRS Report, (Washington, DC, 2018), <https://crsreports.congress.gov/product/pdf/R/R45250>.

³⁰³ Government Accountability Office (GAO), *Indian Health Service: Health Care Services Are Not Always Available to Native Americans*, GAO–05–789, (Washington, DC, 2005), <https://www.gao.gov/assets/gao-05-789.pdf>.

²⁹⁶ Klein, Sarah, Martha Hostetter, and Douglas McCarthy. 2017. *An Overview of Home-Based Primary Care: Learning from the Field*. The Commonwealth Fund. The Commonwealth Fund. June 7, 2017. <https://www.commonwealthfund.org/publications/issue-briefs/2017/jun/overview-home-based-primary-care-learning-field>.

²⁹⁷ HCFA and IHS, Memorandum of Agreement.

not have reliable personal transportation. The rate of AI/ANs without a personal vehicle is more than double that of individuals in other rural areas.³⁰⁴ Per a recent CDC report, approximately 17.1 percent of AI/ANs lack reliable transportation, the highest rate compared to other U.S. populations, and this is a barrier to accessing health care.³⁰⁵ Many AI/ANs have a profound mistrust of the Federal government and mainstream providers based on trauma from a long history of harmful U.S. Tribal policies, such as removal of AI/ANs from homelands and Tribal community structures, bans on cultural practices and language, forced relocation to reservations, abusive boarding school practices, and other destructive policies. AI/AN health disparities are the visible, lingering result of these harmful policies.³⁰⁶

Furthermore, AI/ANs face poorer health outcomes than all other adults on average and have the lowest life expectancy compared to other U.S. populations. For example, AI/ANs have higher rates of obesity, heart disease, and diabetes than other adults in the U.S. population on average.³⁰⁷ The CDC's Provisional Life Expectancy Estimates for 2021 found a severe drop in life expectancy for AI/ANs—decreasing by 6.6 years from 2019 to 2021.³⁰⁸ Not only do AI/ANs, on average, die younger than all other Americans, but this disparity is worsening at an alarming rate. AI/AN life expectancy today is the same as it was for the average American in 1944.³⁰⁹

This evidence indicates that an exception to the four walls requirement

is warranted for IHS/Tribal clinics because the individuals served by these clinics are more likely than those in other groups to meet a higher number of the four criteria we described in this proposed rule. Through Tribal Consultation, Tribal leaders indicated that IHS/Tribal clinics need the flexibility to provide services to AI/ANs where they are located due to their high levels of behavioral health diagnoses, challenges accessing services due to lack of transportation and appropriate infrastructure, historic mistrust of the Federal government and the health care system, and poor health outcomes.

As explained below, we propose that behavioral health clinics and clinics in rural areas would serve as a proxy for their patient populations, instead of limiting the exception for behavioral health clinics to patients with behavioral health disorders or limiting the exception for clinics in rural areas to patients residing in rural areas. We proposed this approach because we believe that these clinics serve predominantly patients with behavioral health disorders or who live in rural areas (as applicable), and to reduce the operational burden of implementing these exceptions. Similar to the proposed exceptions for behavioral health clinics and clinics in rural areas, we are also proposing that the IHS/Tribal clinics would be a proxy for their patient population, but for somewhat different reasons. The operational burden that the proposed proxy approach would address for behavioral health clinics and clinics in rural areas would not be as much of an issue for IHS/Tribal clinics, because the entire patient population of an IHS/Tribal clinic is likely to meet some or all of the four criteria described in this proposed rule. For that same reason, a proxy approach would be appropriate for these clinics. These clinics serve a clearly identifiable group of Medicaid beneficiaries under IHS statutes and regulations: Medicaid beneficiaries whom IHS/Tribal clinics serve under 42 CFR part 136 or other Medicaid beneficiaries whom these clinics may serve under 25 U.S.C. 1680c. As discussed above, the population served by IHS/Tribal clinics, which is predominately AI/AN, is more likely than other groups to meet a higher number of the criteria identified in this proposed rule as warranting an exception.

2. Behavioral Health Clinics

We propose to add a new paragraph (d) to § 440.90 to authorize an exception to the four walls requirement for clinic services provided outside the four walls

by personnel of behavioral health clinics. This exception would not be mandatory in States that opt to cover the clinic services benefit but could be implemented as a State option.

Specifically, we propose an exception for clinics that are primarily organized for the care and treatment of outpatients with behavioral health disorders, including mental health disorders and substance use disorders. We note that this proposed exception would include any clinic services furnished outside of the four walls by a behavioral health clinic, including non-behavioral clinic services such as physical health services.

This proposed exception would include behavioral clinic types that are recognized nationally, such as Community Mental Health Centers, and other behavioral health clinics organized in a State. We recognize that the types of behavioral health clinics within a State may vary, so we are not proposing to limit this exception to specific types of behavioral health clinics. However, to be considered a behavioral health clinic under this proposed exception, the clinic would have to be primarily organized to treat outpatients with behavioral health disorders regardless of the patient mix of the clinic. For example, if a State has established separate licensure or certification requirements for mental health clinics and primary care clinics, under which primary care clinics are licensed to treat outpatients for a range of services beyond the treatment of behavioral health disorders, then we would consider a mental health clinic in that State to be primarily organized to treat outpatients with behavioral health disorders but would not consider a primary care clinic in that State to be primarily organized to treat such outpatients. We recognize that there may be other means by which a State determines that a clinic is primarily organized to treat outpatients with behavioral health disorders (that is, other than through licensure or certification), including behavioral health accreditation by accrediting organizations, such as The Joint Commission, or based on the organizing documents of the clinic, such as a business charter. If this proposal is finalized as described, States that choose to adopt this exception would describe the types of behavioral health clinics such exception applies to in their Medicaid State plan. Just like our proposed exception for IHS/Tribal clinics, we propose to include language in this exception specifying that services subject to the exception would

³⁰⁴ CRS, *Tribal Highway and Public Transportation Programs*, In Focus, (Washington, DC, 2022), <https://crsreports.congress.gov/product/pdf/IF/IF12129>.

³⁰⁵ CDC, National Center for Health Statistics (NCHS), *Lack of Reliable Transportation for Daily Living Among Adults: United States, 2022*, by Amanda E. Ng, Dzifa Adjaye-Gbewonyo, and James Dahlhamer, NCHS Data Brief No. 490, (Hyattsville, MD, 2024), <https://dx.doi.org/10.15620/cdc.135611>.

³⁰⁶ U.S. Commission Civil Rights, *Broken Promises: Continuing Federal Funding Shortfall for Native Americans*, Briefing Report, (Washington, DC, 2018), <https://www.usccr.gov/files/pubs/2018/12-20-Broken-Promises.pdf>.

³⁰⁷ MACPAC, *Medicaid's Role in Health Care for American Indians and Alaska Natives*, Issue Brief, (Washington, DC, 2021), <https://www.macpac.gov/wp-content/uploads/2021/02/Medicaids-Role-in-Health-Care-for-American-Indians-and-Alaska-Natives.pdf>.

³⁰⁸ CDC, NCHS, *Provisional Life Expectancy Estimates for 2021*, by Elizabeth Arias, Betzaida Tejada-Vera, Kenneth D. Kochanek, and Farida B. Ahmad, Vital Statistics Rapid Release Report No. 23, (Hyattsville, MD, 2022), <https://dx.doi.org/10.15620/cdc.118999>.

³⁰⁹ IHS, "Disparities," Indian Health Services, October 2019, <https://www.ihs.gov/newsroom/factsheets/disparities/>.

have to be furnished under the direction of a physician.

Per 2022 data from the Substance Abuse and Mental Health Services Administration (SAMHSA), approximately 94.7 percent of adults nationwide with a substance use disorder did not seek substance use treatment and nearly half of adults nationwide with a mental health disorder did not receive mental health treatment, which suggests that this population may have difficulty accessing behavioral health services.³¹⁰ Lack of transportation and geographic distance from behavioral health services are often cited in research as barriers to behavioral health treatment.³¹¹ One study of transportation-disadvantaged adults found that nearly half of adults nationwide who lacked medical transportation were diagnosed with depression or another mental health disorder.³¹² Studies have found that individuals with behavioral health disorders often report negative experiences with providers and stigmatizing attitudes from providers are common, which can lead to a mistrust of the health care system and forgone care.³¹³ Finally, research has found that individuals with a severe mental illness or substance use disorder experience worse health outcomes and increased risk of premature mortality, with one recent study finding individuals with a severe mental illness or substance use disorder experiencing a shorter life span than comparable individuals by an average of 6 years.³¹⁴

³¹⁰ Substance Abuse and Mental Health Services Administration (SAMHSA), *Key substance use and mental health indicators in the United States: Results from the 2022 National Survey on Drug Use and Health*, HHS Publication No. PEP23-07-01-006, NSDUH Series H-58, (Rockville, MD, 2023), <https://www.samhsa.gov/data/report/2022-nsduh-annual-national-report>.

³¹¹ Priester, Mary Ann, Teri Browne, Aidyn Iachini, Stephanie Clone, Dana DeHart, and Kristen D. Seay. 2016. "Treatment Access Barriers and Disparities among Individuals with Co-Occurring Mental Health and Substance Use Disorders: An Integrative Literature Review." *Journal of Substance Abuse Treatment* 61 (61): 47–59. <https://doi.org/10.1016/j.jsat.2015.09.006>.

³¹² Wallace, Richard J, Paul Hughes-Cromwick, Hillary J Mull, and Snehmay Khasnabis. 2005. "Access to Health Care and Nonemergency Medical Transportation: Two Missing Links." *Transportation Research Record* 1924 (January): 76–84. <https://doi.org/10.3141/1924-10>.

³¹³ Knaak, Stephanie, Ed Mantler, and Andrew Szeto. 2017. "Mental Illness-Related Stigma in Healthcare." *Healthcare Management Forum* 30 (2): 111–16. <https://doi.org/10.1177/0840470416679413>.

³¹⁴ Iturralde, Esti, Natalie Slama, Andrea H. Kline-Simon, Kelly C. Young-Wolff, Don Mordecai, and Stacy A. Sterling. 2021. "Premature Mortality Associated with Severe Mental Illness or Substance Use Disorder in an Integrated Health Care System." *General Hospital Psychiatry* 68 (January): 1–6.

State-specific circumstances may affect the degree to which a State's population of individuals with behavioral health disorders meets the four criteria described in this proposed rule. The Health Resources and Services Administration (HRSA), in coordination with State primary care offices, designates as Health Professional Shortage Areas (HPSAs)³¹⁵ areas experiencing a shortage in primary care, dental care, or mental health care providers for a whole geographic area, a specific population within a geographic area, and facilities that serve these areas. HRSA publishes data for each State on the percent of need met for primary care, dental care, and mental health providers, with a lower percentage indicating a lower availability of providers. It should be noted that the types of mental health providers counted in HPSAs are set in regulation, and based on the regulations, HRSA allows State Primary Care Offices to choose whether to count: psychiatrists only, core mental health professionals (psychiatrists, clinical psychologists, clinical social workers, psychiatric nurse specialists, and marriage and family therapists), or a combination of all types. As of December 31, 2023, there is significant variation among States in the percent of need met for mental health care, with a low of 9 percent and a high of 63 percent.³¹⁶ This variation in availability of mental health care providers may suggest that populations of individuals with behavioral health disorders in some States may have greater difficulty accessing behavioral health services or accessing transportation to a behavioral health provider than those populations in other States. There may also be significant variability between States with regard to behavioral health outcomes and mortality. For example, in 2021 the age-adjusted drug overdose mortality rate by State had significant variation, from a low of 11 per 100,000 to a high of 90 per 100,000.³¹⁷ These differences between populations of individuals with behavioral health disorders in different States may suggest

<https://doi.org/10.1016/j.genhosppsych.2020.11.002>.

³¹⁵ Health Resources & Services Administration (HRSA), "What is Shortage Designation?" HRSA Health Workforce, June 2023, <https://bhw.hrsa.gov/workforce-shortage-areas/shortage-designation>.

³¹⁶ HRSA, Designated Health Professional Shortage Areas Statistics, Designated HPSA Quarterly Summary, (Rockville, MD, 2024), <https://data.hrsa.gov/Default/GenerateHPSAQuarterlyReport>.

³¹⁷ CDC, NCHS, "Drug Overdose Mortality by State," CDC, March 1, 2022, https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm.

that the degree to which a State's population of individuals with behavioral health disorders meets the four criteria may be variable.

This evidence indicates that an exception to the clinic services four walls requirement could be warranted, based on State-specific circumstances, for clinics that are primarily organized for the care and treatment of outpatients with a behavioral health disorder, as these clinics might primarily serve a patient population that may be more likely than other groups to meet more of the four criteria we described in this proposed rule. The evidence also suggests that this patient population is less likely to meet as many of the criteria as consistently nationwide as patients served by IHS/Tribal clinics. Under the proposal, a State could determine that individuals with a behavioral health disorder in that State should be engaged by behavioral health clinic personnel where they are located due to their challenges accessing services, including lack of transportation and geographic distance from services, historic mistrust and stigmatization in the health care system, and poor health outcomes.

We considered proposing that, to qualify for this proposed exception, clinic services would have to be provided specifically to individuals with a behavioral health disorder, in addition to being provided by personnel of a behavioral health clinic. However, we believe that such a requirement would be too operationally burdensome and that instead behavioral health clinics can serve as a proxy for a population that generally consists of individuals with a behavioral health disorder. We recognize there may be circumstances in which a behavioral health clinic furnishes services to an individual who does not have a behavioral health disorder, but it is our understanding that behavioral health clinics generally serve a patient population that consists primarily of individuals with behavioral health disorders (including individuals with a formal behavioral health disorder diagnosis and those with an undiagnosed behavioral health disorder). Thus, these clinics can serve as a proxy for a patient population that is more likely to have such a disorder—and thus, that includes people who are more likely to meet more of the four criteria. In addition, we believe that requiring clinics or States to verify that a clinic patient has a behavioral health disorder and to deny coverage of Medicaid clinic services provided outside the four walls if the patient does not, would be too operationally

burdensome. For example, an individual might experience or present their behavioral health symptoms in an uncommon way, an individual might be misdiagnosed, or an individual might be experiencing a crisis where services are needed urgently and verifying that they have a behavioral health disorder might delay needed care. Because we believe that behavioral health clinics can serve as a proxy for individuals with behavioral health disorders, and because we do not want to make this exception too operationally burdensome, we are not proposing that to qualify for the proposed exception, clinic services must be provided by a behavioral health clinic specifically to an individual with a behavioral health disorder.

3. Clinics Located in Rural Areas

We propose to add a new paragraph (e) to § 440.90 to authorize an exception to the four walls requirement for clinic services provided outside the four walls by personnel of clinics located in rural areas, but that are not RHCs as referenced in section 1905(a)(2)(B) of the Act and § 440.20(b). This exception would not be mandatory in States that opt to cover the clinic services benefit, but could be implemented at State option. Just like our proposed exception for IHS/Tribal clinics and behavioral health clinics, we propose to include language in this exception specifying that services subject to the exception would have to be under the direction of a physician.

Per SAMHSA data, rates of mental illness and substance use disorders are similar in rural and urban areas.³¹⁸ However, individuals in rural areas with a mental illness or substance use disorder are less likely to receive treatment than individuals in urban areas due to more limited access to providers, as rural areas are more likely to lack trained and specialized behavioral health providers.³¹⁹ For example, in 2021 the number of psychologists per 100,000 people in rural counties was less than half of the number in urban counties.³²⁰ A recent

study found that rural individuals on average are 22 percent less likely than urban individuals to utilize primary and specialty clinic services.³²¹ Studies have found that lack of transportation and distance to providers is a common barrier to rural individuals accessing health care services.³²² Furthermore, a recent Government Accountability Office (GAO) report found that rural individuals need to travel 40 miles on average to access specialty services.³²³ With regards to mistrust of the health care system, research has found that rural individuals have historically mistrusted the health care at higher rates, and that some of this mistrust comes from a perception that the health care system prioritizes urban communities over rural communities.³²⁴ Per the CDC, rural individuals are at greater risk of poor health outcomes as they tend to be older and sicker than urban individuals.³²⁵ Finally, according to a CDC National Center for Health Statistics (NCHS) study, age-adjusted mortality rates are higher for rural individuals, with the mortality gap increasing since 1999 between rural and urban individuals.³²⁶

State-specific circumstances may affect the degree to which a State's population of individuals in rural areas meets the four criteria described in this proposed rule. A study found that 21 percent of adults without access to a vehicle or public transit reported skipping needed medical care compared to only 9 percent who did not own a vehicle but had access to public transit.³²⁷ According to a Federal

Highway Administration publication, just under 90 percent of passenger trips in rural areas occur in personal vehicles.³²⁸ For the rural individuals who lack access to a personal vehicle, public transit is generally less available, with an approximate 40 percent of rural individuals living in an area without public transit.³²⁹ However, some States establish rural public transit systems that guarantee service coverage to all residents.³³⁰ This variation between States in their rural populations' access to public transit may suggest that the degree to which a State's rural population is able to access transportation to medical services may differ from State to State. There may also be significant variability between States with regards to health outcomes and mortality. For example, a CDC report found that the percentage of excess mortality from heart disease in rural counties varied significantly between States in the northeast and the south with a 13 percent excess rate for the northeast States and 56 percent for the southern States.³³¹ These differences between State populations of individuals in rural areas may suggest that the degree to which a State's rural population meets the four criteria may be variable.

The evidence indicates that an exception to the clinic services four walls requirement could be warranted, based on State-specific circumstances, for services furnished by clinics located in rural areas that are not RHCs, as these clinics might primarily serve a patient population that may be more likely than other groups to meet more of the four criteria we identified in this proposed rule. The evidence also suggests that this patient population is less likely to meet as many of the criteria as

Five Adults with Limited Public Transit Access Forgo Health Care Because of Transportation Barriers," Robert Wood Johnson Foundation, April 26, 2023, <https://www.rwjf.org/en/insights/our-research/2023/04/more-than-one-in-five-adults-with-limited-public-transit-access-forgo-healthcare-because-of-transportation-barriers.html>.

³²⁸ U.S. Department of Transportation (DOT), Federal Highway Administration (FHWA), *Chapter 11: Rural America, Status of the Nation's Highways, Bridges, and Transit Conditions and Performance Report*, 24th Edition (Washington, DC, 2021), <https://www.fhwa.dot.gov/policy/24cpr/pdf/Chapter11.pdf>.

³²⁹ Id.

³³⁰ Id.

³³¹ CDC, *Potentially Excess Deaths from the Five Leading Cause of Death in Metropolitan and Nonmetropolitan Counties—United States, 2010–2017*, by Macarena C. Garcia, Lauren M. Rossen, Brigham Bastian, Mark Faul, Nicole F. Dowling, Cheryl C. Thomas, Linda Schieb, Yuling Hong, Paula W. Yoon, and Michael F. Iademarco, *Morbidity and Mortality Weekly Report* Vol. 68, No. 10, (Atlanta, GA, 2019), <https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6810a1-H.pdf>.

³¹⁸ SAMHSA, "2022 NSDUH Detailed Tables," SAMHSA, November 13, 2023, <https://www.samhsa.gov/data/report/2022-nsduh-detailed-tables>.

³¹⁹ Morales, Dawn A., Crystal L. Barksdale, and Andrea C. Beckel-Mitchener. 2020. "A Call to Action to Address Rural Mental Health Disparities." *Journal of Clinical and Translational Science* 4 (5): 1–20. <https://doi.org/10.1017/cts.2020.42>.

³²⁰ WWAMI Rural Health Research Center, University of Washington. *Changes in the Supply and Rural-Urban Distribution of Psychologists in the U.S., 2014–2021*. 2022. https://familymedicine.uw.edu/rhrc/wp-content/uploads/sites/4/2022/10/RHRC_DBOCT2022_PSYCHOLOGIST_Andrilla.pdf.

³²¹ Nuako, Akua, Jingxia Liu, Giang Pham, Nina Smock, Aimee James, Timothy Baker, Laura Bierut, Graham Colditz, and Li-Shiun Chen. 2022. "Quantifying Rural Disparity in Healthcare Utilization in the United States: Analysis of a Large Midwestern Healthcare System." Edited by Nickolas D. Zaller. *PLOS ONE* 17 (2): e0263718. <https://doi.org/10.1371/journal.pone.0263718>.

³²² Arcury, Thomas A., John S. Preisser, Wilbert M. Gesler, and James M. Powers. 2005. "Access to Transportation and Health Care Utilization in a Rural Region." *The Journal of Rural Health* 21 (1): 31–38. <https://doi.org/10.1111/j.1748-0361.2005.tb00059.x>.

³²³ GAO, *Rural Hospital Closures*, GAO–21–93, (Washington, DC, 2020), <https://www.gao.gov/assets/gao-21-93.pdf>.

³²⁴ Lister, Jamey J., and Paul J. Joudrey. 2022. "Rural Mistrust of Public Health Interventions in the United States: A Call for Taking the Long View to Improve Adoption." *The Journal of Rural Health* 39 (1): 18–20. <https://doi.org/10.1111/jrh.12684>.

³²⁵ CDC, "About Rural Health," CDC, May 16, 2024, https://www.cdc.gov/rural-health/php/about/?CDC_AAref_Val=https://www.cdc.gov/ruralhealth/about.html.

³²⁶ CDC, NCHS, *Trends in death rates in urban and rural areas: United States, 1999–2019*, by Sally C. Curtin and Merianne Rose Spencer, NCHS Data Brief No. 417, (Hyattsville, MD, 2021), <https://dx.doi.org/10.15620/cdc:109049>.

³²⁷ Smith, Laura Berrie, Michael Karpman, Dulce Gonzalez, and Sarah Morriss, "More than One in

consistently nationwide as patients served by IHS/Tribal clinics. Under the proposal, a State could determine that individuals who reside in rural areas in that State should be engaged where they are located by personnel of a clinic located in a rural area, due to their challenges accessing behavioral health services, overall health care access challenges stemming from lack of transportation and distance from providers, historic mistrust of the health care system, and poor health outcomes. We note that clinics located in rural areas providing optional services as authorized under sections 1902(a)(10) and 1905(a)(9) of the Act and 42 CFR 440.90 are distinct from RHCs providing mandatory services as authorized under sections 1902(a)(10) and 1905(a)(2)(B) of the Act and 42 CFR 440.20(b). RHC services are a separate Medicaid benefit provided by a type of facility that is referenced in section 1905(a)(2)(B) of the Act and 42 CFR 440.20(b), and a four walls requirement does not apply to that benefit under Federal Medicaid law.

We considered proposing that, to qualify for this proposed exception, clinic services would have to be provided specifically to individuals who reside in rural areas, in addition to being provided by personnel of a clinic located in a rural area. However, we believe clinics located in rural areas can serve as a proxy for a population that generally consists of individuals who reside in rural areas, and that such a requirement would be too operationally burdensome. We recognize there may be circumstances in which a clinic located in a rural area furnishes services to an individual who does not reside in a rural area, but it is our understanding that clinics located in rural areas generally serve a patient population that consists primarily of individuals who reside in rural areas. Thus, these clinics can serve as a proxy for a patient population that is more likely to reside in a rural area—and thus, that includes people who are more likely to meet more of the four criteria. In addition, we believe that requiring clinics or States to verify that a clinic patient lives in a rural area, and to deny coverage of Medicaid clinic services provided outside the four walls if the patient does not, would be too operationally burdensome. For example, an individual's address might change frequently, an individual might refuse to provide their address, or the clinic might be located in a rural area that borders a non-rural area. Because we believe that clinics located in rural areas can serve as a proxy for individuals who

reside in rural areas, and because we do not want to make this exception too operationally burdensome, we are not proposing that to qualify for the proposed exception, clinic services must be provided by a clinic located in a rural area specifically to an individual who resides in a rural area.

We have not included a definition of “rural” in proposed rule text, but are considering defining that term in the final rule and are considering various approaches to doing so, on which we seek comment. There are many Federal and State definitions of rural for various programs, and no single definition precisely identifies all rural areas. The Rural Health Information Hub provides a non-official tool that could be used to help identify if a specific location is considered a rural location based on various definitions.³³² Some rural definitions may categorize areas that are generally recognized as suburban as rural, while other definitions may classify sparsely populated remote areas as urban. For example, the population residing in rural areas identified by a more limited rural definition may more closely meet more of the four criteria identified in this proposed rule than the population residing in rural areas identified under a broader definition. Definitions of rural adopted and used by Federal governmental agencies for programmatic purposes include the definition used by the Census Bureau, the definition used by the Office of Management and Budget (OMB), and the definition used by HRSA's Federal Office of Rural Health Policy (FORHP).^{333 334} In addition, we believe that State-level variations may also affect whether certain ways of defining rural are appropriate in specific States. States may have their own definitions of rural under State law or regulation for various programmatic purposes, such as definitions adopted by State primary care offices or State Offices of Rural Health.

Under any definition of rural, the specific areas identified as rural may change over time and that would have a direct impact on the scope of clinics

eligible for this proposed four walls exception. For example, areas identified as rural under the Census definition may change after the decennial census, which may result in some clinics no longer being located in rural areas under that updated definition.

We considered the following approaches to defining rural: adopting one of the commonly used definitions of rural adopted by the Federal governmental agencies referenced above, permitting a State to adopt a definition of rural that is adopted and used by a Federal governmental agency for programmatic purposes, permitting a State to adopt a definition of rural that is adopted and used by a State governmental agency with a role in setting State rural health policy, or not adopting any definition of rural.

We note that the research, data, and reports cited earlier in this section do not all use the same definition of rural, and for four of the citations it is unclear what definition of rural was used. The SAMHSA data, the study on primary and specialty care utilization, and NCHS study use the OMB definition while the CDC health outcomes research uses the Census Bureau definition and the GAO report uses the FORHP definition of rural.

If we adopt a Federal definition, we would finalize in rulemaking that for the purposes of this exception rural is defined as the definition of rural adopted or used by the Census Bureau, OMB, or FORHP (we would adopt only one of these definitions). The benefits to adopting a Federal definition include that the definition would be consistent for all States electing to implement the exception and all clinics located in rural areas in such States. However, if we adopted a specific Federal definition of rural then States could not consider the variation in which their rural populations under different rural definitions meet the four criteria we describe in this proposed rule. In addition, CMS does not directly control any of these Federal definitions, so if we adopt a specific Federal definition then future rulemaking might be necessary to align our rule with another Federal agency's changes to that Federal definition.

The Census Bureau does not specifically define rural but considers any area that is not urban as rural. An urban area must meet certain density standards and contain at least 2,000 housing units or at least 5,000 people. There are 2,644 urban areas defined by the Census Bureau following the 2020 Census. Over 80 percent of the Census-defined urban areas (2,134 urban areas) have populations of less than 50,000

³³² “Am I Rural?—Tool,” Rural Health Information Hub, accessed May 7, 2024, <https://www.ruralhealthinfo.org/am-i-rural>. This tool is not official and should not be relied upon as a formal Federal determination that a location is rural.

³³³ HRSA, “Defining Rural Population,” Health Resources & Services Administration, January 2024, <https://www.hrsa.gov/rural-health/about-us/what-is-rural>.

³³⁴ Response to Comments on Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants, 86 FR 2418 (January 12, 2021). See, <https://www.federalregister.gov/documents/2021/01/12/2021-00443/response-to-comments-on-revised-geographic-eligibility-for-federal-office-of-rural-health-policy>.

people while the remaining 19 percent (510 urban areas) have populations of 50,000 people or more.³³⁵ Following the 2020 Census, the Census Bureau does not sub-categorize urban areas as Urbanized Areas or Urban Clusters.³³⁶ If we adopted the Census Bureau definition, then we would finalize in rulemaking that a rural area is defined as an area identified by the Census Bureau in “Urban Area Criteria for the 2020 Census-Final Criteria,” 87 FR 16706 as not being an urban area. The advantage to the Census Bureau definition of rural is that it is a widely recognized definition, which may make it an easier definition to implement for purposes of an exception to the clinic services four walls requirement, if this proposed rule is finalized. A disadvantage to the Census Bureau definition is that the Census Bureau’s urban area boundaries do not follow other administrative units, such as county or municipality borders, and may be complex to operationalize. The Census Bureau provides TIGERweb Decennial online mapping tools for urban area boundaries at <https://tigerweb.geo.census.gov/> that may be helpful for interested parties considering what it would mean for CMS to finalize a rule that defines rural according to the U.S. Census Bureau’s definition. The CDC research on health outcomes we cite elsewhere in this section used the Census Bureau definition, which demonstrates that this definition can be linked to the four criteria described in this proposed rule. However, the Census Bureau definition is broad, and some policy experts point out that the definition classifies many suburban areas as rural while also classifying towns and small cities with populations of less than 50,000 people as non-rural.³³⁷

OMB also does not specifically define rural, but designates areas as metropolitan, micropolitan, or neither (also known as noncore).³³⁸ A

metropolitan area consists of an urban core of 50,000 or more individuals, a micropolitan area consists of an urban core of 10,000 to 49,999 individuals, and all other areas are considered neither. Areas that are micropolitan or neither are considered rural while metropolitan areas are considered urban.³³⁹ If we adopted the OMB definition, then we would finalize in regulation text that a rural area is defined as an area not identified as metropolitan by OMB, as described in “2020 Standards for Delineating Core Based Statistical Areas,” 86 FR 37770. Like the Census Bureau definition of rural, the OMB definition is a widely recognized definition that may be an easier definition to implement for purposes of an exception to the clinic services four walls requirement, if this proposed rule is finalized. For example, the study on primary and specialty care utilization and the NCHS study on mortality we cite elsewhere in this section use the OMB definition, which demonstrates that this definition can be linked to the four criteria described in this proposed rule. In addition, the NCHS Urban-Rural Classification Scheme for Counties follows the OMB definition of rural and is widely used in health research.³⁴⁰ However, the OMB definition is considered by some policy experts to be too narrow as areas OMB defines as metropolitan include areas that are often considered to be rural, like for example the Grand Canyon.³⁴¹

The last Federal definition of rural we are considering is the FORHP definition, which consists of all non-metropolitan counties, all metropolitan census tracts with Rural-Urban Commuting Area (RUCA) codes four through ten, large area census tracts of at least 400 square miles in area with population density of 35 or less per square mile with RUCA codes two to three, and all outlying metropolitan counties without an Urbanized Area.³⁴² 343 If we adopted the FORHP definition, then we would finalize in regulation text that a rural area is defined as an area identified as rural by FORHP, as described in “Response to Comments on Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants,” 86 FR 2418. We recognize that the FORHP

definition uses terminology that has not yet been updated to align with the latest Census Bureau terminology, that is, FORHP currently refers to urbanized area, but we are still considering the FORHP definition, as is, based on its wide use and the benefits described in this paragraph. We note that FORHP is proposing to update the FORHP definition to incorporate the U.S. Department of Agriculture’s Economic Research Service (ERS) Road Ruggedness Scale (RRS) measure of rugged terrain into the existing definition, specifically for census tracts of at least 20 square miles in area in metro counties with RRS 5 and RUCA code 2 or 3. In addition, if finalized, the update will align the FORHP definition’s use of Census Bureau terminology with the current Census Bureau definition.³⁴⁴ If this proposed update to the FORHP definition is finalized, we would then consider the updated FORHP definition for the final rule over the existing FORHP definition. The advantage to the FORHP definition is that it is more precise, as it is narrower than the Census Bureau definition and broader than the OMB definition. In addition, as described elsewhere in this section, the GAO report that identified rural individuals needing to travel 40 miles on average to access specialty care used the FORHP definition in effect at the time of the report, which demonstrates that this definition can be linked to the four criteria we describe in this proposed rule. However, some have criticized the FORHP definition for excluding some areas that used to be considered rural while others consider the definition to be too expansive.³⁴⁵

Instead of specifying a uniform definition of rural nationwide for this exception, we are also considering allowing States to adopt a definition of rural that has been adopted by a Federal governmental agency. If we permit States to adopt a definition of rural that is adopted by a Federal governmental agency for programmatic purposes, then we would finalize in regulation text that a rural area is defined by the State based upon a reasonable definition adopted by a Federal governmental agency for programmatic purposes. We would not specifically list out the Federal

³³⁵ Census Bureau, “Urban and Rural,” United States Census Bureau, September 2023, <https://www.census.gov/programs-surveys/geography/guidance/geo-areas/urban-rural.html>.

³³⁶ Urban Area Criteria for the 2020 Census-Final Criteria, 87 FR 16706 (Mar. 24, 2022). See, <https://www.federalregister.gov/documents/2022/03/24/2022-06180/urban-area-criteria-for-the-2020-census-final-criteria>.

³³⁷ Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants, 85 FR 59806 (Oct. 23, 2020). See, <https://www.federalregister.gov/documents/2020/09/23/2020-20971/revised-geographic-eligibility-for-federal-office-of-rural-health-policy-grants>.

³³⁸ 2020 Standards for Delineating Core Based Statistical Areas, 86 FR 37770 (July 16, 2021). See, <https://www.federalregister.gov/documents/2021/07/16/2021-15159/2020-standards-for-delineating-core-based-statistical-areas>.

³³⁹ HRSA, Defining Rural Population.

³⁴⁰ CDC, NCHS, “NCHS Urban-Rural Classification Scheme for Counties,” CDC, June 1, 2017, https://www.cdc.gov/nchs/data_access/urban_rural.htm.

³⁴¹ Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants, 85 FR 59806 (Oct. 23, 2020).

³⁴² Response to Comments on Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants, 86 FR 2418 (January 12, 2021).

³⁴³ HRSA, Defining Rural Population.

³⁴⁴ Proposed Inclusion of Terrain Factors in the Definition of Rural Area for Federal Office of Rural Health Policy Grants, 89 FR 32451 (April 26, 2024). See, <https://www.federalregister.gov/documents/2024/04/26/2024-08931/proposed-inclusion-of-terrain-factors-in-the-definition-of-rural-area-for-federal-office-of-rural>.

³⁴⁵ Response to Comments on Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants, 86 FR 2418 (January 12, 2021).

definitions of rural that we consider reasonable in the regulation text. In addition to the Census, OMB, and FORHP definitions, we would consider rural definitions developed by the U.S. Department of Agriculture's Economic Research Service (ERS) to be reasonable definitions for a State to select if we adopt this option in the final rule (this would include RUCAs, Rural-Urban Continuum Codes, Urban-Influence Codes, and Frontier and Remote Area Codes).³⁴⁶ We did not consider adopting any of the ERS definitions as one of the Federal definitions we are considering (as described above) because it is our understanding that the ERS definitions are less commonly used on their own (that is, not in conjunction with other Federal definitions) in identifying rural areas in health care. However, the ERS definitions could be used by States if we opt to permit States to identify a Federal definition. While we do not believe that any of the ERS definitions should be adopted as one definition for all States to follow, if we provide States with the flexibility to adopt a Federal definition, then we want to ensure that we are not too prescriptive in the definitions they may choose from. It is possible that a State could determine that one of the ERS definitions better captures the population of rural individuals that meets the four criteria described in this proposed rule. Under such an approach, States that elect this exception would identify the specific Federal definition of rural (that is, Census Bureau, OMB, FORHP definition, or one of the ERS definitions) they are adopting in their State plan and attest that the selected definition best captures the population of rural individuals that meets more of the four criteria described in this proposed rule. The benefits to this approach include that each State can consider which Federal definition of rural best captures the population of rural individuals that meet more of the four criteria described in this proposed rule for that State (and States would attest to this in their State plan), while also being required to adopt a rural definition commonly accepted as a legitimate definition for programmatic purposes at the national level. Requiring the State to attest that the selected Federal definition best captures the population of rural individuals that meets more of the four criteria would help to ensure that there is an explanation for any variations in the definitions selected by

different states. However, even if the variations in the definitions chosen by different States can be explained, it might burden or cause confusion for some beneficiaries if the States that elect this exception have different definitions of rural. For example, a beneficiary that moves from a State that has adopted this exception with a broader definition of rural to another State that has adopted the exception but has a narrower definition of rural might lose access to clinic services provided outside of the four walls. In addition, if we finalize this proposal, clinics that operate in different States that have adopted this exception might find it confusing or burdensome to track each such State's definition of rural.

If we permit States to adopt a definition of rural that is adopted by a State governmental agency with a role in setting State rural health policy, then we would finalize in regulation text that a rural area is defined by the State based upon a rural definition adopted by a State governmental agency with a role in setting State rural health policy. Under such an approach, a State that elects this exception would describe in its State plan the specific definition of rural that it is adopting, attest that this definition has been adopted by a State governmental agency with a role in setting State rural health policy (such as a State primary care office or State Office of Rural Health), and attest that the selected definition best captures the population of rural individuals that meets more of the four criteria described in this proposal. The benefits to this approach include that States may consider a State definition of rural that best identifies the population of rural individuals that meet more of the four criteria described in this proposed rule, and attest to in their State plan that the definition does so. Requiring the State to attest that the selected definition best captures the population of rural individuals that meets more of the four criteria would help to ensure that there is an explanation for any variations in the definitions selected by different States. In addition, under this approach to defining rural, the State would adopt a rural definition commonly accepted and used to manage State programs, which thus may be a more familiar definition to providers and be easier for a State to implement since that definition is also used for other health policy purposes in that State. However, even if the variations in the definitions chosen by different States can be explained, it might burden or cause confusion for some beneficiaries if the States that elect this exception have

different definitions of rural. For example, a beneficiary that moves from a State that has adopted this exception with a broader definition of rural to another State that has adopted the exception but has a narrower definition of rural may lose access to clinic services provided outside of the four walls. In addition, if we finalize this proposal, clinics that operate in different States that have adopted this exception might find it confusing or burdensome to track each such State's definition of rural.

Finally, if we choose not to define rural in the final rule, then we would finalize proposed regulation text with no definition of rural. Under this approach, a State that elects this exception would choose any definition of rural that can be linked to the four criteria we describe in this proposed rule and meets its program needs, but would not identify the definition in the State plan or submit it to CMS for review and approval. We would require and finalize in rule text that the State would publish its rural definition on a website maintained by the State that is accessible to the public. The benefits to not adopting a definition of rural under the final rule would include that States can consider which definition of rural best captures the population of rural individuals that meets more of the four criteria described in this proposed rule. This approach also recognizes that States may have the best information and data to determine the definition of rural that best meets their operational needs. However, under this approach CMS would not be reviewing State definitions of rural, and a State might adopt a definition of rural that could be considered to be overly broad or overly narrow. For example, a State might adopt a definition of rural that encompasses large urban areas, such as a populous city. As we stated earlier in this section of the proposed rule, we are aware that there are many definitions of rural, so the other approaches we are considering could potentially leave out reasonable definitions of rural, although we are not currently aware of any such reasonable definitions. We invite comment on which approach to defining rural we should adopt if the rule is finalized.

4. Additional Four Walls Considerations

We propose that the proposed exception to the four walls requirement for IHS/Tribal clinics would be a mandatory component of the clinic services benefit for States electing to cover that benefit. We propose that the proposed exceptions for behavioral health clinics and clinics located in

³⁴⁶ U.S. Department of Agriculture (USDA), Economic Research Services (ERS), "Rural Classifications," USDA, September 8, 2023, <https://www.ers.usda.gov/topics/rural-economy-population/rural-classifications/>.

rural areas would be optional for States covering that benefit. In addition, we propose to codify in regulation text our longstanding interpretation (discussed in section XVIII.A of this proposed rule) that existing § 440.90(a) and (b) are mandatory components of the clinic services benefit for States that elect to cover that benefit. Finally, we propose to delete the word “eligible” from existing regulation text at § 440.90(b) because there is no Federal authority for States to provide Medicaid-covered services to individuals who are ineligible for Medicaid, so we believe it is unnecessary to specify that the individuals who would receive services under this exception are eligible.

We propose to make the exception for IHS/Tribal clinics mandatory because the population served by IHS/Tribal clinics more consistently meets the four criteria described above, both within and across States, than the populations targeted by the optional exceptions, especially given the degree of State variability in whether the populations targeted by the optional exceptions meet those criteria. Further, Medicaid is the largest source of third-party payment for services billed by IHS facilities, accounting for nearly two-thirds of health coverage payments to these facilities.³⁴⁷ Given the significant role of Medicaid as a payer for IHS/Tribal clinic services, any reduction in the Medicaid payments IHS/Tribal clinics receive for services (such as a reduction in payment from the AIR to a professional services rate for services furnished outside the four walls by the clinic) might uniquely burden IHS/Tribal clinics. These clinics might need to curtail their available services, or no longer provide services outside the four walls, which could significantly impede their ability to serve their patients. For these reasons, we propose a mandatory exception to the clinic services four walls requirement for IHS/Tribal clinics.

In contrast to the exception for IHS/Tribal clinics, we believe that the exceptions for behavioral health clinics and clinics located in rural areas should be optional because there may be geographic variability in the degree to which the populations served by these clinics meet the four criteria we described above, and thus there may be State-specific variation in the degree to which these populations have the four

characteristics described in this proposed rule. For example, the populations served by behavioral health clinics and clinics located in rural areas may not as consistently face transportation challenges nationwide, to the extent that Tribal populations do. In addition, it is our understanding that Medicaid funding is less often the largest source of payment for behavioral health clinics and clinics located in rural areas, compared to IHS/Tribal clinics. We believe it best to let each State assess the degree to which these two exceptions might be warranted based on the State’s specific circumstances. In making this assessment, each State should consider the degree to which individuals located in rural areas of the State and/or individuals with behavioral health disorders in the State meet the four criteria described in this proposed rule. We solicit comment on the arguments made in this proposed rule in support of the mandatory and optional exceptions, and on whether the optional exceptions should also be mandatory for States opting to cover the clinic services benefit.

If we finalize this proposed rule as proposed, then upon the effective date of the final rule, services qualifying for the exception for IHS/Tribal clinics must be paid for as Medicaid clinic services in States that opt to cover that benefit. Accordingly, we would require States that cover the clinic services benefit to submit a State plan amendment (SPA), as applicable, to attest to coverage of IHS/Tribal clinic services under the exception. Similarly, if we finalize this proposed rule as proposed, then no earlier than the effective date of a SPA or SPAs implementing one or both of the optional exceptions, services provided outside the four walls under the exceptions may be paid for as Medicaid clinic services. Under any of the exceptions, the excepted services could be paid for using a facility-based Medicaid clinic services payment methodology, which for most IHS/Tribal clinics is the AIR.

We are not proposing any additional exceptions to the clinic services four walls requirement. It is our understanding that other populations are better able than those targeted by the proposed exceptions to access services through Medicaid benefits to which a four walls requirement does not apply under Federal Medicaid law (for example, FQHC services, RHC services, outpatient hospital services, etc.). As described in section XVIII.A of this proposed rule, States have considerable discretion regarding the types of clinics

they opt to cover under the clinic services benefit. There are no specific Federal Medicaid credentialing requirements, such as licensure or certification, for providers of the Medicaid clinic services benefit like there are for other Medicaid facility State plan benefits, such as hospitals and nursing facilities. This leads to considerable variability in the types of clinics providing services that a State may cover under the clinic services benefit. We invite comment on whether there are additional populations that are likely to meet the four criteria described in this proposed rule and that have no alternative access to services through Medicaid benefits not subject to a four walls requirement under Federal Medicaid law, and on whether there are additional types of clinics that might serve as a proxy for such a population.

XIX. Changes to the Review Timeframes for the Hospital Outpatient Department (OPD) Prior Authorization Process

The CMS Interoperability and Prior Authorization final rule (89 FR 8758) (Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children’s Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program) creates, improves, or shortens prior authorization timeframes for certain payers such as Medicare Advantage organizations and applicable integrated plans, CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities to respond to prior authorization requests for covered items and services, excluding drugs (89 FR 8878). The final rule requires impacted payers (excluding Qualified Health Plan issuers on the Federally-Facilitated Exchanges) to send prior authorization decisions as expeditiously as the enrollee’s health condition requires or as the beneficiary’s health condition requires but no later than 72 hours for expedited (that is, urgent) requests and 7 calendar days for standard (that is, non-urgent) requests.

As part of the CY 2020 OPPI/ASC final rule with comment period (84 FR 61446 through 61456), CMS established a nationwide prior authorization

³⁴⁷ Assistant Secretary of Planning and Evaluation (ASPE), *How Increased Funding Can Advance the Mission of the Indian Health Service to Improve Health Outcomes for American Indians and Alaska Natives*, Report No. HP–2022–21, (Washington, DC, 2022), <https://aspe.hhs.gov/sites/default/files/documents/1b5d32824c31e113a2df43170c45ac15/aspe-ihs-funding-disparities-report.pdf>.

process and requirements for certain OPD services. OPD providers must submit to the Medicare Administrative Contractor (MAC) a prior authorization request for any service on the list of outpatient department services that require prior authorization. CMS currently requires prior authorization for the following services: blepharoplasty, rhinoplasty, botulinum toxin injections, panniculectomy, vein ablation, cervical fusion with disc removal, implanted spinal neurostimulators, and facet joint interventions. Upon receipt of the prior authorization request, the MAC should review it and issue a decision within specific timeframes, which are listed in the regulation text at § 419.82(d)(1)(iii) and § 419.82(d)(2). These timeframes ensure providers receive timely responses and beneficiaries get appropriate care. While Medicare FFS is not an impacted payer under the CMS Interoperability and Prior Authorization final rule, we propose to align our Medicare FFS prior authorization review timeframe for standard review requests for hospital outpatient department services with the timeframe in this final rule. This change would not only streamline the prior authorization processes so that they are the same across payers but would also help to reduce provider burden by having the same timeframe and reducing the potential for delays in care by decreasing the time beneficiaries and providers wait for prior authorization decisions on standard requests in FFS Medicare. We propose to change the current review timeframe for provisionally affirmed or non-affirmed standard review requests for these services from 10-business days to 7-calendar days in § 419.82(d)(1)(iii). For example, if a standard request is submitted on a Tuesday, June 2, under the new timeframe, a decision must be rendered by the next Monday, June 8, whereas under the old timeframe, the decision must be rendered by Monday, June 15.

We are still considering the impact of aligning our expedited review decision timeframe with the expedited review decision timeframe in the CMS Interoperability and Prior Authorization final rule because, depending on when the expedited request is submitted, it may take longer for OPD provider to receive a decision using the 72-hour timeframe than our current expedited timeframe of 2-business days. The goal of changing the standard review timeframe is not only to align the timeframe across the prior authorization programs but also to reduce the time

beneficiaries wait to access the care they need. Since changing the expedited review decision timeframe from 2-business days to 72 hours would not reduce beneficiaries' wait time in all circumstances, we are not proposing to conform that timeframe with the one in the CMS Interoperability and Prior Authorization final rule at this time, but we may address this issue in future rulemaking.

XX. Provisions Related to Medicaid and the Children's Health Insurance Program (CHIP)

A. Continuous Eligibility in Medicaid and CHIP (42 CFR 435.926 and 457.342)

Continuous eligibility (CE) provides important coverage protections for low-income children who are eligible for Medicaid or CHIP. Research indicates that children who are disenrolled from coverage for all or part of a year are more likely to have fair or poor health status compared to children who have health coverage continuously throughout the year.³⁴⁸ CE, in those States that have adopted it, has shown to reduce financial barriers to accessing health care for low-income families, promote health equity, and provide States with better tools to hold health plans (where applicable) accountable for quality care and improved health outcomes.³⁴⁹ CE policies may also be beneficial to States, as they may result in reduced administrative burden on State agencies associated with repeated eligibility reviews and re-enrollments following a gap in coverage.³⁵⁰

Prior to January 1, 2024, States had the option to provide up to 12 months of continuous coverage to children under age 19 enrolled in Medicaid or CHIP, regardless of changes in circumstances that otherwise would impact their eligibility for these programs. This option has been available to State Medicaid programs under section 1902(e)(12) of the Act and Federal regulations at § 435.926 and to States' separate CHIP programs through Federal regulations at § 457.342. Under

this option, States had the option to elect an age limit under age 19 and/or CE periods shorter than 12 months. However, except for the limited exceptions defined in the regulations, states could not terminate the coverage of children during a CE period.

Section 5112 of Title V, subtitle B of the Consolidated Appropriations Act, 2023 (CAA, 2023) amended section 1902(e)(12) of the Act to make the previously optional CE policy a requirement under the state plan or waiver of the state plan for children enrolled in Medicaid. The CAA, 2023 also added a new paragraph (K) to section 2107(e)(1) of the Act, incorporating by reference Medicaid's CE policy into CHIP. Thus, effective January 1, 2024, States are required to provide a 12-month period of CE that offers continuous coverage to children under the age of 19 in Medicaid and CHIP, with limited exceptions.

The existing Medicaid continuous eligibility regulation includes three exceptions that were unaffected by the CAA, 2023, and that would not be altered by this proposed rule. These exceptions permit States to terminate coverage for children during a CE period if the child or child's representative requests a voluntary termination of eligibility; the agency determines that eligibility was erroneously granted at the most recent determination, redetermination, or renewal of eligibility because of agency error or fraud, abuse, or perjury attributed to the child or the child's representative; or the child is deceased. The CAA, 2023 amended section 1902(e)(12) of the Act to make the CE option mandatory for state Medicaid programs, but it did not foreclose these existing exceptions that CMS had already promulgated pursuant to section 1902(e)(12), which are important to maintain program integrity. We described our intention to retain these exceptions in CMS State Health Official (SHO) Letter #23-004, Section 5112 Requirement for all States to Provide Continuous Eligibility to Children in Medicaid and CHIP under the Consolidated Appropriations Act, 2023, which was issued on September 29, 2023. We do not propose any changes to these exceptions in this proposed rule.

We propose to update the Medicaid regulations at § 435.926 to conform to changes to the CE policy effectuated by the CAA, 2023 amendments to section 1902(e)(12) of the Act, which are incorporated by cross reference into the CHIP regulations at § 457.342(a). Specifically, as required by section 5112 of the CAA, 2023, and under our authority under section 2101(a) of the

³⁴⁸ Brantley, E., & Ku, L. (2022). Continuous eligibility for Medicaid associated with improved child health outcomes. *Medical Care Research and Review*, 79(3), 404–413.

³⁴⁹ Park, E., Alker, J., & Corcoran, A. (2020). Jeopardizing a Sound Investment: Why Short-Term Cuts to Medicaid Coverage During Pregnancy and Childhood Could Result in Long-Term Harm. Retrieved from: <https://www.commonwealthfund.org/publications/issue-briefs/2020/dec/short-term-cuts-medicare-long-term-harm>.

³⁵⁰ Georgetown University. (2021). Advancing Health Equity for Children and Adults with a Critical Tool: Medicaid and Children's Health Insurance Program Continuous Coverage. Retrieved from <https://ccf.georgetown.edu/wp-content/uploads/2021/10/continuity-of-coverage-final.pdf>.

Act to “initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner,” and at section 2107(e)(1)(K) of the Act (cross-referencing section 1902(e)(12) of the Act as amended by CAA, 2023 relating to continuous eligibility), we propose to revise § 435.926(b) to specify that a state must provide CE for the specified period. We also propose to revise § 435.926(b)(1) to remove the option to limit CE to an age younger than 19. We further propose to revise § 435.926(c)(1) to remove the option to limit CE to a period of time of less than 12 months. Finally, we propose to revise § 435.926(d)(1) to remove the option of ending a CE period for a person when they reach the state-specified maximum age, as now all States must provide CE to children until they reach age 19.

Prior to January 1, 2024, States also had the option under § 457.342(b) to disenroll children from a separate CHIP for failure to pay required premiums or enrollment fees required under the state plan, subject to the disenrollment protections afforded under section 2103(e)(3)(C) of the Act (related to premium grace periods) and § 457.570 (related to other disenrollment protections). The CAA, 2023, changed the statutory authority for the CE period in the CHIP statute, requiring that CE “shall” apply to CHIP “in the same manner” as it does to Medicaid. The Medicaid continuous eligibility regulation at § 435.926 never contained an exception permitting States to terminate coverage for failure to pay premiums or enrollment fees, so after the CAA, 2023, the CHIP CE period also could not contain this exception.

Therefore, under the above-mentioned authority in section 2101(a) of the Act to enable States to provide child health assistance in an effective and efficient manner and in section 2107(e)(1) of the Act as amended by CAA, 2023 relating to continuous eligibility, we propose to remove the option in § 457.342(b) to disenroll children from separate CHIP coverage for failure to pay required premiums or enrollment fees during a continuous eligibility period. This change will not preclude States from disenrolling children with an unpaid premium balance at the end of their 12-month CE period, provided the state has followed the premium grace period requirements of section 2103(e)(3)(C) of the Act. Under section 2103(e)(3)(C)(ii) of the Act, the State must provide the child with a grace period of “at least 30 days from the beginning of a new coverage period to make premium payments before the individual’s coverage” may be terminated. Section

2103(e)(3)(C)(ii)(II) of the Act defines “new coverage period” as “the month immediately following the last month for which the premium has been paid.” If a child does not pay a premium in a given month during the CE period, the grace period extends from that month until the 12-month CE period expires. Section 2103(e)(3)(C)(ii) of the Act also requires the State to provide notice no later than 7 days after the first day of the grace period (typically 7 days after the premium payment was due) that failure to make a premium payment within the grace period will result in termination of coverage and when such termination will be effective.

Although current paragraph (b) of § 457.342, which includes a reference to enrollment fees, would be eliminated, the collection of enrollment fees, as referenced in §§ 457.10 and 457.510, would remain an option to States. States would maintain the option to require payment of an enrollment fee prior to initial enrollment. States will also continue to have the option to require payment of the first month’s premium prior to enrolling a child who is determined eligible at application and to require payment of the first month’s premium or re-enrollment fee prior to re-enrolling a child into a new CE period, if the child is determined eligible at renewal.

XXI. Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals

A. Background and Statutory Authority

CMS has broad statutory authority to establish health and safety regulations, which includes the authority to establish requirements that protect the health and safety of pregnant, postpartum, and birthing patients. Several statutes applicable to specific provider and supplier types explicitly give CMS the authority to enact regulations that the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in an institution, while others give CMS the authority to prescribe regulations as may be necessary to carry out the administration of the program.

Sections 1861(e)(1) through (8) of the Social Security Act (the Act) provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861(e)(9) of the Act specifies that a hospital also must meet such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals furnished services in the institution. Under this

authority, the Secretary has established regulatory requirements that a hospital must meet to participate in Medicare at 42 CFR part 482, Conditions of Participation (CoPs) for Hospitals. Section 1905(a) of the Act provides that Medicaid payments from States may be applied to hospital services. Under regulations at 42 CFR 440.10(a)(3)(iii) and 42 CFR 440.20(a)(3)(ii), hospitals are required to meet the Medicare CoPs in order to participate in Medicaid.

Sections 1820 and 1861(mm) of the Act, as amended by section 4201 of the Balanced Budget Act (BBA) of 1997, replaced the EACH/RPCH program with the Medicare Rural Hospital Flexibility Program (MRHFP), under which a qualifying facility can be designated and certified as a critical access hospital (CAH). CAHs participating in the MRHFP must meet the conditions for designation specified in the statute under section 1820(c)(2)(B) of the Act, and to be certified must also meet other criteria the Secretary may require, under section 1820(e)(3) of the Act. Under this authority, the Secretary has established regulatory requirements that a CAH must meet to participate in Medicare at 42 CFR part 485, subpart F.

The CoPs for hospitals and CAHs are organized according to the types of services a hospital or CAH may offer, and include specific, process-oriented requirements for each hospital or CAH service or department. The purposes of these CoPs are to protect patient health and safety and to ensure that quality care is furnished to all patients in Medicare-participating hospitals and CAHs. In accordance with Section 1864 of the Act, State surveyors assess hospital and CAH compliance with the conditions as part of the process of determining whether a hospital qualifies for a provider agreement under Medicare. However, under section 1865 of the Act, hospitals and CAHs can elect to be reviewed instead by private accrediting organizations approved by CMS as having standards that meet or exceed the applicable Medicare standards and survey procedures comparable to those CMS requires for State survey agencies.

1. The U.S. Maternal Health Crisis

The U.S. is currently facing a maternal health crisis which has not only led to a maternal mortality rate that is amongst the highest in high-income countries, but also disproportionately affects racial and ethnic minorities. In 2022, the most recent year for which there is data, there were 22 maternal deaths for every 100,000 live births in the U.S. which is more than double the rate for most other high-income

countries. For example, in 2022, Canada, France, the United Kingdom, Germany, and Japan had maternal death rates of 8.6 deaths per 100,000 live births or lower.³⁵¹ In the U.S. in 2021, 1,205 women were identified as having died while pregnant or within 42 days after pregnancy ended. In 2022, 817 women were identified as having died in this manner.^{352 353} Over 80 percent of pregnancy-related deaths are considered preventable.³⁵⁴ Approximately 13 percent of all pregnancy-related deaths (deaths during and up to one year after pregnancy) occur at the time of delivery, and nearly 12 percent occur between 1 and 6 days after the end of pregnancy.

Native Hawaiian and Pacific Islander women, Black women, and American Indian/Alaska Native (AI/AN) women are two to four times more likely to suffer a pregnancy-related death than non-Hispanic White women.³⁵⁵ Black and AI/AN women experience severe maternal morbidity rates that are more than two times higher than their White counterparts.^{356 357} Systemic societal barriers, including a patient's social determinants of health, have meant that these individuals experience a greater share of these poor maternal health outcomes.^{358 359 360}

Pregnant women who live in rural communities face a higher risk for severe maternal morbidity and have about 60 percent higher risk of

pregnancy-related deaths and are more likely to die before, during, or the year after delivery than those living in urban settings.^{361 362} Pregnant women with disabilities receive lower quality maternity care, experience a higher risk of pregnancy and birth-related complications, and are eleven times more likely to experience maternal death than people without disabilities.^{363 364}

2. Efforts To Improve Maternal Health

CMS has undertaken various efforts to improve the state of maternal health care. In 2023, CMS launched the first ever "Birthing-Friendly" designation icon on CMS' Care Compare online tool.³⁶⁵ To earn the designation, hospitals and health systems report their progress on our Maternal Morbidity Structural Measure to the Hospital Inpatient Quality Reporting (IQR) Program. The measure determines whether a hospital or health system has participated in a Statewide or national perinatal quality improvement collaborative program and implemented evidence-based quality interventions in hospital settings to improve maternal health, such as maternal safety bundles. Maternal safety bundles have demonstrated success in driving improvements, particularly with regards to obstetric hemorrhage, severe hypertension in pregnancy, and nonmedically indicated Cesarean deliveries.^{366 367 368} Hospitals and health

professionals also have access to evidence-based best practices for determining the risk of obstetric hemorrhage and hypertension and for managing patients with these complications (including in an emergency setting). However, these best practices are not universally utilized nor incorporated into facilities' standards of care.³⁶⁹

We also published the quality, safety, and oversight memorandum (QSO-22-05—Hospitals) which encourages hospitals to consider the implementation of evidence-based best practices for the management of obstetric emergencies, along with interventions to address other key contributors to maternal health disparities, and to support the delivery of equitable, high-quality care for all pregnant and postpartum individuals.³⁷⁰ Facilities can implement these best practices voluntarily as part of a hospital's QAPI program (§ 482.21), which requires that hospitals develop, implement, and maintain an effective, ongoing, hospital wide, data-driven quality assessment and performance improvement program.

We have taken several steps to better understand the impacts of the maternal health crisis and the potential need for revisions to the CoPs to protect the health and safety of pregnant and postpartum women. In the FY 2023 IPPS/LTCH PPS final rule, we published responses to a maternal health RFI that solicited feedback on a wide range of maternal health issues and opportunities for CMS to improve maternal health care (87 FR 49290 through 49292). Some commenters were concerned that failure to comply with any new CoP could result in the loss of Medicare certification and that access to obstetrical care would be negatively impacted, potentially exacerbating rates of maternal morbidity/mortality and disparities in obstetrical care. Other commenters supported the creation of a CoP specifically for labor and delivery, to establish minimum health and safety standards across participating hospitals.

We conducted a literature review on maternal health with a focus on obstetric (OB) services delivery, staff training, and best practices for maternal health and safety to help inform the proposals in this rule. We also held a

statewide quality improvement. *Am J Obstet Gynecol* 2018; 218:S4.

³⁶⁹ Jennifer A. Callaghan-Koru et al. Implementation of the Safe Reduction of Primary Cesarean Births safety bundle during the first year of a statewide collaborative in Maryland. *Obstet Gynecol* 2019; 134:109–19.

³⁷⁰ <https://www.cms.gov/files/document/qso-22-05-hospitals.pdf>.

³⁵¹ Munira Gunja et al., Insights into the U.S. Maternal Mortality Crisis: An International Comparison (Commonwealth Fund, June 2024). <https://doi.org/10.26099/cthn-st75>.

³⁵² <https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2022/maternal-mortality-rates-2022.pdf>.

³⁵³ <https://stacks.cdc.gov/view/cdc/103855>.

³⁵⁴ <https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/data-mmrc.html>.

³⁵⁵ <https://www.cms.gov/files/document/maternal-health-may-2022.pdf>.

³⁵⁶ Centers for Disease Control and Prevention. Pregnancy Mortality Surveillance System. Available at: <https://www.cdc.gov/maternal-mortality/php/pregnancy-mortality-surveillance/index.html>. Accessed June 5th, 2024.

³⁵⁷ <https://www.commonwealthfund.org/publications/issue-briefs/2021/oct/severe-maternal-morbidity-united-states-primer#:~:text=Approximately%20140%20of%2010%20000%20women,severe%20maternal%20morbidity%20every%20year.>

³⁵⁸ <https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf>.

³⁵⁹ Taylor, J., Novoa, C., Hamm, K., & Phadke, S. (2021, December 3). Eliminating Racial Disparities in Maternal and Infant Mortality. Center for American Progress. <https://www.americanprogress.org/article/eliminating-racial-disparities-maternal-infant-mortality/>.

³⁶⁰ Hoffman, K.M., Trawalter, S., Axt, J.R., Oliver, M.N. Racial bias in pain assessment and treatment recommendations, and false beliefs about biological differences between blacks and whites. *Proc. Natl. Acad. Sci. U.S.A.* 2016;113(16):4296–4301. doi:10.1073/pnas.1516047113 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4843483/>.

³⁶¹ White House Fact Sheet: Vice President Kamala Harris Announces Call to Action to Reduce Maternal Mortality and Morbidity. <https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/07/fact-sheet-vice-president-kamala-harris-announces-call-to-action-to-reduce-maternal-mortality-and-morbidity/>.

³⁶² Kozhimannil, K.B., Interrante, J.D., Henning-Smith, C., & Admon, L.K. (2019). Rural-urban differences in severe maternal morbidity and mortality in the US, 2007–15. *Health affairs*, 38(12), 2077–2085. Available at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2019.00805>.

³⁶³ Gleason, J.L., Grewal, J., Chen, Z., Cernich, A.N., Grantz, K.L., Risk of Adverse Maternal Outcomes in Pregnant Women With Disabilities. *JAMA Netw. Open.* 2021;4(12):e2138414. doi:10.1001/jamanetworkopen.2021.38414.

³⁶⁴ Willi Horner-Johnson et al., Perinatal Health Risks and Outcomes Among U.S. Women With Self-Reported Disability, 41 *Health Aff.* 2011 (September, 2022), <https://doi.org/10.1377/hlthaff.2022.00497>.

³⁶⁵ <https://data.cms.gov/provider-data/birthing-friendly-hospitals-and-health-systems>.

³⁶⁶ Jennifer A. Callaghan-Koru et al. Implementation of the Safe Reduction of Primary Cesarean Births safety bundle during the first year of a statewide collaborative in Maryland. *Obstet Gynecol* 2019; 134:109–19.

³⁶⁷ Elliott K. Main et al. Reduction of severe maternal morbidity from hemorrhage using a state perinatal quality collaborative. *Am J Obstet Gynecol* 2017;216(3); 298.e1–298.e11.

³⁶⁸ Patricia Lee King et al. Reducing time to treatment for severe maternal hypertension through

series of listening sessions with industry stakeholders, patient advocacy groups, and health care professionals on ways the CoPs can be revised to improve maternal health care outcomes and reduce disparities. We received valuable feedback from stakeholders regarding establishing an OB services CoP, staff training and the importance of providing culturally competent care. Some groups also highlighted the value of recommendations from Maternal Mortality Review Committees (MMRCs). Other stakeholders cautioned on being overly specific (that is, certain diseases) in the CoPs and encouraged CMS to instead leverage existing regulations text or quality metrics rather than create new CoPs.

Finally, we issued a request for information (RFI) in the FY 2025 Inpatient Prospective Payment System (IPPS) proposed rule (89 FR 36498 through 36502) to gather stakeholder feedback on several options for establishing an obstetrical services CoP for participating hospitals, CAHs, and rural emergency hospitals (REHs) and other detailed questions.

Request for Information on Obstetrical Services Standards for Hospitals, CAHs, and REHs: Summary and Responses to Public Comments

In May 2024, we published a Request for Information (RFI) on Obstetrical Services Standards for hospitals, CAHs, and REHs in the FY 2024 Hospital IPPS proposed rule (89 FR 35934). We solicited public comments on developing targeted baseline health and safety standards for obstetrical services. We received comments from a variety of parties interested in addressing obstetrical care including advocacy groups, industry associations, state health departments, labor unions, and professional organizations. Commenters supportive of CoPs for obstetrical care services noted that establishing CoPs for obstetrical care would enhance the quality and safety of maternal care and provide the opportunity to standardize services across various healthcare settings. These commenters also stated that obstetrical services CoPs regarding organization and staffing would promote multidisciplinary, team-based care with specialists, such as cardiologists, maternal fetal medicine practitioners, primary care physicians, and adult congenital heart disease specialists, among others providing care to pregnant women. Other commenters stated that establishing obstetrical training standards for hospital/CAH non-OB units can help to mitigate the impact of OB unit closures on maternal health outcomes and also supported

staff training on respectful care, cultural competency, trauma-informed care, and nondiscrimination. Some commenters supported requiring facilities to report directly to the Maternal Mortality Review Committee (MMRC) and others supported specific transfer protocol requirements.

Other commenters expressed concerns regarding establishing CoPs for obstetrical care services for a variety of reasons including the current regulatory environment related to obstetrical and gynecological services, conflicting regulations between the State and Federal requirements, insufficient clinical evidence, impact on access, regulatory burden, accelerating closures, potential redundancy with CMS' quality measurement programs, severity of consequences for not meeting CoP requirements, and unintended consequences. One commenter stated that existing CoPs provide adequate protection for patients and was concerned that more requirements specific to obstetrical services may lead to overlapping, conflicting or otherwise confusing requirements that may negatively impact care, while others believed that an obstetrical services CoP would not address the main drivers of maternal morbidity and mortality.

After analyzing the issue of high rates of maternal mortality and morbidity in the U.S. receiving feedback from various stakeholders on improving maternal health care, and reviewing available resources and current requirements, we believe that it is necessary to establish new requirements for the provision of obstetrical services to protect the health and safety of pregnant, birthing, and post-partum patients. Currently, there are no baseline care requirements for hospitals and CAHs that are specific to maternal-child services (that is, labor and delivery, prenatal and post-partum care, and care for newborn infants, alternately referred to in this discussion as obstetrical services, obstetrics, maternal health, or maternity care). In addition to obstetrical units, care for pregnant and postpartum patients may also occur in other parts of facilities such as other inpatient units, emergency departments, hospital outpatient departments, as well as in facilities without obstetrical units and/or emergency services. Such care may occur before, during, or after delivery. Based on the issues regarding the delivery of maternity care referenced, we propose a new OB services CoP, including proposed requirements for the organization, staffing, and delivery of OB services and staff training. We also propose revisions to the current hospital and CAH QAPI, hospital and CAH

emergency services requirements, and hospital discharge planning requirements specific to OB services. We also solicit comments on whether these proposed requirements should also apply to REHs.

B. Provisions of the Proposed Regulations

1. Organization, Staffing, and Delivery of Services (§ 482.59 and § 485.649)

a. Background

The Hospital CoPs at 42 CFR 482.51 through 482.58 include requirements for optional services that hospitals are not required by law to provide but may elect to offer to their patients. If a hospital provides an optional service to its patients, the hospital must comply with the requirements of the CoP specific to that service. The hospital CoPs include requirements for optional services such as surgery (§ 482.51), anesthesia (§ 482.52), outpatient services (§ 482.54), emergency services (§ 482.55), and other health care services. CAHs may also opt to provide certain services to its patients. CoPs for the provision of optional CAH services such as surgeries, inpatient psychiatric services, and inpatient rehabilitation services have been established at § 485.639, § 485.647(a)(1) and § 485.647(a)(2), respectively. Outside of an emergency department (ED), hospitals and CAHs may also offer obstetrical services to their patients. Currently, there are no baseline requirements for the organization, staffing, and delivery of such OB services in hospitals and CAHs.

Several accrediting bodies and professional medical specialty societies including the American College of Obstetricians and Gynecologists (ACOG), the Society for Maternal-Fetal Medicine (SMFM), and The Center for Improvement in Healthcare Quality (CIHQ), have discussed recommendations for standards of practice for OB staffing and organization within a hospital care setting. For example, ACOG and SMFM have developed a system that defines four different levels of maternal care that range from least complex care to the most complex care and they have recommended the obstetrical care providers and services, as well as the capabilities and equipment, that should be available at each level based on the patient's need.³⁷¹ They recommend that an OB-GYN physician be present onsite 24 hours a day, 7 days a week (24/7),

³⁷¹ <https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2019/08/levels-of-maternal-care>.

within the two highest facility levels that can treat complex maternal medical conditions (levels III and IV). Within a level II facility, which can treat moderate-to-high-risk maternal medical conditions, ACOG and SMFM suggest that such facility retain a family physician with an OB fellowship or equivalent training can be present in place of an OB-GYN physician. Lastly, they recommend a certified nurse-midwife (CNM), certified midwife (CM), or family physician accompanied by a qualified registered nurse (RN) should be present 24/7 within the lowest level facility that provides basic care for low-risk, uncomplicated conditions (level I).³⁷² ACOG and SMFM also recommend appropriately trained and qualified RNs, along with a formally trained nursing leadership team with maternal care experience for hospitals and CAHs providing maternal care.³⁷³

CIHQ has recommended that an OB-GYN physician with advanced cardiovascular life support and neonatal resuscitation training should always be present at a facility providing emergency OB services.³⁷⁴ They also recommend that OB services be organized to allow for effective communication, collaboration, and coordination of care between the emergency services program and inpatient maternal/child services.³⁷⁵

We understand that State law regarding OB staffing varies, and some States have enacted laws and regulations regarding OB services organizational standards and require levels of maternal care designation. We believe that proposing standards for obstetrical services ensures that all Medicare and Medicaid participating hospitals and CAHs that offer these services are held to a consistent set of requirements, supports high-quality maternity care and protects the health and safety of patients. Therefore, we believe it is necessary to propose CoPs specific to obstetrical services for hospital and CAH CoPs, similar to the current requirements for optional services provided in these facilities.

b. Proposals

We propose at new sections § 482.59 and § 485.649 new CoPs for hospitals and CAHs offering obstetrical services outside of an ED. Specifically, we propose to require that if a hospital or

CAH offers obstetrical services, the services must be well organized and provided in accordance with nationally recognized acceptable standards of practice for physical and behavioral (inclusive of both mental health and substance use disorders) health care of pregnant, birthing, and postpartum patients. If outpatient obstetrical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered. Nationally recognized acceptable standards of practice may be based on medical professional society and/or accrediting organization standards. While these CoPs would not require adherence to a specific organization's guideline or recommendations, we expect that facilities would be able to articulate their standards and the source(s) and to demonstrate that their standards are based on evidence and nationally recognized sources. This overarching requirement for obstetric services is consistent with other hospital and CAH CoPs and is foundational to ensuring high-quality safe care.

At new subsections § 482.59(a) and § 485.649(a), we further propose that the organization of the obstetrical services be appropriate to the scope of services offered by the facility and integrated with other departments of the facility. For example, in order to provide high quality and safe care, a labor and delivery unit needs to ensure good communication and collaboration with services such as laboratory, surgical services, and anesthesia services as applicable. At § 482.59(a)(1) and § 485.649(a)(1), we propose that the OB patient care units (that is, labor rooms, delivery rooms, including rooms for operative delivery, and post-partum/recovery rooms whether combined or separate) be supervised by an individual with the necessary education and training, and specify that that person should be an experienced registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a doctor of medicine or osteopathy. This individual is typically responsible for a variety of activities important to patient safety, such as overseeing staff, training, overall patient care, and supporting communications within the unit and across the facility. Given the importance of the role, ensuring appropriate training and education is imperative.

At § 482.59(a)(2) and § 485.649(a)(2), we propose that obstetrical privileges be delineated for all practitioners providing obstetrical care in accordance with the competencies of each practitioner. The obstetrical service must maintain a roster of practitioners

specifying the privileges of each practitioner. While a variety of practitioners may deliver a wide range of obstetric services and perform a wide range of procedures, not every practitioner can provide all services nor perform every procedure. All hospitals are already required, at § 482.22(c)(6), to have medical staff bylaws that include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. This process ensures that practitioners have the necessary education, training, and experience to provide safe, effective care and safely perform specific procedures. This proposed CoP provides additional specificity for an obstetrics service. Such an approach is consistent with existing hospital optional services CoPs, such as surgical services at § 482.51(a)(4) and, given existing requirements, adds little additional burden. The proposed obstetric services CoPs at § 482.59(a)(2) and § 485.649(a)(2) also recognize that practitioners other than physicians are important to delivering obstetric services and we considered them when developing these provisions. We remind hospitals that existing CoPs allow for the privileging and credentialing of practitioners other than physicians, including nurse midwives (§ 482.12(a) and (c); § 482.22). Specifically, the hospital regulations at § 482.12(c) permit licensed practitioners (for example, nurse practitioners, nurse midwives, etc.), as allowed by the State, to admit patients to a hospital. CMS does not require that these practitioners be employed by, under the supervision of, or associated with, a Doctor of Medicine (MD) or doctor of osteopathic medicine (DO) unless required by State law, regulations, or facility policy. A hospital is not precluded from credentialing and granting privileges to practitioners not listed under § 482.12(c)(1). Additionally, if not otherwise prohibited by State law, a hospital may elect to include these practitioners (such as advanced practice providers, including advanced practice registered nurses, clinical nurse specialists, physician assistants, and nurse midwives) as part of their medical staff. Moreover, the hospital CoPs prohibit a hospital from granting staff membership or professional privileges in the hospital solely upon certification, fellowship, or membership in a specialty body or society. (§ 482.12(a)(7)). In States that permit nurse midwives to admit patients (in accordance with hospital policy and practitioner privileges), per statute

³⁷² <https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2019/08/levels-of-maternal-care>.

³⁷³ <https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2019/08/levels-of-maternal-care>.

³⁷⁴ <https://cihq.org/acc-default-hospitals.asp>.

³⁷⁵ <https://cihq.org/acc-default-hospitals.asp>.

(section 1861(e)(4) of the Act) CMS requires only Medicare patients of a nurse midwife to be under the care of an MD or DO (§ 482.12(c)(2)). CMS does not require Medicaid nor other non-Medicare patients admitted by a nurse midwife to be under the care of an MD or DO.³⁷⁶ For CAHs, CMS does not have the authority to remove the physician oversight requirement for inpatients at § 485.631(b)(1)(iv), as this is a statutory requirement and the physician oversight requirement for outpatients at § 485.631(b)(1)(v) is only applicable if required by State law.

At new subsections § 482.59(b) and § 485.649(b), “Delivery of services”, we propose to require that OB services must be consistent with the needs and resources of the facility. Policies governing obstetrical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care and safety. We additionally propose at paragraphs § 482.59 (b)(1) and § 485.649(b)(1) that labor and delivery room suites have certain basic resuscitation equipment readily available, including a call-in-system, cardiac monitor, and fetal doppler or monitor. We believe a basic set of equipment should be in place for all obstetric services to ensure efficient, effective delivery of care as well as timely response to emergency situations. However, we recognize that different facilities offer different levels of service. We welcome public comment on what is an appropriate minimum set of equipment for all hospitals offering obstetric services.

Furthermore, at § 482.59 (b)(2) and § 485.649(b)(2) we propose that the service ensure that it has protocols, consistent with evidence-based, nationally recognized guidelines, as well as readily available provisions (that is, necessary supplies and equipment on the unit or in close proximity and easily accessed by unit personnel) for obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the facility’s QAPI program. While this requirement does not require any specific items, we would expect provisions to include equipment, in addition to the equipment required under § 482.59 (b)(1) and § 485.649(b)(1), supplies, blood, and medication used in treating emergency cases. Examples of such emergency equipment or supplies could

include: resuscitator, defibrillator, aspirator, and airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, nasogastric tubes, IV therapy supplies, suction machine, and defibrillator. Emergency medications could include analgesics, local anesthetics, anti-arrhythmics, cardiac glycosides, antihypertensives, antiepileptics, uterotonics, anticoagulants, antifibrinolytics, electrolytes and replacement solutions. As discussed in section XXI.B.2 of this proposed rule, obstetric readiness is a concern in avoiding preventable maternal morbidity and mortality. Provisions and protocols, as we propose to require, are one step towards addressing those concerns and improving perinatal outcomes.

We solicit public comments on these proposals, including whether these proposed requirements should be applicable to REHs.

2. Training for Obstetrical Staff in Hospitals and CAHs (§§ 482.59(c), 485.649(c))

a. Background

Given the worsening maternal health crisis as discussed in XXI.A.1.a of this proposed rule and research indicating that over 80 percent of pregnancy-related deaths in the U.S. are preventable, CMS is committed to ensuring that all Medicare and Medicaid participating hospitals and CAHs offering obstetrical services are held to a consistent standard of high-quality maternity care and patient health and safety. Currently, the CoPs for hospitals and CAHs include no baseline requirements for the training of obstetrical staff.

The majority of hospitals participate in the Medicare program through deemed status with an accrediting organization.³⁷⁷ These accrediting organizations may have additional requirements that exceed the Medicare CoP requirements as part of their CMS-approved deeming program. For example, The Joint Commission (TJC) requires education on the provision of care, treatment, and services standards for maternal safety for all staff and providers who treat pregnant/postpartum patients. Specifically, TJC requires training on the hospital’s evidence-based severe hypertension/preeclampsia and hemorrhage procedures.³⁷⁸ The TJC standards also

require that hospitals use in-situ training and drills that include multidisciplinary teams.³⁷⁹

Despite the requirements of accrediting organizations, several organizations have determined that in their view, obstetrical readiness for hospitals with obstetrical services is suboptimal.^{380 381 382} Additionally, the lack of standardized approaches to emergency OB care may contribute to poor maternal health outcomes.^{383 384} Variation in processes of care is problematic because it may lead to increased rates of error.³⁸⁵ Appropriate training, best practice protocols (such as recognizing early warning signs of hemorrhage, preeclampsia, and other adverse events associated with pregnancy and birth), and appropriate transfer protocols are critical to averting avoidable maternal complications and deaths, establishing and maintaining facilities’ obstetrical readiness,³⁸⁶ and ensuring compliance with existing regulations.

Research shows that women with any form of disability are at heightened risk for pregnancy and labor and delivery complications, as well as severe maternal morbidity and mortality, including pre-term birth, hypertensive disorders during pregnancy, gestational diabetes, and cesarean delivery.³⁸⁷ Understanding these risks, and education to help health care practitioners be more comfortable managing care for people with disabilities before, during, and after pregnancy can help ensure patients with

³⁷⁹ <https://www.jointcommission.org/-/media/tjc/documents/standards/r3-reports/r3-issue-24-maternal-12-7-2021.pdf>.

³⁸⁰ <https://www.acog.org/news/news-articles/2022/01/commitment-to-action-eliminating-preventable-maternal-mortality>.

³⁸¹ https://rhrc.umn.edu/wp-content/uploads/2021/09/UMN-emOB-Training-Needed_11.12.20_508.pdf.

³⁸² <https://www.cdcfoundation.org/sites/default/files/files/ReportfromNineMMRCs.pdf>.

³⁸³ Jennifer A. Callaghan-Koru et al. Implementation of the Safe Reduction of Primary Cesarean Births safety bundle during the first year of a statewide collaborative in Maryland. *Obstet Gynecol* 2019;134:109–19.

³⁸⁴ <https://www.acpjournals.org/doi/10.7326/M19-3258>.

³⁸⁵ <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/10/clinical-guidelines-and-standardization-of-practice-to-improve-outcomes>.

³⁸⁶ <https://saferbirth.org/aim-obstetric-emergency-readiness-resource-kit/>.

³⁸⁷ Tarasoff LA, Ravindran S, Malik H, Salaeva D, Brown HK. Maternal disability and risk for pregnancy, delivery, and postpartum complications: a systematic review and meta-analysis. *Am J Obstet Gynecol*. 2020;222(1):27.e1–27.e32. doi: 10.1016/j.ajog.2019.07.01

³⁷⁶ Quality Safety & Oversight Memorandum QSO–23–22–Hospital, September 21, 2123. <https://www.cms.gov/files/document/qso-23-22-hospital.pdf> Accessed April 23 2024.

³⁷⁷ <https://www.jointcommission.org/resources/news-and-multimedia/fact-sheets/facts-about-hospital-accreditation/>.

³⁷⁸ <https://www.jointcommission.org/standards/r3-report/r3-report-issue-24-pc-standards-for-maternal-safety/>.

disabilities receive safe, high quality OB care.³⁸⁸

Research also indicates that women with limited English proficiency (LEP) are also found to experience disparities in OB care and are at risk for mental health conditions, including postpartum depression and substandard newborn care following neonatal intensive care unit (ICU) discharge due to insufficient patient education by staff.^{389 390} Language-concordant care and awareness among medical providers regarding the use of medical interpreters and materials in diverse languages can improve patient satisfaction, decrease medical errors, and improve patient safety.^{391 392 393}

Studies have shown a direct correlation between the experience of a severe maternal event and the development or exacerbation of a mental health disorder, such as posttraumatic stress disorder (PTSD).³⁹⁴ Posttraumatic stress disorder affects about three to four percent of mothers, with higher rates among some population groups. Perinatal PTSD includes PTSD episodes occurring during pregnancy through one year postpartum. Perinatal PTSD negatively affects physical and mental health, interpersonal relationships, and parenting capacity.³⁹⁵ After a severe event, patients and their families may struggle to understand why an event occurred and how they might have received better information or care throughout the experience, adding to

their overall emotional distress.³⁹⁶ These examples highlight the need for new requirements for hospitals that provide obstetrical services.

b. Proposed Requirements for Staff Training for Hospitals and CAHs With OB Services

Given the existing literature and prevalence of health and safety concerns impacting maternal health outcomes (as described earlier in this section), we propose a core set of requirements for hospitals and CAHs offering OB services to protect the health and safety of pregnant, birthing, and postpartum patients. We believe that training of OB services staff on evidence-based best practices and protocols would enhance the quality of care and services provided to pregnant, birthing, and postpartum women and improve patient health and safety.

We therefore propose at new paragraph §§ 482.59(c) and 485.649(c) that hospitals and CAHs with OB services would be required to develop policies and procedures that would ensure that relevant obstetrical services staff would be trained on select topics for improving the delivery of maternal care. We propose at § 482.59(c)(1) and § 485.649(c)(1) training topics would have to reflect the scope and complexity of services offered, including, but not limited to, facility-identified evidence-based best practices and protocols to improve the delivery of maternal care within the facility. Performing critical tasks consistently through standardized practices can reduce errors, especially when fatigue is a factor, and in stressful environments such as the labor and delivery suite or operating room.³⁹⁷ To facilitate improvements in care, the Centers for Disease Control and Prevention (CDC) established perinatal quality collaboratives (PQCs).³⁹⁸ PQCs are state or multistate networks of teams that work to improve the quality of care for mothers and babies by identifying health care processes in need of improvement. In addition, the Health Resource and Services Administration (HRSA) partnered with the Alliance for Innovation on Maternal Health (AIM) to establish patient safety bundles.³⁹⁹ Facilities may participate in local or regional PQCs and implement patient safety bundles. The Institute for

Healthcare Improvement defines bundles as, “a small, straightforward set of evidence-based best practices that, when performed collectively and reliably, have been demonstrated to improve patient outcomes.”⁴⁰⁰ Maternal safety bundles, often implemented through PQCs, have demonstrated success in driving improvements, particularly with regards to obstetric hemorrhage, severe hypertension in pregnancy, and non-medically indicated Cesarean deliveries.^{401 402 403 404} Other examples of evidence-based trainings topics for obstetrical staff may include education in trauma informed care,^{405 406} cultural competency,^{407 408 409 410 411 412 413 414 415 416 417 418 419 420 421 422 423 424 425 426} and

⁴⁰⁰ <https://www.ih.org/insights/what-is-a-bundle>.

⁴⁰¹ Jennifer, A., Callaghan-Koru, et al., Implementation of the Safe Reduction of Primary Cesarean Births safety bundle during the first year of a statewide collaborative in Maryland. *Obstet Gynecol* 2019;134:109–19.

⁴⁰² Elliott K. Main et al. Reduction of severe maternal morbidity from hemorrhage using a state perinatal quality collaborative. *Am. J. Obstet. Gynecol.* 2017;216(3):298.e1–298.e11.

⁴⁰³ Patricia Lee King et al. Reducing time to treatment for severe maternal hypertension through statewide quality improvement. *Am. J. Obstet. Gynecol.* 2018;218:S4.

⁴⁰⁴ <https://www.cms.gov/files/document/qso-22-05-hospitals.pdf>.

⁴⁰⁵ https://saferbirth.org/wp-content/uploads/13-FINAL_AIM_OERRK_RESC.pdf.

⁴⁰⁶ <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/04/caring-for-patients-who-have-experienced-trauma>.

⁴⁰⁷ <https://store.samhsa.gov/sites/default/files/sma16-4931.pdf>.

⁴⁰⁸ Effects of Cultural Sensitivity Training on Health Care Provider Attitudes and Patient Outcomes <https://sigmapubs.online.library.wiley.com/doi/10.1111/j.1547-5069.2004.04029>.

⁴⁰⁹ Lelutiu-Weinberger, Corina. Implementation and Evaluation of a Pilot Training to Improve Transgender Competency Among Medical Staff in an Urban Clinic <https://www.liebertpub.com/doi/full/10.1089/trgh.2015.0009>.

⁴¹⁰ Rotenberg, Sara et al., Disability Training for health Workers: A Global Narrative Systematic Review. *Disability and Health Journal* doi: 10.1016/j.dhjo.2021.101260.

⁴¹¹ Cultural Competency: A Systemic Review of Health Care Provider Educational Interventions. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3137284/>.

⁴¹² <https://journals.sagepub.com/doi/10.1177/0163278712454137>.

⁴¹³ Linda Govere et al., How Effective Is Cultural Competence Training of Healthcare Providers on Improving Patient Satisfaction of Minority Groups? A Systematic Review of Literature. <https://doi.org/10.1111/wvn.12176> October 25, 2016.

⁴¹⁴ <https://onlinelibrary.wiley.com/doi/10.1111/j.1745-7599.2009.00406.x>.

⁴¹⁵ <https://journals.sagepub.com/doi/10.1177/0163278712454137>.

⁴¹⁶ Santana, Maria. How to Practice Person-Centered Care: A conceptual Framework. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5867327/>.

⁴¹⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3726251/>.

³⁸⁸ Gleason JL, Grewal J, Chen Z, Cernich AN, Grantz KL. Risk of Adverse Maternal Outcomes in Pregnant Women With Disabilities. *JAMA Netw Open.* 2021 Dec 1;4(12):e2138414. doi: 10.1001/jamanetworkopen.2021.38414. PMID: 34910153; PMCID: PMC8674748. and Smeltzer SC, Mitra M, Long-Bellil L, Iezzoni LI, Smith LD. Obstetric clinicians' experiences and educational preparation for caring for pregnant women with physical disabilities: a qualitative study. *Disabil Health J.* 2018;11(1):8–13. doi: 10.1016/j.dhjo.2017.07.004).

³⁸⁹ Togioka, Brandon & Seligman, Katherine & Delgado Upegui, Carlos. (2022). Limited English proficiency in the labor and delivery unit. *Current Opinion in Anaesthesiology.* 35. 285–291.

³⁹⁰ Sentell, Tetine & Chang, Ann & Ahn, Hyeon Jun & Miyamura, Jill. (2015). Maternal Language and Adverse Birth Outcomes in a Statewide Analysis. *Women & health.* 56.).

³⁹¹ Togioka, Brandon & Seligman, Katherine & Delgado Upegui, Carlos. (2022). Limited English proficiency in the labor and delivery unit. *Current Opinion in Anaesthesiology.* 35. 285–291. 10.1097/ACO.0000000000001131.

³⁹² Sentell, Tetine & Chang, Ann & Ahn, Hyeon Jun & Miyamura, Jill. (2015). Maternal Language and Adverse Birth Outcomes in a Statewide Analysis. *Women & health.* 56. 10.1080/03630242.2015.1088114.

³⁹³ <https://www.ahrq.gov/sites/default/files/publications/files/lepguide.pdf>.

³⁹⁴ <https://www.sciencedirect.com/science/article/pii/S0884217520303166?via%3Dihub>.

³⁹⁵ <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.01447>.

³⁹⁶ <https://www.sciencedirect.com/science/article/pii/S0884217520303166?via%3Dihub>.

³⁹⁷ <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/10/clinical-guidelines-and-standardization-of-practice-to-improve-outcomes>.

³⁹⁸ <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pqc.htm>.

³⁹⁹ <https://saferbirth.org/about-us/>.

person-centered care.⁴²⁷ 428 429 430 431 432 433 434 We also point readers to training resources at CMS' Medicare Learning Network: <https://www.cms.gov/training-education/medicare-learning-network/web-based-training>.

Additionally, at § 482.59(c)(1)(ii) and § 485.649(c)(1)(ii), we propose that hospitals and CAHs that provide OB services use findings from their QAPI programs, as required at § 482.21 and § 485.641, respectively, to inform obstetrical staff training needs and any additions, revisions, or updates to training topics on an ongoing basis. Stratified data can produce meaningful measures that can be used to expose health disparities, develop interventions to reduce them, and monitor performance to ensure interventions aimed at improving care do not have unintended consequences for certain patients and improve patient outcomes.⁴³⁵ Continuous quality improvement depends on a disciplined and well-defined data-driven process that constantly is monitored and improved.⁴³⁶ We note that patient satisfaction and quality measures may

be an effective way to measure the success of staff training.

At new paragraph § 482.59(c)(2) and § 485.649(c)(2), we propose to require the governing body to identify and document which staff must complete annual training on the topics identified at § 482.59(c)(1) and § 485.649(c)(1). In addition, we propose at § 482.59(c)(3) and § 485.649(c)(3) to require the hospital and CAH to document in the staff personnel records that the training was successfully completed. Further, at new paragraph § 482.59(c)(4) and § 485.649(c)(4), we propose that the hospital and CAH be able to demonstrate staff knowledge on the topics identified at § 482.59(c)(1) and § 485.649(c)(1), respectively. We are not proposing to require the specific manner or method in which a facility would be required to demonstrate that their staff is knowledgeable and competent in the ways to improve the delivery of maternal care, since this would likely vary based on the training delivery method. There are various ways in which a facility can assess their staff knowledge on ways to improve the delivery of maternal care. Facilities could do so through self-assessments, surveys, or questionnaires administered to their staff. Some examples of how a facility can demonstrate knowledge on these concepts include instructor-led training, computer-based or printed self-learning packets that contain a test to demonstrate their staff person's knowledge. In addition, for those trainings that are instructor-led, a question-and-answer session could follow the training. However the facility chooses to demonstrate this knowledge, we would expect the facility to maintain documentation that the training was completed, and that the facility's staff are knowledgeable of the ways to improve the delivery of maternal care.

We would expect facilities to consider the qualifications of the individuals or organizations that would be conducting the staff training and utilize trainers that are knowledgeable on the subjects that they are teaching and are qualified to conduct the training. These requirements allow facilities the flexibility to determine the curriculum that would be used to train their staff on evidence-based best practices and protocols to improve the delivery of maternal care and other training topics as identified by the facilities' QAPI program. We would expect facilities to provide high quality training that is consistent with and tailored to the staff's expected role, with the goal of improving maternal health outcomes. We acknowledge that many hospitals and CAHs may have already

implemented these practices and that those practices may satisfy this proposed requirement. Of note, these required staff trainings are in addition to the education and training necessary for a clinician to administer care within the scope of their practice or for a staff member to perform their job.

While there is, as noted above, ample objective research demonstrating the need for such requirements, we are also asking the public for any additional data, detailed analysis, academic studies, or any other information on the link between the proposed requirements and patient health and safety. We solicit public comment on these proposals, including whether these proposed staff training requirements should be applicable to REHs. We also seek public comment on whether CMS should require specific training on person-centered care, trauma-informed care, cultural competency, and/or other topics as part of the evidence-based training.

3. Quality Assessment and Performance Improvement (QAPI) Program (§ 482.21; § 485.641)

a. Background

i. Existing QAPI CoP Requirements

Medicare-participating hospitals and CAHs are required by CMS regulations to engage in quality activities to improve patient care and outcomes and to facilitate efficient and effective operations under the QAPI program standards (42 CFR 482.21; 42 CFR 485.641). Specifically, the QAPI standards are a data-driven and proactive approach to continuous quality improvement, with the end goal of improving the overall quality of care and services delivered to patients. The governing body is required to be involved in the QAPI program by ensuring that the program reflects the complexity of the facility's organization and services.⁴³⁷ These data and measures remain with the facility; there is no requirement to transmit QAPI data to CMS or other Federal entities.

ii. Data Analysis and Stratification

In executing these QAPI requirements, hospitals and CAHs (including those with OB services) use patient population data to identify, reduce, and eliminate unfavorable patient health and safety outcomes, while identifying opportunities for

⁴³⁷ RNHCIs (at § 403.732), ASCs (at § 416.43), hospices (at § 418.58), hospitals (at § 482.21), transplant programs (at § 482.96), LTC facilities (at § 483.75), HHAs (at § 484.65), CAHs (at § 485.641), CMHCs (at § 485.917), OPOs (at § 486.348), and ESRD dialysis facilities (at § 494.110).

⁴¹⁸ <https://pubmed.ncbi.nlm.nih.gov/12013268/>.

⁴¹⁹ <https://thinkculturalhealth.hhs.gov/clas>.

⁴²⁰ <https://ethnomed.org/>.

⁴²¹ <https://minorityhealth.hhs.gov/clas-behavioral-health-implementation-guide>.

⁴²² https://minorityhealth.hhs.gov/assets/PDF/Evaluation_of_the_Natn_CLAS_Standards_Toolkit_PR3599_final.508Compliant.pdf.

⁴²³ <https://www.cms.gov/about-cms/agency-information/omh/downloads/clas-toolkit-12-7-16.pdf>.

⁴²⁴ <https://www.albany.edu/cphce/bridging-gaps-vital-role-cultural-competence-healthcare>.

⁴²⁵ <https://thinkculturalhealth.hhs.gov/resources/presentations/1/fundamentals-of-the-national-standards-for-culturally-and-linguistical>.

⁴²⁶ <https://thinkculturalhealth.hhs.gov/education/maternal-health-care>.

⁴²⁷ An approach to coordinate health care services to better address an individual's physical, mental, behavioral, and social needs (See <https://www.cms.gov/priorities/innovation/key-concepts/person-centered-care>).

⁴²⁸ <https://www.cms.gov/priorities/innovation/key-concepts/person-centered-care>.

⁴²⁹ <https://www.hrsa.gov/about/organization/bureaus/ohe/health-literacy/culture-language-and-health-literacy>.

⁴³⁰ <https://edit.cms.gov/about-cms/agency-information/omh/downloads/language-access-plan.pdf>.

⁴³¹ <https://www.marchofdimes.org/our-work/beyond-labels>.

⁴³² <https://www.acog.org/education-and-events/emodules/respectful-care>.

⁴³³ <https://www.perinatalgi.org/page/mmtrends>.

⁴³⁴ <https://www.cci.training/courses/maternal-mental-health-support-specialist>.

⁴³⁵ <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2011.0617>.

⁴³⁶ <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/10/clinical-guidelines-and-standardization-of-practice-to-improve-outcomes>.

improvement. As such, CMS considers QAPI a critical tool for improving facilities' maternal health outcomes amid the ongoing maternal health crisis. For while existing QAPI regulations (§ 482.21; § 485.641) require facilities to "develop, implement, and maintain an effective, ongoing, facility-wide, data-driven" QAPI program that focuses on "indicators related to improved health outcomes and the prevention and reduction of medical errors," existing regulations do not require that hospitals focus on addressing the worsening public health crises such as the U.S. maternal health crisis.

Moreover, in performing their data analysis, facilities may aggregate patient data in such a way that masks health outcome differences among patient subpopulations.⁴³⁸ Existing QAPI standards do not require that facilities monitor for or address health disparities, or otherwise analyze or stratify QAPI data by patient subpopulations. Yet, research has repeatedly shown the important role of data collection and analysis by patient subgroup within health care facilities in order to improve patient care consistently across patient populations.^{439 440 441 442 443} Specifically, analysis by patient subgroup can produce meaningful measures that can be used to expose health disparities, develop interventions to reduce them, and monitor performance to ensure interventions to improve care do not have unintended consequences for certain patients.^{444 445}

However, such data practices are not universally applied by hospitals.⁴⁴⁶ The persistent maternal health crisis and well-documented correlations between certain patient demographics and maternal health outcomes as discussed at length in section XXI.A.1 of this proposed rule, strongly indicate that the absence of analyses by diverse subpopulations among obstetrical patients likely serves as a barrier to facilities' effectiveness in achieving performance improvement in maternal

health outcomes. Therefore, we believe requiring QAPI analyses of maternal health data, quality indicators, and outcomes by diverse subpopulations served by a facility would support facilities in establishing structures to assess and improve health and safety conditions on an ongoing basis, thereby promoting access and high-quality care for all pregnant, birthing, and postpartum patients.

iii. Maternal Mortality Review Committees

Initially created in the 1930s to combat high rates of maternal mortality in the U.S.,⁴⁴⁷ Maternal Mortality Review Committees (MMRCs) are multidisciplinary teams that work at the State or local level to engage stakeholders, comprehensively review deaths that occur during or within a year of pregnancy (pregnancy-related deaths), and develop recommendations aimed at preventing future pregnancy-related deaths.^{448 449} As of April 2024, MMRCs exist in 47 States and often function under the authority of State health and safety codes.^{450 451 452} MMRC composition varies but can consist of individuals with training in public health, obstetrics and gynecology, maternal-fetal medicine, nursing, midwifery, forensic pathology, behavioral health professionals, patient advocacy groups, and community-based organizations to determine cause of death, preventability of death, and relationship to pregnancy.^{453 454} Specifically, as of 2021, all existing MMRCs included representation from State public health agencies as well as provider groups (inclusive of hospitals, hospital organizations, State health professional chapters, State medical societies, etc.). Twenty-one out of forty-four (21/44; 47.7 percent) included representation from State Medicaid agencies, 20/44 (45.5 percent) included State behavioral health agencies, 18/44 (40.9 percent) included a violence prevention agency, and 27/44 (61.4 percent) included community-based

organizations.⁴⁵⁵ Among provider groups, 28/44 (63.6 percent) of existing MMRCs included social workers; 12/44 (27.3 percent) included doulas and 14/44 (31.8 percent) substance use counselors.⁴⁵⁶ MMRCs may use a variety of data sources including: birth and death certificate data, prenatal care records, hospital records, autopsy reports, and social services records in their review process.⁴⁵⁷ Yet such data reporting and sharing is dependent upon State requirements and often voluntary for health care facilities.^{458 459} MMRCs generally disseminate annual or biennial reports reflecting their findings.

In FY 2023, CDC supported MMRC initiatives through cooperative agreements in 44 States and 2 territories via its Enhancing Reviews and Surveillance to Eliminate Maternal Mortality (ERASE MM) Program.⁴⁶⁰ Other sources of funding include the Federally-funded and State-administered Title V Maternal and Child Health (MCH) Services Block Grants, State government appropriations, non-governmental grants, philanthropic contributions, and dedicated initiative funds.⁴⁶¹

Despite their pivotal role, MMRCs encounter various challenges, including resource constraints, funding challenges, data accessibility issues (including timeliness of data), operational authority, and limited to no ability to directly implement or enforce their recommendations.^{462 463 464} Moreover while, policies in 36 States and the District of Columbia legally require MMRCs to operate and review pregnancy associated deaths, only 10 States and the District of Columbia mandate the consideration of health disparities during MMRCs' review despite the widening maternal health disparities described in section XXI.A.1

⁴⁵⁵ <https://nashp.org/state-tracker/state-maternal-mortality-review-committee-membership-and-recommendations/>.

⁴⁵⁶ <https://nashp.org/state-tracker/state-maternal-mortality-review-committee-membership-and-recommendations/>.

⁴⁵⁷ <https://www.cdcfoundation.org/sites/default/files/upload/pdf/MMRIAREport.pdf>.

⁴⁵⁸ <https://www.cdcfoundation.org/sites/default/files/upload/pdf/MMRIAREport.pdf>.

⁴⁵⁹ <https://www.guttmacher.org/state-policy/explore/maternal-mortality-review-committees>.

⁴⁶⁰ <https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/index.html>.

⁴⁶¹ <https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/index.html>.

⁴⁶² <https://doi.org/10.1097/AOG.00000000000002417>.

⁴⁶³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6511983/>.

⁴⁶⁴ <https://www.cdc.gov/reproductivehealth/maternal-mortality/preventing-pregnancy-related-deaths/state-strategies.html>.

⁴³⁸ <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2011.0617>.

⁴³⁹ <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2011.0617>.

⁴⁴⁰ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3861327/>.

⁴⁴¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6259664/>.

⁴⁴² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7647227/>.

⁴⁴³ <https://pubmed.ncbi.nlm.nih.gov/16567608/>.

⁴⁴⁴ <https://www.nejm.org/doi/full/10.1056/NEJMp1911700>.

⁴⁴⁵ <https://www.nejm.org/doi/full/10.1056/NEJMp1911700>.

⁴⁴⁶ <https://ifdhe.aha.org/benchmarking-study-us-hospitals-surveys>.

⁴⁴⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6511983/>.

⁴⁴⁸ <https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/index.html>.

⁴⁴⁹ <https://doi.org/10.1097/AOG.00000000000002417>.

⁴⁵⁰ <https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/index.html>.

⁴⁵¹ <https://doi.org/10.1097/AOG.00000000000002417>.

⁴⁵² <https://www.guttmacher.org/state-policy/explore/maternal-mortality-review-committees>.

⁴⁵³ <https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/index.html>.

⁴⁵⁴ <https://doi.org/10.1097/AOG.00000000000002417>.

of this proposed rule.^{465 466} Moreover, thirteen States require that MMRC membership reflect and/or consider the jurisdiction's demographic composition (for example, geographic, racial, socioeconomic status, communities most affected) when selecting Committee members.⁴⁶⁷

Stakeholders highlight the need for improved hospital engagement in data standardization and data collection as part of a comprehensive strategy to reduce rates of maternal mortality. Collaborative and consistent reporting at the hospital level directly impacts the quality and timeliness of MMRCs' work, as well as informs targeted recommendations and next steps within facilities. Specifically, Perinatal Quality Collaboratives (PQC) are a central method for how MMRCs' recommendations are implemented. PQCs are State or regional networks working to improve maternal and infant quality of care by identifying possible improvements in health care processes and leveraging the best available methods to enact changes expeditiously.⁴⁶⁸ As of April 2024, there are 49 State-based PQCs, of which 36 are funded by the CDC.⁴⁶⁹ Through Federal grants and cooperative agreements with the CDC⁴⁷⁰ and/or funding and support from State and local governments, PQCs have achieved notable improvements in maternal health and safety, including in severe pregnancy complications.⁴⁷¹ Of note, participation in State or national Perinatal Quality Improvement (QI) Collaborative is a part of CMS' "birthing friendly" hospital designation for hospitals that provide high quality maternal care.⁴⁷²

As an example of the collaboration between MMRCs and PQCs, the State of California demonstrates the impact that high quality hospital data collection and reporting can have in supporting MMRCs' work and patient care improvements.⁴⁷³ California's MMRC, known as the California Pregnancy-Associated Mortality Review project

(CA-PAMR), was created in 2006 to "identify pregnancy-related deaths, causation, and contributing factors, and then make recommendations on quality improvements to maternity care." CA-PAMR has consistently reported a pregnancy-related mortality rate below the U.S. rate since 2011.⁴⁷⁴ As mentioned above, California's approach centers on a collaborative model, wherein CA-PAMR serves as a data collector, evaluator, and recommender, while the California Maternal Quality Care Collaborative (CMQCC; one of California's PQCs with over 200 hospital members)⁴⁷⁵ works to implement recommendations. This close collaboration has been described as critical to California's success in reducing maternal mortality.⁴⁷⁶ Specifically, the California Maternal Data Center allows for direct links between hospital reporting and State vital records offices for 95 percent of births, allowing for real time evaluation of perinatal metrics and quality improvement benchmarks.⁴⁷⁷ These comprehensive reporting efforts support the development of evidence-based quality improvement toolkits, which have driven a 65 percent reduction in maternal morbidity between 2006 (the year of CA-PAMR and CMQCC's founding) to 2016 in California in the latest analysis.⁴⁷⁸

b. Proposals

Given the above challenges and examples of success from MMRCs' work, we propose to revise the existing QAPI standards (§ 482.21; § 485.641) for hospitals and CAHs that offer obstetrical services.⁴⁷⁹ First, we propose that a hospital or CAH that offers OB services would be required to use its QAPI program to assess and improve health outcomes and disparities among OB patients on an ongoing basis (§ 482.21(b); § 485.641 (e)(1)). Specifically, the facility at a minimum would have to: (1) analyze data and quality indicators collected for the QAPI program by diverse subpopulations as identified by the facility among OB

patients; (2) measure, analyze, and track data, measures, and quality indicators on patient outcomes and disparities in processes of care, services and operations, and outcomes among OB patients; (3) analyze and prioritize patient health outcomes and disparities, develop and implement actions to improve patient health outcomes and disparities, measure results, and track performance to ensure improvements are sustained when disparities exist among OB patients; and (4) conduct at least one performance improvement project focused on improving health outcomes and disparities among the hospital's population(s) of OB patients annually.

For the analysis required in item (1), hospitals have flexibility in determining the data analysis methodology most appropriate for their patient population and number of cases. For example, hospitals would stratify data and quality indicators collected for the QAPI program by diverse subpopulations as identified by the hospital among OB patients. For items 2 and 3, we expect hospitals will be able to use this data analysis to monitor and assess for the presence of disparities. If disparities are identified, we expect hospitals to prioritize QAPI work to address these areas. For all QAPI work, we remind hospitals that such analysis must comply with HIPAA, while ensuring such subpopulations are not excluded from QAPI efforts based solely on low numbers of patients.

In terms of existing Federal maternal health data and metrics and their relation to this proposal, in August 2022 CMS finalized the adoption of two additional maternal health quality measures to the Hospital IQR program, both of which are electronic clinical quality measures including: (1) a measure of severe obstetric complications (which describes the number of inpatient hospitalizations for patients with severe complications occurring during the delivery hospitalization, such as hemorrhage), and (2) a measure of low-risk Cesarean section rates, which describes the share of patients with low-risk pregnancies who give birth via a Cesarean section. Hospitals may use these maternal health quality metrics to inform their QAPI activities and are an example of how a hospital could comply with this new standard. Hospitals may also choose to utilize CMS' mandatory Health Related Social Needs screening metrics and data to inform maternal health QAPI

⁴⁶⁵ <https://www.guttmacher.org/state-policy/explore/maternal-mortality-review-committees>.

⁴⁶⁶ <https://pubmed.ncbi.nlm.nih.gov/31499056/>.

⁴⁶⁷ <https://www.guttmacher.org/state-policy/explore/maternal-mortality-review-committees>.

⁴⁶⁸ <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pqc.htm>.

⁴⁶⁹ <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pqc-states.html>.

⁴⁷⁰ <https://www.cdc.gov/maternal-infant-health/pqc/index.html>.

⁴⁷¹ <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pqc.htm>.

⁴⁷² <https://data.cms.gov/provider-data/birthing-friendly-hospitals-and-health-systems>.

⁴⁷³ <https://www.cmqqc.org/research/maternal-mortality-review-ca-pamr/ca-pamr-recent-data>.

⁴⁷⁴ <https://www.cmqqc.org/research/maternal-mortality-review-ca-pamr/ca-pamr-recent-data>.

⁴⁷⁵ <https://www.cmqqc.org/about-cmqqc/member-hospitals>.

⁴⁷⁶ <https://www.cmqqc.org/about-cmqqc/what-we-do>.

⁴⁷⁷ <https://www.cmqqc.org/about-cmqqc/what-we-do>.

⁴⁷⁸ <https://www.cmqqc.org/who-we-are>.

⁴⁷⁹ For purposes of this proposal, CMS considers a facility to "offer obstetrical services" when the facility "[holds itself] out to the public (by name, posted signs, advertising, or other means) as a place that provides care for obstetrical medical conditions." This is similar to how emergency departments are defined in EMTALA (42 CFR 489.24(b)(2) "Dedicated emergency department").

activities.⁴⁸⁰ Hospitals may also collaborate with their Quality Improvement Organization (QIOs) in this work. We refer readers to the following website which discusses CMS' Action Plan for Maternity Care in greater detail: <https://www.cms.gov/files/document/cms-maternity-care-action-plan.pdf>.

Next, under a new standard for Maternal Health QAPI activities for hospitals (§ 482.21(e)(1)) and CAHs (§ 485.641(d)(4)(i)), we propose to require that for hospitals and CAHs that offer OB services, leadership must be engaged in the facility's QAPI activities. For purposes of this provision, leadership is defined as facility leadership, obstetrical services leadership, or their designate(s).

Per existing state statutes as applicable, facilities are already required to report data to MMRCs.⁴⁸¹ We therefore propose that if a MMRC is available at the State or local jurisdiction in which the facility was located, hospitals (at § 482.21(e)(2)) and CAHs (at § 485.641(d)(4)(ii)) that offer OB services must have to have a process for incorporating MMRC data and recommendations into the facility's QAPI program. Participation in a PQC or pursuing a QI project based on information from a MMRC are examples of how a facility could comply with this proposal. Of note, facilities can review CDC and state resources to identify the coordinating body and/or existence of MMRC in their state or locality.⁴⁸²

c. Solicitation of Comments

We welcome public comments on the enhancements to the existing QAPI standards for hospitals and CAHs that offer obstetrical services proposed above. Our central goal with these proposals is to improve the health and safety of all pregnant, birthing, and postpartum patients in Medicare-participating hospitals and CAHs, including reducing worsened health outcomes among vulnerable subpopulations, and we invite comment on how effectively these proposals would achieve this goal. We are additionally interested in data, evidence, and experience related to QAPI's impact and role in addressing maternal health disparities as well as any benefits, costs, and unintended consequences of the above policies. We welcome public input from a broad

range of commenters, including but not limited to patients, community-based organizations, public health professionals, health care professionals, staff, hospitals, operators, researchers, those representing diverse perspectives (such as those from rural and otherwise underserved communities), those disproportionately providing or engaged in maternal health care for specific populations discussed in this rule such as people experiencing health disparities, social risk factors and mental health conditions and substance use disorder which may lead to stigma, discrimination, and adverse outcomes). We also solicit public comments on the following questions:

- How effectively would these proposals achieve CMS' central goal of improving the health and safety of all pregnant, birthing, and postpartum patients in Medicare-participating hospitals and CAHs, including reducing worsened health outcomes among vulnerable subpopulations?
- To what extent do facilities already stratify, measure, analyze, and track quality data and indicators over time by diverse subpopulations or conduct performance improvement projects focused on reducing maternal health disparities as part of their QAPI activities? What are examples and outcomes of such work to date? What challenges do facilities (including those in rural areas or geographically isolated areas) face in performing such data stratification (for example, administrative recordkeeping processes, information systems, patient willingness to disclose information, and staff time/expertise) and implementing maternal health equity related QAPI projects? How can such challenges be overcome? What is needed for facilities to collect and stratify data by diverse subpopulations?

- What types of data stratifications/subgroups/categories are key to ensuring the health and safety of all pregnant, birthing, and postpartum patient subgroups? How can facilities best ensure their subgroup data collection and analysis reflects the diverse subpopulations served? What is the benefit versus possible unintended consequences of CMS defining and requiring a minimum set of data stratifications/subgroup/categories in facilities' maternal health QAPI program analyses? For example, should facilities be required to, at minimum, collect and stratify data by the subgroups included in MMRIA? How can facilities meaningfully acquire and disseminate subpopulation data in a way that avoids disclosure (that is, protecting individual privacy and confidentiality of their

data), which can lead to increased vulnerability for underserved populations? How should facilities address stratifying small populations?

- How can facilities best involve and/or share the results of the facilities' maternal health equity focused QAPI efforts with patients, their families/caregivers, and community members? What are examples and outcomes of such efforts to date? What gaps and challenges exist?

- Should any of these proposals apply to other types of Medicare-participating facilities besides hospitals and CAHs that offer OB services? For example, should similar requirements apply to REHs? What could be the benefits, challenges, or potential unintended consequences of such policies? How could CMS minimize the burden of any such requirements?

4. Emergency Services Readiness (§ 482.55; § 485.618)

a. Background

In compliance with the EMTALA statute (42 U.S.C. 1395dd) and its implementing regulations (42 CFR 489.24), Medicare-participating hospitals and CAHs with emergency departments must be continually prepared to provide individuals presenting to the emergency department with an appropriate medical screening exam and stabilizing treatment if an emergency medical condition is found or, under certain circumstances, appropriately transfer such individuals to receive stabilizing care at another facility with higher treatment capabilities not available at the originating hospital. Such readiness is essential to the health and safety of emergency services patients, and relies on adequate staff training, provisions, protocols, and supplies.

However, several organizations have reported that that emergency department readiness can be suboptimal, especially for obstetrical, geriatric, and pediatric populations, among others.^{483 484 485 486 487 488} Specific to obstetrical patients, as discussed in section XXI.A.1 of this proposed rule,

⁴⁸³ <https://www.acog.org/news/news-articles/2022/01/commitment-to-action-eliminating-preventable-maternal-mortality>.

⁴⁸⁴ https://rhrc.umn.edu/wp-content/uploads/2021/09/UMN-emOB-Training-Needed_11.12.20_508.pdf.

⁴⁸⁵ <https://www.cdcfoundation.org/sites/default/files/files/ReportfromNineMMRCs.pdf>.

⁴⁸⁶ <https://emscimprovement.center/domains/pediatric-readiness-project/>.

⁴⁸⁷ <https://publications.aap.org/pediatrics/article/142/5/e20182459/38608/Pediatric-Readiness-in-the-Emergency-Department>.

⁴⁸⁸ https://forms.ihf.org/hubfs/Guide%20to%20Recognition%20for%20GEDA%20Sites_FINAL.pdf.

⁴⁸⁰ <https://www.cms.gov/newsroom/fact-sheets/fy-2023-hospital-inpatient-prospective-payment-system-ipp-and-long-term-care-hospitals-ltch-pps>.

⁴⁸¹ <https://www.cdc.gov/maternal-mortality/php/mmrc/index.html>.

⁴⁸² <https://www.cdc.gov/maternal-mortality/php/mmrc/index.html>.

given the worsening maternal morality crisis and declining access to inpatient and outpatient maternity care in the U.S. in recent years, especially in rural and low-income communities, non-obstetrical professionals working in hospital emergency departments, CAHs, and REHs nationwide may experience a higher acuity and frequency of patients needing OB care, which may result in patients receiving care by staff with less training in obstetrical emergencies. Moreover, pregnant women who live in rural communities, have low income, are members of certain racial/ethnic groups (non-Hispanic Black, American Indian/Alaska Native (AI/AN)), and have disabilities experience disproportionately higher rates of pregnancy-related morbidity and mortality. For some pregnant women, the emergency department may be their first and/or only contact with the health care system during the pregnancy. Hospital emergency departments, CAHs, and REHs must therefore continue to ensure they are prepared to meet the needs of these high-risk patient populations in order to maintain high quality of care and reduce disparate health outcomes. Research shows that additional obstetric training for emergency department staff improves staff competencies (that is, skills, knowledge, comfort, confidence, and effectiveness) in managing obstetric emergencies, supporting improved maternal health and safety.^{489 490 491 492 493 494} Similarly, staff training in pediatric readiness^{495 496 497}

and geriatric readiness^{498 499 500 501 502} improves staff capabilities in caring for these populations as well as patient health and safety.

While the hospital Emergency Services CoP requires that “there must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility” (§ 482.55(b)(2)), CMS believes clearer expectations surrounding “qualified in emergency care” and maintenance of qualifications (that is, training) would improve facilities’ readiness to care for patients with emergency conditions, enhancing patient health and safety.

b. Proposal

Given CMS’ commitment to ensuring the health and safety of all emergency services patients, including OB patients, we propose a new standard entitled “Emergency Services Readiness” within the existing Emergency Services CoP for hospitals (§ 482.55) and CAHs (§ 485.618) to set clear expectations as well as improve facility readiness in caring for emergency services patients, including pregnant, birthing, and postpartum patients. Notably, these requirements would apply to all hospitals and CAHs offering emergency services,⁵⁰³ whether or not a hospital/CAH offers an additional specialty service lines (such as OB services). This is done with the intention of ensuring baseline health, safety, and training standards for the care of patients with emergency conditions.

First for hospitals (§ 482.55(c)) and CAHs (§ 485.618(e)) that offer emergency services, we propose that these facilities would be required to have adequate provisions and protocols to meet the emergency needs of patients in accordance with the complexity and scope of services offered. For protocols, hospitals (§ 482.55(c)(1)) and CAHs (§ 485.618(e)(1)) must have protocols consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions. For example, facilities may utilize national medical professional

society, accrediting organization, credentialing body, or other national guidelines to develop appropriate protocols for their emergency services patient populations. While these CoPs would not require adherence to a specific organization’s guideline or recommendations, we expect that facilities would be able to articulate their standards and the source(s) and to demonstrate that their standards are based on evidence and nationally recognized sources. The American College of Emergency Physicians, for instance, has issued multiple guidelines for best practices in managing common and critical emergency conditions and has developed a Geriatric Emergency Department Accreditation Program, which provides best practice standards for this at-risk population.^{504 505} For obstetrical emergencies, the Alliance for Innovation on Maternal Health’s (AIM; a partnership between HRSA and American College of Obstetricians and Gynecologists (ACOG) and other stakeholders) has developed resources which include example protocols and training resources for responding to obstetrical hemorrhage, severe hypertension, perinatal mental health conditions, sepsis, substance use disorder, and cardiac conditions, among others.⁵⁰⁶ ACOG has also developed resources for Obstetric Emergencies in Nonobstetric Settings.⁵⁰⁷ Similarly, the HRSA-supported Emergency Medical Services for Children (EMSC) Innovation and Improvement Center has resources for emergency departments seeking to improve “pediatric readiness.”⁵⁰⁸ We expect hospitals to be able to identify the source of the nationally recognized and evidence-based guidelines utilized in their protocols.

For hospitals (§ 482.55(c)(3)) and CAHs (§ 485.618(e)(2)) that offer emergency services, applicable emergency services personnel, as determined by the facility, would need to be trained on these protocols and provisions annually. However given the diversity of staff and services offered by hospitals and CAHs, we are not proposing which emergency services staff should be trained. Once staff are identified, hospitals and CAHs would be expected to document that applicable staff have successfully completed such facility-identified training and

⁴⁸⁹ Burke SM, Schmitt T, Kennedy P, et al. Emergency Medicine Obstetrics and Gynecology: A Case-Based Curriculum for Residents. *MedEdPORTAL*. 2023;19:11330.

⁴⁹⁰ Espey E, Baty G, Rask J, Chungtuycio M, Pereda B, Leeman L. Emergency in the clinic: a simulation curriculum to improve outpatient safety. *Am J Obstet Gynecol*. Dec 2017;217(6):699.e1–699.e13.

⁴⁹¹ Cooper MI, Papanagnou D, Meguerdichian M, Bajaj K. Emergency Obstetrics for the Emergency Medicine Provider. *MedEdPORTAL*. October 13 2016;12:10481.

⁴⁹² Jacobs PJ. Using High-Fidelity Simulation and Video-Assisted Debriefing to Enhance Obstetrical Hemorrhage Mock Code Training. *J Nurses Prof Dev*. Sep/Oct 2017;33(5):234–239.

⁴⁹³ Hopmann P, Varre JS, Duncan G, Devoe WB, Gable BD. Multidisciplinary Simulation of Trauma in Pregnancy with Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) Utilization. *Cureus*. December 2022; 14(12): e32820.

⁴⁹⁴ Harrington J, Duncan G, D. Angelo KG. Multidisciplinary Simulation Improves Resident Confidence for Pregnant Patients Requiring Surgical Intervention. *Cureus*. Mar 2022;14(3): e23454.

⁴⁹⁵ <https://pubmed.ncbi.nlm.nih.gov/31444254/>.

⁴⁹⁶ <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800400>.

⁴⁹⁷ <https://publications.aap.org/pediatrics/article/144/3/e20190568/76984/Emergency-Department-Pediatric-Readiness-and>.

⁴⁹⁸ <https://www.sciencedirect.com/science/article/pii/S0196064413015527?via%3Dihub>.

⁴⁹⁹ <https://onlinelibrary.wiley.com/doi/10.1111/acem.13880>.

⁵⁰⁰ <https://onlinelibrary.wiley.com/doi/10.1111/j.1741-6612.2010.00499.x>.

⁵⁰¹ <https://www.sciencedirect.com/science/article/pii/S1525861021001961?via%3Dihub>.

⁵⁰² <https://pubmed.ncbi.nlm.nih.gov/37389490/>.

⁵⁰³ For purposes of this proposal, CMS considers a facility to “offer emergency services” when it meets the definition of “dedicated emergency department” as defined in EMTALA (42 CFR 489.24(b) “Dedicated emergency department”).

⁵⁰⁴ <https://www.acep.org/patient-care/clinical-policies>.

⁵⁰⁵ <https://www.acep.org/geda>.

⁵⁰⁶ <https://saferbirth.org/>.

⁵⁰⁷ <https://www.acog.org/programs/obstetric-emergencies-in-nonobstetric-settings>.

⁵⁰⁸ <https://emscimprovement.center/domains/pediatric-readiness-project/>.

demonstrate staff knowledge on these topics.

Finally, for hospitals that offer emergency services, we further propose at § 482.55(c)(2) that provisions include equipment, supplies, and medication used in treating emergency cases. Such provisions must be kept at the hospital and be readily available for treating emergency cases. The available provisions must include: (1) drugs, blood and blood products, and biologicals commonly used in life-saving procedures; (2) equipment and supplies commonly used in life-saving procedures; and (3) a call-in-system for each patient in each emergency services treatment area. These supply requirements are similar to existing CAHs (at § 485.618(b) and (c)) and REHs (at § 485.516(c)(2)) supply standards for emergency services, as well as the surgical services CoP supply requirements (§ 482.51(b)(3)). We are not proposing any new emergency services equipment, supplies, or medication requirements for CAHs or REHs. Of note, hospitals have the flexibility to contract for services (§ 482.12(e)), which could include procurement and storage of blood and blood products.

Like CAHs and REHs, hospitals would have flexibility in identifying and determining the type and necessary quantity of drugs, blood products, biologicals, equipment and supplies commonly used in emergency procedures needed to meet the needs of their patients. This CMS proposal does not require facilities to maintain supplies of particular drugs, biologicals, equipment, or supplies or amounts. Rather each facility would be expected to tailor their equipment and supplies to meet the needs of their patient populations, consistent with the needs, services, and resources of the facility. Examples of drugs and biologicals commonly used in life-saving procedures could include analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrhythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions. Supply and equipment commonly used in life-saving procedures could include airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters. Such standards would be consistent with existing CAH (§ 485.618(b) and (c)) and REH

(§ 485.516(c)(2)) emergency services standards.

Lastly, the proposed requirement for a call-in-system for each patient in each emergency services treatment area is in line with the surgical services CoP (§ 482.51(b)(3)) and promotes patient safety by ensuring patients have a ready means of notifying staff of any emergencies or concerns.

c. Solicitation of Comments

We welcome public comments on the above enhancements to the existing emergency services standards for hospitals and CAHs. Our goal with this section's proposals is to improve the health and safety of all emergency services patients, including pregnant, birthing, and postpartum patients. We seek comments on how effectively these proposals would achieve this goal. We are additionally interested in data, evidence, and experience related to these proposals as well as any benefits, costs, and unintended consequences of the above policies. We welcome public input from a broad range of commenters, including but not limited to patients, community-based organizations, public health professionals, health care professionals, staff, hospitals, operators, and researchers. Specifically, we solicit public comments on the following questions:

- While REHs do have existing equipment, supply, and medication standards, should the above proposals related to provisions, protocols, and staff training apply to REHs as well?
- What would be the benefits versus burden of such an approach? How could any burdens be mitigated?

5. Transfer Protocols (§ 482.43)

a. Background

The Discharge Planning CoP for hospitals at § 482.43 currently require facilities to have an effective discharge planning process that focuses on the patient's goals and treatment preferences and includes the patient and his or her caregivers/support person(s) in the process. The discharge planning CoP include standards for the discharge planning process, the provision and transmission of the patient's necessary medical information, and discharge to post-acute services. However, the hospital Discharge Planning CoP does not currently include baseline requirements related to patient transfers.

Errors can occur during hospital transfers, including incomplete or inaccurate communication at the time of transfer. This is associated with worse

patient outcomes, including delayed diagnoses, redundant tests, longer length of stays, and increased costs.⁵⁰⁹ Additionally, delays from the time a patient is accepted to another hospital to when they are transferred can be exacerbated by limited bed availability.⁵¹⁰ These delays can prevent patients from receiving the medical care they need in a timely manner.

Establishing transfer protocols can enhance patient health and safety by ensuring consistent and thorough communication between healthcare providers, minimize the risks of errors, reduce delays, and ensure that patients receive timely and appropriate care.

Hospitals regularly encounter situations where they may be unable to provide the appropriate level of care to meet the needs of a patient and must transfer the patient to another facility. As noted previously, EMTALA (42 CFR 489.24) requires Medicare-participating hospitals with emergency departments to provide an appropriate medical screening examination to a presenting individual to determine whether an emergency medical condition exists. If the hospital determines that the individual has an emergency medical condition, the hospital must offer stabilizing treatment or, under certain circumstances, appropriately transfer such patients to receive stabilizing care that the originating hospital does not have the capability to provide.⁵¹¹ Roughly 20 percent of patients seen in U.S. emergency departments are admitted to the hospital as inpatients or transferred to a different facility.⁵¹² In 2018, about 2.8 percent of patients were transferred from the ED to another hospital. Lower-volume EDs had the highest transfer rates, at about 5 percent.⁵¹³ However, hospitals that do not have an emergency department or are otherwise not covered by EMTALA, may also have a need to transfer patients to other facilities to receive needed

⁵⁰⁹ Mueller S, Schnipper JL. Physician Perspectives on Interhospital Transfers. *J Patient Safety*. 2019 June; 15(2): 86–89. doi: 10.1097/PTS.0000000000000312.

⁵¹⁰ Carroll M, Fanning C, Herrigel DJ, Parikh A, et al. Interhospital Transfer Handoff Practices Among US Tertiary Care Centers: A Descriptive Study. *J. Hosp Med*. 2017 Dec, 11(6): doi:10.1002/jhm.2577.

⁵¹¹ <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-489/subpart-B/section-489.24>.

⁵¹² American College of Emergency Physicians—ACEP Now (2019). Latest Data Reveal the ED's Role as Hospital Admission Gatekeeper. <https://www.acepnow.com/article/latest-data-reveal-theeds-role-as-hospital-admission-gatekeeper/>.

⁵¹³ American College of Emergency Physicians—ACEP Now (2019). Latest Data Reveal the ED's Role as Hospital Admission Gatekeeper. <https://www.acepnow.com/article/latest-data-reveal-theeds-role-as-hospital-admission-gatekeeper/>.

services. Additionally, patients that are admitted as hospital inpatients may require transfer between facilities to meet the needs of the patient (for example, changing clinical condition, need for specialty and/or higher level of care). It is estimated that each year, patient transfers between acute care hospitals make up approximately 3.5 percent of all hospital inpatient admissions (roughly 1.5 million admissions).⁵¹⁴

Existing CoPs for CAHs and REHs include requirements related to the transfer of patients in the event that the facility is unable to furnish needed services for a patient or the patient requires a higher level of care. For example, the CAH CoPs at § 485.616(a) require CAHs that are members of a rural health network to have an agreement in place with at least one hospital that is also a member of the network for patient transfer. Additionally, the discharge planning requirements at § 485.642(b) require CAHs to discharge, transfer, or refer the patient, where applicable, with all necessary medical information pertaining to the patient's condition. We require similar actions regarding patient transfers for REHs at § 485.538.

Efficient transfers to hospitals that can treat complex conditions and provide higher levels of care is critical for patients that are experiencing obstetrical emergencies or complications, or patients that require immediate post-delivery care. Elements of safe transfer would include: (1) risk identification and determination of conditions necessitating consultation, referral, and transfer; (2) mechanisms and procedures for transfer/transport to a higher-level hospital at all times; (3) a reliable, accurate, and comprehensive communication system between participating hospitals, hospital personnel, and transport teams.⁵¹⁵

b. Proposals

We believe that comprehensive discharge planning CoP for hospitals, including documented requirements for transfer protocols, will enhance this process and better protect the health and safety needs of all patients, including pregnant, birthing, and postpartum women. Having an established process with identified

policies and procedures, and a medical staff that has received training regarding transfer protocols can support hospitals in expediting transfers when necessary. Therefore, we propose revisions to the hospital discharge planning regulations to include requirements for transfer protocols.

We propose at § 482.43(c) to require that hospitals have written policies and procedures for transferring patients under their care. This would be inclusive of hospital inpatients (for example, transfers from the emergency department to inpatient admission, transfers between inpatient units in the same hospital, as well as transfers between inpatient units at different hospitals). This would ensure patients are transferred to the appropriate level of care promptly and without undue delay, in order to meet their needs.

We also propose to require the hospital to provide training to the relevant staff (as determined by the facility) regarding the hospital policies and procedures for transferring patients under its care.

Although we have established requirements for certain facilities regarding patient transfers and propose standards for transfer protocols and training requirements here, in general hospitals are not required to accept or receive patients transferred from other facilities unless the receiving hospital has the capacity to treat the individual (42 CFR 489.24(f)). To ensure that patients receive the care their medical conditions require, we encourage all recipient hospitals to have policies and procedures in place regarding the acceptance of transfers and remind hospitals of their obligations to comply with EMTALA and Federal civil rights laws.⁵¹⁶ EMTALA requires hospitals with emergency departments to provide an appropriate medical screening examination to determine whether an emergency medical condition exists, provide stabilizing treatment if hospital determines that there is an emergency medical condition, and if necessary, to appropriately transfer individuals with an emergency medical condition as needed, whether or not the individual is eligible for Medicare benefits and regardless of ability to pay (42 CFR 489.24(a)). Federal civil rights laws prohibit discrimination based on an individual's race, color, national origin,

sex, religion, disability, and age. Further, hospitals that have specialized capabilities or facilities (including, but not limited to, facilities such as burn units, shock-trauma units, neonatal intensive care units, or, with respect to rural areas, regional referral centers) may not refuse to accept from a referring hospital an appropriate transfer of an individual who requires such specialized capabilities or facilities, if the receiving hospital has the capacity to treat the individual (42 CFR 489.24(f)). We solicit comments on these proposals.

We also solicit public comments on the following questions:

- How often should staff be trained in transfer protocols?
- What definitions or criteria exist to determine if a transfer is carried out “promptly and without undue delay”?
- Should hospitals be required to have written policies and procedures outlining their standards and conditions for accepting transfers?
- Should all hospitals (inclusive of CAHs and REHs) be required to have a documented partnership with another hospital that both provides OB services, as well as has a Medical Fetal Medicine (MFM) specialist available for consultations in urgent situations, if such service(s) are already offered directly by the hospital? What would be the benefits versus burden of such a policy? How could any burden be mitigated?

XXII. Modification to the Hybrid Hospital-Wide All-Cause Readmission and Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measures in the Hospital Inpatient Quality Reporting Program

A. Background

We refer readers to the following final rules for detailed discussions of the history of the Hospital IQR Program, including statutory history, and for the measures we have previously adopted for the Hospital IQR Program measure set:

- The FY 2010 Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System (IPPS/LTCH PPS) final rule (74 FR 43860 through 43861);
- The FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181);
- The FY 2012 IPPS/LTCH PPS final rule (76 FR 51605 through 61653);
- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53503 through 53555);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50775 through 50837);
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249);

⁵¹⁴ Hernandez-Boussard T, Davies S, McDonald K, Wang NE. Interhospital Facility Transfers in the United States: A Nationwide Outcomes Study. *J Patient Saf.* 2017 Dec;13(4):187–191. doi: 10.1097/PTS.000000000000148. PMID: 25397857; PMCID: PMC4956577.

⁵¹⁵ <https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2019/08/levels-of-maternal-care>.

⁵¹⁶ Recipients of Federal financial assistance must comply with Federal civil rights laws, including but not limited to Title VI of the Civil Rights Act of 1964 (45 CFR part 80), Section 504 of the Rehabilitation Act of 1973 (45 CFR part 84), The Age Discrimination Act (45 CFR part 90), and Section 1557 of the Affordable Care Act (45 CFR part 92).

- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 38348);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509);
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58926 through 58959);
- The FY 2022 IPPS/LTCH PPS final rule (86 FR 45360 through 45426);
- The FY 2023 IPPS/LTCH PPS final rule (87 FR 49190 through 49310); and
- The FY 2024 IPPS/LTCH PPS final rule (88 FR 59144 through 59203).

We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations and the FY 2025 IPPS/LTCH PPS proposed rule published on May 2, 2024 (89 FR 36306 through 36341).

B. Proposed Update to the Form, Time, and Manner Requirements for the Hybrid Hospital-Wide All-Cause Readmission (HWR) and Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) Measures for the FY 2026 Payment Determination

1. Background of the Hybrid HWR and Hybrid HWM Measures in the Hospital IQR Program

The Hospital IQR Program previously adopted two hybrid measures: (1) the Hybrid Hospital-Wide Readmission (HWR) measure; and (2) the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure. Hybrid measures use more than one data source for measure calculation; specifically for the Hybrid HWR and Hybrid HWM measures, they use core clinical data elements (CCDEs), linking variables, and claims data (80 FR 49698). CCDEs are a set of clinical variables derived from electronic health records (EHRs) that can be used to risk adjust hospital outcome measures (80 FR 49699). Linking variables are administrative data that can be used to link or merge the CCDEs and administrative claims data for measure calculation (80 FR 49703). These measures are designed to enhance risk adjustment of administrative claims-based outcome measures by utilizing patient clinical data captured in EHRs (80 FR 49698).

We initially solicited public comment on the potential future adoption of hybrid measures into the Hospital IQR Program in the FY 2016 IPPS/LTCH PPS final rule adoption (80 FR 49698 through 49704). In subsequent years, we

adopted both the Hybrid HWR measure and the Hybrid HWM measure with initial voluntary reporting periods. A discussion of the measure history for both measures follows.

The Hybrid HWR was the first hybrid measure introduced into the Hospital IQR Program. The Hybrid HWR measure is designed to capture all unplanned readmissions that arise from acute clinical events requiring urgent rehospitalization within 30 days of discharge. The measure was adopted in a stepwise fashion starting with voluntary reporting periods. In the FY 2018 IPPS/LTCH PPS final rule, we finalized 6 months of voluntary reporting for the CY 2018 reporting period (82 FR 38350 through 38355). In the FY 2020 IPPS/LTCH PPS final rule, we finalized 2 additional years of voluntary reporting, followed by mandatory reporting impacting the FY 2026 payment determination (84 FR 42465 through 42479). Then, in the FY 2024 IPPS/LTCH PPS final rule, we modified the Hybrid HWR measure cohort to include both Medicare fee-for-service (FFS) patients and Medicare Advantage (MA) patients 65 years and older for the FY 2027 payment determination and for subsequent years (88 FR 59161 through 59168).

The Hybrid HWM measure was the second hybrid measure to be adopted into the Hospital IQR Program. The Hybrid HWM measure is an outcome measure that captures the hospital-level, risk-standardized mortality rate (RSMR) of unplanned, all-cause mortality within 30 days of hospital admission for any eligible condition. Similar to the Hybrid HWR measure, we adopted the Hybrid HWM measure in a stepwise fashion, starting with a period of voluntary reporting. We initially adopted the Hybrid HWM measure in the FY 2022 IPPS/LTCH PPS final rule and finalized one voluntary reporting period followed by mandatory reporting impacting the FY 2026 payment determination (86 FR 45365 through 45374). Then in the FY 2024 IPPS/LTCH PPS final rule, we modified the Hybrid HWM measure cohort to include both Medicare fee-for-service (FFS) patients and Medicare Advantage (MA) patients 65 to 94 years old for the FY 2027 payment determination and for subsequent years (88 FR 59161 through 59168).

As previously noted, these hybrid measures use data from claims in combination with CCDEs and linking variables pulled from hospital EHRs. We require that hospitals submit linking variables on 95 percent of hospital discharges (84 FR 42470; 86 FR 45371). The previously finalized linking variables are: (1) CMS Certification

Number; (2) Health and Insurance Claims Number or Medicare Beneficiary Identifier; (3) Date of Birth; (4) Sex; (5) Admission date; and (6) Discharge date (84 FR 42469; 86 FR 45371). The previously finalized CCDEs are vital signs and laboratory results (84 FR 42469; 86 FR 45371). We also previously finalized that hospitals would be required to report CCDEs on 90 percent of discharges in a given reporting period (84 FR 42469; 86 FR 45371). These submission requirements were finalized beginning with mandatory reporting for the FY 2026 payment determination (84 FR 42469 through 42470; 86 FR 45371). We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42465 through 42479) and FY 2022 IPPS/LTCH PPS final rule (86 FR 45365 through 45374) for more information regarding data sources, measure calculation, and risk adjustment requirements. We also refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42506 through 42508), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58941), the CY 2021 PFS final rule (85 FR 84472), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45421) for our previously adopted policies regarding certification, file format, and data submission requirements for hybrid measures in the Hospital IQR Program. For both hybrid measures, hospitals are currently required to submit data for the mandatory reporting period impacting the FY 2026 payment determination, based on performance data from July 1, 2023 through June 30, 2024, by October 1, 2024 (86 FR 45370).

Under our stepwise approach when we adopted the hybrid measures, we finalized that data collected during the voluntary reporting periods would not be publicly reported (84 FR 42470; 86 FR 45371). We also finalized that we would begin public reporting of both hybrid measures' results, beginning with data collected from the July 1, 2023 through June 30, 2024 reporting period, impacting the FY 2026 payment determination (84 FR 42470 through 42471; 86 FR 45371).

2. Proposal To Extend Voluntary Reporting of CCDE and Linking Variable Data for the Hybrid HWR and Hybrid HWM Measures

Based on hospital performance during the most recent voluntary reporting period, it appears that hospitals are unprepared for mandatory reporting of the Hybrid HWR and Hybrid HWM measures. As a part of measure maintenance, we routinely monitor hospital performance on the Hospital IQR Program's measures. We have been closely monitoring the results of

voluntary reporting for both hybrid measures, including most recently the results of the second voluntary period for Hybrid HWR and the first voluntary period for Hybrid HWM. During these periods, approximately one-third of IPPS hospitals participated. The data currently indicate that three-fourths of the participating hospitals would not have met the reporting thresholds for the CCDEs and linking variables if the reporting requirement had been mandatory, and accordingly, would have been subject to a one quarter reduction to their annual payment update under the Hospital IQR Program for the given fiscal year.

The hospitals that participated in the voluntary reporting were mostly large, non-rural, non-critical access, and non-safety net. Based on our experience with implementing new types of digital measures, we understand that small and rural hospitals, as well as hospitals with fewer financial resources, may need additional time and flexibility to successfully implement new measure reporting requirements relative to larger, non-rural hospitals (82 FR 38357). We therefore believe the reporting failure rate may have been even higher if all IPPS hospitals participated.

In addition, we received feedback from hospitals (via email and help desk questions) raising various issues with reporting including issues related to CCDE collection timing and clinical workflow, issues with the types of units required for CCDE values, and achievability of the data submission requirement thresholds. We are investigating whether any of these issues or any other issues may be making it difficult for hospitals to meet CCDE and linking variable thresholds (that is, of 90 percent and 95 percent, respectively, of hospital discharges), and need additional time to analyze and identify the root cause of these challenges.

We appreciate that, in light of the information discussed above, hospitals participating in the Hospital IQR Program may need an additional year to remediate the issues and develop experience with reporting of CCDEs and linking variables before being subject to the associated program payment adjustments for noncompliance. We therefore propose that for the FY 2026 payment determination (based on performance data from July 1, 2023 through June 30, 2024), the submission of CCDEs and linking variables would remain voluntary. We propose that for the FY 2027 payment determination and subsequent years, the submission of CCDEs and linking variables become mandatory.

Under our proposal, a hospital's annual payment determination for FY 2026 would not be affected by the voluntary reporting of CCDEs and linking variables, although we would still evaluate and assess the claims data portion of these measures. The Hybrid HWR and Hybrid HWM measures would be publicly reported based on claims data. This proposal would allow the Hospital IQR Program to publicly display hospital information on these important clinical areas and provide patients with visibility into hospital performance, while providing hospitals with more time to improve reporting on CCDEs and linking variables. Hospitals would continue to receive confidential hospital-specific reports in the Spring as a preview of public reporting. We note that the hospital-specific reports would reflect the CCDEs and linking variables, should hospitals choose to submit them. We continue to evaluate potential changes to the reporting requirements related to CCDEs and linking variables.

We invite public comment on our proposal to continue voluntary reporting of the CCDEs and linking variables for both the Hybrid HWR and Hybrid HWM measures, for the performance period of July 1, 2023 through June 30, 2024, impacting the FY 2026 payment determination for the Hospital IQR Program. We specifically request feedback regarding the difficulties hospitals have in meeting the thresholds and any recommendations hospitals may have based on their experiences reporting on hybrid measures.

XXIII. Individuals Currently or Formerly in the Custody of Penal Authorities

A. Medicare FFS No Legal Obligation To Pay Payment Exclusion and Incarceration (revisions to 42 CFR 411.4)

1. Background

Section 1862(a)(2) of the Act prohibits Medicare payment under Part A or Part B for any expenses incurred for items or services for which the individual furnished such items or services has no legal obligation to pay, and which no other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for, except in the case of Federally qualified health center services. We refer to this payment exclusion as the "no legal obligation to pay" payment exclusion. The no legal obligation to pay payment exclusion is codified in regulation at § 411.4. The regulatory exclusion includes a general rule at § 411.4(a) that

applies to all services (except as provided in § 411.8(b)) and a special condition at § 411.4(b) for services furnished to individuals in custody of penal authorities.

In the 1989 final rule establishing the special condition at § 411.4(b) for services furnished to individuals in custody of penal authorities, we explained that the purpose of § 411.4(b) is to clarify how the no legal obligation to pay payment exclusion applies to services furnished to prisoners (see 54 FR 41716, 41723 (Oct. 11, 1989)) ("1989 final rule"). We explained that prisoners generally have the status of public charges and, as such, have no obligation to pay for the medical care they receive. Consequently, under the statutory no legal obligation to pay payment exclusion, Medicare is prohibited for paying for such care. We noted, however, that in certain circumstances prisoners could have a legal obligation to pay for health care items or services they receive, and in such circumstances, Medicare may pay for the items or services.

As finalized in the 1989 final rule, the special rule at § 411.4(b) specifies the conditions that must be satisfied to establish that a prisoner has a legal obligation to pay for health care items or services, and thus that Medicare may pay for such items or services. Specifically, § 411.4(b) provides that Medicare may pay for services furnished to individuals in custody of police or other penal authorities or in the custody of a government agency under a penal statute only if the following conditions are met: (1) State or local law must require individuals in custody to repay the cost of the medical services they receive while in custody; and (2) the State or local government must enforce the requirement to pay by billing all such individuals, whether or not covered by Medicare or any other health insurance, and by pursuing collection of the amounts they owe in the same way and with the same vigor that it pursues the collection of other debts.

In 2007, we added a definition of "custody" to the special condition at § 411.4(b) for services furnished to individuals in custody of penal authorities (see 72 FR 47130, 47405 through 47406 (Aug. 22, 2007)) ("2007 final rule"). We noted that CMS would not defer to a particular State or local government's definition or interpretation of what constitutes "custody." Instead, we adopted a definition of "custody" that is consistent with how the term has been defined by Federal courts for purposes of the habeas corpus protections of the U.S. Constitution. As finalized,

§ 411.4(b) provides that individuals who are in custody include, but are not limited to, individuals who are under arrest, incarcerated, imprisoned, escaped from confinement, under supervised release, on medical furlough, required to reside in mental health facilities, required to reside in halfway houses, required to live under home detention, or confined completely or partially in any way under a penal statute or rule. We explained that, under this description, individuals who are on parole, probation, bail, or supervised release may be in custody for purposes of the payment exclusion. We also stressed that individuals who are under supervised release for the purpose of receiving medical services on so-called “medical furlough,” and who are required to return to a State or local government facility after the medical services are furnished, are considered to be in custody for purposes of the no legal obligation to pay payment exclusion.

In the 2007 final rule, we responded to several commenters who objected to the breadth of the definition of custody that we adopted. The commenters maintained that the policy would place an unreasonable burden on hospitals, because hospitals often have no means of identifying whether an individual is in custody for purposes of § 411.4(b) if the individual is not physically confined in a correctional facility or brought to the hospital by government authorities. Another commenter added that a hospital has no way of knowing whether an individual who is in custody for purposes of § 411.4(b) has a legal obligation to pay for his or her medical care. In response, we stated that hospitals are not required to seek criminal histories or do background checks on all patients being registered. We explained that, if Medicare denies payment because the individual receiving care is in custody of penal authorities, the provider or supplier will be directed to seek payment from the State or local government that has custody of the individual. We concluded that, if the State or local government believes in such circumstances that it is not responsible for the care provided to the individual, it should be prepared to prove to Medicare either that the individual would not be considered to be in custody under Federal habeas corpus law or that the State or local government has no legal obligation to pay for the services because the conditions in § 411.4(b)(1) and (b)(2) are satisfied.

There have been no further revisions to § 411.4 since it was revised in 2007.

2. Proposal

a. Overview of Proposed Changes

The special condition at § 411.4(b) for services furnished to individuals in custody of penal authorities operates as a rebuttable presumption. The presumption is that individuals who are in custody, as the term is described in § 411.4(b), have no legal obligation to pay for health care items or services they receive while in custody; therefore, Medicare is prohibited from paying for such health care items or services under the no legal obligation to pay payment exclusion. The presumption can be rebutted by a showing that: (1) the State or local government requires individuals in custody to repay the cost of the medical services they receive while in custody; and (2) the State or local government enforces the requirement to pay by billing all such individuals, whether or not covered by Medicare or any other health insurance, and by pursuing collection of the amounts they owe in the same way and with the same vigor that it pursues the collection of other debts.

We propose to narrow the description of “custody” in § 411.4(b), because, as explained in greater detail below, we no longer believe that certain classes of individuals should be presumed to be in custody for purposes of the no legal obligation to pay payment exclusion. Specifically, we propose to remove individuals who are under supervised release or required to live under home detention from the description of “custody” in § 411.4(b), and we propose to strike the phrase “or confined completely or partially in any way under a penal statute or rule.” We are also seeking comments on a proposal, described in greater detail below, to determine when individuals who are required to reside in halfway houses should be considered to be in custody for purposes of the no legal obligation to pay payment exclusion.

In addition to the proposed changes to the description of “custody,” we are also taking this opportunity to reorganize and renumber the regulation at § 411.4(b). Currently, § 411.4(b) includes both a description of “custody” and a statement of the conditions that must be satisfied for payment to be made under Medicare for items or services furnished to individuals in custody of penal authorities. Our proposed reorganization would separately codify the description of “custody” and the special conditions for payments. Specifically, at proposed §§ 411.4(b)(1)(i) through 411.4(b)(1)(iii), we propose to state the conditions that

must be satisfied for Medicare to pay for items or services furnished to an individual in custody of penal authorities; we also propose certain non-substantive edits to the regulatory language adopted from current § 411.4(b). At proposed § 411.4(b)(2), we propose a definition of “penal authority” that would apply generally to § 411.4(b). At § 411.4(b)(3), we propose a description of “custody” that is narrower in scope than the current description.

In addition to these proposed changes, which are discussed in greater detail below, we are making certain non-substantive edits to § 411.4(a) to align the regulatory text with the statutory no legal obligation to pay payment exclusion at section 1862(a)(2) of the Act. Specifically, where the statute refers to items and services, the current regulation refers only to services; consistent with the statute, we propose to refer to both items and services in the regulatory text. We are also adding a reference to Federally Qualified Health Center services at § 411.4(a) to align with the statute. The regulatory text at § 411.4(a)(2) currently states that no other person or organization has a legal obligation to pay, whereas the statute refers only to a person; we propose to delete “organization” from the regulation because the term “person” includes both natural and non-natural persons, and the term “organization” is therefore superfluous. We also propose to align the parenthetical in § 411.4(a)(2) with the statutory parenthetical and to replace the term “beneficiary” in §§ 411.4(a)(1) and 411.4(a)(2) with “individual,” to align with section 1862(a)(2) of the Act.

We also propose to redesignate the special conditions that are specified in §§ 411.4(b)(1) and 411.4(b)(2) as §§ 411.4(b)(1)(i) through 411.4(b)(1)(iii). Under the proposal, the rebuttable presumption in § 411.4(b)(1) would apply to all items or services furnished to individuals in custody of penal authorities, regardless of who provides the items or services. We are seeking comments on whether the scope of the rebuttable presumption in proposed § 411.4(b)(1) should be limited to items or services furnished by the penal authority or by a third party with which the penal authority has arranged to provide the items or services. Were we to limit the scope of the rebuttable presumption in this way, the rebuttable presumption in proposed § 411.4(b)(1) would not apply to items or services furnished to individuals in custody of penal authorities by third parties who do not have an arrangement or contract

with the penal authority to provide the items or services. We are also seeking comments on whether individuals in custody of penal authorities are permitted to arrange for their own health care with third parties who do not have an agreement with the penal authority to provide the items or services.

Lastly, we propose at proposed § 411.4(b)(3)(v) to clarify that an individual who is required to reside in a mental health facility would only be considered to be in custody under the no legal obligation to pay payment exclusion if the individual is required to reside in such a facility under a penal statute or rule.

b. Description of “Custody”—Proposed § 411.4(b)(3)

We propose to redesignate the description of “custody” as § 411.4(b)(3), to remove individuals who are on supervised release and home detention from the current description of “custody,” and to strike the phrase “completely or partially in any way under a penal statute or rule.” (We are also seeking comments on a separate proposal for individuals residing in halfway houses; this proposal is discussed below at section c.) Under the proposal, individuals who have been lawfully released from confinement in jail, prison, penitentiary, or similar institution, or released following arrest (that is, the individuals are no longer physically detained by law enforcement or penal authorities) on bail, parole, probation, or home detention would not be presumed to be in custody for purposes of the no legal obligation to pay payment exclusion, even if such individuals are required to return to jail, prison, penitentiary, or similar institution at some later time (for example, due to conviction or failure to satisfy the conditions of their supervised release). However, individuals who are on “medical furlough” or similar arrangements (that is, the individuals are under the control of law enforcement or penal authorities and required to return to jail or prison after medical services have been provided) would still be considered in custody for purposes of § 411.4(b)(3). Given the differences in terminology used by various Federal, State, and local government penal authorities to refer to different levels of control and confinement in the criminal justice system, we are seeking comments on the appropriateness of the terminology in the existing description of “custody” in our regulations and whether additional or different terminology should be incorporated in the description of

“custody” at § 411.4(b)(3) in the final rule. We are also seeking comment on whether we should explicitly state in regulatory text that individuals on bail, parole, probation, or home confinement are not considered to be in custody for purposes of proposed § 411.4(b).

We propose to narrow the description of custody in § 411.4(b)(3) for several reasons. First, we believe that individuals who have been released from jail or prison on bail, parole, probation, or home detention typically have a legal obligation to pay for the health care items or services they receive. We do not believe that such individuals have the status of public charges, and we do not believe that Federal, State, or local government law enforcement or penal authorities are typically responsible for providing for the health care of such individuals. Therefore, we no longer believe that such individuals (and the providers and suppliers who furnish services to them) should have the burden to prove that the special conditions in existing §§ 411.4(b)(1) and 411.4(b)(2) have been satisfied in order to receive payment from Medicare. We are seeking specific, detailed comments on the circumstances in which individuals who have been released from incarceration on bail, parole, probation, or home detention have a legal obligation to pay for some or all of the health care items or services they receive. We are also seeking comment on what specific health care items or services, if any, are typically furnished by Federal, State, or local governments at no cost to individuals who have been released from jail or prison on bail, parole, probation, or home detention.

We also propose to narrow the description of “custody” in § 411.4(b) to remove barriers to access to Medicare by individuals who are returning to the community after incarceration. According to advocates, confusion about the applicability of the payment exclusion has led individuals released from incarceration to not apply for Medicare, even if they are eligible, or to apply only for Medicaid, because they believe that Medicare will not pay for items or services that they receive under the payment exclusion. Advocates have also maintained that certain providers or suppliers may be hesitant or refuse to treat individuals who are on bail, parole, probation, or home detention because the providers or suppliers believe that Medicare payment is not available for items or services provided to such individuals. As a result, such individuals may delay or forgo necessary treatment, including treatment for substance use disorders,

upon release from incarceration. The proposed changes to the description of “custody” would clarify that Medicare may pay for health care items and services furnished to an individual while on bail, parole, probation, or home detention, provided the individual has a legal obligation to pay for such items or services, without having to prove that the special conditions in § 411.4(b)(1) have been satisfied. (See section XII.2 of this proposed rule for a discussion of proposed modifications to the special enrollment periods (SEP) for formerly incarcerated individuals under §§ 406.27(d) and 407.23(d) that would also increase access to Medicare for individuals returning to the community from incarceration.)

Finally, our proposal to narrow the description of “custody” in § 411.4(b) would bring the Medicare no legal obligation to pay payment exclusion into greater alignment with certain related Social Security and Medicaid provisions. CMS relies on data provided by the Social Security Administration to identify individuals who are in custody of penal authorities. However, under Social Security regulations, individuals who are released from incarceration on parole, probation, or home detention are generally not considered to be confined for purposes of a limitation on payment of certain benefits (see section 202(x)(1) of the Social Security Act (42 U.S.C. 402)), and the Social Security data does not track such individuals. Our proposal to narrow the description of “custody” would improve the alignment between the no legal obligation to pay regulation at § 411.4(b) and the data that is used to help carry out the rule. We note, however, that there would still be substantive differences between the Social Security definition of “confinement” and the proposed description of “custody” at § 411.4(b)(3). Most notably, the Social Security Administration suspends benefits if the individual has been convicted of a criminal offense and sentenced to a period of confinement, and based on that conviction remains confined for more than 30 days. In contrast, under proposed § 411.4(b)(3), an individual is considered to be in custody of penal authorities for purposes of the Medicare no legal obligation to pay payment exclusion if the individual is under arrest; confined in jail, prison, penitentiary, or similar institution while awaiting trial (that is, the person has not yet been convicted); or confined in jail, prison, penitentiary, or similar institution following conviction for any period of time,

including sentences of less than 30 days. We note these differences are a result of Medicare's statutory no legal obligation to pay payment exclusion. Specifically, we believe that individuals who are confined to jail while awaiting trial typically do not have a legal obligation to pay for health care items or services. We seek comments on whether such individuals confined to jail while awaiting trial typically pay for health care items or services they receive or have a legal obligation to do so.

Our proposal to narrow the description of "custody" in § 411.4(b)(3) would also bring the Medicare no legal obligation to pay payment exclusion into closer alignment with Medicaid. Under Medicaid regulations, Federal Financial Participation (FFP) is not available for services provided to individuals who are inmates of public institutions (see § 435.1009), and an "inmate of a public institution is defined generally as 'a person living in a public institution'" (see § 435.1010). According to Medicaid State Health Official Letter (SHO) # 16-007, however, individuals who are on parole, probation, or home confinement are generally not considered to be inmates for purposes of Medicaid (see SHO # 16-007 (RE: To facilitate successful re-entry for individuals transitioning from incarceration to their communities) (April 28, 2016)). By no longer including such individuals in the Medicare description of "custody" at § 411.4(b)(3), our proposal would improve dually eligible individuals' access to both Medicare and, potentially, Medicaid, including accessing benefits for already-enrolled individual. For example, advocates have shared anecdotally that some Medicaid agencies automatically suspend payment for services to an individual whose Medicare benefits are suspended due to a presumption that the individual is in custody. In addition, according to advocates, some individuals who are recently released from jail or prison on bail, parole, probation, or home detention have only enrolled in Medicaid, because they believe, even where they have a legal obligation to pay, that Medicare will not pay for their health care under the no legal obligation to pay payment exclusion. Our proposal to narrow the description of "custody" in § 411.4(b)(3) is intended to remove this real or perceived barrier to Medicare access.

We caution that, even if we finalize the proposed modification of the description of "custody" in § 411.4(b)(3), the generally applicable no legal obligation to pay payment

exclusion at § 411.4(a) would continue to apply to services furnished to individuals on bail, parole, probation, or home detention in the same way it applies to any other Medicare beneficiary who receives an item or service where there is no legal obligation to pay. The no legal obligation to pay payment exclusion in § 411.4(a) is a general rule that is applicable to *all* health care items or services (except Federally qualified health center services and as provided in § 411.8(b)) received by any Medicare beneficiary, regardless of whether the individual is in custody of penal authorities. Nothing in the proposed modification of the special condition at § 411.4(b) would affect the scope of the general rule at § 411.4(a). Thus, if an individual on bail, parole, probation, or home detention has no legal obligation to pay for a health care item or service, the general rule at § 411.4(a) would continue to prohibit Medicare from paying for such a service, regardless of the scope of the description of "custody" in § 411.4(b)(3). For example, if a State or local government requires substance use disorder counseling as a condition of parole, and the State or local government does not charge all parolees for such services, then the parolee has no legal obligation to pay for such service under § 411.4(a); therefore, Medicare is prohibited under § 411.4(a) from paying for the service. We are seeking comments on what types of medically necessary health care items or services, if any, are typically provided at no cost to individuals on parole, probation, or home detention.

c. Halfway Houses

According to the National Institute of Justice (NIJ), a research, development, and evaluation agency of the U.S. Department of Justice, the term "halfway house" usually refers to temporary housing, provided in a community-based residential facility, which uses around-the-clock supervision and offers services to assist with the transition from incarceration to the community (see <https://crimesolutions.ojp.gov/ratedpractices/90#1-0>). The NIJ notes that, although the degree to which services are provided to residents varies significantly among halfway house programs, the following characteristics are common to most halfway houses: (1) constant supervision and daily contact between staff and returning individuals; (2) a requirement for participants to abide by rules (such as curfews and drug testing); and (3) access to employment, education, life skills training, and additional services as needed (such as

substance use disorder treatment and counseling).

As the name suggests, halfway houses occupy a middle ground between complete custodial incarceration and unconditional release, and there appears to be wide variation in the degree of control exercised over halfway house residents in various State, local, and Federal facilities. We are therefore soliciting comments on whether halfway house residents typically have a legal obligation to pay for health care items and services, and if so, to what extent (that is, do they have a legal obligation to pay for all or most health care items or services, or only certain items or services) and under what conditions. In particular, we are interested in receiving detailed comments, with examples as appropriate, focusing specifically on the legal obligation that halfway house residents have to pay for the health care items and services they receive.

To provide greater focus for our comment solicitation on halfway houses, we propose regulatory text at § 411.4(b)(3)(vi) that is drawn from the Medicaid payment exclusion rule at § 435.1009. As explained in SHO # 16-007, FFP is available for services furnished to Medicaid-eligible individuals living in halfway houses, provided the following conditions are met: (1) residents are not precluded from working outside the facility in employment available to individuals who are not under justice system supervision; (2) residents can use community resources (libraries, grocery stores, recreation, education, etc.) at will; and (3) residents can seek health care treatment in the broader community to the same or similar extent as other Medicaid enrollees in the state. SHO # 16-007 adds that "at will" is consistent with certain house rule restrictions and travel limitations, and stipulates that the State Medicaid agency must ensure that the halfway house meets the requirements enumerated above.

Consistent with Medicaid guidance, we propose at § 411.4(b)(3)(vi) to consider an individual to be in custody for purposes of the special condition for payment at § 411.4(b) if the individual is required to reside in a halfway house under any of the following conditions: residents are precluded from working outside the facility in employment that is available to individuals who are not under penal authority supervision; residents may not use community resources (for example, libraries, grocery stores, recreation, or educational institutions) at will; or residents may not seek health care items and services

in the broader community to the same or similar extent as individuals who are not under penal authority supervision. Like Medicaid, we would interpret “at will” to be consistent with certain house rule restrictions and travel limitations. Our proposal to align the Medicare no legal obligation to pay payment exclusion at § 411.4(b) with Medicaid guidance would facilitate access to Medicare for dually eligible individuals returning to the community from incarceration and residing in halfway houses.

Consistent with our discussion above regarding bail, parole, probation, and home detention, we note that the general no legal obligation to pay payment exclusion at § 411.4(a) would continue to apply to services furnished to individuals in halfway houses even if those individuals do not meet any of the conditions in proposed § 411.4(b)(3)(vi) and thus are not considered to be in custody for purposes of § 411.4(b). If an individual has no legal obligation to pay for a health care item or service, then Medicare may not pay for the item or service.

We are seeking comments on whether individuals who reside in halfway houses under the conditions described in proposed § 411.4(b)(3)(vi) typically do not have a legal obligation to pay for health care items or services, or whether fewer, other, or additional factors compared to the factors described in the proposal would form a more appropriate basis for a presumption that the individual is in custody and has no legal obligation to pay for health care items or services.

d. Definition of Penal Authority— Proposed § 411.4(b)(2)

As noted above, we propose to reorganize § 411.4(b) to separately codify the special conditions under which payment may be for items or services provided to an individual in custody at §§ 411.4(b)(1)(i) through 411.4(b)(1)(iii) and the description of “custody” at § 411.4(b)(3). We also propose to define “penal authority” at § 411.4(b)(2) as a police department or other law enforcement agency, a government agency operating under a penal statute, or a State, local or Federal jail, prison, penitentiary, or similar institution. We are aware that private contractors in some circumstances may be responsible for operating certain penal institutions or halfway houses, and we are seeking comment on whether such contractors should explicitly be included in the proposed definition of “penal authority.” The proposed definition is intended to be broad enough to include all agencies or

institutions that might place or hold an individual in custody, as the term is described at proposed § 411.4(b)(3), regardless of whether the individual has been convicted of a crime. We are aware that the term “penal authority” does not appear to be commonly used outside of the Medicare context. We are seeking comments on whether other terminology would be more appropriate or would align more closely with terms commonly used in the criminal justice system. We are also seeking comments on whether the proposed definition of “penal authority” is too broad or narrow for purposes of the no legal obligation to pay payment exclusion.

B. Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals

1. Background

The Consolidated Appropriations Act, 2021 provided the authority to establish Medicare Part A and B special enrollment periods (SEP) for individuals due to exceptional conditions. In the final rule titled “Medicare Program; Implementing Certain Provisions of the Consolidated Appropriations Act, 2021 and Other Revisions to Medicare Enrollment and Eligibility Rules” which appeared in the **Federal Register** on November 3, 2022 (87 FR 66454), CMS used this authority to establish an SEP for formerly incarcerated individuals. Individuals who use this SEP are able to enroll in Medicare Premium Part A and Part B and avoid potential gaps in coverage and late enrollment penalties (LEPs). As established in §§ 406.27(d)(1) and 407.23(d)(1), an individual is eligible to enroll in Medicare Parts A and/or B using this SEP so long as they demonstrate that they are eligible for Medicare and failed to enroll or reenroll in Parts A and/or B due to being in custody of penal authorities, and there is a record of release either through discharge documents or data available to the Social Security Administration (SSA). The SEP provisions at §§ 406.27(d) and 407.23(d) incorporate the description of ‘in custody of penal authorities’ from the payment exclusion parameters already established in § 411.4(b). In the November 2022 final rule, we stated that it was important to align the scope of the SEP with the scope of individuals specified in § 411.4(b) as individuals in custody of penal authorities; alignment with § 411.4(b) provides a measure of assurance that individuals who are no longer subject to the payment exclusion are able to enroll in Medicare (Part B and, if necessary, premium Part A). We also noted that we would continue to

assess the impact of alignment of the SEP with the scope of the payment exclusion. (87 FR 66464).

2. Proposal

Section 202 of the Act generally provides the basis for SSA to determine an individual’s eligibility for old age, survivors, and disability insurance (OASDI) benefits, also known as social security benefits, under Title II of the Act. For most Medicare beneficiaries, entitlement to Medicare Part A is based on entitlement to OASDI benefits under Title II per section 226 of the Act.⁵¹⁷ In addition, the SSA is responsible for determining entitlement to Part A and eligibility for Part B of Medicare. (See Pub. L. 103–296, sec. 105.) Section 202(x) of the Act suspends payment of OASDI benefits to prisoners, certain other inmates of publicly funded institutions, fugitives, probationers, and parolees, including when an individual is confined in a jail, prison, or other penal institution or correctional facility pursuant to conviction of a criminal offense for a period of more than 30 days. We propose to amend the SEP at §§ 406.27(d)(1) and 407.23(d)(1) to align the SEP triggering event more closely with the bases on which an individual’s OASDI benefit is reinstated or initiated rather than on the scope of the Medicare payment exclusion in § 411.4(b). We believe that these proposed amendments would streamline the administrative process for determining an individual eligible for this SEP and align eligibility for this SEP with an individual’s obligation and ability to pay for services that would otherwise be covered by Medicare. Furthermore, we believe that the alignment of this SEP with the initiation or reinstatement of OASDI benefits is appropriate, as it allows a population facing many challenges reintegrating into society to enroll or reenroll in Medicare by having premiums deducted from their OASDI benefits, rather than paying out of pocket.

The proposed amendments to § 411.4(b), discussed in section XXIII.A of this proposed rule, would narrow the list of settings where an individual is presumed to have no obligation to pay for Medicare-covered items and services—and, thus, Medicare is prohibited from paying for those services—because the individual is in custody of a penal authority. The rebuttable presumption at § 411.4(b) provides the individual an opportunity

⁵¹⁷ For more detailed information about entitlement and eligibility for Medicare, please refer to sections 226, 226A, 1818, 1818A, 1836, and 1881A of the Act and 42 CFR parts 406 and 407.

to indicate to CMS that the other entity did not cover certain items or services and ask that Medicare provide payment, but this option is moot if the individual is not able to enroll in Medicare. (See section XXIII.A of this proposed rule for more information about the rebuttable presumption and operation of the payment exclusion.) Under the current version of this SEP, beneficiary advocate groups raised concerns about the possibility for scenarios where an individual is not able to enroll when their items and services could be covered by Medicare, or they are able to enroll (and pay monthly premiums) but Medicare is not able to pay for their services.

In making determinations about the suspension of OASDI benefits due to an individual's incarceration, SSA uses data it collects from jails, prisons, other penal institutions or correctional facilities and certain mental health institutions regarding individuals confined in those and similar institutions for the reasons outlined in section 202(x)(1)(A) of the Act. See SSA System of Records Notice: Prisoner Update Processing System 60–0269, at 64 FR 11076 (Mar. 8, 1999) and updated at 72 FR 69723 (Dec. 10, 2007), 78 FR 40542 (Jul. 5, 2013) and 83 FR 54969 (Nov. 1, 2018). However, information about individuals within the full scope of the current provisions at § 411.4(b), including not only individuals who are confined in certain institutions but also individuals who are under arrest but not yet convicted, on medical furlough, or residing in half-way houses may not be as extensively or reliably available. As a result, making eligibility determinations for the SEP for Formerly Incarcerated Individuals as it is currently drafted is operationally difficult. In addition, the current SEP for Formerly Incarcerated Individuals incorporates the rebuttable presumption that is included in § 411.4(b) for situations where an individual (or healthcare provider seeking to bill Medicare for the services) can demonstrate that state or local law requires individuals to repay the cost of medical services while they are in custody and the state or local government entity enforces the requirement to pay by billing all such individuals, whether or not covered by Medicare or any other health insurance, and by pursuing collection of the amounts they owe in the same way and with the same vigor that it pursues the collection of other debts. However, SSA does not have a role in administering the Medicare payment exclusion in § 411.4(b). Therefore, there is a high

likelihood of potential inconsistency and administrative burden with tying the implementation of the SEP at §§ 406.27(d)(1) and 407.23(d)(1) to the Medicare payment exclusion under § 411.4(b). Although the proposed changes to § 411.4(b) discussed in section XXIII.A to narrow the scope of the payment exclusion would flow through to §§ 406.27(d) and 407.23(d) without amendment to the SEP parameters, we believe that addressing the rebuttable presumption and potential administration burden is appropriate and will reduce potential confusion.

Further, since the establishment of the SEP in January 2023, we have received feedback that raised concerns about tying SEP eligibility to the Medicare payment definition at § 411.4(b) and how SSA has begun administering the SEP using the data in SSA's systems. We have heard that the SEP eligibility parameters are confusing and potentially prevent or discourage eligible individuals from accessing the SEP. Conversely, situations may arise in which an individual is enrolled in Medicare using the SEP due to SSA data; however, due to the payment exclusion and limited exceptions for these settings, claims for health care may not be paid even if the specific state or local government does not provide health care in this type of setting.

Under our proposal, we intend that SSA would make a determination of an individual's eligibility to enroll using the Medicare SEP at §§ 406.27(d)(1) and 407.23(d)(1) based on the data SSA collects and keeps in its systems for determining OASDI benefit suspensions and any additional documentation provided by individuals to demonstrate that they have been released from incarceration. By more closely aligning the eligibility criteria for the SEP for Formerly Incarcerated Individuals with the data used by SSA in applying the OASDI benefit suspension requirement in section 202(x)(1)(A) of the Act, we intend that the SEP can be more efficiently and accurately administered. With the proposed revisions, the SEP at §§ 406.27(d) and 407.23(d) will provide an opportunity, beginning January 1, 2025, for an individual to enroll in Medicare if the individual was released from incarceration on or after January 1, 2023, failed to enroll in Medicare (Premium Part A or Part B) due to being incarcerated, and is still within the 12-month SEP described in §§ 406.27(d) and 407.23(d).

Overall, we propose to revise the eligibility requirements at §§ 406.27(d) and 407.23(d), beginning January 1,

2025, to remove the use of a release from the “custody of penal authorities as described in § 411.4(b)” and instead tie the eligibility for this SEP to whether an individual is “released from confinement in a jail, prison, or other penal institution or correctional facility,” which is phrasing that is more consistent with section 202(x)(1)(A)(i) of the Act. However, we are not proposing that a criminal conviction or formal sentencing be required for an individual to have been confined in a jail, prison, or other penal institution or correctional facility because conviction of crime is not required for the payment exclusion in § 411.4(b) to apply. As this differs from the requirements under section 202(x)(1)(A) of the Act, we also solicit comment on what documentation an individual can provide to demonstrate they were confined and released without conviction to determine eligibility for the SEP for formerly incarcerated individuals under §§ 406.27(d) and 407.23(d). Further, individuals who have escaped confinement are not considered to be “released” from confinement. Under our proposal, both §§ 406.27(d) and 407.23(d) would use the terms “incarcerated” and “incarceration” as a general reference for individuals who meet either standard. This proposed change in the eligibility criteria for the SEP for Formerly Incarcerated Individuals would align more closely with the standards SSA uses to determine whether an individual is within the scope of the limitation on payment of OASDI benefits established by section 202(x)(1)(A)(i) of the Act.

In the rulemaking to adopt and finalize §§ 406.27(d) and 407.23(d), we did not fully contemplate the implications of tying the SEP's eligibility criteria to the Medicare no legal obligation to pay payment exclusion (which includes a rebuttable presumption). A rebuttable presumption like the one available under the payment exclusion does not work well in enrollment context because although payment can be determined at the service level, an enrollment is either effectuated or not. It may be that for some services, the presumption that the individual has no legal obligation to pay can be rebutted while for other services it is not rebutted based on the scope of the state or local entity's policies and the individual's (or the healthcare providers) ability to provide sufficient evidence. However, enrollment in Medicare, including the obligation to pay Medicare premiums, would not vary with the specific service. While the proposed changes to § 411.4(b) would

narrow the range of settings in which an individual is presumed to be in custody and another entity is responsible for the individual's health care coverage, we believe that the proposed revisions to §§ 406.27(d) and 407.23(d) would best address concerns about access to and confusion with the SEP for individuals who have been released from incarceration.

We propose several changes to §§ 406.27(d) and 407.23(d) to significantly align the SEP eligibility criteria, beginning January 1, 2025, with the criteria used by SSA to determine whether an individual is incarcerated. Throughout, our proposed changes are largely to replace references to an individual being in custody of penal authorities as described in § 411.4(b) with references to an individual's confinement in a jail, prison, or other penal institution or correctional facility. First, we propose to amend the introductory text in paragraph (d) of both §§ 406.27 and 407.23 to state the general rule that there is an SEP for Medicare eligible individuals who are no longer incarcerated after January 1, 2023. We use "incarcerated" and "incarceration" in this introductory language and in paragraph (d)(3), respectively, to include both being in custody of penal authorities as described in § 411.4(b) (and in the proposed revisions to paragraph (d)(1) of each regulation regarding the current scope of the SEP) and being confined as described in our proposed amendments to paragraph (d)(2) of each regulation. Using the term "incarcerated" is consistent with how these regulations were originally established and leads to more streamlined and less repetitive regulation text. We are seeking comments on this proposal, especially its implications for people in halfway houses, to ensure access to the SEP for formerly incarcerated individuals.

Second, we propose to reorganize paragraphs (d)(1) and (d)(2) to establish the rules for eligibility for and the duration of the SEP for releases from incarceration during the periods between (1) January 1, 2023, through December 31, 2024, and (2) on and after January 1, 2025. We propose to revise paragraphs §§ 406.27(d)(1) and 407.23(d)(1) to state the current parameters and duration for the SEP that are applicable to releases after January 1, 2023, and before January 1, 2025. The current eligibility requirements are proposed to be redesignated as paragraph (d)(1)(i) and the current duration of the SEP (from current §§ 406.27(d)(2) and 407.23(d)(2)) are proposed to be redesignated paragraph (d)(1)(ii), with clarifications

that the date of release is used as part of the eligibility criteria. At §§ 406.27(d)(2) and 407.23(d)(2) we propose to establish new parameters and duration for the SEP that would be applicable beginning January 1, 2025. Specifically, we propose at new §§ 406.27(d)(2)(i) and 407.23(d)(2)(i) that an individual released for releases that occur on and after January 1, 2025, from confinement in a jail, prison, or other penal institution or correctional facility would be eligible for the SEP. The existing parameters (currently at §§ 406.27(d)(1) and 407.23(d)(1)) that the individual must demonstrate that they are eligible for Medicare and failed to enroll or reenroll due to being incarcerated and there is a record of release either through discharge documents or data available to SSA would continue to be applicable and are therefore included in proposed §§ 406.27(d)(2)(i) and 407.23(d)(2)(i). At new §§ 406.27(d)(2)(ii) and 407.23(d)(2)(ii), we propose that beginning January 1, 2025, the SEP starts the day an individual is released from incarceration as determined by SSA and ends the last day of the 12th month after the month in which the individual is released. As noted above, individuals who use this SEP are able to enroll in Medicare Premium Part A and Part B without LEPs and this would continue to be the case whether individual uses this SEP before or after January 1, 2025.

Under this proposal, as originally intended with the SEP, individuals will have a clearer understanding for how to access this enrollment opportunity to ensure they do not have any gaps in coverage or any LEPs as they leave incarceration.

3. Technical Corrections

In the November 2022 final rule that established the SEP for formerly incarcerated individuals, we provided at §§ 406.27(d)(3) and 407.23(d)(3) that generally entitlement would begin the first day of the month following the month of enrollment. We also provided that an individual had the option to choose a retroactive entitlement date for a period not to exceed 6 months, provided that the individual pays the monthly premiums for the period of coverage. Upon further examination of the regulations, we have identified a number of technical errors in §§ 406.27(d)(3) and 407.23(d)(3) that we are taking this opportunity to propose to correct.

First, the language in § 407.23(d)(3)(ii) states that the individual has the option to request entitlement retroactive to the *date of release* from incarceration and

this implies that coverage could start in the middle of the month. Entitlement for Medicare, regardless of the enrollment period being used or whether entitlement is prospective or retrospective, always begins on the first day of a month. As such, we propose to revise the language above to state that coverage could begin retroactive to the beginning of the month of release from incarceration. We note that the payment exclusion in § 411.4(b) may continue to apply to any items and services furnished during the period between the first of that month and the actual date of release, provided that the individual or other person has no legal obligation to pay for such services as articulated in § 411.4(a).

Second, in §§ 406.27(d)(3)(ii) and 407.23(d)(3)(ii), we erroneously cited § 406.31 when referencing the requirement for individuals to pay monthly premiums for all periods of coverage. We propose to correct the reference to § 406.31 in § 406.27(d)(3)(ii) with § 406.32(f) and the reference in § 407.23(d)(3)(ii) to § 408.4.

Third, we also stated at § 407.23(d)(3)(ii) that if the individual requests retroactive enrollment and the application is filed within the first 6 months of the SEP, the effective date could be retroactive to the release from incarceration. If the individual requests retroactive enrollment and the application is filed in the last 6 months of the SEP, the coverage effective date could be retroactive to 6 months after the date of release from incarceration. This provision results in the same coverage effective date regardless of when the individual applies during the last six months of the SEP, which we do not think is consistent with our policy goal of providing formerly incarcerated individuals the ability to make the healthcare decisions best suited to their needs and provide them the opportunity to avoid or minimize gaps of coverage (87 FR 66463). We believe the best way to remedy this situation is to link the retroactive period of coverage to the date when the individual applies for Medicare coverage, not when they are released from incarceration. As such, we propose to revise § 407.23(d)(3)(ii) to state that if the individual requests retroactive enrollment and the application is filed in the last 6 months of the SEP, the coverage effective date is retroactive to the 6th month before the month of enrollment. We believe this proposed approach strikes an appropriate balance of reducing gaps in coverage without creating excessive (and potentially costly) retroactive periods of coverage. We also propose to make similar changes at

§ 406.27(d)(3)(ii) for the sake of consistency and clarity.

XXIV. Overall Hospital Quality Star Rating Modification To Emphasize the Safety of Care Measure Group: Request for Information (RFI)

A. Summary

We seek public input on potential methodologic modifications regarding the Safety of Care measure group within the Overall Hospital Quality Star Rating published on the provider comparison tool on *Medicare.gov* (<https://www.medicare.gov/care-compare/>). Patient safety constitutes a fundamental component of the CMS National Quality Strategy, representing a sustained commitment to fostering optimal health outcomes and ensuring the safest possible care for all patients.⁵¹⁸ This Request for Information (RFI) is aimed at gathering broad public input on increasing the Safety of Care measure group's contribution to the Overall Hospital Quality Star Rating. We also note our intention to potentially issue additional RFIs or undertake rulemaking on this topic in the future.

B. Background

The Overall Hospital Quality Star Rating provides a summary of certain existing hospital quality information on *Medicare.gov* based on publicly available quality measure results reported through CMS' hospital quality measurement programs, by assigning hospitals between one and five stars, a way that is simple and easy for patients to understand (85 FR 86193). The Overall Hospital Quality Star Rating methodology was developed and is maintained according to the guiding principles of scientific validity, maximizing inclusion of hospitals and measure information, accounting for heterogeneity of available measures and hospital reporting, accommodating changes in the underlying measures, aligning with CMS hospital quality measure programs to the extent feasible, transparency of the methodology, and responsiveness to input from interested parties. The Overall Hospital Quality Star Rating was first introduced and reported on our Hospital Compare website in July 2016 (now reported on *Medicare.gov*) and has been refreshed multiple times, with the most current refresh planned for July 2024.⁵¹⁹

In the CY 2021 OPPS/ASC final rule (85 FR 86193), we codified the Overall Hospital Quality Star Rating methodology, including several

methodology refinements, intended to improve the simplicity and predictability of measure emphasis within the methodology over time, and comparability of ratings among hospitals. We also finalized the inclusion of Veterans Health Administration (VHA) hospitals and Critical Access Hospitals (CAHs) in the Overall Hospital Quality Star Rating. In the CY 2023 OPPS/ASC final rule (87 FR 72233), we provided additional information on the previously finalized policy to incorporate VHA hospitals and finalized a proposal to amend 42 CFR 412.190 to revise how we would refresh the Overall Hospital Quality Star Rating annually.

C. Current Overall Hospital Quality Star Rating Methodology

Measures reported on the provider comparison tool on *Medicare.gov* (<https://www.medicare.gov/care-compare/>) that meet the criteria for inclusion in the Overall Hospital Quality Star Rating are organized into five conceptually coherent measure groups: Safety of Care, Mortality, Readmission, and Patient Experience (all of which include outcome measures), and Timely and Effective Care (which includes a selection of process measures).

The current Overall Hospital Quality Star Rating methodology includes seven general steps. First, the direction of all included measures that indicate better performance with a lower score are reversed to uniformly indicate that a higher score indicates better performance for all the measures, and all measure scores are standardized to a single, common scale to account for differences in measure score units. Second, measures are arranged into measure groups. Each measure group contains a number of publicly reported measures to produce a robust measure group score, which are reflective of differences in hospital quality. Third, the measure group scores are calculated as a simple average of measure scores. Measure group scores are then standardized to a common scale making varying scores comparable. Fourth, the hospital summary score is calculated as a weighted average of measure group scores. Specifically, each measure group score is multiplied by the assigned weight for that group. The weighted measure group scores are then summated to generate the hospital summary score. If a hospital has no measure scores in a group (for example, by not achieving sufficient sample size in any of the measures), the weight is redistributed proportionally across the remaining groups. Fifth, minimum

reporting thresholds are applied. To receive a Star Rating, hospitals must report at least three measures in at least three measure groups, one of which must be either the Mortality or Safety of Care measure groups. Sixth, peer grouping is applied. Hospitals are grouped into one of three peer groups based on the number of measure groups for which they report at least three measures: a 3-measure peer group, a 4-measure peer group, and a 5-measure peer group. Seventh, a clustering algorithm is applied within each peer group to assign hospital summary scores to star ratings so that one star is the lowest and five stars is the highest.

For additional details regarding the methodology, we refer readers to § 412.190(d) and the Overall Hospital Quality Star Rating Methodology Reports, available at <https://qualitynet.cms.gov/inpatient/public-reporting/overall-ratings/resources>.

D. Safety of Care in Star Ratings

A foundational commitment of providing healthcare services is to ensure safety, as embedded in the centuries-old Hippocratic Oath, "First, do no harm." Yet, the landmark reports *To Err is Human* and *Crossing the Quality Chasm* surfaced major deficits in healthcare quality and safety.^{520 521} These reports resulted in widespread awareness of the alarming prevalence of patient harm and, over the past two decades, healthcare facilities implemented various interventions and strategies to improve patient safety, with some documented successes.⁵²² Furthermore, the COVID-19 public health emergency (PHE) strained the healthcare system substantially, introducing new safety risks and negatively impacting patient safety in the normal delivery of care.^{523 524}

⁵²⁰ Institute of Medicine (US) Committee on Quality of Health Care in America, Kohn, L.T., Corrigan, J.M., & Donaldson, M.S. (Eds.). (2000). *To Err is Human: Building a Safer Health System*. National Academies Press (US).

⁵²¹ Institute of Medicine (US) Committee on Quality of Health Care in America. (2001). *Crossing the Quality Chasm: A New Health System for the 21st Century*. National Academies Press (US).

⁵²² Agency for Healthcare Research and Quality. (February 2021). *National Healthcare Quality and Disparities Report chartbook on patient safety*. Rockville, MD. Available at: <https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/chartbooks/patientsafety/2019qdr-patient-safety-chartbook.pdf>.

⁵²³ Lastinger LM, Alvarez CR, Kofman A, Konnor RY, Kuhar DT, Nkwata A, Patel PR, Pattabiraman V, Xu SY, Dudeck MA. Continued increases in the incidence of healthcare-associated infection (HAI) during the second year of the coronavirus disease 2019 (COVID-19) pandemic. *Infect Control Hosp Epidemiol.* 2023 Jun;44(6):997–1001. doi: 10.1017/ice.2022.116. Epub 2022 May 20. PMID: 35591782; PMCID: PMC9237489.

⁵¹⁸ <https://www.cms.gov/files/document/cms-national-quality-strategy-handout.pdf>.

⁵¹⁹ Placeholder for 2024 Stars QUS.

Safety gaps and further risks in healthcare delivery were illuminated as a result of the COVID-19 PHE, revealing a lack of resiliency in the healthcare system.^{525 526 527} Therefore, we are increasing efforts to emphasize the importance of patient safety for both patients and healthcare workers. To accomplish these goals, the federal government is taking a multi-pronged inter-Agency approach to improve safety. The Agency for Healthcare Research and Quality (AHRQ) on behalf of the Department of Health & Human Services (HHS) established the National Action Alliance to Advance Patient and Workforce Safety as a public-private collaboration to improve both patient and workforce safety and move towards zero harm in healthcare.⁵²⁸ In September 2023, the President's Council of Advisors on Science and Technology (PCAST) published the "Report to the President: A Transformational Effort on Patient Safety," with a call to action to renew "our nation's commitment to improving patient safety."⁵²⁹ The report put forth a recommendation as part of the call to action to "establish and maintain federal leadership for the improvement of patient safety as a national priority." We also acknowledged a noticeable decline in patient safety measure scores during the COVID-19 PHE which reinforces the emphasis on patient safety established in several CMS initiatives, including the National Quality Strategy and Universal Foundation.^{530 531} Additionally,

hospitals report data on healthcare-associated infection (HAI) measures through a number of CMS quality programs, including the Hospital-Acquired Condition (HAC) Reduction and Hospital Value-Based Purchasing Programs. These programs are designed to improve patient quality of care and safety, as well as reduce complications and mortality, by rewarding hospitals that achieve high scores on measures, including HAI measures, and penalizing those that do not meet or exceed established performance standards.⁵³² However, it is possible in the current Overall Star Rating methodology for a hospital to score very low in the Safety of Care measure group yet still receive a high Star Rating due to their high performance in other measure groups. Therefore, we seek to explore potential adjustments to the Overall Hospital Quality Star Ratings methodology that would greater emphasize the measures within the Safety of Care measure group, in alignment with other CMS and HHS efforts to improve patient safety across all programs.

There are currently eight measures in the Safety of Care measure group, including six HAI measures (HAI-1—HAI-6), one Complications measure after total hip or total knee replacement (Hip/Knee), and one composite adverse event measure (Patient Safety and Adverse Events Composite (PSI-90)). While this group of measures has been the same since the inception of the Overall Hospital Quality Star Rating, the specific safety measures included may be subject to change in the future. Measures reported on the provider comparison tool on *Medicare.gov* (<https://www.medicare.gov/care-compare/>) undergo a rigorous development process which includes extensive measure testing, vetting by interested parties, evaluation by the Consensus-based Entity (currently, Battelle, which convenes the Partnership for Quality Measurement), and undergoing rulemaking for inclusion in CMS programs and public reporting. As such, the Overall Hospital Quality Star Rating methodology uses the measures as required under the CMS programs, with measure scores as reported on *Medicare.gov* at the time of the Overall Hospital Quality Star Rating calculation. Thus, any measures that are removed or suspended from one of the CMS hospital quality measure programs and not published on *Medicare.gov* would no longer be included. Similarly, any measures that are added to the CMS

programs and displayed on *Medicare.gov* may be included in the Overall Hospital Quality Star Rating; for example, upcoming measures such as the Severe Obstetric Complication (87 FR 48780), Failure-to-Rescue (89 FR 35934), Hospital Harm-Severe Hypoglycemia (89 FR 35934) and Hospital Harm-Opioid-related Adverse Events (87 FR 48780) measures may be considered for inclusion in the Safety of Care measure group. The assessment presented here is based only on the current group of eight measures as listed above, but the Overall Hospital Quality Star Rating methodology is designed with the flexibility to accommodate such changes in the future.

The current methodology places the highest emphasis on the Safety of Care and Mortality measure groups. First, the measure group weights currently utilized in the Overall Hospital Quality Star Rating methodology are based on CMS policy and interested party feedback. Currently, the Safety of Care, Mortality, Readmission, and Patient Experience measure groups are each weighted 22 percent while the Timely and Effective Care measure group is weighted 12 percent (Table 103). Interested parties generally agreed that outcome measures should have more weight since they represent strong indicators of quality and are most important to patients in making healthcare decisions. Interested parties and stakeholders broadly considered the current weightings to be acceptable.

The Safety of Care and Mortality groups are further emphasized in the reporting threshold to receive a Star Rating: hospitals must report at least three measures in each of at least three measure groups, one of which must specifically be Safety of Care or Mortality (85 FR 86228). This decision was partially informed by interested party feedback on the relative importance of patient safety and prevention of mortality.

Given the current ongoing efforts to advance patient safety, we investigated options to even further emphasize the patient safety measures in the Overall Hospital Quality Star Rating, above and beyond the emphasis of the current methodology.

We conducted an internal analysis utilizing data from the July 2023 refresh of the Overall Hospital Quality Star Rating to determine correlations between the Safety of Care measure group and performance in the Overall Hospital Quality Star Rating. There were 3,076 hospitals that met the criteria to receive a Star Rating. Among the 3,076 rated hospitals, 2,995 (97 percent) had at least 1 Safety of Care measure and

⁵²⁴ Patel, PR, Weiner-Lastinger, LM, Dudeck, MA, et al. Impact of COVID-19 pandemic on central-line-associated bloodstream infections during the early months of 2020, National Healthcare Safety Network. *Infect Control Hosp Epidemiol* 2021. doi: 10.1017/ice.2021.108.

⁵²⁵ Agency for Healthcare Research and Quality. (2021). AHRQ PSNet Annual Perspective: Impact of the COVID-19 Pandemic on Patient Safety. <https://psnet.ahrq.gov/perspective/ahrq-psnet-annual-perspective-impact-covid-19-pandemic-patient-safety>.

⁵²⁶ Fleisher, L.A., Schreiber, M.D., Cardo, D., and Srinivasan, M.D. (2022). Health care safety during the pandemic and beyond—building a system that ensures resilience. *N Engl J Med*, 386: 609–611. <https://www.nejm.org/doi/full/10.1056/NEJMp2118285>.

⁵²⁷ Implications of the COVID-19 pandemic for patient safety: a rapid review. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.

⁵²⁸ AHRQ. (2023). National Action Alliance To Advance Patient and Workforce Safety. <https://www.ahrq.gov/cpi/about/otherwebsites/action-alliance.html>.

⁵²⁹ https://www.whitehouse.gov/wp-content/uploads/2023/09/PCAST_Patient-Safety-Report_Sept2023.pdf.

⁵³⁰ Fleisher, L.A., Schreiber, M., Cardo, D., Srinivasan, A. (2022). Health Care Safety during the Pandemic and Beyond—Building a System That Ensures Resilience. *The New England Journal of Medicine*, 386(7): 609–611. DOI: 10.1056/NEJMp2118285.

⁵³¹ <https://www.cms.gov/aligning-quality-measures-across-cms-universal-foundation>.

⁵³² <https://www.cms.gov/blog/first-do-no-harm>.

therefore received a Safety of Care group score, while 2,615 (85 percent) had at least 3 Safety of Care measures. Our analysis showed a strong relationship between the Safety of Care measure group and the Star Rating. Hospitals that did well in Safety of Care tended to also do well on the Star Rating; however, there were a few hospitals that performed in the bottom quartile (lowest

performing 25 percent) of the Safety of Care measure group that still received a 5-star rating. Of the 3,076 hospitals that received a Star Rating, 658 hospitals with at least three Safety of Care measures scored in the lowest quartile of the Safety of Care measure group and 19 hospitals received a 5-star rating, representing 0.6 percent of all rated hospitals (Table 101). An additional 94

hospitals fell into the lowest quartile of Safety of Care when the analysis was based on hospitals that reported just one or two Safety of Care measures. In general, these hospitals attained 5-star ratings despite poor Safety of Care performance by achieving high performance scores across the other measure groups.

TABLE 101: Safety Performance of Hospitals by Star Rating (3+ Safety measures)

	Safety Score Range	N	1 Star	2 Stars	3 Stars	4 Stars	5 Stars
Lowest Quartile	-5.60, -0.38	658	128	230	184	97	19
All Hospitals	-5.60, 2.12	2615	216	575	733	680	411

We assessed reporting of individual Safety of Care measures and performance in the Safety of Care measure group by various hospital characteristics. We observed significant variation in the number of Safety of Care measures reported across different types of hospitals, typically with fewer measures for hospitals that have generally lower volume and so are less likely to reach sufficient case volume for individual measurements. Specifically:

non-teaching hospitals, safety net hospitals,⁵³³ critical access hospitals, smaller (<100 beds) hospitals, rural hospitals, and hospitals not qualifying for Medicare Disproportionate Share Hospital (DSH) payments were likely to report fewer Safety of Care measures compared to teaching, non-safety net-, non-critical access, hospitals with 100+ beds, urban, and DSH-qualifying hospitals (Table 102). There was a broad distribution in performance scores

across hospital types; however, certain hospital characteristics appear to be associated with performance on the Safety of Care measure group. For example, smaller hospitals are more likely to fall toward the extremes of the performance score distribution while larger hospitals fall more toward the center, and safety net hospitals tend to fall into lower quartiles than non-safety net hospitals (Table 102).

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⁵³³ Safety net hospitals are defined as those committed to caring for populations without stable access to care, specifically public hospitals or

private hospitals with a Medicaid caseload greater than one standard deviation above their respective state's mean private hospital Medicaid caseload.

https://www.cmshospitalchartbook.com/sites/default/files/Pfmc-by-Char_HW-Rdmn_2015.pdf.

TABLE 102: Safety Performance of Hospitals by Hospital Characteristics

		Number of Hospitals Reporting Safety of Care Measures				Distribution of Safety of Care Measure Group Scores			
	N	1 measure	2	3	4+ measures	Q1 Safety	Q2	Q3	Q4
All Hospitals with Safety Score & Star Rating	2995	153 (5.1%)	227 (7.6%)	316 (10.6%)	2299 (76.8%)	752 (25.1%)	757 (25.3%)	816 (27.2%)	670 (22.4%)
Specialty status									
Specialty	941	22 (2.3%)	38 (4.0%)	64 (6.8%)	817 (86.8%)	235 (25.0%)	240 (25.5%)	263 (27.9%)	203 (21.6%)
Non-Specialty	1932	120 (6.2%)	174 (9.0%)	232 (12.0%)	1406 (72.8%)	477 (24.7%)	490 (25.4%)	529 (27.4%)	436 (22.6%)
Teaching Status									
Non-Teaching	1739	135 (7.8%)	194 (11.2%)	267 (15.4%)	1143 (65.7%)	462 (26.6%)	402 (23.1%)	453 (26.0%)	422 (24.3%)
Teaching	1148	8 (0.7%)	20 (1.7%)	34 (3.0%)	1086 (94.6%)	255 (22.2%)	329 (28.7%)	343 (29.9%)	221 (19.3%)
Safety net Status									
Non-safety net	2281	100 (4.4%)	142 (6.2%)	224 (9.8%)	1815 (79.6%)	516 (22.6%)	576 (25.3%)	663 (29.1%)	526 (23.1%)
Safety net	586	42 (7.2%)	70 (11.9%)	71 (12.1%)	403 (68.8%)	194 (33.1%)	154 (26.3%)	129 (22.0%)	109 (18.6%)
Critical Access									
Non-Critical Access	2804	58 (2.1%)	157 (5.6%)	291 (10.4%)	2298 (82.0%)	692 (24.7%)	729 (26.0%)	791 (28.2%)	592 (21.1%)
Critical Access	191	95 (49.7%)	70 (36.6%)	25 (13.1%)	1 (0.5%)	60 (31.4%)	28 (14.7%)	25 (13.1%)	78 (40.8%)
Bed Size									
< 100 beds	951	140 (14.7%)	201 (21.1%)	262 (27.5%)	348 (36.6%)	277 (29.1%)	210 (22.1%)	197 (20.7%)	267 (28.1%)
100+ beds	1922	2 (0.1%)	11 (0.6%)	34 (1.8%)	1875 (97.6%)	435 (22.6%)	520 (27.1%)	595 (31.0%)	372 (19.4%)
Geographic Location									
Urban	1924	25 (1.3%)	43 (2.2%)	120 (6.2%)	1736 (90.2%)	433 (22.5%)	487 (25.3%)	582 (30.2%)	422 (21.9%)

	N	Number of Hospitals Reporting Safety of Care Measures				Distribution of Safety of Care Measure Group Scores			
		1 measure	2	3	4+ measures	Q1 Safety	Q2	Q3	Q4
Rural	949	117 (12.3%)	169 (17.8%)	176 (18.5%)	487 (51.3%)	279 (29.4%)	243 (25.6%)	210 (22.1%)	217 (22.9%)
Disproportionate Share Hospital Status*									
DSH-eligible (DSH_cost >0)	2399	41 (1.7%)	128 (5.3%)	213 (8.9%)	2017 (84.1%)	611 (25.5%)	639 (26.6%)	677 (28.2%)	472 (19.7%)
DSH_cost: 1 st Quintile	479	10 (2.1%)	30 (6.3%)	45 (9.4%)	394 (82.3%)	101 (21.1%)	117 (24.4%)	148 (30.9%)	113 (23.6%)
DSH_cost: 2 nd Quintile	489	10 (2.0%)	24 (4.9%)	49 (10.0%)	406 (83.0%)	112 (22.9%)	142 (29.0%)	144 (29.4%)	91 (18.6%)
DSH_cost: 3 rd Quintile	408	16 (3.9%)	55 (13.5%)	83 (20.3%)	254 (62.3%)	124 (30.4%)	101 (24.8%)	96 (23.5%)	87 (21.3%)
DSH_cost: 4 th Quintile	511	2 (0.4%)	8 (1.6%)	19 (3.7%)	482 (94.3%)	136 (26.6%)	128 (25.0%)	163 (31.9%)	84 (16.4%)
DSH_cost: 5 th Quintile	512	3 (0.6%)	11 (2.1%)	17 (3.3%)	481 (93.9%)	138 (27.0%)	151 (29.5%)	126 (24.6%)	97 (18.9%)
Non-DSH (DSH_COST =0)	474	101 (21.3%)	84 (17.7%)	83 (17.5%)	206 (43.5%)	101 (21.3%)	91 (19.2%)	115 (24.3%)	167 (35.2%)

BILLING CODE 4120-01-C**E. Potential Future Options to Greater Emphasize Patient Safety in the Overall Hospital Quality Star Rating**

As part of the national commitment to improving patient safety, we seek feedback on whether hospitals that performed in the bottom quartile (lowest-performing 25 percent) in the Safety of Care measure group should be eligible to receive the highest 5-star rating. We are considering modifying the Overall Hospital Quality Star Rating methodology, specifically the Safety of Care measure group, to reinforce our dedication to emphasize patient safety

across CMS. In this section we discuss three options identified to modify the Overall Hospital Quality Star Rating methodology.

1. Reweighting the Safety of Care Measure Group

We conducted an internal analysis to explore the impact of modifying the weighting system for measure groups in the Overall Hospital Quality Star Rating utilizing data from the July 2023 refresh. Specifically, we explored increasing the weight assigned to the Safety of Care measure group from the current 22 percent to 30 percent while proportionally reducing the weights

assigned to the other measure groups to examine the isolated effect of reweighting while otherwise adhering to the current methodology. The exact weighting values noted in this RFI are not prescriptive and could be adjusted based on interested party feedback to be more easily interpretable (for example, to 30 percent, 20 percent, and 10 percent), however, the results reported reflect this preliminary reweighting scenario that preserves proportionality between the remaining groups. Current and potential new weights for each measure group are detailed in Table 103.

TABLE 103: Overall Star Ratings Weighting by Group

Group	Star Ratings Weight (w_d)	Potential New Weight
Safety of Care	22%	30%
Mortality	22%	19.7%
Readmission	22%	19.7%
Patient Experience	22%	19.7%
Timely and Effective Care	12%	10.8%

Our analysis showed that by modifying the weight of the Safety of Care measure group to 30 percent, out of 3,076 hospitals, 213 hospitals would receive a higher Star Rating than when using the current weighting, while 233 hospitals would receive a lower Star Rating. Specifically, among the 752 rated hospitals in the lowest quartile of the Safety of Care measure group, 16 hospitals would achieve a higher Star Rating, while 133 hospitals would receive a lower Star Rating; only 3 of the 752 hospitals would receive a 5-star rating. Implementing this option would reduce the number of hospitals that perform poorly in Safety of Care yet still obtain the highest 5-star rating. However, reweighting the Safety of Care measure group would slightly reduce the influence of other measure groups on the Overall Hospital Quality Star Rating.

2. Policy-Based 1-Star Reduction for Poor Performance on Safety of Care

We are considering a post hoc policy-based adjustment that would reduce the Star Rating of any hospital in the lowest quartile of Safety of Care (based on at least three measure scores) by one star. Using 2023 Overall Hospital Quality Star Ratings data, applying a 1-star reduction for all hospitals in the lowest quartile of Safety of Care with at least three safety measures would result in 530 hospitals, out of 3,076 hospitals, receiving a lower Star Rating. This option would emphasize safety through a new standard for all hospitals regardless of their Star Rating. Since the minimum Star Rating is one star, hospitals already getting one star would not get a further star reduction and therefore would effectively be exempt from this policy-based adjustment. Additionally, some hospitals that perform excellently in all other measure groups except the Safety of Care measure group would still receive a 1-star reduction.

3. Reweighting the Safety of Care Measure Group Combined With a Policy-Based Star Rating Cap

We are considering increasing the weight of the Safety of Care measure group to 30 percent (and proportionally reducing the weights assigned to the other measure groups, as described in Table 103) while also applying a policy that would limit hospitals in the lowest quartile of Safety of Care (based on at least three measure scores) to a maximum of four stars out of five. Using 2023 Overall Hospital Quality Star Ratings data, implementing a cap of four stars in the lowest quartile of Safety of Care with at least three safety measures combined with the reweighting for all hospitals would result in 235 hospitals, out of 3,076 hospitals, receiving a lower Star Rating and the reduction by 1 star for two hospitals in the lowest quartile of Safety of Care that would otherwise still receive a 5-star rating if only the reweighting solution was applied. This option provides a more targeted solution to the issue of hospitals performing poorly in Safety of Care receiving a 5-star rating and applies equally to all hospitals, reserving the 5-star rating for hospitals achieving a minimum threshold in Safety of Care.

We also explored alternative options for emphasizing patient safety, such as applying only the 4-star rating maximum or combining reweighting of the Safety of Care measure group with a policy-based 1-star reduction, however, these options did not effectively reach our goal of emphasizing patient safety. In our analysis, applying a 4-star rating maximum to hospitals in the lowest quartile of Safety of Care with at least three safety measures would have less impact, resulting in only 19 out of 3,076 hospitals receiving a lower Star Rating from five stars to four stars. Conversely, applying a combination of reweighting the Safety of Care measure group with a 1-star reduction may be considered an ‘over-correction’, resulting in 635 out of 3,076 hospitals receiving a lower Star

Rating with the greatest impact on hospitals already receiving two, three, or four stars in the current methodology.

Feedback solicited during fall 2023 from interested parties, including patients, patient advocates, technical experts, and clinicians, supported the increasing emphasis on Safety of Care in the Overall Hospital Quality Star Rating methodology.⁵³⁴ However, there was varying feedback from interested parties on the methods to do so, with concerns including a decreased emphasis on the other measure groups, particularly Mortality, and the adequacy of the Safety of Care group measures as currently established to truly represent the experience of patient safety at a hospital.

F. Solicitation of Public Comment

We are currently seeking comments on potential modifications to the Safety of Care measure group in the Overall Hospital Quality Star Rating methodology. We are requesting input from interested parties on the following options: (1) reweighting the Safety of Care measure group; (2) applying a policy-based adjustment that reduces the Star Rating of any hospital in the lowest quartile of Safety of Care (based on at least three measures in the group) by one star; (3) reweighting the Safety of Care measure group combined with a policy-based 4-star rating maximum on Star Rating of any hospital in the lowest quartile of Safety of Care (based on at least three measures in the group). Specifically, we are requesting comment on the following questions:

- Do you support re-weighting the Overall Hospital Quality Star Rating measure groups to give greater weight to Safety of Care as described in option 1? Do you agree with the potential new weights for each measure group (as shown in Table 103)?

- Do you support reducing the Star Rating for hospitals with a low Safety of Care score as described in option 2? Do

⁵³⁴ <https://mmshub.cms.gov/sites/default/files/Star-Ratings-TEP-Summary-Report-Oct23.pdf>.

you agree with the potential policy to apply a 1-star reduction to all hospitals in the lowest quartile of Safety of Care?

- Do you support a combination of reweighting the Safety of Care measure group with a 4-star maximum on Star Rating as described in option 3?
- Do you have feedback or preference towards an approach of both up-scoring high performers and down-scoring poor performers as in options 1 and 3, or an approach of just down-scoring poor performers as in option 2?
- What are other methodological approaches that could be used to emphasize the Safety of Care measure group?
- With respect to the potential changes to the Overall Hospital Quality Star Rating methodology, are there any special considerations for small, rural or safety net hospitals (including Critical Access hospitals)?

Any modification to the Overall Hospital Quality Star Rating methodology would be addressed through future notice-and-comment rulemaking.

XXIII. Files Available to the Public Via the Internet

The Addenda to the OPPTS/ASC proposed rules and final rules with comment period are published and available via the internet on the CMS website. In the CY 2019 OPPTS/ASC final rule with comment period (83 FR 59154), for CY 2019, we changed the format of the OPPTS Addenda A, B, and C by adding a column titled “Copayment Capped at the Inpatient Deductible of \$1,364.00” where we flag, through use of an asterisk, those items and services with a copayment that is equal to or greater than the inpatient hospital deductible amount for any given year (the copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year). In the CY 2022 OPPTS/ASC final rule with comment period (85 FR 86266), we updated the format of the OPPTS Addenda A, B, and C by adding a column titled “Drug Pass-Through Expiration during Calendar Year” where we flagged, through the use of an asterisk, each drug for which pass-through payment was expiring during the calendar year on a date other than December 31. For CY 2025 and subsequent years, we proposed to retain these columns that are updated to reflect the drug codes for which pass-through payment is expiring in the applicable year.

In the CY 2023 OPPTS/ASC final rule with comment period (87 FR 72250) for

CY 2023, we changed the format of the OPPTS Addenda A, B, and C by adding a column titled “Drug Pass-Through Expiration during Calendar Year” to include devices, so that the column reads: “Drug and Device Pass-Through Expiration during Calendar Year” where we flagged, through the use of an asterisk, each drug and device for which pass-through payment was expiring during the calendar year on a date other than December 31.

For CY 2024 we deleted the column titled “Copayment Capped at the Inpatient Deductible” and instead added a new column for “Adjusted Beneficiary Copayment” to identify any copayment adjustment due to either the inpatient deductible amount copayment cap or the inflation-adjusted copayment of a Part B rebatable drug per section 1833(t)(8)(F) and section 1833(i)(9) of the Act, as added by section 11101 of the Inflation Reduction Act (IRA). We also added another column for notes. The “Note” column contains multiple messages including, but not limited to, inflation-adjusted copayment of a Part B rebatable drug, the copayment for a code capped at the inpatient deductible, or 8 percent of the reference product add-on applied for a biosimilar.

In addition, for CY 2024, we updated the format of the OPPTS Addenda A, B, and C by adding another column for “IRA Coinsurance Percentage” to identify the percentage for the inflation-adjusted copayment of a Part B rebatable drug per section 1833(t)(8)(F) and section 1833(i)(9) of the Act, as added by section 11101 of the Inflation Reduction Act (IRA).

For CY 2025 and subsequent years we propose to keep the same format for the addenda A, B, and C, and we are not proposing any additional changes for CY 2025.

To view the Addenda to this proposed rule pertaining to CY 2025 payments under the OPPTS, we refer readers to the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices>; select “CMS-1809-P” from the list of regulations. All OPPTS Addenda to this proposed rule are contained in the zipped folder titled “2025 NPRM OPPTS Addenda” in the related links section at the bottom of the page. To view the Addenda to this proposed rule pertaining to CY 2025 payments under the ASC payment system, we refer readers to the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices>; select “CMS-1809-P” from the list of regulations. The ASC Addenda to this

proposed rule are contained in a zipped folder titled “2025 NPRM Addendum AA, BB, DD1, DD2, EE, and FF” in the related links section at the bottom of the page.

XXIV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

If you comment on these information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by September 9, 2024.

A. ICRs for the Hospital Outpatient Quality Reporting (OQR) Program

a. Background

In section XV of this proposed rule, we discuss the requirements for the Hospital OQR Program. The Hospital OQR Program is generally aligned with the CMS quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program. We refer readers to the CY 2024 OPPTS/ASC final rule with comment period (88 FR 82131 through 82140) for detailed discussions of the previously finalized Hospital OQR Program ICRs which are currently approved under OMB control number 0938-1109 (expiration date February 28, 2025).

In this proposed rule, we propose to adopt four web-based measures that would impact previously approved burden estimates: (1) the Hospital Commitment to Health Equity (HCHE) measure, beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (4) the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM), beginning with voluntary reporting for the CY 2026 reporting period and mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination.

We also propose changes to the Hospital OQR Program that would not impact the previously approved burden estimates. We propose to remove two claims-based measures beginning with the CY 2025 reporting period/CY 2027 payment determination: (1) Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain measure; and (2) Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure. We further propose to modify the public reporting of data for the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients)—Psychiatric/Mental Health Patients stratification so that it may be published on Care Compare in addition to the *data.cms.gov* downloadable files beginning in CY 2025. Lastly, we propose to require electronic health record (EHR) technology to be certified to all eCQMs available to report beginning with the CY 2025 reporting period/CY 2027 payment determination.

In the CY 2024 OPPS/ASC final rule with comment period, we calculated reporting burden estimates for the Hospital OQR Program by utilizing the Bureau of Labor Statistics (BLS) mean hourly wage rate for Medical Records Specialists (88 FR 82132). Specifically, we used the “general medical and surgical hospitals” industry to estimate the mean wage, as this categorization aligns the closest with the Hospital OQR

Program care setting compared to other industries, such as “office of physicians” or “nursing care facilities.” The most recent data from BLS’ May 2023 National Occupational Employment and Wage Estimates reflects a mean hourly wage of \$27.69 per hour for medical records specialists working in “general medical and surgical hospitals” (SOC 29-2072).⁵³⁵ We calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, consistent with previous years. This is a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($\$27.69 \times 2 = \$55.38$) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to hospitals using a wage plus benefits estimate of \$55.38 per hour throughout the discussion in this section of this rule for the Hospital OQR Program.

In the CY 2024 OPPS/ASC final rule with comment period, our burden estimates were based on an assumption that approximately 3,350 hospital outpatient departments (HOPDs) would report data to the Hospital OQR Program (88 FR 82132). For this proposed rule, based on the most recent available data from the CY 2024 Hospital OQR Program payment determination, we estimate that 3,200 HOPDs will report data to the Hospital OQR Program for the CY 2025 reporting period/2027 payment determination.

b. Information Collection Burden Estimate for the Proposed Adoption of the Hospital Commitment to Health Equity Measure Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination

In section XIV.B.1 of this proposed rule, we propose to adopt the web-based HCHE measure beginning with the CY 2025 reporting period/CY 2027 payment determination. For this measure, HOPDs would be required to report on attestations of “yes” or “no” to a set of five domains related to organizational efforts towards health equity once annually using a CMS-designated information system, as described in section XIV.B.1.b of this proposed rule. We estimate the reporting burden associated with this measure to be, on average across all 3,200 HOPDs, no

more than 10 minutes per HOPD per year, as we believe the burden for HOPDs to report this measure would be very similar to the burden for hospital inpatient departments to report the same measure once annually under the Hospital IQR Program. We refer readers to the currently approved burden estimate for the HCHE measure in the Hospital IQR Program under OMB control number 0938–1022 (expiration date January 31, 2026) and as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49385).

Using an estimate of 10 minutes (or 0.167 hours) per HOPD per year, we estimate that this measure adoption would result in a total annual burden increase of 533 hours ($0.167 \text{ hours} \times 3,200 \text{ HOPDs}$) at a cost of \$29,518 ($533 \text{ hours} \times \$55.38/\text{hr}$) across program-eligible HOPDs.

c. Information Collection Burden Estimate for the Proposed Adoption of the Screening for Social Drivers of Health (SDOH) Measure Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

In section XIV.B.2 of this proposed rule, we propose to adopt the web-based Screening for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. For this measure, HOPDs would be required to report whether they screened patients for five Health Related Social Needs (HRSN) domains, as described in section XIV.B.2.a of this proposed rule.

HOPDs would be able to collect data for the measure using a self-selected screening tool. We expect that most HOPDs would likely collect data through a screening tool incorporated into their EHR or other patient intake process, such as those we describe as examples in section XIV.B.2.e of this proposed rule. We estimate the information collection burden related to conducting patient screening associated with this measure to be 2 minutes (0.033 hours) per patient. This is based on the currently approved burden estimate for the Hospital IQR Program under OMB control number 0938–1022 for the same measure with patient screening for the same HRSN domains and the same frequency of data reporting, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49385 through 49386).

To provide an estimate of patient volume for the purposes of calculating

⁵³⁵ U.S. Bureau of Labor Statistics, Occupational Outlook Handbook, Medical Records Specialists. Accessed April 29, 2024. Available at: <https://www.bls.gov/oes/current/oes292072.htm>.

the information collection burden associated with this measure, we utilized data derived from the American Hospital Association which estimates 2,399 outpatient visits per 1,000 population in CY 2022⁵³⁶ and multiplied this by the estimated total U.S. population in CY 2022⁵³⁷ to estimate the total number of outpatient visits across all U.S. community hospitals. Then, in order to derive an estimate for only the 3,200 program-eligible HOPDs in the Hospital OQR Program, we multiplied the total number of outpatient visits by a ratio of program-eligible HOPDs to all U.S. community hospitals. Therefore, we estimate that each year 498,843,518 patients (2,399 outpatient visits per 1,000 population in CY 2022) $\times$ 333,287,557 total U.S. population in 2022 $\times$ (3,200 HOPDs $\div$ 5,129 U.S. community hospitals⁵³⁸) would be screened when reporting on the measure becomes mandatory. As submission rates among facilities may vary, we conservatively estimate that for voluntary reporting for the CY 2025 reporting period, 50 percent of HOPDs would survey 50 percent of patients, and beginning with the first mandatory reporting period, 100 percent of HOPDs would survey 100 percent of patients.

We determine the cost for patients (or their representative) undertaking administrative and other tasks, such as filling out a survey or intake form, using a post-tax wage of \$24.49/hr based on the report “Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices,” which identifies the approach for valuing time when individuals undertake activities on their own time.⁵³⁹ To derive the costs for patients (or their representatives), a measurement of the usual weekly earnings of wage and salary workers of \$1,139 is divided by 40 hours to calculate an hourly pre-tax wage rate of \$28.48/hr.⁵⁴⁰ This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 14 percent calculated by comparing pre-and post-tax income,⁵⁴¹ resulting in the post-tax hourly wage rate of \$24.49/hr. Unlike our state and private sector wage adjustments, we are not adjusting patient wages for fringe benefits and other indirect costs since the individuals’ activities, if any, would occur outside the scope of their employment.

Measure data aggregated to the hospital level as a numerator and a denominator would be submitted via the HQR system annually. Similar to the

currently approved burden estimate for web-based measures reported via the HQR system for the Hospital OQR Program under OMB control number 0938–1109 (expiration date January 31, 2026), we estimate a burden of 10 minutes per HOPD to report the measure data. Therefore, we estimate that each HOPD would spend 10 minutes (0.167 hours) annually to report the Screening for SDOH measure data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total burden increase for patients of 4,115,459 hours (498,843,518 patients $\times$ 50 percent response rate $\times$ 50 percent of HOPDs $\times$ 0.033 hours per patient) at a cost of \$100,787,591 (4,115,459 hours $\times$ \$24.49/hr). Beginning with the CY 2026 mandatory reporting period, we estimate an annual total burden increase for patients of 16,461,836 hours (498,843,518 patients $\times$ 0.033 hours per patient) at a cost of \$403,150,364 (16,461,836 hours $\times$ \$24.49/hr).

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase for program-eligible HOPDs of 267 hours (3,200 HOPDs $\times$ 50 percent of HOPDs $\times$ 0.167 hours per HOPDs) at a cost of \$14,786 (267 hours $\times$ \$55.38/hr). Beginning with the CY 2026 mandatory reporting period, we estimate a total collection and reporting burden increase for program-eligible HOPDs of 533 hours (3,200 HOPDs $\times$ 0.167 hours per HOPD) at a cost of \$29,518 (533 hours $\times$ \$55.38/hr).

d. Information Collection Burden Estimate for the Proposed Adoption of the Screen Positive Rate for Social Drivers of Health (SDOH) Measure Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

In section XIV.B.3 of this proposed rule, we propose to adopt the Screen Positive Rate for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. We refer readers to the currently approved burden estimate for the Screen Positive Rate for SDOH measure in the Hospital IQR Program under OMB control number 0938–1022 for the same measure and the same frequency of data reporting, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49386). As discussed in section XIV.B.3.g of this proposed rule, if a hospital participates in both the

Hospital OQR and Hospital IQR Programs, the hospital would need to submit data on this measure separately under each program. As such, we are estimating the burden separately under each program.

For this measure, HOPDs would be required to report on the number of patients who screened positive for one or more of the five domains (reported as five separate rates to reflect each of the five HRSN domains) divided by the total number of patients screened. We previously included the collection burden associated with screening patients in our discussion of the Screening for SDOH measure. Thus, for the Screen Positive Rate for SDOH measure, we estimate only the additional burden for HOPD reporting via the HQR system since patients would not need to provide, and HOPDs would not need to collect, any additional information for this measure. We continue to estimate that, for voluntary reporting for the CY 2025 reporting period, 50 percent of HOPDs would submit data, and beginning with the first mandatory reporting period, 100 percent of HOPDs would submit data.

Measure data aggregated to the hospital level as a numerator and a denominator would be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the Hospital OQR Program under OMB control number 0938–1109, we estimate a burden of 10 minutes per HOPD to report the measure data. Therefore, we estimate that each HOPD would spend 10 minutes (0.167 hours) annually to report the Screen Positive Rate for SDOH measure data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase of 267 hours (0.167 hours $\times$ 3,200 HOPDs $\times$ 50 percent of HOPDs) at a cost of \$14,786 (267 hours $\times$ \$55.38), and beginning with the CY 2026 reporting period, we estimate a total annual collection and reporting burden increase for hospitals of 533 hours (0.167 hours $\times$ 3,200 HOPDs) at a cost of \$29,518 (533 hours $\times$ \$55.38/hr) across all program-eligible HOPDs.

e. Information Collection Burden Estimate for the Proposed Adoption of the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM), Beginning With Voluntary Reporting for the CY 2026 Reporting Period and Mandatory Reporting Beginning With the CY 2027 Reporting Period/CY 2029 Payment Determination

In section XV.C.1.b of this proposed rule, we propose to adopt the Information Transfer PRO-PM beginning with voluntary reporting for the CY 2026 reporting period and mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination.

The Information Transfer PRO-PM would use PRO data regarding recovery instructions, collected by HOPDs through a nine-item survey instrument administered to patients post-operatively. The modes of PRO data collection can include completion of the post-operative surveys electronically.

To provide an estimate of patient volume for the purposes of calculating the information collection burden associated with this measure, we utilized data derived from the American Hospital Association related to hospital outpatient visits to estimate that each year 498,843,518 patients (2,399 outpatient visits per person in CY 2022⁵⁴² × 333,287,557 total U.S. population in 2022⁵⁴³ × (3,200 HOPDs ÷ 5,129 U.S. community hospitals⁵⁴⁴)) would be screened if the measure became mandatory. As submission rates among facilities may vary, we conservatively estimate that for voluntary reporting for the CY 2025 reporting period, 50 percent of HOPDs would survey 50 percent of patients, and beginning with the first mandatory reporting period, 100 percent of HOPDs would survey 100 percent of patients. While we have also proposed to allow HOPDs to report a sample of at least 300 completed patient surveys, we propose to require all patients to be surveyed for this measure once mandatory reporting begins.

We estimate each patient would require an average of 6 minutes⁵⁴⁵ (0.1 hours) to complete the survey. As described in section XXIV.B.c of this proposed rule, for purposes of calculating patient burden, we determine the cost for patients (or their representatives) undertaking administrative and other tasks, such as filling out a survey or intake form, using a post-tax wage of \$24.49/hr based on

the report “Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices,” which identifies the approach for valuing time when individuals undertake activities on their own time.⁵⁴⁶ Unlike our state and private sector wage adjustments, we are not adjusting patient wages for fringe benefits and other indirect costs since the individuals’ activities, if any, would occur outside the scope of their employment.

Measure data would be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the Hospital OQR Program under OMB control number 0938–1109, we estimate a burden of 10 minutes per HOPD to report the measure data. Therefore, we estimate that each HOPD would spend 10 minutes (0.167 hours) annually to report the Information Transfer PRO-PM data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total burden for patients of 12,471,088 hours (498,843,518 patients × 50 percent response rate × 50 percent of HOPDs × 0.1 hours per patient surveyed) at a cost of \$305,416,945 (12,471,088 hours × \$24.49/hr). Beginning with the CY 2026 mandatory reporting period, we estimate an annual total burden for patients of 49,884,352 hours (498,843,518 patients × 0.1 hours per patient) at a cost of \$1,221,667,780 (49,884,352 hours × \$24.49/hr).

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden for program-eligible HOPDs of 267 hours (3,200 HOPDs × 50 percent of HOPDs × 0.167 hours per HOPD) at a cost of \$14,786 (267 hours × \$55.38/hr). Beginning with the CY 2026 mandatory reporting period, we estimate a total collection and reporting burden for program-eligible HOPDs of 533 hours (3,200 HOPDs × 0.167 hours per HOPD) at a cost of \$29,518 (533 hours × \$55.38/hr).

f. Information Collection Burden for the Proposed Removal of Two Claims-Based Measures

In sections XV.C.2.a and XV.C.2.b of this proposed rule, we propose to remove two claims-based measures beginning with the CY 2025 reporting period/CY 2027 payment determination: (1) MRI Lumbar Spine for Low Back Pain measure; and (2) Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure. Because these measures are calculated using Medicare fee-for-

service (FFS) claims that are already reported to the Medicare program for payment purposes, removing these measures would not result in a change in burden associated with OMB control number 0938–1109.

g. Information Collection Burden for the Proposal to Publicly Report Data for the Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients Stratification on Care Compare Beginning in CY 2025

In section XV.F.2 of this proposed rule, we propose to publicly report data for the Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients stratification on Care Compare beginning in CY 2025. Because we are not proposing to require HOPDs to collect or submit any additional data for purposes of this public reporting, this proposal would not result in a change in burden associated with OMB control number 0938–1109.

h. Information Collection Burden for the Proposal To Require EHR Technology To Be Certified to All eCQMs Available To Report Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination

In section XV.E.2.b of this proposed rule, we propose to require EHR technology to be certified to all eCQMs (electronic clinical quality measures) available to report beginning with the CY 2025 reporting period/CY 2027 payment determination. We do not expect HOPDs would experience an increase in information collection burden associated with this proposal because the use of EHR technology that is certified to all available eCQMs is already required for the Promoting Interoperability Program (83 FR 41672) and the Hospital IQR Program (84 FR 42604).

g. Summary of Proposed Information Collection Burden Estimates for the Hospital OQR Program

In summary, we estimate that the proposals in this proposed rule would result in a total HOPD burden increase of 66,348,321 hours at a cost of \$1,624,936,216 annually for all 3,200 program-eligible HOPDs from the CY 2025 reporting period/CY 2027 payment determination through the CY 2027 reporting period/CY 2029 payment determination. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1109 (expiration date February 28, 2025). (See Tables 104, 105 and 106.)

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2025 Reporting Period							
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of HOPDs reporting	Average number records per HOPDs per quarter	Annual burden (hours) per HOPD	Proposed annual burden (hours) across HOPDs	Previously finalized annual burden (hours) across HOPDs	Net difference in annual burden hours
Addition of the HCHE Measure	10	1	3,200	1	0.167	533	0	+533
Addition of the Screening for SDOH Measure (Voluntary Survey)	0.033	1	1,600	77,944	2,572	4,115,459	0	+4,115,459
Addition of the Screening for SDOH Measure (Voluntary Reporting)	10	1	1,600	1	0.167	267	0	+267
Addition of the Screen Positive Rate for SDOH (Voluntary Reporting)	10	1	1,600	1	0.167	267	0	+267
	Total Change in Information Collection Burden Hours: +4,116,526							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+4,116,526) = \$100,846,681							

**Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109
for the CY 2026 Reporting Period**

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2026 Reporting Period							
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of HOPDs reporting	Average number records per HOPD per quarter	Annual burden (hours) per HOPD	Proposed annual burden (hours) across HOPDs	Previously finalized annual burden (hours) across HOPDs	Net difference in annual burden hours
Addition of the HCHE Measure	10	1	3,200	1	0.167	533	0	+533
Addition of the Screening for SDOH Measure (Mandatory Survey)	0.033	1	3,200	155,889	5,144	16,461,836	0	+16,461,836
Addition of the Screening for SDOH Measure (Mandatory Reporting)	10	1	3,200	1	0.167	533	0	+533
Addition of the Screen Positive Rate for SDOH (Mandatory Reporting)	10	1	3,200	1	0.167	533	0	+533
Addition of the Information Transfer PRO-PM (Voluntary Survey)	0.1	1	1,600	77,944	7,794	12,471,088	0	+12,471,088
Addition of the Information Transfer PRO-PM (Voluntary Reporting)	10	1	1,600	1	0.167	267	0	+267
	Total Change in Information Collection Burden Hours: +28,934,791							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+28,934,791) = \$708,670,649							

**TABLE 106: SUMMARY OF PROPOSED HOSPITAL OQR PROGRAM
INFORMATION COLLECTION BURDEN CHANGE BEGINNING WITH THE CY 2027
REPORTING PERIOD/CY 2029 PAYMENT DETERMINATION**

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2027 Reporting Period								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of HOPDs reporting	Average number records per HOPD per quarter	Annual burden (hours) per HOPD	Proposed annual burden (hours) across HOPDs	Previously finalized annual burden (hours) across HOPDs	Net difference in annual burden hours
Addition of the HCHE Measure	10	1	3,200	1	0.167	533	0	+533
Addition of the Screening for SDOH Measure (Mandatory Survey)	0.033	1	3,200	155,889	5,144	16,461,836	0	+16,461,836
Addition of the Screening for SDOH Measure (Mandatory Reporting)	10	1	3,200	1	0.167	533	0	+533
Addition of the Screen Positive Rate for SDOH (Mandatory Reporting)	10	1	3,200	1	0.167	533	0	+533
Addition of the Information Transfer PRO-PM (Mandatory Survey)	0.1	1	3,200	155,889	15,589	49,884,352	0	+49,884,352
Addition of the Information Transfer PRO-PM (Mandatory Reporting)	10	1	3,200	1	0.167	533	0	+533
Total Change in Information Collection Burden Hours: +66,348,321								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+66,348,321) = \$1,624,936,216								

We request comment on how we can reduce burden on HOPDs for both these new information collections as well as recommendations for the removal of other existing information collections to offset these new burdens.

B. ICRs for the Rural Emergency Hospitals Quality Reporting (REHQR) Program

a. Background

In section XVI of this proposed rule, we discuss the requirements for the REHQR Program. The REHQR Program is generally aligned with the CMS quality reporting program for HOPDs known as the Hospital OQR Program. We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 82148 through 82149) for detailed

discussions of the previously finalized REHQR Program ICRs, which are currently approved under OMB control number 0938-1454 (expiration date April 30, 2027).

In this proposed rule, we propose to adopt three web-based measures that would impact previously approved burden estimates: (1) the Hospital Commitment to Health Equity (HCHE)

measure, beginning with the CY 2025 reporting period/CY 2027 program determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination; and (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination.

We also propose to extend the reporting period for the previously adopted Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure beginning with the CY 2027 program determination. We believe this proposal would not impact the previously approved burden estimates if finalized.

In the CY 2024 OPPI/ASC final rule with comment period, we calculated reporting burden estimates for the REHQR Program by utilizing the BLS mean hourly wage rate for Medical Records Specialists (88 FR 82148). Specifically, we used the “general medical and surgical hospitals” industry to estimate the mean wage, as this categorization aligns the closest with the REHQR Program care setting compared to other medical record specialist related industries, such as “office of physicians” or “nursing care facilities.” The most recent data from BLS’ May 2023 National Occupational Employment and Wage Estimates reflects a mean hourly wage of \$27.69 per hour for medical records specialists working in “general medical and surgical hospitals” (SOC 29–2072).⁵⁴⁷ We calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($\$27.69 \times 2 = \$55.38$) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to REHs.

In the CY 2024 OPPI/ASC final rule with comment period, our burden estimates were based on an assumption that approximately 746 hospitals could transition to REH status assuming that all eligible hospitals in states which have passed or amended necessary legislation enabling transition to occur

as of March 2023 choose to do so and we stated that we would update our estimates once more information was made available (88 FR 82148). For this proposed rule, based on the actual number of acute care and critical access hospital conversions to REH status as of April 22, 2024, we estimate that 25 REHs would report data to the REHQR Program during the CY 2025 reporting period unless otherwise noted. While the exact number of REHs required to submit data may vary due to status changes to and from an REH, as reiterated in section XVI.A of this proposed rule, REHs are required by statute to submit quality data. Therefore, for purposes of estimating burden, we assume that all 25 REHs would submit data under the REHQR Program beginning with the CY 2025 reporting period.

b. Information Collection Burden for the Proposed Adoption of the Hospital Commitment to Health Equity (HCHE) Measure Beginning With the CY 2025 Reporting Period/CY 2027 Program Determination

In section XIV.B.1 of this proposed rule, we propose to adopt the web-based HCHE measure beginning with the CY 2025 reporting period/CY 2027 program determination. For this measure, REHs would be required to report on attestations of “yes” or “no” to a set of five domains related to organizational efforts towards health equity, as described in section XIV.B.1.b of this proposed rule.

We estimate the reporting burden associated with this measure to be, on average across all 25 REHs, no more than 10 minutes per REH per year, as we believe the burden that is annually reported by hospital inpatient departments under the Hospital IQR Program would be very similar to annual reporting by REHs on the same measure. We refer readers to the currently approved burden for the HCHE measure in the Hospital IQR Program under OMB control number 0938–1022 (expiration date January 31, 2026) and as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49385).

Using an estimate of 10 minutes (or 0.167 hours) per REH per year, we estimate that this measure adoption would result in a total annual burden increase of 4 hours ($0.167 \text{ hours} \times 25 \text{ REHs}$) at a cost of \$222 ($4 \text{ hours} \times \$55.38/\text{hr}$) across all REHs.

c. Information Collection Burden for the Proposed Adoption of the Screening for Social Drivers of Health (SDOH) Measure Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Program Determination

In section XIV.B.2 of this proposed rule, we propose to adopt the Screening for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination. We refer readers to the currently approved burden for the Screening for SDOH measure for the Hospital IQR Program under OMB control number 0938–1022 (expiration date January 31, 2026). For this measure, REHs would be required to report whether they screened patients for five Health Related Social Needs (HRSNs) domains as described in section XIV.B.2.a of this proposed rule.

REHs would be able to collect data for the measure using a self-selected screening tool. We expect that most REHs would likely collect data through a screening tool incorporated into their EHR or other patient intake process, such as those we describe as examples in section XIV.B.2.e of this proposed rule. We estimate the information collection burden related to conducting patient screening associated with this measure to be 2 minutes (0.033 hours) per patient. This is based on the currently approved burden estimate for the Hospital IQR Program for the same measure with patient screening for the same HRSN domains and the same frequency of data reporting, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49385 through 49386).

To provide an estimate of patient volume for the purposes of calculating the information collection burden associated with this measure we utilized data derived from a Definitive Healthcare survey which calculated that Medicare FFS patients account for 35.6 percent of hospital payer mix and a MedPAC report that determined hospitals which have converted to REH status average 4,200 outpatient visits for Medicare FFS beneficiaries to estimate that each year 11,798 ($4,200 \div 35.6 \text{ percent}$) patients would be screened per REH when reporting on the measure becomes mandatory.^{548 549} We therefore estimate a total of approximately 295,000 patients ($11,798 \text{ patients} \times 25 \text{ REHs}$) would be screened across all 25 REHs. As submission rates among

facilities may vary, we conservatively estimate that for voluntary reporting for the CY 2025 reporting period, 50 percent of REHs would survey 50 percent of patients, and beginning with the first mandatory reporting period, REHs would survey 100 percent of patients.

We determine the cost for patients (or their representative) undertaking administrative and other tasks, such as filling out a survey or intake form, using a post-tax wage of \$24.49/hr based on the report “Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices,” which identifies the approach for valuing time when individuals undertake activities on their own time.⁵⁵⁰ To derive the costs for patients (or their representatives), a measurement of the usual weekly earnings of wage and salary workers of \$1,139 is divided by 40 hours to calculate an hourly pre-tax wage rate of \$28.48/hr.⁵⁵¹ This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 14 percent calculated by comparing pre- and post-tax income,⁵⁵² resulting in the post-tax hourly wage rate of \$24.49/hr. Unlike our state and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals’ activities, if any, would occur outside the scope of their employment.

Measure data aggregated to the hospital level as a numerator and a denominator would be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the Hospital OQR Program under OMB control number 0938–1109 (expiration date February 28, 2025), which REHs would have been eligible to report under prior to conversion to REH status, we estimate a burden of 10 minutes per REH to report the measure data. Therefore, we estimate that each REH would spend 10 minutes (0.167 hours) annually to report the Screening for SDOH measure data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase for patients of 2,434 hours (295,000 patients $\times$ 50 percent response rate $\times$ 50 percent of REHs $\times$ 0.033 hours per patient) at a cost of \$59,609 (9,735 hours $\times$ \$24.49/hr). Beginning with the CY 2026 reporting period, we estimate a total collection and reporting burden increase for patients of 9,735 hours (295,000

patients $\times$ 0.033 hours per patient) at a cost of \$238,410 (9,735 hours $\times$ \$24.49/hr).

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase for REHs of 2 hours (25 REHs $\times$ 50 percent of REHs $\times$ 0.167 hours) at a cost of \$111 (2 hours $\times$ \$55.38/hr). Beginning with the CY 2026 reporting period, we estimate a total collection and reporting burden increase for REHs of 4 hours (25 REHs $\times$ 0.167 hours) at a cost of \$222 (4 hours $\times$ \$55.38/hr).

d. Information Collection Burden for the Proposed Adoption of the Screen Positive Rate for Social Drivers of Health (SDOH) Measure Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Program Determination

In section XIV.B.3 of this proposed rule, we propose to adopt the Screen Positive Rate for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 program determination. We refer readers to the currently approved burden estimate for the Screen Positive Rate for SDOH measure in the Hospital IQR Program under OMB control number 0938–1022 for the same measure and the same frequency of data reporting, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49386).

For this measure, REHs would be required to report on an annual basis the number of patients who screened positive for one or more of the five domains (reported as five separate rates to reflect each of the five HRSN domains) divided by the total number of patients screened. We previously included the burden associated with screening patients in our discussion of the Screening for SDOH measure. Thus, for the Screen Positive Rate for SDOH measure, we estimate only the additional burden for a REH reporting via the HQR system since patients would not need to provide, and REHs would not need to collect, any additional information for this measure. We continue to estimate that, for voluntary reporting for the CY 2025 reporting period, 50 percent of REHs would survey 50 percent of patients, and beginning with the first mandatory period, REHs would survey 100 percent of patients.

Measure data aggregated to the hospital level as a numerator and a denominator would be submitted via the HQR system annually. Similar to the

currently approved burden estimate for web-based measures reported via the HQR system for the Hospital OQR Program under OMB control number 0938–1109 (expiration date February 28, 2025), which REHs would have been eligible to report under prior to conversion to REH status, we estimate a burden of 10 minutes per REH to report the measure data. Therefore, we estimate that each REH would spend 10 minutes (0.167 hours) annually to report the Screen Positive Rate for SDOH measure data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase of two hours (0.167 hours $\times$ 25 REHs $\times$ 50 percent of REHs) at a cost of \$111 (2 hours $\times$ \$55.38/hr), and beginning with the CY 2026 reporting period, we estimate a total annual collection and reporting burden increase for REHs of 4 hours (0.167 hours $\times$ 25 REHs) at a cost of \$222 (4 hours $\times$ \$55.38/hr) across all REHs.

e. Information Collection Requirements for the Proposal To Extend the Reporting Period From for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery Measure Beginning With the CY 2027 Program Determination

In section XVI.C.2 of this proposed rule, we propose to extend the reporting period from 1 year to 2 years for the Risk-Standardized Hospital Visits within 7 Days after Hospital Outpatient Surgery measure, beginning with the CY 2027 program determination. We refer readers to a similar proposal which was finalized for the claims-based Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure under the Hospital OQR Program in the CY 2019 OPPS/ASC final rule (83 FR 59106).

Because this claims-based measure is calculated using data that are already reported to the Medicare program for payment purposes, there is no burden associated with the collection and submission of data for this measure. Accordingly, our proposal to extend the reporting period from 1 to 2 years would not result in additional burden for REHs.

f. Summary of Proposed Information Collection Burden Estimates for the REHQR Program

In summary, we estimate that the proposals in this proposed rule, if finalized as proposed, would result in an increase of 9,747 hours at a cost of \$239,076 for 25 REHs annually from the CY 2025 reporting period through the CY 2026 reporting period. We will

(expiration date April 30, 2027). (See Tables 107 and 108.)

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PROGRAM DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1454 for the CY 2025 Reporting Period							
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of REHs reporting	Average number records per REH per quarter	Annual burden (hours) per REH	Proposed annual burden (hours) across REHs	Previously finalized annual burden (hours) across REHs	Net difference in annual burden hours
Addition of the HCHE Measure	10	1	25	1	0.167	4	0	+4
Addition of the Screening for SDOH Measure (Voluntary Survey)	0.033	1	13	11,800	187.2	2,434	0	+2,434
Add Screening for SDOH Measure (Voluntary Reporting)	10	1	13	1	0.167	2	0	+2
Addition of the Screen Positive Rate for SDOH (Voluntary Reporting)	10	1	13	1	0.167	2	0	+2
	Total Change in Information Collection Burden Hours: +2,442							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+2,442) = \$60,053							

**TABLE 108: SUMMARY OF PROPOSED REHQR PROGRAM INFORMATION
COLLECTION BURDEN CHANGE BEGINNING WITH THE CY 2026 REPORTING
PERIOD/CY 2028 PROGRAM DETERMINATION**

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1454 for the CY 2026 Reporting Period								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of REHs reporting	Average number records per REH per quarter	Annual burden (hours) per REH	Proposed annual burden (hours) across REHs	Previously finalized annual burden (hours) across REHs	Net difference in annual burden hours
Addition of the Hospital Commitment to Health Equity (HCHE) Measure	10	1	25	1	0.167	4	0	+4
Addition of the Screening for Social Drivers of Health (SDOH) Measure (Mandatory Survey)	0.033	1	25	11,800	295,000	9,735	0	+9,735
Addition of the Screening for SDOH Measure (Mandatory Reporting)	10	1	25	1	0.167	4	0	+4
Addition of the Screen Positive Rate for SDOH (Mandatory Reporting)	10	1	25	1	0.167	4	0	+4
Total Change in Information Collection Burden Hours: +9,747								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+9,747) = \$239,076								

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We request comment on how we can reduce burden on REHs for both these new information collection as well as recommendations for the removal of other existing information collections to offset these new burdens.

C. ICRs for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

a. Background

In section XVII of this proposed rule, we discuss the requirements for the ASCQR Program. We refer readers to the CY 2024 OPPTS/ASC final rule (88 FR 82140 through 82148) for detail regarding the previously finalized

ASCQR Program ICRs which are currently approved under OMB control number 0938-1270 (expiration date August 31, 2025).

In section XIV.B of this proposed rule, we propose to adopt three measures that would impact previously approved burden estimates: (1) the Facility Commitment to Health Equity (FCHE) measure, beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination;

and (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. In section XVII.E.2.a of this proposed rule, we propose that ASCs would submit data annually for these measures using the CMS-designated information system (currently, the Hospital Quality Reporting [HQR] system).

In the CY 2024 OPPTS/ASC final rule with comment period, we calculated reporting burden estimates for the ASCQR Program by utilizing the BLS mean hourly wage rate for Medical

Records Specialists (88 FR 82140). Specifically, we used the “general medical and surgical hospitals” industry to estimate the mean wage, as this categorization aligns the closest with the ASCQR Program care setting compared to other medical record specialist related industries, such as “office of physicians” or “nursing care facilities.” The most recent data from BLS’ May 2023 National Occupational Employment and Wage Estimates reflects a mean hourly wage of \$27.69 per hour for medical records specialists working in “general medical and surgical hospitals” (SOC 29–2072).⁵⁵³ We calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($\$27.69 \times 2 = \$55.38$) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we would calculate cost burden to ASCs using a wage plus benefits estimate of \$55.38 per hour throughout the discussion in this section of this rule for the ASCQR Program.

Based on the most recent analysis of the CY 2024 payment determination data, we found that, of the 5,536 ASCs that were actively billing Medicare, 4,196 were required to participate in the ASCQR Program. Of the 1,340 ASCs not required to participate in the program, 279 ASCs did so and met full requirements. On this basis, we estimate that 4,475 ASCs ($4,196 + 279$) would submit data for the ASCQR Program for the CY 2025 reporting period/CY 2027 payment determination.

b. Information Collection Burden for the Proposed Adoption of the Facility Commitment to Health Equity (FCHE) Measure Beginning With the CY 2025 Reporting Period/CY 2027 Payment Determination

In section XIV.B.1 of this proposed rule, we propose to adopt the FCHE measure for the ASCQR Program beginning with the CY 2025 reporting period/CY 2027 payment determination. For this measure, ASCs would be required to report an attestation of “yes” or “no” to a set of five domains related to organizational efforts towards health equity, as described in section XIV.B.1.b of this proposed rule.

We estimate the reporting burden associated with this measure to be, on average across all 4,475 ASCQR Program

eligible facilities, no more than 10 minutes per ASC per year, based on the currently approved burden for the same measure under the Hospital IQR Program under OMB control number 0938–1022 (expiration date January 31, 2026). This also aligns with our estimated burden per providers for HOPDs and REHs, discussed above.

Using an estimate of 10 minutes (0.167 hours) per ASC per year, we estimate that this measure adoption would result in a total annual collection and reporting burden increase of 746 hours ($0.167 \text{ hours} \times 4,475 \text{ ASCs}$) at a cost of \$41,313 ($746 \text{ hours} \times \$55.38/\text{hr}$) across program-eligible ASCs.

c. Information Collection Burden for the Proposed Adoption of the Screening for Social Drivers of Health (SDOH) Measure, Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

In section XIV.B.2 of this proposed rule, we propose to adopt the Screening for SDOH measure for the ASCQR Program beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. For this measure, ASCs would be required to report whether they screened patients for five Health Related Social Needs (HRSN) domains as described in section XIV.B.2.a of this proposed rule.

As described in section XIV.B.2.e of this proposed rule, ASCs would be able to collect data for this measure using a self-selected screening tool. We expect that most ASCs would collect data through a screening tool incorporated into their EHR or other patient intake process, such as those we describe as examples in section XIV.B.2.e of this proposed rule. We estimate the information collection burden related to conducting patient screening associated with this measure would be 2 minutes (0.033 hours) per patient. This estimate is based on the currently approved burden for the Hospital IQR Program for the same measure, requiring the reporting of patient screening for the same HRSN domains and the same frequency of data reporting, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49385 through 49386).

To provide an estimate of patient volume for the purposes of calculating the information collection burden associated with this measure, we utilized data derived from the ASC

Quality Collaborative (ASCQC) related to ASC patient fall benchmarking data as this metric applies to all patients rather than a subset. We estimate that each year approximately 2,330 patients ($10,427,619 \text{ admissions}^{554} \div 4,475 \text{ ASCs}$) would be screened per ASC annually once reporting on the measure becomes mandatory. As submission rates among facilities may vary, we conservatively estimate that, for voluntary reporting for the CY 2025 reporting period, 50 percent of ASCs would survey 50 percent of patients, and beginning with the first mandatory reporting period, ASCs would survey and report on 100 percent of patients.

We determine the cost for patients (or their representative) undertaking administrative and other tasks, such as filling out a survey or intake form, using a post-tax wage of \$24.49/hr based on the report “Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices,” which identifies the approach for valuing time when individuals undertake activities on their own time.⁵⁵⁵ To derive the costs for patients (or their representatives), a measurement of the usual weekly earnings of wage and salary workers of \$1,139 is divided by 40 hours to calculate an hourly pre-tax wage rate of \$28.48/hr.⁵⁵⁶ This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 14 percent calculated by comparing pre- and post-tax income,⁵⁵⁷ resulting in the post-tax hourly wage rate of \$24.49/hr. Unlike our state and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs because the individuals’ activities, if any, would occur outside the scope of their employment.

Measure data aggregated to the ASC level as a numerator and a denominator would be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the ASCQR Program under OMB control number 0938–1270 (expiration date August 31, 2025), we estimate a burden of 10 minutes per ASC to report the measure data. Therefore, we estimate that each ASC would spend 10 minutes (0.167 hours) annually to report the Screening for SDOH measure data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase for patients of 86,028 hours ($10,427,619 \text{ patients} \times 50 \text{ percent response rate} \times 50$

percent of ASCs $\times$ 0.033 hours per patient) at a cost of \$2,106,826 (86,028 hours $\times$ \$24.49/hr). Beginning with the CY 2026 reporting period, we estimate a total collection and reporting burden increase for patients of 344,111 hours (10,427,619 patients $\times$ 0.033 hours per patient) at a cost of \$8,427,278 (344,111 hours $\times$ \$24.49/hr).

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase for program-eligible ASCs of 373 hours (4,475 ASCs $\times$ 50 percent of ASCs $\times$ 0.167 hours) at a cost of \$20,657 (373 hours $\times$ \$55.38/hr). Beginning with the CY 2026 reporting period, we estimate a total collection and reporting burden increase for program-eligible ASCs of 746 hours (4,475 ASCs $\times$ 0.167 hours) at a cost of \$41,313 (746 hours $\times$ \$55.38/hr).

d. Information Collection Burden for the Proposed Adoption of the Screen Positive Rate for Social Drivers of Health (SDOH) Measure Beginning With Voluntary Reporting for the CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

In section XIV.B.3 of this proposed rule, we propose to adopt the Screen Positive Rate for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. We refer

readers to the currently approved burden for the Screen Positive Rate for SDOH measure in the Hospital IQR Program under OMB control number 0938–1022 for the same measure and the same frequency of data reporting, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49386). For this measure, we propose that ASCs would be required to report annually the number of patients who screened positive for one or more of the five domains (reported as five separate rates to reflect each of the five HRSN domains) divided by the total number of patients screened.

We previously included the burden associated with screening patients in our discussion of the Screening for SDOH measure. Thus, for the Screen Positive Rate for SDOH measure, we estimate only the additional burden for an ASC reporting via the HQR system since patients would not need to provide, and ASCs would not need to collect, any additional information for this measure. We continue to estimate that, for voluntary reporting for the CY 2025 reporting period, 50 percent of ASCs would survey 50 percent of patients, and beginning with the first mandatory reporting period, 100 percent of ASCs would submit data.

Measure data aggregated to the hospital level as a numerator and a denominator would be submitted via the HQR system annually. Similar to the currently approved burden estimate for web-based measures reported via the HQR system for the ASCQR Program

under OMB control number 0938–1270 (expiration date August 31, 2025), we estimate a burden of 10 minutes per ASC to report the measure data. Therefore, we estimate that each ASC would spend 10 minutes (0.167 hours) annually to report the Screen Positive Rate for SDOH measure data to CMS.

For the CY 2025 voluntary reporting period, we estimate a total collection and reporting burden increase of 373 hours (0.167 hours $\times$ 4,475 ASCs $\times$ 50 percent of ASCs) at a cost of \$20,657 (373 hours $\times$ \$55.38). Beginning with the CY 2026 reporting period, we estimate a total annual collection and reporting burden increase for ASCs of 746 hours (0.167 hours $\times$ 4,475 ASCs) at a cost of \$41,313 (746 hours $\times$ \$55.38/hr) across program-eligible ASCs.

e. Summary of Proposed Information Collection Burden Estimates for the ASCQR Program

In summary, we estimate that the proposals in this proposed rule would result in an increase of 346,349 hours at a cost of \$8,551,217 for 4,475 program-eligible ASCs from the CY 2025 reporting period/CY 2027 payment determination through the CY 2026 reporting period/CY 2028 payment determination. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1270 (expiration date August 31, 2025). (See Tables 109 and 110.)

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**TABLE 109: SUMMARY OF PROPOSED ASCQR PROGRAM INFORMATION
COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/CY 2027
PAYMENT DETERMINATION**

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2025 Reporting Period							
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of ASCs reporting	Average number records per ASC per quarter	Annual burden (hours) per ASC	Proposed annual burden (hours) across ASCs	Previously finalized annual burden (hours) across ASCs	Net difference in annual burden hours
Addition of the FCHE Measure	10	1	4,475	1	0.167	746	0	+746
Addition of the Screening for SDOH Measure (Voluntary Survey)	2	1	2,238	1,165	38.4	86,040	0	+86,028
Addition of the Screening for SDOH Measure (Voluntary Reporting)	10	1	2,238	1	0.167	373	0	+373
Addition of the Screen Positive Rate for SDOH (Voluntary Reporting)	10	1	2,238	1	0.167	373	0	+373
	Total Change in Information Collection Burden Hours: +87,520							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+87,520) = \$2,189,453							

**TABLE 110: SUMMARY OF PROPOSED ASCQR PROGRAM INFORMATION
COLLECTION BURDEN CHANGE FOR THE CY 2026 REPORTING PERIOD/CY 2028
PAYMENT DETERMINATION**

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2026 Reporting Period								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of ASCs reporting	Average number records per ASC per quarter	Annual burden (hours) per ASC	Proposed annual burden (hours) across ASCs	Previously finalized annual burden (hours) across ASCs	Net difference in annual burden hours
Addition of the FCHE Measure	10	1	4,475	1	0.167	746	0	+746
Addition of the Screening for SDOH Measure (Mandatory Survey)	2	1	4,475	2,330	76.9	344,111	0	+344,111
Addition of the Screening for SDOH Measure (Mandatory Reporting)	10	1	4,475	1	0.167	746	0	+746
Addition of the Screen Positive Rate for SDOH (Mandatory Reporting)	10	1	4,475	1	0.167	746	0	+746
Total Change in Information Collection Burden Hours: +346,349								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+346,349) = \$8,551,217								

BILLING CODE 4120-01-C*D. ICRs Related to Medicaid Clinic Services Four Walls Exceptions*

As discussed in section XVII of this proposed rule, we propose three additional exceptions to the four walls requirement under the Medicaid clinic services benefit at 42 CFR 440.90. Specifically, we propose to add a mandatory four walls exception for IHS/Tribal clinics at § 440.90(c) and optional exceptions for behavioral health clinics and clinics located in rural areas at § 440.90(d) and (e). To attest to compliance with proposed § 440.90(c) and to effectuate the options at proposed § 440.90(d) and (e), States that cover the clinic services benefit would have to submit one or more Medicaid State plan amendments (SPAs).

The PRA burden associated with submitting the SPAs implementing the proposed Medicaid clinic services four walls exceptions will be addressed as part of an associated SPA preprint being

developed by CMS and submitted to OMB for approval under OMB control number 0938-1188 (CMS-10398).

E. ICRs for Changes to the Review Timeframes for Hospital Outpatient Department (OPD) Prior Authorization Process

In the CY 2020 OPPTS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop a method for controlling unnecessary increases in the volume of covered OPD services (84 FR 61142, 61446 through 61456).⁵⁵⁸ As part of the CY 2021 OPPTS/ASC final rule with comment period, we added additional service categories to the prior authorization process (85 FR 85866, 86236 through 86248). Through the CY

⁵⁵⁸ See also Correction Notice issued January 3, 2020 (85 FR 224).

2023 OPPTS/ASC final rule with comment period, we added an eighth service category to the prior authorization process for certain hospital OPD services (87 FR 71748, 72224 through 72233). The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In alignment with the CMS Interoperability and Prior Authorization final rule (87 FR 76238), we propose to change the current review timeframes for provisionally affirmed or non-affirmed requests from 10 business days to 7 calendar days for standard reviews after receiving the prior authorization request for OPD services under Medicare FFS. The ICR associated with prior authorization requests for these covered outpatient department services is the required documentation submitted by providers. The prior authorization request must include all relevant documentation necessary to

show that the service meets applicable Medicare coverage, coding, and payment rules, and the request must be submitted before the service is provided to the beneficiary and before the claim is submitted for processing.

The burden associated with the changes in review timeframes for the OPD prior authorization process will be the time and effort necessary for the submitter to locate and obtain the relevant supporting documentation to show that the service meets applicable coverage, coding, and payment rules. The submitter will then forward the information to CMS or its contractor (MAC) for review and determination of a provisional affirmation. We expect that this information will generally be maintained by providers within the normal course of business and that this information will be readily available. We estimate that the average time for office clerical activities associated with this task will be 30 minutes, equivalent to normal prepayment or postpayment medical review. We anticipate that most prior authorization requests will be sent by means other than mail, such as electronically or by fax. However, we estimate a cost of \$5 per request for mailing medical records. Based on data from 2019–2022, we estimate that there will be 127,397 initial requests mailed per year. In addition, we estimate there will be 41,806 resubmissions of a

request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be \$846,015 (169,203 mailed requests × \$5). We also estimate that an additional 3 hours per provider will be required for attending educational meetings and reviewing training documents.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data from the Bureau of Labor Statistics (BLS) and based on the 2022 median rate for Miscellaneous Healthcare Support Occupations.⁵⁵⁹ Based on the BLS information, we estimate an average clerical hourly rate of \$18.53 with a loaded rate of \$37.06. The prior authorization program does not create any new documentation or administrative requirements. Instead, it will just require the same documents needed to support claim payments to be submitted earlier in the claim process. We use the clerical rate since we do not believe that clinical staff will need to spend more time completing the documentation than they will need in the absence of the prior authorization policy. The hourly rate reflects the time needed for the additional clerical work of submitting the prior authorization request itself. We estimate that the total annual number of submissions will be 564,010 (394,808 submissions through fax or electronic means + 169,203

mailed submissions). Therefore, we estimate that the annual burden hours allotted across all providers will be 316,412 hours (.5 hours × 564,010 submissions plus 3 hours × 11,469 providers for education). The annual burden cost is \$12,572,244 (316,412 hours × \$37.06 plus \$846,015 for mailing costs). CMS estimates the annual burden to be 316,412 hours and \$12,572,244 million. The ICR approved under OMB control number 0938–1368 will be revised and submitted to OMB for approval of this extension.

Table 111 below is a chart reflecting the total burden and associated costs for the provisions included in this proposed rule with the comment period. The previously approved Paperwork Reduction Act package (CMS–10711) is currently undergoing the renewal process. CMS did not make any changes to the information collection, such as the number of respondents, responses, or other information collection requirements. However, there is a one-hour change in the burden hours, from 316,413 to 316,412, likely due to rounding up in the previous year’s calculations. The burden costs have increased from \$11,561,950 to \$12,572,244 due to an increase in the average clerical hourly rate from \$17.13 in 2019 to \$18.53 in 2022.

TABLE 111: TOTAL BURDEN FOR NEW SERVICE CATEGORY

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Addition of a New Service Category for Hospital Outpatient Department (OPD) Prior Authorization Process	-1	+\$1.0 million

* Numbers rounded.

F. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

In section XXII.B.2 of this proposed rule, we propose that for the FY 2026 payment determination, the submission of CCDEs and linking variables associated with the Hybrid Hospital-Wide Readmission (HWR) measure and the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure would remain voluntary. We are not proposing any other modifications to either measure.

In the FY 2020 IPPS/LTCH PPS final rule and the FY 2022 IPPS/LTCH PPS final rule, we estimated the burden for

voluntary reporting for the Hybrid HWR (84 FR 42603 and 42604) and Hybrid HWM measures (86 FR 45508), respectively. In both final rules, we stated that we encourage all hospitals to submit data for the Hybrid HWR and Hybrid HWM measures during the voluntary reporting period. Our previously finalized burden estimates assume that all hospitals will participate during the voluntary reporting period in order to not underestimate the burden on participating hospitals. Therefore, we do not anticipate any changes to the burden currently approved for the Hospital IQR Program under OMB

control number 0938–1022 (expiration date January 31, 2026).

G. ICRs for Continuous Eligibility (42 CFR 435.926 and 457.342)

In section XX of this proposed rule, we propose to align the Medicaid and CHIP regulations with the continuous eligibility requirements under section 5112 of Title V, subtitle B (hereafter, “section 5112”) of the CAA, 2023. To comply with section 5112 of the CAA, 2023, States must submit a CHIP SPA and a Medicaid SPA to provide continuous eligibility for children if they do not already do so in their CHIP or Medicaid State plans, or if their

⁵⁵⁹ https://www.bls.gov/oes/current/oes_nat.htm.

current continuous eligibility SPAs do not comply with the CAA, 2023 requirements. CMS has already received approval for the burden estimates for the CHIP continuous eligibility SPA under OMB control number 0938–1148 (CMS–10398) and for the Medicaid continuous eligibility SPA under OMB control number 0938–1188 (CMS–10434). We do not anticipate any changes to the approved burden estimates.

H. ICRs Regarding Organization, Staffing and Delivery of Services for Hospitals (§ 482.59 a and b) and CAHs (§ 485.649 a Through b)

We calculated the estimated hourly rates based upon the national mean salary for that particular position increased by 100 percent to account for overhead costs and fringe benefits (using the May 2023 National Occupational Employment and Wage Estimates, Bureau of Labor Statistics (BLS) at https://www.bls.gov/oes/current/oes_nat.htm. The wage and salary data from the BLS do not include health, retirement, and other fringe benefits, or the rent, utilities,

information technology, administrative, and other types of overhead costs supporting each employee. The HHS-wide guidance on preparation of regulatory and paperwork burden estimates states that doubling salary costs is a good approximation for including these overhead and fringe benefit costs.

Table 112 presents the BLS occupation code and title, the facility provider position, the estimated average or mean hourly wage, and the adjusted hourly wage (with a 100 percent markup of the salary to include fringe benefits and overhead costs).

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TABLE 112: ESTIMATED HOURLY WAGE BY OCCUPATIONAL GROUP

BLS (NAICS) Occupation Code	BLS Occupation Category	Mean Hourly Wage (a)	Loaded Hourly Wage (b = a × 2)	Loaded Average Hourly Wage for Group (c = b1+b2...+bn/n)
Leadership & Senior Staff:				\$194
11-1011	Chief Executive	\$124.47	\$248.94	
11-9111	Medical and Health Services Manager	\$64.64	\$129.28	
23-1011	Lawyer	\$84.84	\$169.68	
29-1210	Physician	\$126.85	\$253.70	
11-3031	Financial Manager	\$84.05	\$168.10	
Administrative Staff:				\$68
11-3010	Administrative Services & Facilities Manager	\$56.56	\$113.12	
19-3022	Survey Researchers	\$32.05	\$64.10	
19-3099	Social Scientists	\$49.14	\$98.28	
43-6013	Medical Secretary	\$20.85	\$41.70	
29-2072	Medical Records Specialist	\$25.81	\$51.62	
43-4000	Information and Record Clerk	\$20.49	\$40.98	
Care Staff:				\$104

BLS (NAICS) Occupation Code	BLS Occupation Category	Mean Hourly Wage (a)	Loaded Hourly Wage (b = a × 2)	Loaded Average Hourly Wage for Group (c = b1+b2...+bn/n)
29-1210	Physician	\$126.85	\$253.70	
29-1071	Physician Assistant	\$62.74	\$125.48	
29-1171	Nurse Practitioner	\$61.78	\$123.56	
29-1141	Registered Nurse	\$45.42	\$90.84	
21-1022	Healthcare Social Worker	\$32.42	\$64.84	
31-1131	Nursing Assistant	\$19.04	\$38.08	
31-1120	Home Health and Personal Care Aide	\$16.05	\$32.10	
19-3033	Clinical and Counseling Psychologist	\$51.25	\$102.50	
Technical Staff:				\$112
15-0000	All Computer and Mathematical Occupations	\$54.39	\$108.78	
15-2051	Data Scientists	\$57.23	\$114.46	
All Staff (Average)				\$109
All Staff with Triple Weight to Care Staff (Average)				\$130
Patients:				\$31
00-000	All Occupations Average	\$31.48	\$62.96	

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We propose new requirements for hospitals and CAHs that provide obstetrical (OB) services. We propose that if a hospital or Critical Access Hospital (CAH) provides OB services, such services must be well-organized and in accordance with nationally recognized acceptable standards of practices for physical and behavioral health of pregnant, birthing, and postpartum patients. We also propose that any outpatient OB services would be consistent in quality with inpatient OB services in accordance with the complexity of services offered. In addition, we propose that the organization of the OB service be appropriate to the scope of services offered by the facility and integrated with other departments of the facility.

We further propose that the OB patient care units be supervised by an individual with the necessary education and training, and specify that person should be an experienced registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a doctor of medicine or osteopathy. In addition, hospitals and CAHs must delineate and document obstetrical privileges for all practitioners providing obstetrical care in accordance with the competencies of each practitioner.

For delivery of services, we propose that OB services must be consistent with the needs and resources of the facility. Policies governing OB care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care and safety. We additionally propose that

labor & delivery room suites have certain basic resuscitation equipment readily available, including a call-in-system, cardiac monitor, and fetal doppler or monitor. Furthermore, the service must ensure that it has adequate provisions and protocols, consistent with nationally recognized and evidence-based guidelines for OB emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the facility's QAPI program.

To identify the number of hospitals and CAHs that would be subject to the proposed provisions, we utilized the Center for Medicare and Medicaid Services' Provider of Services File—Hospital and Non-Hospital Facilities. We excluded hospitals and CAHs that do not provide obstetric services, as

well as Rural Emergency Hospitals that are not subject to these CoPs. Using this methodology, we obtained a total of 513 CAHs and 4,415 hospitals that provide obstetric services.⁵⁶⁰

We believe that most hospitals and CAHs that provide OB services already have internal standards and protocols to ensure that OB services are well organized and to provide high-quality care that is appropriate to the level of services provided and integrated with other departments of the facility. We also expect that they have internal standards and protocols to ensure compliance with nationally accepted guidelines for OB emergencies, complications, immediate post-delivery care, and other patient health and safety events. Many hospital accrediting organizations also have specific requirements governing care for pregnant and postpartum patients that would meet the proposed requirements. For example, The Joint Commission (TJC) has wide-ranging requirements for hospitals that provide perinatal care, covering everything from providing information to families in a way that is easy to understand to providing initial care for complications such as hemorrhage, hypertensive disorders, fetal heart rate abnormalities.⁵⁶¹ We expect, however, that some hospitals and CAHs may need to spend time ensuring that these standards and their sources are well-documented.

As outlined in 84 FR 51732, writing new policies related to patient care is estimated to take eight hours for each member of the staff involved in the care policy. We have estimated wages as indicated in Table 112 and included the involvement of a physician at \$2,029.60 (8 × \$253.70), a lawyer at \$1357.44 (8 ×

\$169.68), a registered nurse at \$726.72 (8 × \$90.84), a medical secretary at \$333.6 (8 × \$41.70), and a medical and health services manager at \$1,034.24 (8 × \$129.28) for a total estimated cost of \$5,481.60 per policy. This estimate leads to an average hourly cost of \$137.04 (\$5481.60 ÷ 40) per staff member involved in ensuring that these standards and their sources are well-documented. We assume that documentation would consist of one comprehensive policy per facility.

We do not expect that all facilities would need to spend 40 hours to meet these requirements. We expect that there will be no burden for TJC-accredited facilities since the organization has wide-ranging requirements for hospitals and CAHs, with the requirements increasing as the complexity of OB care offered increases. To account for this reduction in the overall burden, we used CMS' CASPER (Certification and Survey Provider Enhanced Reports)⁵⁶² to identify TJC-accredited hospitals and CAHs. According to CASPER, approximately 72.2 percent of Medicare and Medicaid approved hospitals are accredited by The Joint Commission (TJC), as well as 25 percent of Critical Access Hospitals (CAHs).

To calculate the hourly burden for this proposed requirement, in Table 113 we multiply the number of facilities by the number of responses per facility, applying the discount for hospitals and CAHs that are accredited by TJC, by the hourly burden estimate. To determine the associated cost, we multiply the revised hourly burden estimate by the average hourly labor cost. Using this formula, in Table 113 we estimate a

total burden of 79,853 hours at a cost of \$10,943,006.

Table 114 provides the annual burden estimate over a 10-year period. We do not estimate a burden for updating these policies and procedures after their initial development in year 1 since regularly reviewing and updating policies is a standard business practice for healthcare facilities that must comply with applicable federal, state, and local laws, regulations and ordinances that periodically change. As such, the total estimate over 10 years is 79,853 hours at a cost of \$10,943,006.

For the requirement that facilities delineate and document obstetrical privileges for all practitioners providing obstetrical care, we expect that most hospitals and CAHs already have knowledge regarding their practitioners' competencies. We expect, however, that they would need to spend time to build a roster of practitioners specifying each practitioner's privileges and to update this roster annually. We estimate that building and ensuring that this roster is up to date would take 8 hours of work annually by a medical secretary at \$333.6 (8 × \$41.70). As shown in Tables 115 and 116, we estimate that this provision would cost \$2,180,736 annually and \$21,807,360 over 10 years.

For the requirements that the OB patient care units be supervised by an individual with the necessary education and training, as well as ensuring that labor and delivery room suites have certain basic resuscitation equipment readily available, and that the facility has adequate provisions for obstetrical emergencies, we provide the estimated cost in the regulatory impact analysis section below.

TABLE 113: BURDEN ESTIMATE FOR ORGANIZATION, STAFFING, AND DELIVERY OF SERVICES REQUIREMENT BY PROVIDER TYPE

Provider Type	Number of Providers (a)	Number of Responses (b = a × 1)	Annualized Hourly Burden (c)	TJC Overlap Discount (d = 1 - TJC overlap discount)	Hourly Wage Cost (e)	Total Hourly Burden (f = b × c × d × e)	Total Hourly Burden Cost (g = e × f)
Hospital	5,797	5,797	40	0.278	\$137.04	64,463	\$8,833,960
CAH	513	513	40	0.75	\$137.04	15,390	\$2,109,046
Total	6,310	6,310				79,853	\$10,943,006

⁵⁶⁰ Provider of Services File—Hospital & Non-Hospital Facilities. Available at <https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file>

hospital-non-hospital-facilities/data. Accessed April 10, 2024.

⁵⁶¹ The Joint Commission Edition. Program: Perinatal Care, "Chapter: Provision of Care, Treatment, and Services." Available at <https://e->

[dition.jcrrc.com/MainContent.aspx](https://www.jcrrc.com/MainContent.aspx). Accessed April 10, 2024.

⁵⁶² Quality, Certification & Oversight Reports (QCOR). CASPER (4/16/2024). qcor.cms.gov.

TABLE 114: 10 YEAR BURDEN ESTIMATE FOR ORGANIZATION, STAFFING, AND DELIVERY OF SERVICES REQUIREMENT

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Total 10 Year Burden
Hourly Burden	79,853	0	0	0	0	0	0	0	0	0	79,853
Hourly Burden Cost	\$10,943,006	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$10,943,006

TABLE 115: BURDEN ESTIMATE FOR DELINEATING PRACTITIONERS OBSTETRICAL SERVICES BY PROVIDER TYPE

Provider Type	Number of Providers (a)	Annualized Hourly Burden (b)	Hourly Wage Cost (c)	Total Hourly Burden (d = a × b)	Total Hourly Burden Cost (e = c × d)
CAH	513	8	\$43.20	4,104	\$177,293
Hospital	5,797	8	\$43.20	46,376	\$2,003,443

TABLE 116: 10 YEAR BURDEN ESTIMATE FOR DELINEATING PRACTITIONERS OF OBSTETRICAL SERVICES

Year	Hourly Burden	Hourly Burden Cost
1	50,480	\$2,180,736
2	50,480	\$2,180,736
3	50,480	\$2,180,736
4	50,480	\$2,180,736
5	50,480	\$2,180,736
6	50,480	\$2,180,736
7	50,480	\$2,180,736
8	50,480	\$2,180,736
9	50,480	\$2,180,736
10	50,480	\$2,180,736
10 Year total Cost	504,800	\$21,807,360

I. ICRs Regarding OB Staff Training for Hospitals (§ 482.59(c) and CAHs (§ 485.649(c))

We propose that hospitals and CAHs that provide OB services must develop policies and procedures to ensure that staff are trained on select topics related to improving the delivery of maternal care. The training must reflect the scope and complexity of services offered and must include, but is not limited to, facility-identified evidence-based best practices and protocols to improve the delivery of maternal care within the facility. They would also need to be trained in any additional topics as identified by the facility's QAPI program. We also propose that the governing body must identify and document which staff must complete annual training on these topics. The

facility must further document that training was successfully completed and must be able to demonstrate staff knowledge on these topics. Lastly, we propose that the efficacy of the training must be reviewed and assessed on an ongoing basis, based on the results of data, measures, and quality indicators from its QAPI program.

As outlined in 84 FR 51732, writing new policies related to patient care is estimated to take eight hours for each member of the staff involved in the care policy. We have estimated wages as indicated in Table 112 and included the involvement of a physician at \$2,029.60 (8 × \$253.70), a lawyer at \$1,357.44 (8 × \$169.68), a registered nurse at \$726.72 (8 × \$90.84), a medical secretary at \$333.6 (8 × \$41.70), and a medical and health services manager at \$1,034.24 (8 × \$129.28) for a total estimated cost of

\$5,481.60 per policy. This estimate leads to an average hourly cost of \$137.04 (\$5,481.60 ÷ 40) per staff member involved in ensuring that these standards and their sources are well-documented. We assume that documentation would consist of one comprehensive policy per facility. We do not estimate a burden for reviewing and assessing the efficacy of these efforts since we address this below in the section, "Revisions to QAPI (§ 482.21) Standards for OB Services". We also do not estimate a burden for documentation that training was completed as updating employee records is also a customary business practice. As indicated in Table 117 and Table 118, we estimate that the development of the proposed OB staff training policies and procedures will

take 252,400 hours to complete and cost \$34,588,896.

TABLE 117: YEAR 1 BURDEN ESTIMATE FOR OB STAFF TRAINING POLICIES AND PROCEDURES BY PROVIDER TYPE

Provider Type	Number of Providers (a)	Number of Responses (b = a × 1)	Annualized Hourly Burden (c)	Hourly Wage Cost (d)	Total Hourly Burden (e = b × c)	Total Hourly Burden Cost (f = d × e)
Hospital	5,797	5,797	40	\$137.04	231,880	\$31,776,835
CAH	513	513	40	\$137.04	20,520	\$2,812,061
Total	6,310	6,310			252,400	\$34,588,896

TABLE 118: 10 YEAR BURDEN ESTIMATE FOR OB STAFF TRAINING POLICIES AND PROCEDURES

Year	Hourly Burden	Hourly Burden Cost
1	252,400	\$34,588,896
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
10 Year total Cost	252,400	\$34,588,896

J. ICRs Regarding Revisions to QAPI (§ 482.21) Standards for OB Services

We propose that hospitals and CAHs with OB services must use their QAPI program to address health disparities among OB patients on an ongoing basis. They must also measure and monitor for health disparities among OB patients and develop and implement actions to address these disparities and monitor subsequent results. Moreover, on an annual basis, they must conduct at least one performance improvement project focused on reducing maternal health disparities. In addition to the proposed QAPI requirements, we propose that OB leadership be engaged in the facility's QAPI requirement. We further propose that if a Maternal Mortality Review Committee (MMRC) is available at the state or local jurisdiction in which the facility is located, the facility must and have a process for incorporating MMRC data and recommendations into the facility's QAPI program.

The costs associated with data collection would include the cost for

facilities to modify their information technology infrastructure to ensure that they capture all features relevant for the diverse subpopulations that the facility identifies. Given that many facilities already collect some of these patient characteristics, such as race and ethnicity, we estimate that planning, programming, and performing quality checks would take 8 hours in the first year and 4 hours in all subsequent years. We anticipate a mixture of staff from computer and mathematical occupations would oversee these changes at an average hourly cost of \$108.78. This leads to an average cost of \$870.24 (8 × \$108.78) per provider in the first year and \$435.12 (4 × \$108.78) per provider in subsequent years. As indicated in Table 119 we estimate that in the first year, updating infrastructure would cost a total of \$5,491,214. In Table 120, we provide the estimated total 10-year cost which we estimate at \$30,201,679.

Based on our experience working with healthcare data, we anticipate that stratification of data and quality

indicators, together with monitoring the results after actions are taken to address these disparities would take 8 hours annually. We anticipate that data scientists would oversee these efforts at an average hourly cost of \$114.46. This leads to an average cost of \$915.68 (8 × \$114.46) per provider annually. Table 121 provides the estimated cost in year 1 and Table 122 provides the estimated cost over 10 years. We estimate an annual cost of \$5,777,941 with a total cost of \$57,779,408 over 10 years.

The final collection of information costs related to this requirement come from the proposed provision of information to MMRCs. We estimate that for each maternal death, collection of information to be submitted to the MMRC would take 4 hours of work by a physician at \$1,014.80 (4 × \$253.70) and 4 hours of work by a medical records specialist \$206.48 (4 × \$51.62) for a total estimated cost of \$1,221.28 per maternal death. This estimate leads to an average hourly cost of \$152.66 (8 ÷ \$1,221.28) per staff member involved in providing information to the MMRC.

The number of maternal deaths has varied widely in recent years. In 2021, there was a spike in maternal deaths with the number of deaths increasing to 1,205, compared to 861 deaths in 2020 and 754 deaths in 2019. Preliminary data from 2022 suggests that the number of maternal deaths is declining and beginning to return to pre-2021 levels with 818 recorded deaths. Given uncertainty about how many deaths will occur in future years, we assume that an

average of 850 deaths annually. A review of public sources suggests that most states have MMRCs and, as such, most hospitals and CAHs would be subject to this provision. While many hospitals and CAHs are already providing information to MMRCs, we are not able to estimate the exact number of deaths that are already being reviewed. As such, we continue to assume that 850 deaths would be subject to this proposed provision

annually. We also assume that facilities would provide the information to only one MMRC even if they are located in a jurisdiction that has both a state and local MMRC. Since we are unable to divide deaths that occur in hospitals and CAHs, we provide a single cost estimate for both facility types. Table 119 provides the estimated annual cost for the proposed MMRC reporting provisions and Table 120 provides the estimated cost over 10 years.

TABLE 119: YEAR 1 BURDEN ESTIMATE FOR QAPI DATA SYSTEM
MODIFICATIONS BY PROVIDER TYPE

Provider Type	Number of Providers (a)	Number of Responses (b = a × 1)	Annualized Hourly Burden (c)	Hourly Wage Cost (d)	Total Hourly Burden (e = b × c)
Hospital	5,797	5,797	8	\$108.78	46,376
CAH	513	513	8	\$108.78	4,104
Total	6,310	6,310			50,480

TABLE 120: 10 YEAR BURDEN ESTIMATE FOR QAPI DATA SYSTEM
MODIFICATIONS

Year	Hourly Burden	Hourly Burden Cost
1	50,480	\$5,491,214
2	25,240	\$2,745,607
3	25,240	\$2,745,607
4	25,240	\$2,745,607
5	25,240	\$2,745,607
6	25,240	\$2,745,607
7	25,240	\$2,745,607
8	25,240	\$2,745,607
9	25,240	\$2,745,607
10	25,240	\$2,745,607
10 Year total Cost	277,640	\$30,201,679

TABLE 121: YEAR 1 BURDEN ESTIMATE FOR QAPI DATA STRATIFICATION AND
MONITORING BY PROVIDER TYPE

Provider Type	Number of Providers (a)	Number of Responses (b = a × 1)	Annualized Hourly Burden (c)	Hourly Wage Cost (d)	Total Hourly Burden (e = b × c)	Total Hourly Burden Cost (f = d × e)
Hospital	5,797	5,797	8	\$114.46	46,376	\$5,308,197
CAH	513	513	8	\$114.46	4,104	\$469,744
Total	6,310	6,310			50,480	\$5,777,941

TABLE 122: 10 YEAR BURDEN ESTIMATE FOR QAPI DATA STRATIFICATION AND MONITORING

Year	Hourly Burden	Hourly Burden Cost
1	50,480	\$5,777,941
2	50,480	\$5,777,941
3	50,480	\$5,777,941
4	50,480	\$5,777,941
5	50,480	\$5,777,941
6	50,480	\$5,777,941
7	50,480	\$5,777,941
8	50,480	\$5,777,941
9	50,480	\$5,777,941
10	50,480	\$5,777,941
10 Year total Cost	504,800	\$57,779,408

TABLE 123: YEAR 1 BURDEN ESTIMATE FOR MMRC REPORTING

Provider Type	Number of Providers	Annual Maternal Deaths (a)	Hourly Burden per Death (b)	Hourly Wage Cost (c)	Total Hourly Burden (d = a × b)	Total Hourly Burden Cost (e = c × d)
Hospitals and CAHs	6,310	850	8	\$152.66	6,800	\$1,038,088

TABLE 124: 10 YEAR BURDEN ESTIMATE FOR MMRC REPORTING

Year	Hourly Burden	Hourly Burden Cost
1	6,800	\$1,038,088
2	6,800	\$1,038,088
3	6,800	\$1,038,088
4	6,800	\$1,038,088
5	6,800	\$1,038,088
6	6,800	\$1,038,088
7	6,800	\$1,038,088
8	6,800	\$1,038,088
9	6,800	\$1,038,088
10	6,800	\$1,038,088
10 Year total Cost	68,000	\$10,380,880

K. ICRS Regarding Emergency Services Readiness in Emergency Services (\$ 482.55) for Hospitals

We propose a new standard for emergency services readiness and to improve staff readiness for providing emergency services to all hospital patients, including pregnant and postpartum patients. The first proposed standard would require hospitals with emergency services to have adequate provisions and protocols, consistent with nationally accepted guidelines, for

the care of patients with emergency conditions (including but not limited to patients with OB emergencies, complications, immediate post-delivery care). Applicable staff would be required to be trained on these protocols and provisions. We also propose that equipment, supplies, and medication used in treating emergency cases are kept at the hospital and are readily available for treating emergency cases.

As outlined in 84 FR 51732, writing new policies related to patient care is estimated to take eight hours for each

member of the staff involved in the care policy. Since the proposed standard for emergency services involves adding a new standard to an existing policy, we estimate that it would take half the amount of time as writing a new policy, or 4 hours for each staff member involved. We have estimated wages as indicated in Table 112 and included the involvement of a physician at \$1,014.80 (4 × \$253.70), a lawyer at \$678.72 (4 × \$169.68), a registered nurse at \$363.36 (4 × \$90.84), a medical secretary at

\$166.80 (4 × \$41.70), and a health services manager at \$517.12 (4 × \$129.28) for a total estimated cost of \$2,740.80 per policy. This estimate leads to an average hourly cost of

\$137.04 (\$2,740.80 ÷ 20) per staff member involved in developing this standard. We do not estimate a burden for updating standards since reviewing and updating policies and procedures is

a customary business practice. As indicated in Table 125 and Table 126, we estimate that creating this standard would cost hospitals \$15,888,418 with a total hourly burden of 115,940 hours.

TABLE 125: YEAR 1 BURDEN ESTIMATE FOR EMERGENCY SERVICES READINESS

Provider Type	Number of Providers (a)	Number of Responses (b = a × 1)	Annualized Hourly Burden (c)	Hourly Wage Cost (d)	Total Hourly Burden (e = b × c)	Total Hourly Burden Cost (f = d × e)
Hospital	5,797	5,797	20	\$137.04	115,940	\$15,888,418

TABLE 126: 10 YEAR BURDEN ESTIMATE FOR EMERGENCY SERVICES READINESS

Year	Hourly Burden	Hourly Burden Cost
1	115,940	\$15,888,418
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
10 Year total Cost	115,940	\$15,888,418

L. Transfer Protocols in Discharge Planning (§ 482.43) for Hospitals

We propose transfer protocol requirements for hospitals transferring patients under their care to the appropriate level of care, including to another hospital, as necessary to meet the needs of the patient and stabilize any emergency conditions (including but not limited to patients with OB emergencies, complications, immediate post-delivery care). 87 FR 40350

estimated that for rural emergency hospitals (REHs), developing a transfer agreement with at least one hospital would require 2 hours of work from an administrator and a clerical person. We believe that hospitals would face a similar burden for this requirement. Using estimated wages as indicated in Table 112, we estimate that this requirement would include the involvement of a medical secretary at \$83.40 (2 × 41.70) and a medical and health services manager at \$258.56 (2 ×

129.28) for a total estimate cost of \$341.96 per hospital. This estimate leads to an average hourly cost of \$85.49 (\$341.96 ÷ 4) per staff member involved in developing this standard. We do not estimate a burden for updating transfer protocols since reviewing and updating policies and procedures is a customary business practice. As indicated in Table 126 and Table 127, we estimate that creating these protocols would cost hospitals \$1,982,342 with a total hourly burden of 23,188 hours.

TABLE 127: YEAR 1 BURDEN ESTIMATE FOR TRANSFER PROTOCOLS

Provider Type	Number of Providers (a)	Number of Responses (b = a × 1)	Annualized Hourly Burden (c)	Hourly Wage Cost (d)	Total Hourly Burden (e = b × c)	Total Hourly Burden Cost (f = d × e)
Hospital	5,797	5,797	4	\$85.49	23,188	\$1,982,342

TABLE 128: 10 YEAR BURDEN ESTIMATE FOR TRANSFER PROTOCOLS

Year	Hourly Burden	Hourly Burden Cost
1	23,188	\$1,982,342
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0
10 Year total Cost	23,188	\$1,982,342

M. Total Costs for All ICRs Related to Maternal Health

In Tables 129 and 130, we provide the total hourly burden estimate and cost for all proposed collection of information requirements related to maternal health as outlined in Tables 114, 116, 118, 120, 122, 124, 126, and 128. Overall, we estimate that the

proposed requirements would have a total burden of 1,826,621 hours over 10 years at a cost of \$183,571,989.

We would note that our estimates rely on two key assumptions. First, our estimates are not able to take into account maternal deaths that hospitals and CAHs are already reporting to MMRCs. We seek comments on ways to identify the number of deaths already

being reported to avoid overestimating the cost of this requirement. Second, we assume that facilities located in a jurisdiction with more than one MMRC would only report deaths to a single MMRC. Some facilities could, however, report this information to more than one MMRCs. We seek comments on both these assumptions.

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TABLE 129: MATERNAL HEALTH COLLECTION OF INFORMATION REQUIREMENTS HOURLY BURDEN

Year	Organization, Staffing, and Delivery of Services	Delineating Practitioners of Obstetrical Services	OB Staff Training Policies and Procedures	QAPI Data System Modifications	QAPI Data Stratification and Monitoring	MMRC Reporting	Emergency Services Readiness	Transfer Protocols	Hourly Burden for All Requirements
1	79,853	50,480	252,400	50,480	50,480	6,800	115,940	23,188	629,621
2	0	50,480	0	25,240	50,480	6,800	0	0	133,000
3	0	50,480	0	25,240	50,480	6,800	0	0	133,000
4	0	50,480	0	25,240	50,480	6,800	0	0	133,000
5	0	50,480	0	25,240	50,480	6,800	0	0	133,000
6	0	50,480	0	25,240	50,480	6,800	0	0	133,000
7	0	50,480	0	25,240	50,480	6,800	0	0	133,000
8	0	50,480	0	25,240	50,480	6,800	0	0	133,000
9	0	50,480	0	25,240	50,480	6,800	0	0	133,000
10	0	50,480	0	25,240	50,480	6,800	0	0	133,000
10 Year Total Cost	79,853	504,800	252,400	277,640	504,800	68,000	115,940	23,188	1,826,621

**TABLE 130: MATERNAL HEALTH COLLECTION OF INFORMATION
REQUIREMENTS HOURLY BURDEN COST**

Year	Organization, Staffing, and Delivery of Services	Delineating Practitioners of Obstetrical Services	OB Staff Training Policies and Procedures	QAPI Data System Modifications	QAPI Data Stratification and Monitoring	MMRC Reporting	Emergency Services Readiness	Transfer Protocols \$482.43	Hourly Burden Cost for All Requirements
1	\$10,943,006	\$2,180,736	\$34,588,896	\$5,491,214	\$5,777,941	\$1,038,088	\$15,888,418	\$1,982,342	\$77,890,641
2	\$0	\$2,180,736	\$0	\$2,745,607	\$5,777,941	\$1,038,088	\$0	\$0	\$11,742,372
3	\$0	\$2,180,736	\$0	\$2,745,607	\$5,777,941	\$1,038,088	\$0	\$0	\$11,742,372
4	\$0	\$2,180,736	\$0	\$2,745,607	\$5,777,941	\$1,038,088	\$0	\$0	\$11,742,372
5	\$0	\$2,180,736	\$0	\$2,745,607	\$5,777,941	\$1,038,088	\$0	\$0	\$11,742,372
6	\$0	\$2,180,736	\$0	\$2,745,607	\$5,777,941	\$1,038,088	\$0	\$0	\$11,742,372
7	\$0	\$2,180,736	\$0	\$2,745,607	\$5,777,941	\$1,038,088	\$0	\$0	\$11,742,372
8	\$0	\$2,180,736	\$0	\$2,745,607	\$5,777,941	\$1,038,088	\$0	\$0	\$11,742,372
9	\$0	\$2,180,736	\$0	\$2,745,607	\$5,777,941	\$1,038,088	\$0	\$0	\$11,742,372
10	\$0	\$2,180,736	\$0	\$2,745,607	\$5,777,941	\$1,038,088	\$0	\$0	\$11,742,372
10 Year Total Cost	\$10,943,006	\$21,807,360	\$34,588,896	\$30,201,677	\$57,779,410	\$10,380,880	\$15,888,418	\$1,982,342	\$183,571,989

BILLING CODE 4120-01-C**XXV. Response to Comments**

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble; and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XXVI. Economic Analyses**A. Statement of Need**

This proposed rule is necessary to make updates to the Medicare hospital OPPS rates. It is also necessary to make changes to the payment policies and rates for outpatient services furnished

by hospitals and CMHCs in CY 2025. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We are proposing to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2023, through and including December 31, 2023, and processed through June 30, 2024, and updated HCRIS cost report information.

This proposed rule is also necessary to make updates to the ASC payment rates for CY 2025, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in ASCs in CY 2025. Because ASC payment rates are based on the OPPS relative payment weights for most of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC, not less frequently than every 2 years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59079), we finalized a policy to

update the ASC payment system rates using the hospital market basket update instead of the CPI-U for CY 2019 through 2023. In the CY 2024 OPPS/ASC final rule, we finalized a policy to extend the 5-year interim period by an additional 2 years, through CY 2024 and CY 2025, to enable us to more accurately analyze whether the application of the hospital market basket update to the ASC payment system resulted in a migration of services from the hospital setting to the ASC setting (88 FR 81960).

This proposed rule is also necessary to create three additional exceptions to the four walls requirement under the Medicaid clinic services benefit at 42 CFR 440.90. Specifically, we propose to add a mandatory four walls exception for IHS/Tribal clinics at 42 CFR 440.90(c) and optional exceptions for behavioral health clinics and clinics located in rural areas at 42 CFR 440.90(d) and (e). As discussed in section XVII.A of this proposed rule, our current regulation at 42 CFR 440.90(b) allows for an exception to the four walls requirement only for certain clinic services furnished to individuals who are unhoused.

This proposed rule is also necessary to improve the quality of obstetrical services in hospitals and Critical Access Hospitals (CAHs). The United States has the highest maternal mortality rate among OECD countries.⁵⁶³ This mortality rate has increased sharply in recent years rising from 17.4 deaths per 100 thousand live births in 2018, to 32.9 deaths per 100 thousand live births in 2021,⁵⁶⁴ with most of the increased deaths in 2020 and 2021 being Covid-19 related deaths.⁵⁶⁵ The causes of pregnancy-related deaths has shifted in recent years with a decline in traditional causes, such as hemorrhage, hypertensive disorders of pregnancy, and thromboembolism, and an increase in cardiovascular problems and other medical conditions.⁵⁶⁶ ⁵⁶⁷ Nearly a third of all pregnancy-related deaths occur between the day of delivery and the 6 days that follow, with another 20

percent of deaths occurring 7 to 42 days postpartum.⁵⁶⁸

Within the United States, there are widespread differences in maternal mortality rates based on age, race, and geographical location. According to the National Center for Health Statistics, the maternal mortality rates for women in the United States over 40 years of age in 2021 was nearly 8 times greater than for women under 25 years of age, with mortality rates for non-Hispanic black women over 40 years of age more than 21 times higher than the rate for Hispanic women under 25 years of age.⁵⁶⁹ Similarly, pregnancy-related mortality rates are higher in rural areas vis-à-vis urban areas.⁵⁷⁰ Beyond deaths, maternal morbidity, defined as “any health condition attributed to and/or aggravated by pregnancy and childbirth that has a negative impact on the woman’s wellbeing”,⁵⁷¹ remains a common occurrence, with rates also varying by age and race.⁵⁷² ⁵⁷³

Pregnancy-related mortality and morbidity have large health and economic costs. One study estimates that between 2018 and 2020, pregnancy-related mortalities lead to the loss of nearly 114,000 years of potential life lost (YPLL) and cost more than \$27.4 billion based on the value of statistical life (VSL).⁵⁷⁴ Another study finds that severe maternal morbidity, as measured by 21 ICD-10 codes that the Centers for Disease Control and Prevention (CDC) identified, is associated with a 75 percent increase in costs for Medicaid patients and a more than doubling in costs for commercially insured patients during the prenatal to 30 days postpartum period.⁵⁷⁵ Focusing specifically

on nine maternal morbidities among the 2019 US birth cohort from birth to 5-years postpartum, researchers estimated they had a cost of \$32.3 billion for birthing parents and their children, with \$18.7 billion due to medical costs and \$13.6 billion coming from non-medical costs.⁵⁷⁶

Although studies vary in their methodology, time period pre-post birth analyzed, medical conditions analyzed, and cost estimates, they overall suggest that maternal morbidity and mortality impose a high health and safety, as well as economic costs on birth parents, children, and society.⁵⁷⁷ Given these costs, we are implementing conditions of participation (COPs) that are designed to help reduce maternal mortality and morbidity.

We propose requirements that hospital and CAH OB patient care units be supervised by an individual with the necessary education and training and have certain basic resuscitation equipment readily available. We also propose that staff involved with OB services be trained on key topics related to improving the delivery of maternal care. Hospitals and CAHs would also be required to utilize data from their QAPI program to implement one quality improvement project to address disparities in maternal care and to engage with MMRCs and integrate information from MMRCs into their QAPI program. We also propose that hospitals and CAHs have basic resuscitation equipment available and train their staff on emergency procedures for all patients. Finally, we propose that all hospital staff receive annual training on proper transfer protocols.

B. Overall Impact of Provisions of This Proposed Rule

We have examined the impacts of this rule, as required by Executive Order 12866, as amended, on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled “Modernizing Regulatory Review” (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), and Executive

⁵⁶³ Tikkanen, R., et al., *Maternal Mortality and Maternity Care in the United States Compared to 10 Other Developed Countries*. 2020, Commonwealth Fund.

⁵⁶⁴ Hoyert, D.L., *Maternal Mortality Rates in the United States, 2021–2023*, NCHS Health E-Stats.

⁵⁶⁵ United States Government Accountability Office, *MATERNAL HEALTH: Outcomes Worsened and Disparities Persisted During the Pandemic*. 2022.

⁵⁶⁶ Creanga, A.A., et al., *Pregnancy-Related Mortality in the United States, 2011–2013*. *Obstetrics & Gynecology*, 2017. 130(2): 366–373.

⁵⁶⁷ Wang, S., et al., *Maternal Mortality in the United States: Trends and Opportunities for Prevention*. *Annual Review of Medicine*, 2023. 74(1): 199–216.

⁵⁶⁸ Peterson, E.E., et al., *Vital Signs: Pregnancy-Related Deaths, United States, 2011–2015, and Strategies for Prevention, 13 States, 2013–2017*. *Morbidity and Mortality Weekly Report*, 2019. 68(18): 423–429.

⁵⁶⁹ Hoyert, D.L., *Maternal Mortality Rates in the United States, 2021–2023*, NCHS Health E-Stats.

⁵⁷⁰ Merkt, P.T., et al., *Urban-rural differences in pregnancy-related deaths, United States, 2011–2016*. *American Journal of Obstetrics and Gynecology*, 2021. 225(2): 183.e1–183.e16.

⁵⁷¹ Firoz, T., et al., *Measuring maternal health: focus on maternal morbidity*. *Bull World Health Organ*, 2013. 91(10): 794–796.

⁵⁷² Liese, K.L., et al., *Racial and Ethnic Disparities in Severe Maternal Morbidity in the United States*. *Journal of Racial and Ethnic Health Disparities*, 2019. 6(4): p. 790–798.

⁵⁷³ Leonard, S.A., et al., *Racial and ethnic disparities in severe maternal morbidity prevalence and trends*. *Annals of Epidemiology*, 2019. 33: 30–36.

⁵⁷⁴ White Robert, S., et al., *Economic burden of maternal mortality in the USA, 2018–2020*. *Journal of Comparative Effectiveness Research*, 2022. 11(13): 927–933.

⁵⁷⁵ Black, C.M., et al., *Costs of Severe Maternal Morbidity in U.S. Commercially Insured and Medicaid Populations: An Updated Analysis*. *Women’s Health Reports*, 2021. 2(1): 443–451.

⁵⁷⁶ O’Neil, S.S., et al., *Societal cost of nine selected maternal morbidities in the United States*. *PLOS ONE*, 2022. 17(10): e0275656.

⁵⁷⁷ Moran, P.S., et al., *Economic burden of maternal morbidity—A systematic review of cost-of-illness studies*. *PLOS ONE*, 2020. 15(1): e0227377.

Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866, as amended, and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 titled “Modernizing Regulatory Review” (hereinafter, the Modernizing E.O.) amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President’s priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) (\$200 million or more in any 1 year). Based on our estimates, OMB’s Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) as measured by an effect on the economy of \$200 million or more in any 1 year. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Based on our estimates, OMB’s Office of Information and Regulatory Affairs has determined that this rulemaking is “significant”. Therefore, OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

We estimate that the total increase in Federal Government expenditures under the OPPTS for CY 2025, compared to CY

2024, due to the changes to the OPPTS in this proposed rule, would be approximately \$1.78 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2025 we estimate that the OPPTS expenditures, including beneficiary cost-sharing, for CY 2025 would be approximately \$88.2 billion, which is approximately \$5.2 billion higher than estimated OPPTS expenditures in CY 2024. Table 131 of this proposed rule displays the distributional impact of the proposed CY 2025 changes in OPPTS payment to various groups of hospitals and for CMHCs.

We note that under our proposed CY 2025 policy, drugs and biologicals are generally paid at ASP plus 6 percent, WAC plus 6 percent, or 95 percent of AWP, as applicable.

We estimate that the proposed update to the conversion factor would increase total OPPTS payments by 2.6 percent in CY 2025. The proposed changes to the APC relative payment weights, the proposed changes to the wage indexes, the proposed continuation of a payment adjustment for rural SCHs, including EACHs, and the proposed payment adjustment for cancer hospitals would not increase total OPPTS payments because these changes to the OPPTS are budget neutral. However, these updates would change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2024 and CY 2025, considering all budget-neutral payment adjustments, changes in estimated total outlier payments, the application of the frontier State wage adjustment, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act would increase total estimated OPPTS payments by 2.3 percent.

We estimate the total increase (from changes to the ASC provisions in this proposed rule, as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures (not including beneficiary cost-sharing) under the ASC payment system for CY 2025 compared to CY 2024, to be approximately \$202 million. Tables 132 and 133 of this proposed rule display the redistributive impact of the CY 2025 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

We estimate that under our proposal to create three additional exceptions to the Medicaid clinic services benefit four walls requirement for IHS/Tribal clinics, behavioral health clinics, and clinics

located in rural areas that total Medicaid transfers would increase by \$1.18 billion for fiscal years 2025 through 2029. This includes a Federal impact of \$1.15 billion and State impact of \$30 million.

For the OB services provisions of this proposed rule, in Tables 160 and 161, we provide the total estimated cost and hourly burden of these proposed requirements both annually and over 10 years, excluding collection of information costs that we have already estimated above. Overall, we estimate that these proposed requirements would cost an average of approximately \$428 million and take 2.8 million hours to complete. Over 10 years, we estimate that the total cost would be approximately \$4.28 billion and take 28.3 million hours to complete. Below, we provide the cost estimates for each of the proposed requirements.

C. Detailed Economic Analyses

1. Estimated Effects of OPPTS Changes in This Proposed Rule

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2025 policy changes on various hospital groups. We post our hospital-specific estimated payments for CY 2025 on the CMS website with the other supporting documentation for this final rule with comment period. To view the hospital-specific estimates, we refer readers to the CMS website at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>. On the website, select “Regulations and Notices” from the left side of the page and then select “CMS–1809–P” from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 131 of this proposed rule. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A of this proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting or impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available but do not attempt to predict behavioral responses to our policy changes in order to isolate the effects associated with specific policies or updates, but any policy that

changes payment could have a behavioral response. In addition, we have not made any adjustments for future changes in variables, such as service volume, service-mix, or number of encounters.

b. Estimated Effects of OPSS Changes on Hospitals

Table 131 shows the estimated impact of this proposed rule on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-Balanced Budget Act (BBA) amount. We also include CMHCs in the first line that includes all providers. We include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 131, and we discuss them separately below, because CMHCs have historically been paid only for partial hospitalization services under the OPSS and are a different provider type from hospitals. In the CY 2024 OPSS/ASC final rule (88 FR 81833), we finalized paying CMHCs for partial hospitalization services and intensive outpatient services under APCs 5851 through 5854. For CY 2025, we propose to maintain the same APC structure and update each APC payment rate to reflect the most recent available cost data.

The estimated increase in the total payments made under the OPSS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor, as discussed in detail in section II.B of this proposed rule.

Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The proposed IPPS market basket percentage increase applicable to the OPD fee schedule for CY 2025 is 3.0 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 3.0 percent by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.4 percentage point for CY 2025 (which is also the productivity adjustment for FY 2025 in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36205)) resulting in the proposed CY 2025 OPD fee schedule increase factor

of 2.6 percent. We are using the OPD fee schedule increase factor of 2.6 percent in the calculation of the proposed CY 2025 OPSS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the estimates in Table 131 of this proposed rule.

To illustrate the impact of the CY 2025 changes, our analysis begins with a baseline simulation model that uses the CY 2024 relative payment weights, the FY 2024 final IPPS wage indexes that include reclassifications, and the final CY 2024 conversion factor. Table 131 shows the estimated redistribution of the increase or decrease in payments for CY 2025 over CY 2024 payments to hospitals and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2024 and CY 2025 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 2.6 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the estimated impact taking into account all payments for CY 2025 relative to all payments for CY 2024, including the impact of changes in estimated outlier payments and changes to the pass-through payment estimate (Column 5).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we proposed to maintain the current adjustment percentage for CY 2025. Because the proposed updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2025 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services would change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this proposed rule would redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2024 and CY 2025 by various groups

of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed rates for CY 2025 would increase Medicare OPSS payments by an estimated 2.3 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPSS ratio between payment and cost and removing payments to CMHCs results in an estimated 2.4 percent increase in Medicare payments to all other hospitals. These estimated payments would not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 131 shows the total number of facilities (3,511), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2023 hospital outpatient and CMHC claims data to model CY 2024 and CY 2025 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2024 or CY 2025 payment and entities that are not paid under the OPSS. The latter entities include CAHs, IHS and tribal hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A of this proposed rule. At this time, we are unable to calculate a DSH variable for hospitals that are not also paid under the IPPS because DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPSS hospitals (3,413), excluding the hold harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their "pre-BBA amount" as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 32 CMHCs at the bottom of the impact table (Table 131 and discuss that impact separately below.

Column 2: APC Recalibration—All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also

reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals would experience a 0.1 increase, with the impact ranging from a decrease of 0.1 percent to an increase of 0.3, depending on the number of beds. Rural hospitals will experience an estimated decrease of 0.1 overall. Major teaching hospitals will experience an estimated decrease of 0.1 percent.

Column 3: Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration, the updates for the wage indexes with the FY 2025 IPPS post-reclassification wage indexes, the rural adjustment, the frontier adjustment, and the cancer hospital payment adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year and using a CY 2024 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the proposed CY 2025 changes in wage index policy, discussed in section II.C of this proposed rule. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we propose to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2025, as described in section II.E of this proposed rule. We modeled a budget neutrality adjustment for the proposed cancer hospital payment adjustment because the proposed payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2025 is 0.87, which is different from the 0.88 PCR target adopted in the CY 2024 OPPI/ASC final rule with comment period (88 FR 81589). We note that, in accordance with section 16002 of the 21st Century Cures Act, we are applying a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.88, not the 0.87 target payment-to-cost ratio we propose in section II.F of this proposed rule.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix,

and the rural adjustment constant and using the CY 2025 scaled weights and a CY 2024 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2024 and CY 2025.

Column 4: All Budget Neutrality Changes Combined With the Market Basket Update

Column 4 demonstrates the combined impact of all the proposed changes previously described and the update to the conversion factor of 2.6 percent. Overall, these changes would increase payments to urban hospitals by 2.8 percent and to rural hospitals by 3.5 percent. Rural sole community hospitals would receive an estimated increase of 3.4 percent while other rural hospitals would receive an estimated increase of 3.6 percent.

Column 5: All Changes for CY 2025

Column 5 depicts the full impact of the proposed CY 2025 policies on each hospital group by including the effect of all changes for CY 2025 and comparing them to all estimated payments in CY 2024. Column 5 shows the combined budget neutral effects of Columns 2 and 3; the OPD fee schedule increase; the impact of estimated OPPI outlier payments, as discussed in section II.G of proposed rule; the change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIV of this proposed rule); and other proposed rule adjustments to the CY 2025 OPPI payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2024 update (and assumed, for modeling purposes, to be the same number for CY 2025), we included 106 hospitals in our model because they had both CY 2023 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2025 would increase payments to all facilities by 2.3 percent for CY 2024. We modeled the independent effect of all changes in Column 5 using the final relative payment weights for CY 2024 and the proposed relative payment weights for CY 2025. We used the final conversion factor for CY 2024 of \$87.382 and the proposed CY 2025 conversion factor of \$89.379 discussed in section II.B of this proposed rule.

Column 5 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36572) of 4.1 percent (1.04142)

to increase charges on the CY 2023 claims, and we used the overall CCR in the April 2024 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2024. Using the CY 2023 claims and a 4.1 percent charge inflation factor, we currently estimate that outlier payments for CY 2024, using a multiple threshold of 1.75 and a fixed-dollar threshold of \$7,750, would be approximately 0.85 percent of total payments. The estimated current outlier payments of 0.85 percent are incorporated in the comparison in Column 5. We used the same set of claims and a charge inflation factor of 8.5 percent (1.084555) and the CCRs in the April 2024 OPSF, with an adjustment of 1.03331 (89 FR 36573), to reflect relative changes in cost and charge inflation between CY 2023 and CY 2025, to model the proposed CY 2025 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed dollar threshold of \$8,000. The charge inflation and CCR inflation factors are discussed in detail in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36572 through 36573).

Overall, we estimate that facilities will experience an increase of 2.3 percent under this proposed rule in CY 2025 relative to total spending in CY 2024. This projected increase (shown in Column 5) of Table 131 of this proposed rule reflects the proposed 2.6 percent OPD fee schedule increase factor, adding the 0.15 difference in estimated outlier payments between CY 2024 (0.85 percent) and CY 2025 (1.0 percent), minus 0.44 percent for the change in the pass-through payment estimate between CY 2024 and CY 2025. We estimate that the combined effect of all changes for CY 2025 would increase payments to urban hospitals by 2.4 percent. Overall, we estimate that rural hospitals would experience a 2.8 percent increase as a result of the combined effects of all the changes for CY 2025.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes would include an increase of 2.1 percent for major teaching hospitals and an increase of 2.5 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated increase of 2.6 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience an increase of 2.3 percent, proprietary hospitals would experience an increase of 3.5 percent, and governmental hospitals will experience an increase of 2.4 percent.

c. Estimated Effects of OPPS Changes on CMHCs

The last line of Table 131 demonstrates the isolated impact on CMHCs, which historically have only furnished partial hospitalization services under the OPPS. As discussed in section VIII.C of this proposed rule, we propose for CY 2025 to continue paying CMHCs using APCs 5851 through 5854. We modeled the impact of this APC policy, assuming CMHCs will continue to provide the same PHP care as seen in the CY 2023 claims used

for ratesetting in this proposed rule. We note that the CY 2023 claims used for this CY 2025 proposed rule do not include any provision of IOP services. We did not exclude days with one or two services from our modeling for CY 2025, because our proposed rule policy would pay the per diem rate for APC 5853 for such days beginning in CY 2025. As a result of the final PHP APC changes for CMHCs, we estimate that CMHCs would experience a 7.2 percent increase in CY 2025 payments relative to their CY 2024 payments (shown in Column 5). For a detailed discussion of

our proposed PHP policies, please see section VIII of this proposed rule.

Column 3 shows the estimated impact of adopting the proposed FY 2025 wage index values, which result in an estimated change of 0.7 percent to CMHCs. Column 4 shows that combining the OPD fee schedule increase factor, along with the proposed changes in APC policy for CY 2025 and the proposed FY 2025 wage index updates, would result in an estimated increase of 7.7 percent.

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TABLE 131: ESTIMATED IMPACT OF THE PROPOSED CY 2025 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	(1)	(2)	(3)	(4)	(5)
	Number of Hospitals	APC Recalibration (all changes)	New Wage Index and Provider Adjustments	All Budget Neutral Changes (combined cols 2 & 3) with Market Basket Update	All Changes
ALL PROVIDERS *	3,511	0.0	0.1	2.7	2.3
ALL HOSPITALS	3,413	0.1	0.2	2.9	2.4
(excludes hospitals held harmless and CMHCs)					
URBAN HOSPITALS	2,722	0.1	0.1	2.8	2.4
LARGE URBAN	1,291	0.2	-0.3	2.4	2.2
(GT 1 MILL.)					
OTHER URBAN	1,431	0.0	0.4	3.1	2.5
(LE 1 MILL.)					
RURAL HOSPITALS	691	-0.1	1.0	3.5	2.8
SOLE COMMUNITY	356	-0.1	0.9	3.4	2.7
OTHER RURAL	335	-0.1	1.0	3.6	3.1
BEDS (URBAN)					
0 - 99 BEDS	920	0.3	0.4	3.3	2.8
100-199 BEDS	763	0.2	0.2	3.0	2.5
200-299 BEDS	423	0.2	-0.1	2.7	2.3
300-499 BEDS	383	0.1	0.1	2.9	2.4
500 + BEDS	233	-0.1	0.0	2.5	2.2
BEDS (RURAL)					
0 - 49 BEDS	330	0.0	1.0	3.6	2.9
50- 100 BEDS	203	-0.1	0.6	3.2	2.5
101- 149 BEDS	83	-0.2	1.0	3.4	3.0
150- 199 BEDS	44	-0.2	1.4	3.8	3.0
200 + BEDS	31	-0.2	1.1	3.4	3.1
REGION (URBAN)					
NEW ENGLAND	121	0.0	-1.8	0.7	0.5
MIDDLE ATLANTIC	298	0.0	-0.6	2.0	1.8
SOUTH ATLANTIC	445	0.1	0.3	3.0	2.7
EAST NORTH CENT.	417	-0.1	0.4	3.0	2.7
EAST SOUTH CENT.	166	0.0	1.7	4.3	3.9
WEST NORTH CENT.	177	-0.1	1.6	4.1	2.8
WEST SOUTH CENT.	453	0.4	1.6	4.7	4.3
MOUNTAIN	210	0.1	0.0	2.7	1.8
PACIFIC	386	0.2	-1.2	1.6	1.4
PUERTO RICO	49	0.9	0.3	3.7	3.3
REGION (RURAL)					
NEW ENGLAND	21	-0.2	0.8	3.2	2.9
MIDDLE ATLANTIC	53	-0.2	0.6	3.1	2.6
SOUTH ATLANTIC	109	-0.1	0.1	2.5	2.1
EAST NORTH CENT.	110	-0.2	0.9	3.3	3.0
EAST SOUTH CENT.	132	-0.2	1.9	4.4	3.9
WEST NORTH CENT.	79	-0.1	1.8	4.3	3.0

	(1)	(2)	(3)	(4)	(5)
	Number of Hospitals	APC Recalibration (all changes)	New Wage Index and Provider Adjustments	All Budget Neutral Changes (combined cols 2 & 3) with Market Basket Update	All Changes
WEST SOUTH CENT.	122	0.3	1.5	4.4	4.0
MOUNTAIN	41	-0.2	1.6	4.0	1.9
PACIFIC	24	-0.2	-1.0	1.4	1.1
TEACHING STATUS					
NON-TEACHING	2,093	0.2	0.2	3.0	2.5
MINOR	882	0.1	0.5	3.2	2.7
MAJOR	438	-0.1	-0.2	2.3	2.1
DSH PATIENT PERCENT					
0	8	1.4	-0.1	3.9	5.4
GT 0 - 0.10	223	0.4	0.6	3.6	3.0
0.10 - 0.16	207	0.3	0.3	3.2	2.6
0.16 - 0.23	524	0.3	0.0	3.0	2.5
0.23 - 0.35	1,151	0.0	0.4	3.1	2.5
GE 0.35	905	-0.1	-0.1	2.4	2.1
DSH NOT AVAILABLE **	395	2.6	0.0	5.2	4.9
URBAN TEACHING/DSH					
TEACHING & DSH	1,163	0.0	0.1	2.7	2.3
NO TEACHING/DSH	1,156	0.2	0.1	2.9	2.4
NO TEACHING/NO DSH	8	1.4	-0.1	3.9	5.4
DSH NOT AVAILABLE2	395	2.6	0.0	5.2	4.9
TYPE OF OWNERSHIP					
VOLUNTARY	1,967	0.0	0.1	2.7	2.3
PROPRIETARY	1,017	0.8	0.6	4.0	3.5
GOVERNMENT	429	-0.1	0.1	2.7	2.4
CMHCs	32	4.3	0.7	7.7	7.2

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all proposed CY 2025 OPPS policies and compares those to the CY 2024 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2025 hospital inpatient wage index. The final rural SCH adjustment would continue our current policy of 7.1 percent, so the budget neutrality factor is 1. The final budget neutrality adjustment for the cancer hospital adjustment is 1.0006 because the proposed CY 2025 target payment-to-cost ratio is less than the CY 2024 PCR target.

Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 2.6 percent OPD fee schedule update factor (3.0 percent reduced by 0.4 percentage points for the productivity adjustment).

Column (5) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have the frontier adjustment to Column 3 in this table.

These 3,511 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

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d. Estimated Effect of OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment would increase for services for which the OPPS payments would rise and decrease for services for which the OPPS payments would fall. For further discussion of the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.H of this proposed rule. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be approximately 17.8 percent for all services paid under the OPPS in CY 2025. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the proposed CY 2025 comprehensive APC payment policy discussed in section II.A.2.b of this proposed rule. We note that the individual payments, and therefore copayments, associated with services may differ based on the setting in which they are furnished. However, at the aggregate system level, we do not currently observe significant impact on beneficiary coinsurance as a result of those policies.

e. Estimated Effects of OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs, as discussed in section XIII of this final rule. Hospitals, CMHCs, and ASCs would be affected by the changes in this proposed rule. Additionally, as discussed in section VIII.A.2 of this proposed rule, we established payment for IOP furnished by RHCs, FQHCs, and Opioid Treatment Programs. These providers of IOP are not paid under the OPPS and are not included in the impact analysis shown in Table 131. However, the proposed payment amount for OPPS APC 5861 would affect payments to RHCs and FQHCs since under sections 1834(o)(5)(A) and 1834(y)(3)(A) of the Act payment for IOP services in these settings is required to be equal to the payment determined for IOP services in the hospital outpatient department.

f. Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect of the update on the Medicare program is expected to be an increase of \$1.78 billion in program payments for OPPS services furnished in CY 2025. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We estimate that the changes in this proposed rule would increase these Medicaid beneficiary payments by approximately \$155 million in CY 2025. Currently, there are approximately 11.5 million dual-eligible beneficiaries, which represent approximately 40 percent of Medicare Part B fee-for-service beneficiaries. The impact on Medicaid was determined by taking 40 percent of the beneficiary cost-sharing impact. The national average split of Medicaid payments is 58 percent Federal payments and 42 percent State payments. Therefore, for the estimated \$155 million Medicaid increase, approximately \$90 million would be from the Federal government and \$65 million would be from State governments.

g. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we proposed and the reasons for our selected alternatives are discussed throughout this proposed rule.

h. Proposed Add-On Payment for High-Cost Drugs to the Indian Health Service (IHS) All-Inclusive Rate (AIR)

For CY 2025, we propose to pay Indian Health Service (IHS) and tribal hospitals separately for high-cost drugs (Part B drugs with daily costs over \$1,334) furnished in hospital outpatient departments through an add-on payment, in addition to the All-Inclusive Rate (AIR), using the IHS authority⁵⁷⁸ under which the annual AIR is calculated. This policy is projected to increase Medicare program expenditures by approximately \$30 million in CY 2025. We refer readers to section X.C of this proposed rule for further discussion of this policy.

2. Estimated Effects of CY 2024 ASC Payment System Changes

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII of this proposed rule, we are

setting the CY 2025 ASC relative payment weights by scaling the proposed CY 2025 OPPS relative payment weights by the proposed CY 2025 ASC scalar of 0.873. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 132 and 133.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system after application of any quality reporting reduction be reduced by a productivity adjustment. In CY 2019, we adopted a policy for the annual update to the ASC payment system to be the hospital market basket update for CY 2019 through CY 2023. In the CY 2024 OPPS/ASC final rule with comment period, we extended this 5-year interim period an additional 2 years through CYs 2024 and 2025. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period, ending with the applicable fiscal year, year, cost reporting period, or other annual period). For ASCs that fail to meet their quality reporting requirements, the CY 2025 payment determinations would be based on the application of a 2.0 percentage point reduction to the annual update factor, which is the hospital market basket update for CY 2025. We calculated the proposed CY 2025 ASC conversion factor by adjusting the CY 2024 ASC conversion factor by 0.9958 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2024 and CY 2025, which includes our proposed limit on wage index declines of greater than 5 percent, and by applying the CY 2025 productivity-adjusted hospital market basket update factor of 2.6 percent (which is equal to the proposed inpatient hospital market basket percentage increase of 3.0 percent reduced by a productivity adjustment of 0.4 percentage point). The proposed CY 2025 ASC conversion factor is \$54.675 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2025 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2023 and CY 2025 with precision. We believe the net effect on Medicare expenditures resulting from the proposed CY 2025

⁵⁷⁸ Sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248), Public Law 83-568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*).

changes would be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups, as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs would experience changes in payment that differ from the aggregated estimated impacts presented below.

b. Estimated Effects of ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform a wide range of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect of the proposed update to the CY 2025 payments on an individual ASC would depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion includes tables that display estimates of the impact of the proposed CY 2025 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2023 claims data. Table 132 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2024 payments to estimated CY 2025 payments, and Table 133 shows a comparison of estimated CY 2024 payments to estimated CY 2025 payments for procedures that we estimate would

receive the most Medicare payment in CY 2024.

In Table 132, we have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical specialty and ancillary items and services groups. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 132.

- Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group, which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes, as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.

- Column 2—Estimated CY 2024 ASC Payments were calculated using CY 2023 ASC utilization data (the most recent full year of ASC utilization) and CY 2024 ASC payment rates. The surgical specialty groups are displayed in descending order based on estimated CY 2024 ASC payments.

- Column 3—Estimated CY 2025 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that is attributable to proposed updates to ASC payment rates for CY 2025 compared to CY 2024.

As shown in Table 132, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the proposed update to ASC payment rates for CY 2025 would

result in a 2 percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 2 percent increase in aggregate payment amounts for musculoskeletal system procedures, a 2 percent increase in aggregate payment amounts for nervous system procedures, a 3 percent increase in aggregate payment amounts for digestive system procedures, a 2 percent increase in aggregate payment amounts for cardiovascular system procedures, and a 2 percent increase in aggregate payment amounts for genitourinary system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and changes in policy. In general, spending in each of these categories of services is increasing due to the 2.6 percent payment rate update which is offset by roughly 0.4 percentage points as a result of the proposed CY 2025 ASC wage indexes and the proposed ASC wage index scalar of 0.9958, resulting in a net 2.2 percent payment rate update. After the payment rate update is accounted for, aggregate payment increases or decreases for a category of services can be higher or lower than a 2.2 percent increase, depending on if payment weights in the OPPS APCs that correspond to the applicable services increased or decreased or if the most recent data show an increase or a decrease in the volume of services performed in an ASC for a category. For example, we estimate a 3 percent increase in gastrointestinal procedure payments. The increase in payment rates for gastrointestinal procedures is a result of relative increase in the OPPS relative weights for the Upper GI Procedures and Lower GI Procedures clinical families. These changes are further increased by the 2.2 percent ASC overall rate increase for these procedures. For estimated changes for selected procedures, we refer readers to Table 132 provided later in this section.

TABLE 132: ESTIMATED IMPACT OF THE CY 2025 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2024 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2024 ASC Payments (in Millions) (2)	Estimated CY 2025 Percent Change (3)
Total	\$6,810	2
Eye	\$2,003	2
Musculoskeletal	\$1,320	2
Nervous System	\$1,227	2
Gastrointestinal	\$1,005	3
Cardiovascular	\$332	2
Genitourinary	\$257	2

Table 133 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2025. The table displays 30 of the procedures receiving the greatest estimated CY 2024 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending

order by estimated CY 2024 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2024 ASC Payments were calculated using CY 2023 ASC utilization (the most recent full year of ASC utilization) and the CY 2024 ASC payment rates. The estimated

CY 2024 payments are expressed in millions of dollars.

- Column 4—Estimated CY 2025 Percent Change reflects the percent differences between the estimated ASC payment for CY 2024 and the estimated payment for CY 2025 based on the proposed update.

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TABLE 133: ESTIMATED IMPACT OF THE PROPOSED CY 2025 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2024 ASC Payment (in millions) (3)	Estimated CY 2025 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	\$1,329	2
27447	Total knee arthroplasty	\$336	2
45380	Colonoscopy and biopsy	\$256	3
45385	Colonoscopy w/lesion removal	\$241	3
63685	Ins/rplc spi npg/rcvr pocket	\$214	4
63650	Implant neuroelectrodes	\$181	3
43239	Egd biopsy single/multiple	\$177	6
27130	Total hip arthroplasty	\$168	2
66991	Xcapsl ctrc rmvl insj 1+	\$127	0
64483	Njx aa&/strd tfrm epi l/s 1	\$107	2
64590	Ins/rpl prph sac/gstr npg/r	\$103	2
66982	Xcapsl ctrc rmvl cplx wo ecp	\$97	2
64635	Destroy lumb/sac facet jnt	\$87	3
29827	Sho arthrs srg rt8tr cuf rpr	\$85	3
36902	Intro cath dialysis circuit	\$76	4
64493	Inj paravert f jnt l/s 1 lev	\$72	2
64561	Implant neuroelectrodes	\$68	4
66821	After cataract laser surgery	\$66	2
G0105	Colorectal scrn; hi risk ind	\$65	3
0784T	Ins/rplmt eltrd ra spi nstim	\$52	-4
65820	Relieve inner eye pressure	\$48	2
0275T	Perq lamot/lam lumbar	\$47	4
G0121	Colon ca scrn not hi rsk ind	\$44	3
C9740	Cysto impl 4 or more	\$43	6
62323	Njx interlaminar lmbrr/sac	\$42	5
15823	Revision of upper eyelid	\$40	3
64721	Carpal tunnel surgery	\$39	3
64628	Trml dstrj ios bvn 1st 2 l/s	\$35	1
27279	Arthrd si jt perq/min nvas	\$34	3
27446	Revision of knee joint	\$32	2

BILLING CODE 4120-01-C**c. Estimated Effects of ASC Payment System Policies on Beneficiaries**

We estimate that the CY 2025 update to the ASC payment system would be generally positive (that is, result in lower cost-sharing) for beneficiaries with respect to the new procedures to be designated as office-based for CY 2025. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the

procedure payment (other than for certain preventive services), although the majority of HOPD procedures have a 20-percent copayment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will usually be less than the OPPS copayment amount for the same services. (The only exceptions will be if the ASC coinsurance amount exceeds the hospital inpatient deductible since the statute requires that OPPS copayment amounts not exceed the hospital inpatient deductible. Therefore, in limited circumstances, the ASC coinsurance amount may exceed the

hospital inpatient deductible and, therefore, the OPPS copayment amount for similar services.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. While the ASC payment system bases most of its payment rates on hospital cost data used to set OPPS relative payment weights, services that are performed a majority of the time in a physician office are generally paid the lesser of the ASC amount according to the standard ASC ratesetting methodology or at the nonfacility practice expense-based amount payable under the PFS. For

those additional procedures that we propose to designate as office-based in CY 2025, the beneficiary coinsurance amount under the ASC payment system generally will be no greater than the beneficiary coinsurance under the PFS because the coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

Accounting Statements and Tables for OPPS and ASC Payment System

As required by OMB Circular A–4 (available on the Office of Management and Budget website at: <https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf>), we

have prepared accounting statements to illustrate the impacts of the OPPS and ASC changes in this proposed rule. The first accounting statement, Table 134, illustrates the classification of expenditures for the CY 2025 estimated hospital OPPS incurred benefit impacts associated with the final CY 2024 OPD fee schedule increase. The second accounting statement, Table 135, illustrates the classification of expenditures associated with the 3.1 percent CY 2025 update to the ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers. The third

accounting statement, Table 136 contains the classification of the costs associated with the proposed health and safety standards for obstetrical services in hospitals and critical access hospitals. This includes the total cost, benefits and transfers as outlined in the collection of information section in Table 130, and the regulatory impact analysis as provided in Table 161. Since there are no transfers and we are not able to quantify the benefits of these provisions, we do not include them in the table. This statement provides our best estimate for the proposed health and safety standards for obstetrical services in hospitals and critical access hospitals provisions.

TABLE 134: ACCOUNTING STATEMENT: CY 2025 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2024 TO CY 2025 ASSOCIATED WITH THE CY 2025 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	\$1,780 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS

TABLE 135: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2024 TO CY 2025 AS A RESULT OF THE CY 2025 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	\$150 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	\$150 million

TABLE 136: ACCOUNTING STATEMENT: HEALTH AND SAFETY STANDARDS FOR OBSTETRICAL SERVICES IN HOSPITALS AND CRITICAL ACCESS HOSPITALS

Category	Estimate	Units		
		Year Dollar	Discount Rate	Period Covered
Annualized Monetized Costs (\$million/year)	454	2023	2%	2024-2033

TABLE 137: FOUR WALLS: ACCOUNTING STATEMENT: MEDICAID CLINIC SERVICES FOUR WALLS EXCEPTIONS

Annual monetized transfers	Primary estimate (in millions of dollars)	Low estimate (in millions of dollars)	High estimate (in millions of dollars)	Transfers		
				Year dollars	Discount rate (percent)	Period covered
From Federal Government to States....	213.6	102.3	339.1	2025	2	2025-2029
From States to Health Care Providers...	219.6	103.8	357.8	2025	2	2025-2029

3. Effects of Changes in Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

a. Background

We refer readers to the CY 2024 OPPI/ASC final rule with comment period (88 FR 81961 through 82012) for the previously estimated effects of changes to the Hospital OQR Program for the CY 2026 payment determination and subsequent years. Of the 3,062 hospital outpatient departments (HOPDs) that met eligibility requirements for the CY 2024 payment determination for the Hospital OQR Program, we determined that 117 HOPDs did not meet the requirements to receive the full annual Outpatient Department (OPD) fee schedule increase factor while an additional 58 HOPDs elected not to participate.

b. Impact of CY 2025 OPPI/ASC Proposed Rule Proposals

In this proposed rule, we propose to adopt four measures: (1) the Hospital Commitment to Health Equity (HCHE) measure, beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for Social Drivers of Health (SDOH) measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; (3) the Screen Positive Rate for SDOH measure, beginning with voluntary reporting for the CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (4) the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM),

beginning with voluntary reporting for the CY 2026 reporting period and mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination.

In addition, we propose to remove two claims-based measures beginning with the CY 2025 reporting period/CY 2027 payment determination: (1) the MRI Lumbar Spine for Low Back Pain measure; and (2) the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery measure. We further propose to require electronic health record (EHR) technology to be certified to all electronic clinical quality measures (eCQMs) available to report for the CY 2025 reporting period/CY 2027 payment determination and subsequent years.

Lastly, we propose to modify the public reporting of data for the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients)—Psychiatric/Mental Health Patients stratification so that it may be published on Care Compare in addition to the *data.cms.gov* downloadable files beginning in CY 2025.

We refer readers to section XXIV.B (Collection of Information) of this proposed rule for a detailed discussion of the calculations estimating the changes to the information collection and reporting burden for proposed data requirements under the Hospital OQR Program for the estimated 3,200 program-eligible HOPDs. A summary table (see Table 106) shows an estimated total information collection and reporting burden increase of 66,348,321 hours at a cost of \$1,624,936,216 annually associated with our proposals for the CY 2027 reporting period/CY 2029 payment determination and subsequent years compared to our

currently approved information collection burden estimates.

In section XIV.B.1 of this proposed rule, we propose to adopt the HCHE measure. For HOPDs to receive a point for each of the domains in the measure, affirmative attestations are required for each of the elements within a domain. To attest affirmatively to all of the domains in the measure, HOPDs may incur costs associated with activities such as updating facility policies, engaging senior leadership, participating in new quality improvement activities, performing additional data analysis, and training staff. The extent of these costs would vary depending on what activities the HOPD is already performing, HOPD size, and the choices each HOPD makes in order to meet the criteria necessary to attest affirmatively.

In section XIV.B.2 of this proposed rule, we propose to adopt the Screening for SDOH measure. HOPDs that are not currently administering some screening mechanism and elect to begin doing so as a result of this measure adoption proposal would likely incur some non-recurring costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as different HOPDs may utilize different modes of data collection (for example paper-based, electronically patient-directed, clinician-facilitated, etc.). In addition, depending on the method of data collection utilized, the time required to complete the screening may add a negligible amount of time to patient visits.

In section XIV.B.3 of this proposed rule, we propose to adopt the Screen Positive Rate for SDOH measure, which would not result in any additional economic impacts beyond those discussed for the associated Screening for SDOH measure or in section XXIV.B

(Collection of Information) of this proposed rule.

In section XV.C.1.b of this proposed rule, we propose to adopt the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM). For HOPDs that are not currently collecting these data and elect to begin doing so as a result of this measure there would be some costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as HOPDs may utilize different modes of data collection (collected by facilities or authorized third-party vendors post-discharge through a web-based survey instrument, distributed electronically) and have differing response rates influencing data volume. While we assume the majority of hospitals will report data for this measure directly to CMS, we assume some hospitals may elect to submit measure data via a third-party survey vendor, for which there are associated costs. Under OMB control number 0938-1240 for the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey (expiration date November 30, 2024), an estimate of approximately \$4,000 per hospital is used to account for these costs.

In section XV.E.2.b of this proposed rule, we propose to require EHR technology to be certified to all eCQMs available to report. We do not expect HOPDs would experience an increase in information collection burden for the Hospital OQR Program as discussed in section XXIV.B (Collection of Information) of this proposed rule, because this proposal does not require HOPDs to submit new data to CMS and the use of EHR technology that is certified to all available eCQMs has been required for the Medicare Promoting Interoperability Program (83 FR 41672) and the Hospital IQR Program (84 FR 42604). In addition, due to the differences in the build of respective CEHRT deployed in HOPDs, the mapping required to capture required data for measure calculation, and the range of HOPD participation in the development, implementation, and testing of new CEHRT functionality, an estimated cost impact of the policy is not quantifiable as it will vary by CEHRT and HOPD. For certifying a new eCQM in the eCQM measure set specifically, we expect some costs for HOPDs so that HOPDs have the option to report it.

In section XV.F.2 of this proposed rule, we propose to publicly report data for the Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients stratification on Care Compare, which would not result in any additional economic impacts beyond those discussed in section XXIV.B (Collection of Information) of this proposed rule.

4. Effects of Changes in Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program

a. Background

We refer readers to the CY 2024 OPPI/ASC final rule with comment period (88 FR 82149) for the previously estimated effects of changes to the REHQR Program for the CY 2024 reporting period and subsequent years. For the CY 2025 reporting period, we have estimated there would be 25 REHs mandated to report under the REHQR Program based on hospital conversations as of April 22, 2024. We use this number of REHs for our impact analyses knowing that more jurisdictions will pass or amend necessary legislation enabling transitions, acknowledging that the number of conversions could be less than or significantly greater than this estimate with time.

b. Impact of CY 2025 OPPI/ASC Proposed Rule Proposals

In this proposed rule, we propose to adopt three measures: (1) the Hospital Commitment to Health Equity (HCHE) measure beginning with the CY 2025 reporting period; (2) the Screening for Social Drivers of Health (SDOH) measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period; and (3) the Screen Positive Rate for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period. We also propose to extend the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure beginning with the CY 2025 reporting period.

We refer readers to section XXIV.C (Collection of Information) of this proposed rule for a detailed discussion of the calculations estimating the changes to the information collection and reporting burden for proposed data requirements under the REHQR Program for the estimated 25 REHs. A summary table (see Table 108)) demonstrates an estimated total information collection

and reporting burden for 25 REHs of 9,747 hours at a cost of \$239,076 annually associated with our proposals for the CY 2026 reporting period/CY 2028 program determination and subsequent years.

In section XIV.B.1 of this proposed rule, we propose to adopt the HCHE measure. For REHs to receive a point for each of the domains in the measure, affirmative attestations are required for each of the statements within a domain. To attest affirmatively to all of the domains in the measure, REHs may incur costs associated with activities such as updating facility policies, engaging senior leadership, participating in new quality improvement activities, performing additional data analysis, and training staff. The extent of these costs would vary depending on what activities the REH is already performing, and the individual choices each REH makes in order to meet the criteria necessary to attest affirmatively.

In section XIV.B.2 of this proposed rule, we propose to adopt the Screening for SDOH measure. REHs that are not currently administering some screening mechanism and elect to begin doing so as a result of this measure adoption proposal would likely incur some costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as different REHs may utilize different modes of data collection (for example paper-based, electronically patient-directed, clinician-facilitated, etc.). In addition, depending on the method of data collection utilized, the time required to complete the screening may add a negligible amount of time to patient visits.

In section XIV.B.3 of this proposed rule, we propose to adopt the Screen Positive Rate for SDOH measure, which would not result in any additional economic impacts beyond those discussed for the associated Screening for SDOH measure or in section XXIV.C (Collection of Information) of this proposed rule.

In section XVI.C.2 of this proposed rule, we propose to extend the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure from 1 to 2 years and to establish when an REH would be required to submit data under the REHQR Program after converting to an REH, which, if finalized as proposed, would not result in any additional economic impacts beyond those discussed in section XXIV.C (Collection of Information) of this proposed rule.

5. Effects of Changes in Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

a. Background

We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 82143) for the previously estimated effects of changes to the ASCQR Program for the CY 2027 payment determination. In section XVII of this proposed rule, we discuss our proposals affecting the ASCQR Program. Based on the most recent analysis of the CY 2024 payment determination data, we found that, of the 5,536 ambulatory surgical centers (ASCs) that were actively billing Medicare, 4,196 were required to participate in the ASCQR Program. Of the 1,340 ASCs not required to participate in the program, 279 ASCs did so and met full requirements. On this basis, we estimate that 4,475 ASCs (4,196 + 279) would submit data for the ASCQR Program for the CY 2025 reporting period unless otherwise noted. We note that this estimate is a decrease of 334 ASCs from our estimate of 4,809 provided in the CY 2024 OPPS/ASC final rule with comment period (88 FR 82143) due to results from more recent data analysis regarding numbers of eligible ASCs.

b. Impact of CY 2025 OPPS/ASC Proposed Rule Proposals

In section XIV.B of this proposed rule, we propose to adopt three measures: (1) the Facility Commitment to Health Equity (FCHE) measure beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) the Screening for Social Drivers of Health (SDOH) measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (3) the Screen Positive Rate for SDOH measure beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

We refer readers to section XXIV.D (Collection of Information) of this proposed rule for a detailed discussion of the calculations estimating the changes to the information collection and reporting burden for proposed data requirements under the ASCQR Program for the estimated 4,475 program-eligible ASCs. A summary table (see Table 110)) demonstrates an estimated total information collection and reporting burden increase for 4,475 ASCs of 346,349 hours at a cost of \$8,551,217 annually associated with our proposals

for the CY 2026 reporting period/CY 2028 payment determination and subsequent years, compared to our currently approved information collection burden estimates.

In section XIV.B.1 of this proposed rule, we propose to adopt the FCHE measure. For ASCs to receive a point for each of the domains in the measure, affirmative attestations are required for each of the statements within a domain. To attest affirmatively to all of the domains in the measure, ASCs may incur costs associated with activities such as updating facility policies, engaging senior leadership, participating in new quality improvement activities, performing additional data analysis, and training staff. The extent of these costs would vary depending on what activities the ASC is already performing, ASC size, and the individual choices each ASC makes in order to meet the criteria necessary to attest affirmatively.

In section XIV.B.2 of this proposed rule, we propose to adopt the Screening for SDOH measure. ASCs that are not currently administering some screening mechanism and elect to begin doing so as a result of this measure adoption proposal would likely incur some non-recurring costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as different ASCs may utilize different modes of data collection (for example paper-based, electronically patient-directed, clinician-facilitated, etc.). In addition, depending on the method of data collection utilized, the time required to complete the screening may add a negligible amount of time to patient visits.

In section XIV.B.3 of this proposed rule, we propose to adopt the Screen Positive Rate for SDOH measure, which would not result in any additional economic impacts beyond those discussed for the associated Screening for SDOH measure or in section XXIV.D (Collection of Information) of this proposed rule.

6. Effects of Changes in Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

In section XXII of this proposed rule, we propose that for the FY 2026 payment determination, the submission of core clinical data elements and linking variables associated with the Hybrid Hospital-Wide Readmission (HWR) measure and the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure would remain voluntary. This proposal would have no impact on participating

hospitals because we are not modifying either measure.

7. Effects of Proposed Changes for Individuals Currently or Formerly in the Custody of Penal Authorities

a. Medicare FFS No Legal Obligation To Pay Payment Exclusion and Incarceration (Revisions to 42 CFR 411.4)

The individuals currently or formerly in the custody of penal authorities provisions are discussed in section XXIII of this proposed rule. Section XXIII of this proposed rule describes our proposals to revise the regulations to clarify the “no legal obligation to pay” payment exclusion codified in regulation at § 411.4. Specifically, we propose to narrow the description of custody in § 411.4(b) because we no longer believe that certain classes of individuals should be presumed to be in custody for purposes of the no legal obligation to pay payment exclusion, reorganize and renumber the regulation at § 411.4(b), make certain non-substantive edits to § 411.4(a) to align the regulatory text with the statutory no legal obligation to pay payment exclusion, and define “penal authority.”

We expect that our proposal to narrow the description of “custody” will reduce burden for individuals on bail, parole, probation, or home detention and those providers and suppliers that treat them, because it will no longer be necessary to rebut the presumption that such individuals do not have a legal obligation to pay for their own healthcare in order for Medicare to pay for their health care items or services. We anticipate that our proposed revisions will ensure that Medicare properly pays for services for individuals who are on bail, parole, probation, or home detention. We also anticipate that this proposal will have a negligible impact on Medicare costs, as it does not add new covered services or benefits; rather, the proposed revisions merely remove a real or perceived barrier so that individuals on bail, parole, probation, or home detention can more easily access the Medicare benefits for which they are legally entitled.

b. Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals

We propose to revise the eligibility criteria for the Medicare special enrollment period (SEP) for formerly incarcerated individuals at §§ 406.27(d)(1) and 407.23(d)(1). Specifically, for releases on and after January 1, 2025, we propose to base the

determination of when an individual is no longer incarcerated on SSA's data collected in its systems for determining OASDI benefit suspensions in section 202(x)(1)(A) of the Act and any additional documentation provided by individuals to demonstrate that they have been released from incarceration. Our proposal would limit the current eligibility criteria for this SEP, which reference to the Medicare payment exclusion at § 411.4(b), to releases between January 1, 2023, and December 31, 2024.

The SEP for formerly incarcerated individuals at §§ 406.27(d)(1) (for Premium Part A) and 407.23(d)(1) (for Part B) starting in 2023 provides eligible individuals an opportunity to enroll in Medicare upon release from incarceration without waiting for the General Enrollment Period (GEP) and facing penalties for delayed enrollment. We anticipate that the proposed revisions to the SEP for formerly incarcerated individuals will provide clarity and make accessing this SEP easier upon release from incarceration, especially for a population facing many challenges reintegrating into society. However, we do not anticipate a significant impact on utilization of the SEP since there is no evidence that the current requirements have created barriers to those who want to use the SEP. As a result of this assumption, we expect a negligible impact on Medicare costs.

8. Estimated Effects of Medicaid Clinic Services Four Walls Exceptions

a. Background

As discussed in more detail in section XVIII, we propose to add exceptions to the four walls requirement under the Medicaid clinic services benefit for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas. The exception for IHS/Tribal clinics would be mandatory for States that cover the clinic services benefit while the exceptions for behavioral health clinics and clinics located in rural areas would be at State option. We believe that this proposal will help States strengthen and improve access to Medicaid clinic services for the populations served by IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas, and that it is responsive to the concerns we have heard from Tribes, the TTAG, the STAC, States, and other interested parties. In addition, we believe this proposal will advance health equity and improve health care access for the populations served by IHS/Tribal clinics, behavioral health

clinics, and clinics located in rural areas.

b. Overall Estimated Effects of Medicaid Clinic Services Four Walls Exceptions

The aggregate economic impact of this proposed regulation is estimated to be \$1.18 billion in transfers for fiscal years 2025–2029. This includes a Federal impact of \$1.15 billion and impacts to States of \$30 million. For the purposes of this analysis, we estimated the impacts separately for Medicaid clinic services furnished outside of the four walls for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas. Uncertainties in the estimate result in an estimated range of \$554 million to \$1.82 billion in the Federal impact and a range of \$7 million to \$95 million in the State impact.

Current Medicaid clinic services expenditures were estimated using financial reporting for 2022. Estimated expenditures for IHS/Tribal Medicaid clinic services represent those expenditures not attributable to the following Medicaid services: inpatient hospital, outpatient hospital, prescription drugs, FQHC, and RHCs; in 2022, these expenditures included expenditures for IHS/Tribal Medicaid clinic services provided outside of the four walls (due to the grace period discussed below). We assumed that 15 percent of expenditures for Medicaid clinic services were related to behavioral health based on general behavioral health utilization and spending patterns. We assumed that 17 percent of remaining Medicaid clinic services expenditures were attributable to clinics in rural areas based on 17 percent of the Medicaid population residing in rural areas. Estimated baseline Federal Medicaid expenditures for Medicaid clinic services in 2025 are \$934 million at IHS/Tribal clinics, \$530 million for behavioral health services provided at Medicaid clinics, and \$495 million for Medicaid clinic services provided in rural areas. The estimates for behavioral health services provided at Medicaid clinics and Medicaid clinic services provided in rural areas do not include Medicaid clinic services expenditures from IHS/Tribal clinics.

It is important to note that IHS/Tribal clinic services provided outside of the clinic's four walls are currently being paid for by Medicaid programs, under a CMS "grace period" that currently extends through February 11, 2025. For a more detailed discussion on this grace period please see section XVIII.A of this proposed rule. Unless the proposed exception for IHS/Tribal clinics is

finalized, States will not be permitted to pay for Medicaid clinic services provided outside of the four walls of an IHS/Tribal clinic after February 11, 2025, when the grace period ends.

Table 138 demonstrates our estimates for the economic impact of an exception to the Medicaid clinic services four walls requirement for IHS/Tribal clinics. For the proposed IHS/Tribal clinic exception at 42 CFR 440.90(c), we assumed that 19 percent of current total IHS/Tribal clinic services expenditures were for services provided outside of clinics, based on information provided by the Tribes. Allowing current claiming practices to continue, trended for changes in expected cost, utilization, and enrollment each year, we estimate that Federal expenditures for services provided outside of clinics will be \$1.09 billion for fiscal years 2025 through 2029. State expenditures on Medicaid clinic services provided to AI/AN Medicaid beneficiaries by IHS/Tribal clinics are Federally matched at 100 percent. State expenditures on Medicaid clinic services provided to Medicaid beneficiaries who are not AI/AN are matched at the otherwise applicable Federal matching percentage, which is generally less than 100 percent. The estimate assumes 100 percent Federal share for all IHS/Tribal clinic services expenditures, but we acknowledge that a very small portion of these IHS/Tribal clinic services expenditures may be attributed to Medicaid beneficiaries who are not AI/AN, resulting in State expenditures. Data from which to estimate these State expenditures were unavailable for this analysis. Note that this impact estimate does reflect or account for the grace period only through February 11, 2025, the baseline for the impact estimate does not reflect or account for the grace period for dates after the expiration of the grace period. From February 12, 2025 forward, the estimate compares projections under current law, which does not allow States to pay for Medicaid clinic services provided outside of clinics against projections under the proposed regulation, which would permit States to pay for IHS/Tribal clinic services provided outside of clinics. When the grace period is factored into the analysis for dates after the expiration of the grace period and spending under the proposed regulation is compared to expenditures under current practice, which allows payment for clinic services provided outside of IHS/Tribal clinics due to the grace period, we estimate little to no impact.

TABLE 138: IHS/TRIBAL CLINIC EXCEPTION FEDERAL SHARE IMPACT FOR 5 YEARS

	2025 (in millions)	2026 (in millions)	2027 (in millions)	2028 (in millions)	2029 (in millions)	5-year total (in millions)
High Estimate	\$329	\$328	\$326	\$325	\$323	\$1,631
Best Estimate	\$219	\$218	\$217	\$216	\$216	\$1,086
Low Estimate	\$110	\$109	\$109	\$108	\$108	\$544

Tables 139 and 140 demonstrate our estimates for the economic impact of exceptions to the four walls requirement under the Medicaid clinic services benefit for behavioral health clinics and clinics located in rural areas that are not IHS/Tribal clinics. We acknowledge that we have not included a definition of “rural” in proposed rule text, but are considering defining that term in the final rule and are considering various approaches to doing so, on which we seek comment. For purposes of our estimates of the economic impact of our proposed exception to the four walls requirement for clinics located in rural areas, our analysis defines rural areas using the RUCA classifications. We also acknowledge that for our proposed exception to the four walls requirement

for behavioral health clinics would include any clinic services furnished outside of the four walls by a behavioral health clinic, including non-behavioral clinic services such as physical health services. However, for purposes of our economic impact we are unable to quantify the cost of non-behavioral clinic services. For our proposed behavioral health clinic exception at 42 CFR 440.90(d) and clinics located in rural areas exception at 42 CFR 440.90(e), we assumed a 5 percent increase in current spending in each category due to increased payment for clinic services performed outside of the four walls. Growth in utilization and expenditures for clinic services provided both by behavioral health clinics and clinics in rural areas is

expected to be limited by provider shortages in these areas of practice. Because the proposed exceptions at 42 CFR 440.90(d) and (e) are at State option, we assume that States representing 25 percent of States providing coverage of the Medicaid clinic services benefit will implement one or both of the optional exceptions. Estimated expenditures are trended each year for changes in expected cost, utilization, and enrollment. We estimate that Federal expenditures will be \$35 million for fiscal years 2025 through 2029 for clinic services furnished by behavioral health clinics, and \$30 million for fiscal years 2025 through 2029 for clinic services furnished by clinics in rural areas.

TABLE 139: BEHAVIORAL HEALTH CLINIC EXCEPTION IMPACT FOR 5 YEARS

	2025 (in millions)	2026 (in millions)	2027 (in millions)	2028 (in millions)	2029 (in millions)	5-year total (in millions)
Federal Share Impacts						
High Estimate	\$18	\$18	\$18	\$18	\$18	\$90
Best Estimate	\$7	\$7	\$7	\$7	\$7	\$35
Low Estimate	\$1	\$1	\$1	\$1	\$1	\$5
State Share Impacts						
High Estimate	\$9	\$9	\$9	\$9	\$9	\$45
Best Estimate	\$3	\$3	\$3	\$3	\$3	\$15
Low Estimate	\$1	\$1	\$1	\$1	\$1	\$5

TABLE 140: CLINIC LOCATED IN RURAL AREAS EXCEPTION IMPACT FOR 5 YEARS

Clinic located in rural areas exception (dollars in millions)	2025 (in million)	2026 (in millions)	2027 (in millions)	2028 (in millions)	2029 (in millions)	5-year total
Federal Share Impacts						
High Estimate	\$20	\$20	\$20	\$20	\$20	\$100
Best Estimate	\$6	\$6	\$6	\$6	\$6	\$30
Low Estimate	\$1	\$1	\$1	\$1	\$1	\$5
State Share Impacts						
High Estimate	\$10	\$10	\$10	\$10	\$10	\$50
Best Estimate	\$3	\$3	\$3	\$3	\$3	\$15
Low Estimate	\$1	\$1	\$0	\$0	\$0	\$2

Projected Medicaid clinic services expenditures may differ from our current estimates, including the amounts broken out for IHS/Tribal clinics, clinic services provided by behavioral health clinics, and clinic services provided by clinics in rural areas. There is uncertainty in how much current and projected IHS/Tribal Medicaid clinic services spending is attributable to Medicaid clinic services provided outside of the four walls. The IHS/Tribal clinic impact may range from \$544 million to \$1.63 billion over 5 years due to uncertainty in the level of spending for Medicaid clinic services provided outside of IHS/Tribal clinics.

Uncertainty in provider availability and beneficiary demand result in uncertainty in the potential for changes in utilization and costs. The Federal impact for Medicaid clinic services furnished by behavioral health clinics may range from \$5 million to \$90 million and the Federal impact for clinic services furnished by clinics in rural areas may range from \$5 million to \$100 million over five years. State impacts over five years may range from \$5 million to \$45 million for clinic services furnished by behavioral health clinics and \$2 million to \$50 million for clinic services furnished by clinics in rural areas.

Table 141 demonstrates the total economic impact for our proposed regulation to include exceptions to the four walls requirement under the Medicaid clinic services benefit for IHS/ Tribal clinics, behavioral health clinics, and clinics located in rural areas. The total estimated impact of this proposed regulation over five years is \$1.18 billion, including Federal impact of \$1.15 billion and State impact of \$30 million. The impact may range from a low of \$561 million to a high of \$1.92 billion, including a range in the Federal estimate of \$554 million to \$1.82 billion and a range in the State impact of \$7 million to \$95 million.

TABLE 141: TOTAL IMPACT ESTIMATES FOR FIVE YEARS

	Federal Share Impact (in millions)	State Share Impact (in millions)	Total Impact (in millions)
IHS/Tribal clinic exception	\$1,086	\$0	\$1,086
Behavioral health clinic exception	\$35	\$15	\$50
Clinics located in rural areas exception	\$30	\$15	\$45
All clinic services exceptions	\$1,151	\$30	\$1,181

c. Benefits of Medicaid Clinic Services Four Walls Exceptions

The proposed changes to the Medicaid clinic services benefit are expected to benefit Medicaid beneficiaries, Tribes, and States by improving access to care for the populations served by IHS/Tribal clinics, behavioral health clinics, and

clinics in rural areas. The proposed exceptions to the four walls requirement under the Medicaid clinic services benefit for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas would help improve access to care for these clinics' patient populations by allowing services to be furnished where the beneficiary is

located. We refer readers to section XVIII.B of this proposed rule for more robust discussions on how the populations served by these clinics might benefit from exceptions to the Medicaid clinic services benefit four walls requirement and how these exceptions would improve access to

care. These potential benefits cannot be monetarily quantified at this time.

d. Alternative Medicaid Clinic Services Four Walls Exceptions Considered

We considered a few different alternatives in determining the best way to address the concerns we heard from Tribes, the TTAG, the STAC, States, and other interested parties about the four walls requirement under the Medicaid clinic services benefit. We considered including an exception to the four walls requirement only for the population served by IHS/Tribal clinics, but we viewed that alternative as too limited. As we discuss in detail in section XVIII.B of this proposed rule, we concluded that the patient populations served by behavioral health clinics and clinics in rural areas might also benefit from exceptions to the four walls requirement for those clinics. We also considered proposing an exception, in addition to the three exceptions we propose in this rule, for any other populations that are identified by States as likely to meet the four criteria described in this proposed rule as warranting an exception to the four walls requirement and that have no alternative access to services through Medicaid benefits that are not subject to a four walls requirement under Federal Medicaid law. Ultimately, it is our understanding that other populations are better able to access services through Medicaid benefits to which a four walls

requirement does not apply under Federal Medicaid law (for example, FQHC services, RHC services, outpatient hospital services, etc.) than the populations targeted by the proposed exceptions. As we indicate in section XVIII.B of this proposed rule, we invite comment on our assumptions about other populations that may benefit from an exception to the four walls requirement under the Medicaid clinic services benefit. We also considered making the exceptions to the four walls requirement mandatory for behavioral health clinics and clinics located in rural areas, but, as we discuss in more detail in section XVIII.B of this proposed rule, it is our understanding that there is greater State variability in the degree to which the populations targeted by the behavioral health and rural exceptions meet the four criteria we identified than the population served by IHS/Tribal clinics. We note for readers that we also invited public comment on these assumptions in section XVIII.B of this proposed rule. Finally, as we discuss in section XVIII.B of this proposed rule, we have not proposed a specific definition of rural for our exception for clinics located in rural areas and invite public comment on the alternatives we are considering and describe in that section of the proposed rule.

9. Effects of Continuous Eligibility in Medicaid and CHIP

As discussed in section XX of this proposed rule, we propose to codify the requirement of the CAA, 2023 for States to provide 12 months of continuous eligibility for children under age 19 enrolled in Medicaid and CHIP, with limited exceptions. In addition, we propose to remove the option to disenroll children from CHIP during a continuous eligibility period due to failure to pay premiums. These regulation changes implement the statutory requirement in section 5112 of Title V, subtitle B of the Consolidated Appropriations Act, 2023.

The proposed regulation to require 12-month continuous eligibility in Medicaid and CHIP is estimated to increase annual average enrollment in Medicaid and CHIP by approximately 124,000 by 2028 (75,000 in Medicaid and 49,000 in CHIP). The total estimated impact of this proposed regulation over 5 years is \$2,466 million, including Federal impact of \$1,592 million and state impact of \$874 million. Enrollment may range from an increase of around 92,000 to an increase of around 159,000 by 2028. The total impact may range from a low of \$1,837 million to a high of \$3,154 million, including a range in the Federal estimate of \$1,185 million to \$2,039 million and a range in the state impact of \$652 million to \$1,115 million. (See Table 142.)

TABLE 142: IMPACT OF 12-MONTH CONTINUOUS ELIGIBILITY IN MEDICAID AND CHIP

(dollars in millions)	2024	2025	2026	2027	2028	5-year total
Federal Share Impacts						
Best Estimate	\$250	\$326	\$332	\$339	\$345	\$1,592
Low Estimate	\$186	\$243	\$248	\$252	\$256	\$1,185
High Estimate	\$319	\$419	\$426	\$434	\$441	\$2,039
State Share Impacts						
Best Estimate	\$148	\$177	\$180	\$183	\$186	\$874
Low Estimate	\$111	\$132	\$134	\$137	\$138	\$652
High Estimate	\$189	\$225	\$230	\$234	\$237	\$1,115

TABLE 143: ACCOUNTING STATEMENT FOR 12-MONTH CONTINUOUS ELIGIBILITY IN MEDICAID AND CHIP

Annual monetized transfers	Primary estimate (in millions of dollars)	Low estimate (in millions of dollars)	High estimate (in millions of dollars)	Transfers		
				Units		
				Year dollars	Discount rate (percent)	Period covered
From Federal Government to States....	317.8	236.4	407	2025	2	2024-2028
From States to Health Care Providers...	174.8	130.3	222.7	2025	2	2024-2028

10. Effects of Proposed Requirements for Obstetrical Services in Hospitals and Critical Access Hospitals (CAHs)

a. Organization, Staffing and Delivery of Services for Hospitals (§ 482.59a Through b) and CAHs (§ 482.649a Through b)

In section XXIV, we have estimated the cost for hospitals and CAHs to develop internal standards and protocols to ensure that services are well organized and to provide high-quality care that is appropriate to the level of services provided and integrated with other departments of the facility, as well as to ensure compliance with nationally recognized and evidence-based guidelines for OB emergencies, complications, immediate post-delivery care, and other patient health and safety events. We have also estimated the cost for hospitals and CAHs to delineate and document obstetrical privileges for all practitioners providing obstetrical services in accordance with the competencies of each practitioner. Below, we estimate the cost for ensuring that OB patient care units (*i.e.*, labor rooms, delivery rooms, including rooms

for operative delivery, and post-partum/ recovery rooms whether combined or separate) be supervised by an individual with the necessary education and training, and specify that person should be an experienced registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a doctor of medicine or osteopathy. We also estimate the cost for the proposal that are also proposing that labor and delivery room suites have certain basic resuscitation equipment readily available, including a call-in-system, cardiac monitor, and a fetal doppler or monitor.

While hospitals and CAHs already likely to already have an individual supervising OB patient care unit, there is variation across facilities regarding whether they have the necessary education and training related to OB patient care. Many facilities, especially larger hospitals that have large birth volumes, are likely to already have an experienced individual with the necessary education and training. Smaller facilities with lower birth volumes, in contrast, may be less likely to have an individual and need to

recruit a new individual to meet the proposed requirement. Given uncertainty about the number of facilities that already have an experienced individual who would meet the requirement, we assume that each facility would need to hire one individual, who we assume would be a registered nurse, to meet the requirement. To estimate the cost of hiring this individual, we reviewed research related to the cost of registered nurse turnover. A review of academic literature found that each RN turnover cost employers between \$21,514 and \$88,000.⁵⁷⁹ We take the midpoint of these two estimates, or \$54,757 per individual hired. As shown, in Tables 144 and 145, we estimate that this requirement will cost facilities \$345,516,670 in both year 1 and over 10 years. We seek comments on data sources to estimate the number of facilities that are likely to already have an individual who meets the proposed requirements. We also seek comments on other sources of data to estimate the cost for hiring an individual with the necessary education and training to meet this requirement.

TABLE 144: QUALIFIED OB SUPERVISOR COST

Provider Type	Number of Providers (a)	Staff Members Needed per Provider (b)	Total Staff Members Needed (c = a × b)	Average Cost per Staff Member (d)	Total Annual Cost (e = c × d)	Average Cost per Facility (f = e / b)
CAH	513	1	513	\$54,757	\$28,090,341	\$54,757
Hospital	5,797	1	5,797	\$54,757	\$317,426,329	\$54,757

⁵⁷⁹ Bae, S.H., *Noneconomic and economic impacts of nurse turnover in hospitals: A systematic review*. Int Nurs Rev, 2022. 69(3): 392–404.

TABLE 145: QUALIFIED OB SUPERVISOR 10 YEAR COST

Year	Total Cost
1	\$345,516,670
2	\$0
3	\$0
4	\$0
5	\$0
6	\$0
7	\$0
8	\$0
9	\$0
10	\$0
10 Year Total Cost	\$345,516,670

To estimate the cost for having certain basic resuscitation equipment readily available, we reviewed public data sources to estimate the cost of purchasing a call-in system, cardiac monitor, and a fetal doppler or monitor. While we were not able to identify public estimates for the price of call-in systems, based on our experience we estimate that they would cost \$2,500 to \$3,500 per system. Reviewing the web pages of various online suppliers, we found that fetal dopplers and fetal monitors cost between \$502 and \$8,995^{580 581} and cardiac monitors cost between \$1,071 and \$10,246.⁵⁸² For each of these systems, we use the mid-point of the price estimate and assume that each call-in system would cost \$3,000, each fetal monitor or fetal

doppler would cost \$4,749, and each cardiac monitor would cost \$5,659.

According to the Centers for Disease Control and Prevention there were a total of 3,667,758 births in 2022.⁵⁸³ With a total of 6,310 hospitals and CAHs with obstetrical units, this leads to an average of 581 ($3,667,758 \div 6,310$) births per hospital and CAH or an average of 1.59 births per facility per day. We estimate that each birth will take 1 day on average. To account for variation in birth volumes throughout the year, we assume that each facility would need to prepare for double the number of average births per day, or 3.18 patients. Since equipment cannot be divided, we assume that facilities will need to have equipment available for 4 patients daily. We assume that each facility already has one fetal

monitor and cardiac monitor but do not assume that they will have a call-in system.

Based on our experience working in obstetrical units, we estimate a fetal doppler or monitor would be needed for each room/suite, a call-in system would be needed for each room/suite, and cardiac monitors would be needed for half the rooms/suites. As such, we estimate that each facility would need to purchase 3 fetal monitors or fetal dopplers at \$14,247 ($\$4,749 \times 3$), 1 cardiac monitor at \$5,659 ($\$5,659 \times 1$), and 4 call-in systems at \$12,000 ($\$3,000 \times 4$) for an average per facility cost of \$31,906. As indicate in tables 146 and 147, we estimate that this requirement would cost a total of \$201,326,860 over 10 years.

TABLE 146: OBSTETRICAL EQUIPMENT COST

Provider Type	Number of Providers (a)	Average Per Facility Cost (b)	Total Annual Cost (c = a × b)	Average Cost per Facility (d = c / b)
CAH	513	\$31,906	\$16,367,778	\$31,906
Hospital	5,797	\$31,906	\$184,959,082	\$31,906

⁵⁸⁰ Medical, U. *FETAL DOPPLERS*. 2024 May 8, 2024 [cited 2024 May 8]; Available from: <https://www.usamedicalsurgical.com/fetal-dopplers/>.

⁵⁸¹ CardiacDirect. *Fetal Monitors*. 2024 [cited 2024 May 8]; Available from: https://www.cardiacdirect.com/product-category/fetal-monitors/?utm_source=google&utm_medium=cpc&utm_term=fetal%20heart%20monitor&utm_content=acq!v3!1163626993_kwd-295102856827__607346518010_g_c_&utm_campaign=FetalMonitor&gad_source=1&gclid=EAIaIQobChMIsLqpo8fhQMVLyEtBh3deAZuEAAAYASAAEgIcx_D_BwE.

⁵⁸² CardiacDirect. *Patient Monitors*. 2024 May 8, 2024 [cited 2024 May 8]; Available from: https://www.cardiacdirect.com/product-category/patient-monitors/?min_price=0&max_price=10250&page=1.

⁵⁸³ Osterman, M.J.K.H., Brady E., Martin, Joyce A.; Driscoll, Anne K.; Valenzuela, Claudia P., *Births: Final Data for 2022*, in *National Vital Statistics Reports*, U.S.D.o.H.a.H. Services, Editor. 2024, Centers for Disease Control and Prevention.

TABLE 147: OBSTETRICAL EQUIPMENT 10 YEAR COST

Year	Total Cost
1	\$201,326,860
2	\$0
3	\$0
4	\$0
5	\$0
6	\$0
7	\$0
8	\$0
9	\$0
10	\$0
10 Year Total Cost	\$201,326,860

b. OB Staff Training for Hospitals (\$ 482.59(c)) and CAHs (\$ 485.649(c))

We propose that hospitals and CAHs with OB services must develop policies and procedures to ensure that staff are trained on key topics related to improving the delivery of maternal care. The training must reflect the scope and complexity of services offered, including, but not limited to, evidence-based best practices and protocols to improve the delivery of maternal care within the facility. We also propose that they use findings from their QAPI to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis. We also propose that the governing body must identify and document which staff must complete annual training on these topics. The facility must further document that training was successfully completed and must be able to demonstrate staff knowledge on these topics. In the collection of information section, we have already estimated the costs for developing policies and procedures to ensure that staff are trained on key topics related to improving the delivery of maternal care, as well as documentation that training was completed and staff knowledge on these topics. We estimate that staff training on evidence-based best practices and protocols would take 2 hours per employee and that each facility would spend 1 hour training staff on additional topics identified by the facility’s QAPI program. This leads

to a total hourly burden of 3 hours per employee trained. While hospitals and CAHs have flexibility regarding which OB staff will receive training, we expect that they would likely to focus their training on medical staff who are working directly with OB patients. This includes surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists, registered nurses (RNs), and Licensed Practical Nurses/Licensed Vocational Nurses (LPNs/LVNs). To estimate the number of employees in CAHs and hospitals that would likely receive training, we first obtained data from the Bureau of Labor Statistics (BLS) on the number of surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists, RNs, and LPNs/LVNs working in hospitals (NAICS 622000). Since the BLS does not provide separate employment statistics for CAHs and hospitals, we assume that the number of employees needing training and, henceforth, the costs would be in proportion to the size of facilities, specifically the number of certified beds. We obtained information on the number of certified beds in hospitals and CAHs from CMS’ Q1 2024 Provider of Services File—Hospital & Non-Hospital Facilities.⁵⁸⁴ Using this database, we estimate that 98.88 percent of certified beds for hospitals with OB services are in hospitals with the remaining 1.12 percent in CAHs. In hospitals, which have a larger number of beds, there is likely to be a

greater division of staff among units, with medical staff specifically designated to work in OB units and with pregnant patients, while other medical staff members will not work with pregnant patients. In contrast, critical access hospitals (CAHs), which are smaller in size, are likely to have medical staff that work across units given their small size. Based on our experience, we estimate that between 10 and 30 percent of medical staff in hospitals and 60 to 100 percent of medical staff in CAHs would receive the training. Given the variation for hospitals, we take the midpoint of the two estimates and assume that 20 percent of hospital medical staff and 80 percent of medical staff in CAHs would receive training. We also assume that each facility would require staff to be trained on these topics annually. As indicated in Table 148 and Table 149, we estimate that the proposed requirements would have an annual cost of approximately \$150 million with an average per facility cost of \$24,719 for hospitals and \$12,601 for CAHs. Over 10 years, the proposed requirements are estimated to take 14.2 million hours to complete and cost approximately \$1.50 billion. We seek comments on whether hospitals and CAHs would require more or fewer groups of medical staff or other facility staff to receive this training. We are also seeking comments regarding data sources with other ways to measure share of staff who are likely to receive training in each facility type.

⁵⁸⁴ Centers for Medicare and Medicaid Services. Provider of Services File—Hospital & Non-Hospital

Facilities, Q1 2024. <https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file-hospital-non-hospital-facilities/data> (Accessed April 30, 2024).

TABLE 148: OBSTETRICAL SERVICES STAFF TRAINING ANNUAL COST

Provider Type	Number of Providers (a)	Number of Certified Beds (b)	Share of all Hospital and CAH Certified Beds (c)	Total Yearly Cost if All Hospital and CAH Medical Staff were Trained (d)	Total Hospital and CAH Medical Staff (e)	Share of Medical Staff Receiving Training (f)	Total Number of Staff Members (g = c × e)	Total Annual Cost (h = c × d × f)	Total Hourly Burden (i = f × g × 3)	Average Cost per Staff Member (j = h / (f × g))	Average Cost per Facility (k = h / a)
CAH	513	12,582	0.011	\$724,555,386	2,284,580	0.8	25,478	\$6,464,223	61,147	\$317	\$12,601
Hospital	5,797	1,115,641	0.989	\$724,555,386	2,284,580	0.2	2,259,102	\$143,295,022	1,355,461	\$317	\$24,719

TABLE 149: OBSTETRICAL SERVICES STAFF TRAINING 10 YEAR COST

Year	Total Hourly Burden	Total Hourly Burden Cost
1	1,416,608	\$149,759,244
2	1,416,608	\$149,759,244
3	1,416,608	\$149,759,244
4	1,416,608	\$149,759,244
5	1,416,608	\$149,759,244
6	1,416,608	\$149,759,244
7	1,416,608	\$149,759,244
8	1,416,608	\$149,759,244
9	1,416,608	\$149,759,244
10	1,416,608	\$149,759,244
10 Year Total Cost	14,166,080	\$1,497,592,442

c. Quality Assessment and Performance Improvement Program (QAPI) for Hospitals (§ 482.21(b)(4)) and CAHs (§ 485.641(e)(1))

At § 482.21(b)(4) and § 485.641(e) we are proposing modification to the QAPI program for hospitals and CAHs with OB services, respectively. Specifically, for obstetrical patients, facilities would have four new requirements: (1) analyzing data and quality indicators collected for the QAPI program by diverse subpopulations, as identified by the facility among obstetrical patients; (2) measuring, analyzing and tracking data, measures, and quality indicators on patient outcomes and disparities in processes of care, and services and operations, among obstetrical patients; (3) analyzing and prioritizing patient health outcomes and disparities, developing and implementing actions to improve patient health outcomes and disparities, measuring results, and tracking performance to ensure

improvements are sustained when disparities exist among obstetrical patients; and (4) conducting at least one performance improvement project focused on improving health outcomes and disparities among the hospital's population(s) of obstetrical patients annually.

In the ICR, we have already discussed the expected burden for collecting data and quality indicators for obstetrical patients and their outcomes and disparities in processes of care and services and operations. We believe that these data would serve as the foundation to allow facilities to develop and implement actions to improve outcomes and reduce disparities when they exist. We would expect that these data would likely be the focus of the required performance improvement project focused on improving health outcomes and reducing disparities among obstetrical patients.

To estimate the cost of tracking and implementing at least one quality improvement project, we utilized estimates from existing regulations governing QAPI program. Specifically, 81 FR 68688 estimates that collecting and analyzing data for all a long-term care facilities' improvement projects will take 20 hours, with another 20 years annually spent on implementing and documenting improvement projects. Given that the requirement we are proposing involves only a single improvement project and we have already accounted for the costs of collecting the data in the ICR, we anticipate that the ongoing annual burden for each facility to analyze the data and implement and document their improvement project(s) will be 30 hours. Using loaded hourly wage rates from Table 112, we anticipate that this will include the participation of a hospital executive at \$1,861.28 (\$232.66 × 8 hours), an RN at \$931.00 (\$93.10 ×

10 hours), a physician at \$1,729.64 (\$216.08 × 8 hours), and a data scientist at \$368.96 (\$92.24 × 4 hours) for a total

per facility cost of \$4,889.88 annually and an average hourly cost of \$163. As indicated in tables 150 and 151, we

estimate that this requirement will cost \$30,855,143 annually and \$308,551,428 over 10 years.

TABLE 150: ANNUAL COST FOR ADDRESSING HEALTH EQUITY THROUGH QAPI PROGRAM

Provider Type	Number of Providers (a)	Annualized Hourly Burden (b)	Hourly Wage Cost (c)	Total Hourly Burden (d = a × b)	Total Hourly Burden Cost (e = c × d)
CAH	513	30	\$163.00	15,390	\$2,508,508
Hospital	5,797	30	\$163.00	173,910	\$28,346,634

TABLE 151: 10 YEAR COST FOR ADDRESSING HEALTH EQUITY THROUGH QAPI PROGRAM

Year	Total Hourly Burden	Total Hourly Burden Cost
1	189,300	\$30,855,143
2	189,300	\$30,855,143
3	189,300	\$30,855,143
4	189,300	\$30,855,143
5	189,300	\$30,855,143
6	189,300	\$30,855,143
7	189,300	\$30,855,143
8	189,300	\$30,855,143
9	189,300	\$30,855,143
10	189,300	\$30,855,143
10 Year Total Cost	1,893,000	\$308,551,430

d. Maternal Health QAPI Activities for Hospitals (§ 482.21(e)) and CAHs (§ 485.641(d)(4))

Using loaded hourly wage rates from Table 112, we expect that when the MMRC provides information to

hospitals and CAHs, incorporating this information into the facility’s QAPI program would include the participation of a physician at \$864.32 (\$216.08 × 4 hours) and an RN at \$372.40 (\$93.10 × 4 hours) for a total cost of \$1,236.72 per facility. Altogether,

we estimate that annually it would take 8 hours to complete at an average hourly cost of \$154.59 (\$1,236.72 ÷ 8 hours) per facility. As indicated in tables 152 and 153, we estimate that total annual cost will be \$7,803,703 and the 10-year total cost will be \$7,803,703.

TABLE 152: MMRC INFORMATION AND QAPI INCORPORATION ANNUAL COST

Provider Type	Number of Providers (a)	Annualized Hourly Burden (b)	Hourly Wage Cost (c)	Total Hourly Burden (d = a × b)	Total Hourly Burden Cost (e = c × d)
CAH	513	8	\$154.59	4,104	\$634,437
Hospital	5,797	8	\$154.59	46,376	\$7,169,266

TABLE 153: MMRC INFORMATION AND QAPI INCORPORATION 10 YEAR COST

Year	Total Hourly Burden	Total Hourly Burden Cost
1	50,480	\$7,803,703
2	50,480	\$7,803,703
3	50,480	\$7,803,703
4	50,480	\$7,803,703
5	50,480	\$7,803,703
6	50,480	\$7,803,703
7	50,480	\$7,803,703
8	50,480	\$7,803,703
9	50,480	\$7,803,703
10	50,480	\$7,803,703
10 Year Total Cost	504,800	\$78,037,030

e. Emergency Services Readiness for Hospitals (§ 482.55(c)) and CAHs (§ 485.618(e))

The proposed standard for emergency services readiness aims to improve staff readiness for providing emergency services to all hospital and CAH patients, including pregnant and postpartum patients. It would require hospitals and CAHs with emergency services to have adequate provisions and protocols, consistent with nationally recognized and evidence-based guidelines, for the care of patients with emergency conditions. Hospitals and CAHs would be required to train applicable emergency services personnel, as determined by the facility, on these protocols and provisions on an annual basis and document that applicable staff have successfully completed the training and demonstrate their knowledge on these topics. For hospitals only, provisions must include equipment, supplies, and medication used in treating emergency cases. Provisions must include: (1) Drugs, blood and blood products, and biologicals commonly used in emergency procedures; (2) Equipment and supplies commonly used in emergency procedures; and (3) a call-in-system for each patient in each emergency services treatment area.

In section XXIV, we have already discussed the cost for hospitals to ensure that they have adequate protocols in place for emergency services, as well as to document that applicable staff have successfully completed the training and demonstrate their knowledge on these topics. The proposed training requirement for hospitals and CAHs provides flexibility regarding which staff will receive

training. We expect, however, that they would likely focus their training on medical staff within emergency departments. This staff includes surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists, registered nurses, and LPNs/LVNs.

To estimate the number of employees in CAHs and REHs that would likely receive training, we first obtained data from the Bureau of Labor Statistics (BLS) on the number of surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists, registered nurses, and LPNs/LVNs working in hospitals (NAICS 622000). Since the BLS does not provide separate employment statistics for CAHs and hospitals, we assume that the number of employees needing training and, henceforth, the costs would be in proportion to the size of facilities, specifically the number of certified beds. We obtained information on the number of certified beds in hospitals and CAHs from CMS' Q1 2024 Provider of Services File—Hospital & Non-Hospital Facilities.⁵⁸⁵ Using this database, we estimate that 98.88 percent of certified beds for hospitals are in hospitals with the remaining 1.12 percent in CAHs.

Based on our experience, we expect that initial staff training would take approximately 3 hours per employee. Using data from Table 112 on loaded wage rates for each employee type, we estimated the cost for training all

medical staff in hospitals and CAHs in year 1 using the following formula: loaded wage rate for medical staff (surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists, registered nurses, and LPNs/LVNs) × total number of each medical staff type working in hospitals and CAHs × 3 hours per employee. Using this formula, we estimate that training all medical staff would cost \$724,555,386.

In hospitals, which have a larger number of beds, there is likely to be a greater division of staff among units, with medical staff specifically designated to work in emergency departments. In contrast, CAHs, which are smaller in size, are likely to have medical staff that work across units given their small size. We assume, therefore, that 20 percent of medical staff in hospitals and all medical staff in CAHs would receive the training. To calculate the year 1 cost for hospitals and CAHs, therefore, we use the following formula: Total cost for training all hospital/CAH medical staff × % hospital(CAH) medical staff receiving training × Share of all Hospital and CAH Certified Beds. As indicated in Table 154, we expect that the proposed requirement would cost approximately \$8 million for CAHs and \$143 million for hospitals in year 1.

For subsequent years, we expect that refresher training for medical staff, who received the full training in previous years, would take 1 hour to complete. In addition, new staff would need to receive the full 3-hour training. With an annual hospital turnover rate of

⁵⁸⁵ Centers for Medicare and Medicaid Services. Provider of Services File—Hospital & Non-Hospital Facilities, Q1 2024. <https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file-hospital-non-hospital-facilities/data> (Accessed April 30, 2024).

approximately 21 percent,⁵⁸⁶ we would expect 21 percent of employees each year to be new employees who would need 3 hours of training and 79 percent of employees would need 1 hour of training. To calculate the burden for years 2 to 10, therefore, we use the following formula: (Total cost for

training all hospital/CAH medical staff × % hospital(CAH) medical staff needing initial training × Share of all Hospital and CAH Certified Beds) + (Total cost for training all hospital/CAH medical staff × % hospital(CAH) medical staff receiving needing initial training × Share of all Hospital and CAH

Certified Beds). As indicated in Table 155 using this formula, we estimate that the rule would cost approximately \$72 million in years 2 to 10. Table 156 provides the total cost over 10 years which we estimate at \$796,234,077.

TABLE 154: YEAR 1 EMERGENCY SERVICES PROTOCOL TRAINING COST

Provider Type	Number of Providers (a)	Number of Certified Beds (b)	Share of all Hospital and CAH Certified Beds (c)	Total Yearly Cost if All Hospital and CAH Medical Staff were Trained (d)	Total Hospital and CAH Medical Staff (e)	Share of Medical Staff Receiving Training (f)	Total Number of Staff Members (g = c × e)	Total Hourly Annual Cost (h = c × d × f)	Total Hourly Burden (i = f × g × 3)	Average Cost per Staff Member (j = h / (f × g))	Average Cost per Facility (k = h / a)
CAH	513	12,582	0.011	\$724,555,386	2,284,580	1	25,478	\$8,080,278	76,433	\$317	\$15,751
Hospital	5,797	1,115,641	0.989	\$724,555,386	2,284,580	0.2	2,259,102	\$143,295,022	1,355,461	\$317	\$24,719

TABLE 155: YEAR 2 EMERGENCY SERVICES PROTOCOL TRAINING COST

Provider Type	Number of Providers (a)	Number of Certified Beds (b)	Share of all Hospital and CAH Certified Beds (c)	Total Yearly Cost if All Hospital and CAH Medical Staff were Trained (d)	Total Hospital and CAH Medical Staff (e)	Share of Medical Staff Receiving Training (f)	Total Number of Staff Members (g = c × e)	Total Hourly Annual Cost (h = c × d × f)	Total Hourly Burden (i = (f × g × .79 × 1) + (f × g × .21 × 3))	Average Cost per Staff Member (j = h / (f × g))	Average Cost per Facility (k = h / a)
CAH	513	12,582	0.011	\$342,956,216	2,284,580	1	25,478	\$3,824,665	36,178	\$150	\$7,455
Hospital	5,797	1,115,641	0.989	\$342,956,216	2,284,580	0.2	2,259,102	\$67,826,310	641,585	\$150	\$11,700

⁵⁸⁶ Nursing Solutions Incorporated, 2024 NSI National Health Care Retention & RN Staffing Report. 2024.

TABLE 156: 10 YEAR EMERGENCY SERVICES PROTOCOL TRAINING COST

Year	Total Hourly Burden	Total Hourly Burden Cost
1	1,431,895	\$151,375,300
2	677,763	\$71,650,975
3	677,763	\$71,650,975
4	677,763	\$71,650,975
5	677,763	\$71,650,975
6	677,763	\$71,650,975
7	677,763	\$71,650,975
8	677,763	\$71,650,975
9	677,763	\$71,650,975
10	677,763	\$71,650,975
10 Year Total Cost	7,531,766	\$796,234,077

To estimate the cost for having certain basic resuscitation equipment readily available, we consulted with medical experts on the requirements. Based on their experience, we expect that the most hospitals with emergency services will already have drugs, blood and blood products, and biologicals commonly used in emergency procedures, as well as equipment and supplies commonly used in emergency procedures. As such, we do not estimate a burden for these requirements. There is likely, however, to be wide variation

in hospitals for the call-in systems. Based on our experience, we estimate that 50 percent of hospitals will already have call-in systems while 50 percent will need to install them in their emergency departments.

As we noted above in estimating the cost for call-in system for obstetrical rooms/suites, while we were not able to identify public estimates for the price of call-in systems, based on our experience we estimate that they would cost \$2,500 to \$3,500 per system, and we utilize the mid-point of the price estimate and assume each call-in system will cost

\$3,000. We assume that 20 percent of hospital beds are allocated for emergency services and assume that there will need to be a call-in system for each bed. As indicated in Tables 157 and 158, we estimate that this requirement would cost a total of \$334,629,300 in year 1 and over 10 years. We seek comments on data sources that we can use to estimate the number of hospitals that already have call-in systems as well as the share of hospital beds that are devoted to emergency care.

TABLE 157: Year 1 Emergency Services' Call-In System Requirement Cost

Provider Type	Hospital Beds (b)	Number of Providers (a)	Share of Hospitals Needing Call-in Systems (c)	Share of Beds Needing Call-In System (d)	Call-In Systems Needed (e = b × c × d)	Price per Call-In System (f)	Total Annual Cost (g = e × f)	Average Cost per Facility (h = g / (a × c))
Hospital	1,115,641	5,797	0.5	0.2	111,564	\$3,000	\$334,692,300	\$115,471

TABLE 158: 10 Emergency Services’ Call-In System Requirement Cost

Year	Total Cost
1	\$334,692,300
2	\$0
3	\$0
4	\$0
5	\$0
6	\$0
7	\$0
8	\$0
9	\$0
10	\$0
10 Year Total Cost	\$334,692,300

f. Transfer Protocols in Discharge Planning for Hospitals (§ 482.43(c))

We propose that hospitals have written policies and procedures for transferring patients under their care to the appropriate level of care, promptly and without undue delay to meet patients’ needs. Since hospital inpatients are included in those who may need to be transferred, we believe that medical staff across hospitals, and

not just those in emergency departments, would need to receive training on transfer protocols. Specifically, we expect that all surgeons, physicians, physician assistants, nurse practitioners, nurse midwives, nurse anesthetists in hospitals would receive this training. We do not expect, however, that LPNs would receive this training and similarly expect that most RNs would not receive this training. Rather, we

expect that among RNs, only experienced RNs who serve as transfer coordinators would receive it and estimate that this is only 5 percent of RNs nationwide. We estimate that each employee would require 1 hour of training annually and assume that that this training would occur on an annual basis. As indicated in tables 159 and 160, we expect that this requirement to cost \$71,246,104 annually and \$710,461,040 over 10 years.

TABLE 159: Transfer Protocol Training Annual Cost

Provider Type	Number of Providers (a)	Number of Certified Beds (b)	Share of all Hospital and CAH Certified Beds (c)	Total Hospital and CAH Medical Staff Receiving Training (d)	Total Number of Staff Members Receiving Training (e – c × d)	Total Hourly Annual Cost (f = e × j)	Total Hourly Burden (g = f × g)	Average Cost per Staff Member (h = f / g)	Average Cost per Facility (k = h / a)
Hospital	5797	1,115,641	0.989	422,240	417,531	\$71,246,104	417,531	\$171	\$12,290

TABLE 160: Transfer Protocol Training Annual Cost 10 Year Cost

Year	Total Hourly Burden	Total Hourly Burden Cost
1	417,531	\$71,246,104
2	417,531	\$71,246,104
3	417,531	\$71,246,104
4	417,531	\$71,246,104
5	417,531	\$71,246,104
6	417,531	\$71,246,104
7	417,531	\$71,246,104
8	417,531	\$71,246,104
9	417,531	\$71,246,104
10	417,531	\$71,246,104
10 Year Total Cost	4,175,310	\$710,461,040

g. Summary of Regulatory Impact Analysis for Obstetrical and Emergency Services

In Tables 160 and 161 we provide an estimate of the total annual and 10-year financial and hourly burden for the proposed requirements related to obstetrical and emergency services that include: (1) organization, staffing, and delivery of services for hospitals and CAHs as outlined in Table 145 and Table 147; (2) obstetrical services staff training for hospitals and CAHs as outlined in Table 149; (3) quality assessment and performance improvement program requirements for hospitals and CAHs as outlined in Table 151; (4) maternal health QAPI activity requirements for hospitals and CAHs as outlined in Table 153; (5) emergency

services readiness requirements for hospitals and CAHs in Table 156 and Table 158; and (6) transfer protocols training for hospitals as outlined in Table 160. These estimates exclude the cost for collection of information requirements that we have estimated above in Table 129 and 130 to cost \$174,597,139 million over 10 years and take 1,768,881 hours to complete. Overall, we estimate the total financial cost of the requirements would be approximately \$4.27 billion and take 28.3 million hours to complete over 10 years.

We are seeking comments on several issues related to the regulatory impact analysis, including the following:

- Are there additional data sources that estimate the number of medical

staff, who work with obstetrical patients?

- Are there additional data sources to estimate the number of hospital and CAH obstetrical rooms/suites?

- Are there any additional data sources to estimate the cost for the provisions of cardiac monitors, call-in systems, and fetal doppler or monitors?

- Are there additional data sources to estimate the number of medical staff who work with emergency care units?

- Are there data sources to estimate the number of hospital room/suites that are allocated for emergency services?

- Are there any additional staff members who are likely to receive training for emergency services and obstetrical services?

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TABLE 161: REGULATORY IMPACT ANALYSIS SUMMARY, ANNUAL AND 10-YEAR COST ESTIMATES

Year	Qualified OB Supervisor	Obstetrical Services Equipment	Obstetrical Services Staff Training	Quality Assessment and Performance Improvement Program (QAPI)	MMRC Information and QAPI Incorporation	Emergency Preparedness Training	Emergency Services' Call-In System Requirement	Transfer Protocol Training	Total Cost for All Requirements
1	\$345,516,670	\$201,326,860	\$149,759,244	\$30,855,143	\$7,803,703	\$151,375,300	\$334,692,300	\$71,246,104	\$1,292,575,324
2	\$0	\$0	\$149,759,244	\$30,855,143	\$7,803,703	\$71,650,975	\$0	\$71,246,104	\$331,315,169
3	\$0	\$0	\$149,759,244	\$30,855,143	\$7,803,703	\$71,650,975	\$0	\$71,246,104	\$331,315,169
4	\$0	\$0	\$149,759,244	\$30,855,143	\$7,803,703	\$71,650,975	\$0	\$71,246,104	\$331,315,169
5	\$0	\$0	\$149,759,244	\$30,855,143	\$7,803,703	\$71,650,975	\$0	\$71,246,104	\$331,315,169
6	\$0	\$0	\$149,759,244	\$30,855,143	\$7,803,703	\$71,650,975	\$0	\$71,246,104	\$331,315,169
7	\$0	\$0	\$149,759,244	\$30,855,143	\$7,803,703	\$71,650,975	\$0	\$71,246,104	\$331,315,169
8	\$0	\$0	\$149,759,244	\$30,855,143	\$7,803,703	\$71,650,975	\$0	\$71,246,104	\$331,315,169
9	\$0	\$0	\$149,759,244	\$30,855,143	\$7,803,703	\$71,650,975	\$0	\$71,246,104	\$331,315,169
10	\$0	\$0	\$149,759,244	\$30,855,143	\$7,803,703	\$71,650,975	\$0	\$71,246,104	\$331,315,169
10 Year Total Cost	\$345,516,670	\$201,326,860	\$1,497,592,442	\$308,551,430	\$78,037,030	\$796,234,077	\$334,692,300	\$712,461,040	\$4,274,411,849

TABLE 162: REGULATORY IMPACT ANALYSIS SUMMARY, ANNUAL AND 10-YEAR HOURLY ESTIMATES

Obstetrical Services Staff Training	Addressing Health Equity Through QAPI Program	MMRC Information and QAPI Incorporation	Patient Transfer Training	Emergency Preparedness Training	Total Hourly Cost for All Requirements
1,416,608	189,300	50,480	417,531	1,431,895	3,505,814
1,416,608	189,300	50,480	417,531	677,763	2,751,682
1,416,608	189,300	50,480	417,531	677,763	2,751,682
1,416,608	189,300	50,480	417,531	677,763	2,751,682
1,416,608	189,300	50,480	417,531	677,763	2,751,682
1,416,608	189,300	50,480	417,531	677,763	2,751,682
1,416,608	189,300	50,480	417,531	677,763	2,751,682
1,416,608	189,300	50,480	417,531	677,763	2,751,682
1,416,608	189,300	50,480	417,531	677,763	2,751,682
1,416,608	189,300	50,480	417,531	677,763	2,751,682
14,166,080	1,893,000	504,800	4,175,310	7,531,766	28,270,956

BILLING CODE 4120-01-C**h. Benefits**

There are a wide variety of benefits associated with the proposed requirements for obstetrical services in hospitals and CAHs.

First, there are the financial benefits. As we noted above in the statement of need, research suggests that maternal mortality and morbidity have widespread negative effects on pregnant and postpartum patients and their families and high financial costs for payors. One study found that pregnancy-related mortality cost in the United States more than \$27.4 billion and resulted in the loss of 114,000 years of potential life between 2018 and 2020.⁵⁸⁷ Another study showed that from birth to 5 years postpartum, nine maternal morbidities among the 2019 US birth cohort cost birthing parents and their children \$32.3 billion, with \$18.7 billion due to medical costs and \$13.6 billion related to non-medical costs.^{588 589} A third study found that severe maternal morbidity during the prenatal to 30 day postpartum period was associated with a 75 percent increase in medical costs for patients utilizing Medicaid and a more than

doubling in medical costs for commercially insured patients.⁵⁹⁰ While these studies vary in their methodology, the pre-post birth time period analyzed, medical conditions analyzed, and cost estimates, they suggest that maternal morbidity and mortality impose high health and safety, as well as economic costs on birth parents, children, payors, and society.⁵⁹¹

We believe that the policies we are proposing will help reduce maternal morbidity and mortality and their associated costs for pregnant and postpartum patients and their families, as well as payors. Specifically, the proposed requirements that OB services are well-organized and in accordance with acceptable standards of practices, have adequate provisions and protocols for OB emergencies, complications, immediate post-delivery care and other patient health and safety events as identified as part of the facility's QAPI program, and that OB patient care units are supervised by an individual with the necessary education and training will provide the foundation for ensuring uniform high-quality OB services. Similarly, requiring hospitals and CAHs to delineate and document obstetrical privileges for all practitioners will benefit patients by helping ensure that practitioners have the necessary education, training, and experience to provide safe, effective care and safely

perform specific procedures. Finally, the requirement that labor and delivery room suites have certain basic resuscitation equipment readily available will help ensure efficient and effective care that can help reduce patient morbidity and mortality.

Similarly, OB staff training and appropriate transfer protocols can also help avert avoidable maternal complications and deaths.⁵⁹² Finally, engagement with recommendations from MMRCs and QAPI stratification of data can help facilities better identify unfavorable patient health and safety outcomes, which can allow them to better tailor policies to address these issues.

Beyond reductions in maternal morbidity and mortality and their associated financial benefits, the proposed policies are likely also to reduce inequality among pregnant and postpartum women from different groups. For example, research shows that among women with any form of disability, there is a heightened risk for labor and delivery complications, as well as severe maternal morbidity and mortality. If hospitals and CAHs include training that helps health care practitioners better understand these risks and be more comfortable providing care to women with a disability, they may be able to better provide safe, high quality obstetric care, reducing obstetrical complications. Research also suggests that due to insufficient patient education by staff, women with limited English proficiency (LEP) experience

⁵⁸⁷ White Robert, S., et al., *Economic burden of maternal mortality in the USA, 2018–2020*. Journal of Comparative Effectiveness Research, 2022. 11(13): 927–933.

⁵⁸⁸ O'Neil, S.S., et al., *Societal cost of nine selected maternal morbidities in the United States*. PLOS ONE, 2022. 17(10): e0275656.

⁵⁸⁹ These nine conditions included the following: amniotic fluid embolism, cardiac arrest, gestational diabetes mellitus, hemorrhage, hypertensive disorders, mental health conditions, renal disease, sepsis, and venous thromboembolism.

⁵⁹⁰ Black, C.M., et al., *Costs of Severe Maternal Morbidity in U.S. Commercially Insured and Medicaid Populations: An Updated Analysis*. Women's Health Reports, 2021. 2(1): 443–451.

⁵⁹¹ Moran, P.S., et al., *Economic burden of maternal morbidity—A systematic review of cost-of-illness studies*. PLOS ONE, 2020. 15(1): e0227377.

⁵⁹² <https://saferbirth.org/aim-obstetric-emergency-readiness-resource-kit/>.

disparities in obstetric care and are at risk for mental health conditions, including post-partum depression and substandard newborn care following neonatal ICU discharge.⁵⁹³ If facilities engage in increasing language-concordant care and awareness among providers regarding the use of medical interpreters and materials in diverse languages, they may be able to improve patient satisfaction, decrease medical errors, and improve patient safety.^{594 595} Similarly, stratification of patient data can produce insights into health disparities that allow facilities to develop interventions to reduce them, with research showing that data collection and analysis by patient subgroup within health care facilities has an important impact on improving patient care consistently across patient populations.^{596 597 598 599 600}

Beyond the benefits for obstetrical patients, our proposed requirements are likely to have positive effects on the health and safety for patients generally. Our proposed requirements for hospitals to have written policies and procedures for transferring patients under their care and train medical staff regarding transfer protocols can support hospitals in expediting transfers when necessary. Efficient transfers to hospitals that can treat complex conditions and provide higher levels of care for all patients as needed. Similarly, our proposed requirement that hospitals with emergency services must have adequate provisions and protocols for the care of patients with emergency conditions and train applicable staff on these protocols and provisions, is also likely to improve patient health and safety. Additional obstetric training for emergency

department staff improves staff competencies (*i.e.*, skills, knowledge, comfort, confidence, and effectiveness) in managing obstetric emergencies, supporting improved maternal health and safety,^{601 602 603 604 605 606} while training in pediatric readiness,^{607 608} and geriatric readiness^{609 610 611 612 613} improves staff capabilities in caring for these populations.

We seek comments on additional benefits from our proposed requirements, as well as ways to quantify the health, safety, and financial benefits we have identified above.

i. Alternatives Considered

We considered a variety of approaches when developing the proposed obstetrical services requirements for hospitals and CAHs. One approach was to leave the

development of policies to improve obstetrical services to accrediting agencies or individual States. We decided against this approach, however, since there is likely to be wide variation across States and accrediting agencies in their requirements, leading to variation in obstetrical services for patients depending on the facility or State where they are located.

We also considered requiring specific topics for the proposed OB services training requirement as well as for the requirement to train staff on the protocols for the care of patients with emergency conditions. We ultimately decided, however, to provide facilities with flexibility in how they approach these trainings so that they could provide it in a way that leads to the best improvements in and highest quality of care for pregnant and postpartum women. Similarly, we considered defining specific subpopulations that facilities must analyze when using their QAPI program to identify inequalities in health outcomes. Ultimately, however, we decided to provide facilities with flexibility regarding which subpopulations they analyze since features of patient populations are likely to vary greatly across different facilities.

D. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed or final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities that will review this proposed rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

⁵⁹³ Togioka, Brandon & Seligman, Katherine & Delgado Upegui, Carlos. (2022). Limited English proficiency in the labor and delivery unit. *Current Opinion in Anesthesiology*. 35. 285–291.

⁵⁹⁴ Sentell, Tetine & Chang, Ann & Ahn, Hyeon Jun & Miyamura, Jill. (2015). Maternal Language and Adverse Birth Outcomes in a Statewide Analysis. *Women & health*. 56. 10.1080/03630242.2015.1088114.

⁵⁹⁵ <https://www.ahrq.gov/sites/default/files/publications/files/leppguide.pdf>.

⁵⁹⁶ Weinick, R.M. and R. Hasnain-Wynia, Quality Improvement Efforts Under Health Reform: How To Ensure That They Help Reduce Disparities—Not Increase Them. *Health Affairs*, 2011. 30(10): p. 1837–1843.

⁵⁹⁷ Bardach, N.S. and M.D. Cabana, The unintended consequences of quality improvement. *Curr Opin Pediatr*, 2009. 21(6): p. 777–82.

⁵⁹⁸ Perzynski, A.T., et al., Patient portals and broadband internet inequality. *J Am Med Inform Assoc*, 2017. 24(5): p. 927–932.

⁵⁹⁹ Antonio, M.G., O. Petrovskaya, and F. Lau, Is research on patient portals attuned to health equity? A scoping review. *J Am Med Inform Assoc*, 2019. 26(8–9): p. 871–883.

⁶⁰⁰ Sequist, T.D., et al., Effect of quality improvement on racial disparities in diabetes care. *Arch Intern Med*, 2006. 166(6): p. 675–81.

⁶⁰¹ Burke SM, Schmitt T, Kennedy P, et al. Emergency Medicine Obstetrics and Gynecology: A Case-Based Curriculum for Residents. *MedEdPORTAL*. 2023;19:11330.

⁶⁰² Espey E, Baty G, Rask J, Chungtuyc M, Pereda B, Leeman L. Emergency in the clinic: a simulation curriculum to improve outpatient safety. *Am J Obstet Gynecol*. Dec 2017;217(6):699.e1–699.e13.

⁶⁰³ Cooper MI, Papanagnou D, Meguerdichian M, Bajaj K. Emergency Obstetrics for the Emergency Medicine Provider. *MedEdPORTAL*. Oct 13 2016;12:10481.

⁶⁰⁴ Jacobs PJ. Using High-Fidelity Simulation and Video-Assisted Debriefing to Enhance Obstetrical Hemorrhage Mock Code Training. *J Nurses Prof Dev*. Sep/Oct 2017;33(5):234–239.

⁶⁰⁵ Hopmann P, Varre JS, Duncan G, Devoe WB, Gable BD. Multidisciplinary Simulation of Trauma in Pregnancy with Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) Utilization. *Cureus*. Dec 2022;14(12):e32820.

⁶⁰⁶ Harrington J, Duncan G, D. Angelo K G. Multidisciplinary Simulation Improves Resident Confidence for Pregnant Patients Requiring Surgical Intervention. *Cureus*. Mar 2022;14(3):e23454.

⁶⁰⁷ Ames, S.G., et al., Emergency Department Pediatric Readiness and Mortality in Critically Ill Children. *Pediatrics*, 2019. 144(3).

⁶⁰⁸ Newgard, C.D., et al., Emergency Department Pediatric Readiness and Short-term and Long-term Mortality Among Children Receiving Emergency Care. *JAMA Network Open*, 2023. 6(1): p. e2250941–e2250941.

⁶⁰⁹ Keyes, DC, et al., Impact of a New Senior Emergency Department on Emergency Department Recidivism, Rate of Hospital Admission, and Hospital Length of Stay. *Annals of Emergency Medicine*, 2014. 63(5): p. 517–524.

⁶¹⁰ Dresden, S.M., et al., Geriatric Emergency Department Innovations: The Impact of Transitional Care Nurses on 30-day Readmissions for Older Adults. *Acad Emerg Med*, 2020. 27(1): p. 43–53.

⁶¹¹ Foo, C.L., et al., Geriatric assessment and intervention in an emergency department observation unit reduced re-attendance and hospitalisation rates. *Australas J Ageing*, 2012. 31(1): p. 40–6.

⁶¹² Chong, E., et al., Emergency Department Interventions for Frailty (EDIFY): Front-Door Geriatric Care Can Reduce Acute Admissions. *Journal of the American Medical Directors Association*, 2021. 22(4): p. 923–928.e5.

⁶¹³ Gettel, C.J., et al., An Outcome Comparison Between Geriatric and Nongeriatric Emergency Departments. *Ann Emerg Med*, 2023. 82(6): p. 681–689.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is \$115.22 per hour, including overhead and fringe benefits https://www.bls.gov/oes/current/oes_nat.htm. Assuming an average reading speed, we estimate that it would take approximately 8 hours for the staff to review half of this proposed or final rule. For each entity that reviews the rule, the estimated cost is \$921.76 (8 hours × \$115.22). Therefore, we estimate that the total cost of reviewing this regulation is \$3,481,487.52 (\$921.76 × 3,777).

D. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed or final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities that will review this proposed rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is \$129.28 per hour, including overhead and fringe benefits https://www.bls.gov/oes/current/oes_nat.htm. Assuming an average reading speed, we estimate that it would take approximately 8 hours for the staff to review half of this proposed or final rule. For each entity that reviews the rule, the estimated cost is \$1,034.24 (8 hours × \$129.28). Therefore, we estimate that the total cost of reviewing this regulation is \$3,903,221.76 (\$1,034.24 × 3,777).

E. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that many hospitals are considered small businesses either by the Small Business Administration's size standards with total revenues of \$41.5 million or less in any single year or by the hospital's not-for-profit status. Most ASCs and most CMHCs are considered small businesses with total revenues of \$16.5 million or less in any single year. For details, we refer readers to the Small Business Administration's "Table of Size Standards" at <http://www.sba.gov/content/table-small-business-sizestandards>.

Individuals and states are not included in the definition of a small entity. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We believe that this threshold would be reached by the requirements proposed in this proposed rule. As a result, the Secretary has determined that this proposed rule may have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this proposed rule would increase payments to small rural hospitals by approximately 3 percent; therefore, it should have a negligible impact on approximately 533 small rural hospitals. We note that the estimated payment impact for any category of small entity will depend on both the services that they provide as well as the payment policies and/or payment systems that may apply to them. Therefore, the most applicable estimated impact may be based on the specialty, provider type, or payment system.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

F. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold is approximately \$183 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector. This proposed rule would not impose a mandate that would result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than \$183 million in any 1 year.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have examined the OPPS and ASC provisions included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they would not have a substantial direct effect on State, local, or tribal governments, preempt State law, or otherwise have a Federalism implication. As reflected in Table 131 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 2.4 percent under this proposed rule. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule would affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant. However, as noted in section XXIII of this proposed rule, this rule should not have a significant effect on small rural hospitals.

H. Conclusion

The changes we are finalizing in this proposed rule would affect all classes of hospitals paid under the OPSS as well as both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPSS would experience a modest increase or a minimal decrease in payment for services furnished under the OPSS in CY 2025. Table U168 demonstrates the estimated distributional impact of the OPSS budget neutrality requirements that would result in a 2.3 percent increase in payments for all services paid under the OPSS in CY 2025, after considering all of the changes to APC reconfiguration and recalibration, as well as the OPD fee schedule increase factor, wage index changes, including the frontier State wage index adjustment, and estimated payment for outliers, changes to the pass-through payment estimate, and changes to outlier payments. However, some classes of providers that are paid under the OPSS would experience more significant gains or losses in OPSS payments in CY 2025.

The updates we are making to the ASC payment system for CY 2025 would affect each of the approximately 6,100 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC would depend on its mix of patients, the proportion of the ASC's patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year than in previous years. Table U169 demonstrates the estimated distributional impact among ASC surgical specialties of the productivity-adjusted hospital market basket update factor of 2.6 percent for CY 2025.

Finally, our proposal to include additional exceptions to the four walls requirement under the Medicaid clinic services for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas is estimated to have an \$1.18 billion impact in transfers for fiscal years 2025–2029. Table 110 demonstrates the Federal and State share impacts on IHS/Tribal clinics, behavioral health clinics, clinics located in rural areas, and in aggregate. As explained earlier in this section of the proposed rule, there is uncertainty in the potential for changes in utilization and costs of clinic services because of uncertainty in provider availability and beneficiary demand.

Chiquita Brooks-LaSure,
Administrator of the Centers for

Medicare & Medicaid Services,
approved this document on June 21,
2024.

List of Subjects

42 CFR Part 406

Diseases, Health facilities, Medicare.

42 CFR Part 407

Medicare.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 435

Aid to Families with Dependent Children, Grant programs—health, Medicaid, Reporting and recordkeeping requirements, Supplemental Security Income (SSI), Wages.

42 CFR Part 440

Grant programs—health, Medicaid.

42 CFR Part 457

Administrative practice and procedure, Grant programs—health, Health insurance, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Incorporation by Reference, Medicaid, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

■ 1. The authority citation for part 406 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i–2, 1395i–2a, 1395p, 1395q and 1395hh.

■ 2. Section 406.27 is amended by revising paragraph (d) to read as follows:

§ 406.27 Special enrollment periods for exceptional conditions.

* * * * *

(d) *SEP for formerly incarcerated individuals.* An SEP exists for Medicare eligible individuals who are no longer incarcerated on or after January 1, 2023.

(1) *SEP parameters and duration before January 1, 2025—(i) Eligibility.* An individual is eligible for this SEP if they are released from the custody of penal authorities between January 1, 2023, and December 31, 2024, as described in § 411.4(b) of this subchapter. The individual must demonstrate that they are eligible for Medicare and failed to enroll or reenroll in Medicare premium Part A due to being in custody of penal authorities and there is a record of release either through discharge documents or data available to SSA.

(ii) *SEP duration.* The SEP starts the day of the individual's release from the custody of penal authorities and ends the last day of the 12th month after the month in which the individual is released from the custody of penal authorities.

(2) *SEP parameters and duration beginning January 1, 2025—(i) Eligibility.* An individual is eligible for this SEP if they are released from confinement in a jail, prison, or other penal institution or correctional facility on or after January 1, 2025, and demonstrate that they are eligible for Medicare and failed to enroll or reenroll in Medicare premium Part A due to being so confined, and there is a record of release, either through discharge documents or data available to SSA.

(ii) *SEP duration.* The SEP starts the day an individual is released from confinement as determined by SSA and ends the last day of the 12th month after the month in which the individual is released from confinement in a jail, prison, or other penal institution or correctional facility.

(3) *Entitlement—(i) General rule.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

(ii) *Special rule.* An individual has the option of requesting entitlement for a retroactive period of up to 6 months provided the date does not precede the month of their release from incarceration, the date is on or after January 1, 2023, and the individual pays the monthly premiums for the period of coverage (as required under § 406.32(f)). If retroactive enrollment is requested

and the application is filed within the first 6 months of the SEP, the effective date is retroactive to the beginning of the month of their release from incarceration. If retroactive enrollment is requested and the application is filed in the last 6 months of the SEP, the coverage effective date is retroactive to the 6th month before the month of enrollment.

* * * * *

PART 407—SUPPLEMENTARY MEDICAL INSURANCE (SMI) ENROLLMENT AND ENTITLEMENT

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

Authority: 42 U.S.C. 1302, 1395p, 1395q, and 1395hh.

■ 4. Section 407.23 is amended by revising paragraph (d) to read as follows:

§ 407.23 Special enrollment periods for exceptional conditions.

* * * * *

(d) *SEP for formerly incarcerated individuals.* An SEP exists for Medicare eligible individuals who are no longer incarcerated on or after January 1, 2023.

(1) *SEP parameters and duration before January 1, 2025—(i) Eligibility.* An individual is eligible for this SEP if they are released from the custody of penal authorities between January 1, 2023, and December 31, 2024, as described in § 411.4(b) of this subchapter. The individual must demonstrate that they are eligible for Medicare and failed to enroll or reenroll in SMI due to being in the custody of penal authorities and there is a record of release either through discharge documents or data available to SSA.

(ii) *SEP duration.* The SEP starts the day of the individual's release from the custody of penal authorities and ends the last day of the 12th month after the month in which the individual is released from the custody of penal authorities.

(2) *SEP parameters and duration beginning January 1, 2025—(i) Eligibility.* An individual is eligible for this SEP if they are released from confinement in a jail, prison, or other penal institution or correctional facility on or after January 1, 2025, and demonstrate that they are eligible for Medicare and failed to enroll or reenroll in SMI due to being so confined, and there is a record of release, either through discharge documents or data available to SSA.

(ii) *SEP duration.* The SEP starts the day an individual is released from confinement as determined by SSA and ends the last day of the 12th month after

the month in which the individual is released from confinement in a jail, prison, or other penal institution or correctional facility.

(3) *Entitlement—(i) General rule.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on after January 1, 2023.

(ii) *Special rule.* An individual has the option of requesting entitlement for a retroactive period of up to 6 months provided the date does not precede the month of their release from incarceration, the date is on or after January 1, 2023, and the individual pays the monthly premiums for the period of coverage (as required under § 408.4). If retroactive enrollment is requested and the application is filed within the first 6 months of the SEP, the effective date is retroactive to the beginning of the month of their release from incarceration. If retroactive enrollment is requested and the application is filed in the last 6 months of the SEP, the coverage effective date is retroactive to the 6th month before the month of enrollment.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 5. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 6. Section 410.27 is amended by revising paragraph (a)(1)(iv)(B)(1) to read as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

(a) * * *

(1) * * *

(iv) * * *

(B) * * *

(1) For purposes of this section, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished as specified in §§ 410.47 and 410.49, respectively. Through December 31, 2025, the presence of the physician or nonphysician practitioner for the purpose of the supervision of

pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services includes virtual presence through audio/video real-time communications technology (excluding audio-only); and

* * * * *

■ 7. Section 410.28 is amended by revising paragraph (e)(2)(iii) to read as follows:

§ 410.28 Hospital or CAH diagnostic services furnished to outpatients: Conditions.

* * * * *

(e) * * *

(2) * * *

(iii) Through December 31, 2025, the presence of the physician or nonphysician practitioner under paragraphs (e)(2)(i) and (ii) of this section includes virtual presence through audio/video real-time communications technology (excluding audio-only).

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 8. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 9. Section 411.4 is revised to read as follows:

§ 411.4 Items and services for which neither the beneficiary nor any other person is legally obligated to pay.

(a) *General rule.* Except in the case of Federally qualified health center services and as provided in § 411.8(b) (for services paid by a governmental entity), Medicare may not pay for an item or service under part A or part B if—

(1) The individual has no legal obligation to pay for the item or service; and

(2) No other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for the item or service.

(b) *Special conditions for payment for items or services furnished to an individual in the custody of a penal authority.* (1) An individual in the custody of a penal authority is considered to have a legal obligation to pay for items or services furnished to the individual only if the following conditions are met:

(i) State or local law requires the individual to pay the cost of items and services that the individual receives ;

(ii) The penal authority enforces the requirement to pay for items or services

by billing all individuals who receive such items or services, whether or not covered by Medicare or any other health insurance; and

(iii) The penal authority pursues collection of amounts owed for items or services received in the same way and with the same vigor that it pursues the collection of other debts.

(2) For purposes of this paragraph, a penal authority means a police department or other law enforcement agency, a government agency operating under a penal statute, or a State, local or Federal jail, prison, penitentiary, or similar institution.

(3) For purposes of this paragraph, an individual is considered to be in the custody of a penal authority if the individual is:

- (i) Under arrest;
- (ii) Incarcerated in a jail, prison, penitentiary, or similar institution;
- (iii) Temporarily outside of a jail, prison, penitentiary, or similar institution on medical furlough or similar arrangement;
- (iv) Escaped from confinement by a penal authority;
- (v) Required to reside in a mental health facility under a penal statute or rule; or
- (vi) Required to reside in a halfway house under any of the following conditions:

(A) Residents are precluded from working outside the facility in employment that is available to individuals who are not under penal authority supervision;

(B) Residents may not use community resources (for example, libraries, grocery stores, recreation, or educational institutions) at will; or

(C) Residents may not seek health care items and services in the broader community to the same or similar extent as individuals who are not under penal authority supervision.

PART 416—AMBULATORY SURGICAL SERVICES

■ 10. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.11. Section 416.164 is amended by revising paragraphs (a)(4) and (b)(6) to read as follows:

§ 416.164 Scope of ASC Services.

(a) * * *

(4) Drugs and biologicals for which separate payment is not allowed under the hospital outpatient prospective payment system (OPPS);

* * * * *

(b) * * *

(6) Non-opioid pain management drugs, biologicals, and medical devices as determined by CMS under § 416.174;

* * * * *

■ 12. Section 416.171 is amended by revising paragraph (b)(1) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

* * * * *

(b) * * *

(1) Covered ancillary services specified in § 416.164(b), with the exception of radiology services and certain diagnostic tests as provided in § 416.164(b)(5) and non-opioid pain management drugs, biologicals, and medical devices as determined by CMS under § 416.174.

* * * * *

■ 13. Revise § 416.174 to read as follows:

§ 416.174 Payment for non-opioid pain management drugs, biologicals, and medical devices.

(a) *Eligibility for separate payment for non-opioid pain management drugs and biologicals.* From January 1, 2025 through December 31, 2027, a non-opioid drug or biological is eligible for separate payment for an applicable calendar year if CMS determines it meets the following requirements through that year's rulemaking:

(1) The drug is approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), under an abbreviated new drug application under section 505(j), or, in the case of a biological product, is licensed under section 351 of the Public Health Service Act. The product also has a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors.

(2) The drug or biological does not have transitional pass-through payment status under § 419.64 of this subchapter. In the case where a drug or biological otherwise meets the requirements under this section and has transitional pass-through payment status that expires during the calendar year, the drug or biological will qualify for separate payment as specified in this paragraph (a) during such calendar year on the first day of the next quarter following the expiration of its pass-through status.

(3) The drug or biological has payment that is packaged into a payment for a covered OPD service (or group of services) under a policy in this part.

(b) *Eligibility for separate payment for non-opioid medical devices.* From January 1, 2025, through December 31, 2027, a medical device is eligible for separate payment for an applicable calendar year if CMS determines it meets all of the following requirements through that year's rulemaking:

(1) The medical device is used to deliver a therapy to reduce postoperative pain, or produce postsurgical or regional analgesia, and has an application under section 515 of the Federal Food, Drug, and Cosmetic Act that has been approved with respect to the device, has been cleared for market under section 510(k) of such Act, or is exempt from the requirements of section 510(k) of such Act pursuant to subsection (l) or (m) or section 510 of such Act or section 520(g) of such Act.

(2) The medical device has demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal.

(3) The medical device does not have transitional pass-through payment status under § 419.66 of this subchapter. In the case where a medical device otherwise meets the requirements under this section and has transitional pass-through payment status that expires during the calendar year, the medical device will qualify for separate payment as specified in this paragraph (b) during such calendar year on the first day of the next calendar year quarter following the expiration of its pass-through status.

(4) The medical device has payment that is packaged into a payment for a covered OPD service (or group of services) under a policy in this part.

(c) *Payment Amount.* From January 1, 2025 through December 31, 2027, the amount of payment for a qualifying non-opioid treatment for pain relief is as follows:

(1) For a qualifying drug or biological as defined in paragraph (a) of this section, the amount of payment is the amount determined under section 1847A of the Act for the drug or biological that exceeds the portion of the otherwise applicable Medicare OPD fee schedule amount, which is determined to be zero dollars for calendar year 2025, subject to paragraph (c)(3) of this section.

(2) For a qualifying medical device as defined in paragraph (b) of this section, the amount of payment is the amount of the hospital's charges for the device, adjusted to cost, that exceeds the portion of the otherwise applicable Medicare OPD fee schedule amount, which is determined to be zero dollars

for calendar year 2025, subject to paragraph (c)(3) of this section.

(3) Payment limitation. The payment amounts in paragraphs (c)(1) and (2) of this section shall not exceed the estimated average of 18 percent of the OPD fee schedule amount of the volume weighted average of the five OPD services with which the non-opioid treatment for pain relief is furnished most frequently.

■ 14. Section 416.320 is amended by revising paragraph (b) to read as follows:

§ 416.320 Retention and removal of quality measures under the ASCQR Program.

* * * * *

(b) *Immediate measure suspension.* If CMS determines that the collection and reporting activities related to a measure potentially raise patient safety concerns, CMS will immediately suspend the measure from the ASCQR Program and will promptly notify ASCs and the public of the suspension of the measure. CMS will address the suspension and propose to retain, modify, or remove the measure in the next feasible rulemaking cycle.

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 15. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 16. Section 419.2 is amended by revising paragraph (b)(15) to read as follows:

§ 419.2 Basis of payment.

* * * * *

(b) * * *

(15) Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including but not limited to, diagnostic radiopharmaceuticals below the per-day diagnostic radiopharmaceutical packaging threshold for the applicable year, contrast agents, and pharmacologic stress agents);

* * * * *

■ 17. Section 419.41 is amended by adding paragraphs (h) and (i) to read as follows:

§ 419.41 Calculation of national beneficiary copayment amounts and national Medicare program payment amounts.

* * * * *

(h) *Payment for non-pass-through therapeutic radiopharmaceuticals.* For a therapeutic radiopharmaceutical for

which payment is not packaged into a payment for a covered outpatient department (OPD) service (or group of services) and that does have on transitional pass-through payment status as described in § 419.64, to calculate the program payment and copayment amounts CMS does the following:

(1) Determines the Average Sales Price (ASP) for the therapeutic radiopharmaceutical for the quarter established under the methodology described by section 1847A of the Act. If that amount is not available, then CMS calculates the mean unit cost (MUC) using the most recently available claims data for that therapeutic radiopharmaceutical.

(2) Subtracts from the amount determined under paragraph (h)(1) of this section the amount of the applicable Part B deductible provided under § 410.160 of this chapter.

(3) Multiplies the amount determined under paragraph (h)(1) of this section (less any applicable deductible under paragraph (h)(2) of this section) by 20 percent. This is the beneficiary's copayment amount for the drug or biological.

(4) Subtracts the amount determined under paragraph (h)(3) of this section from the amount determined under paragraph (h)(1) of this section (less any applicable deductible determined under paragraph (h)(2) of this section). This amount is the preliminary program amount.

(5) Adds to the preliminary program amount determined under paragraph (h)(4) of this section the amount by which the copayment amount would have exceeded the inpatient hospital deductible for that year. This amount is the final Medicare program payment amount.

(i) *Payment for non-pass-through diagnostic radiopharmaceuticals.* For a diagnostic radiopharmaceutical for which payment is not packaged into a payment for a covered outpatient department (OPD) service (or group of services) and that does not have transitional pass-through payment status as described in § 419.64, to calculate the program payment and copayment amounts CMS does the following:

(1) Calculates the mean unit cost (MUC) using the most recently available claims data for that diagnostic radiopharmaceutical.

(2) Subtracts from the amount determined under paragraph (i)(1) of this section the amount of the applicable Part B deductible provided under § 410.160 of this chapter.

(3) Multiplies the amount determined under paragraph (i)(1) of this section (less any applicable deductible under paragraph (h)(2) of this section) by 20 percent. This is the beneficiary's copayment amount for the drug or biological.

(4) Subtracts the amount determined under paragraph (i)(3) of this section from the amount determined under paragraph (i)(1) of this section (less any applicable deductible determined under paragraph (i)(2) of this section). This amount is the preliminary program amount.

(5) Adds to the preliminary program amount determined under paragraph (i)(4) of this section the amount by which the copayment amount would have exceeded the inpatient hospital deductible for that year. This amount is the final Medicare program payment amount.

■ 18. Section 419.43 is amended by adding paragraph (k) to read as follows:

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

* * * * *

(k) *Payment for non-opioid pain management drugs and biologicals.* (1) *Eligibility for separate payment for non-opioid pain management drugs and biologicals.* From January 1, 2025, through December 31, 2027, a drug or biological is eligible for separate payment for an applicable calendar year if CMS determines it meets the following requirements through that year's rulemaking:

(i) The drug is approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), under an abbreviated new drug application under section 505(j), or, in the case of a biological product, is licensed under section 351 of the Public Health Service Act. The product has a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors.

(ii) The drug or biological does not have transitional pass-through payment status under § 419.64 of this subchapter. In the case where a drug or biological otherwise meets the requirements under this section and has transitional pass-through payment status that expires during the calendar year, the drug or biological will qualify for separate payment as specified in this paragraph (k) during such calendar year on the first day of the next calendar year quarter following the expiration of its pass-through status.

(iii) The drug or biological has payment that is packaged into a payment for a covered OPD service (or group of services) under a policy in this section.

(2) *Eligibility for separate payment for non-opioid medical devices.* From January 1, 2025, through December 31, 2027, a medical device is eligible for separate payment for an applicable calendar year if CMS determines it meets the following requirements through that year's rulemaking:

(i) The medical device, is used to deliver a therapy to reduce postoperative pain, or produce postsurgical or regional analgesia, and has an application under section 515 of the Federal Food, Drug, and Cosmetic Act that has been approved with respect to the device, been cleared for market under section 510(k) of such Act, or is exempt from the requirements of 510(k) of such Act pursuant to subsection (l) or (m) or section 510 of such Act or section 520(g) of such Act.

(ii) The medical device has demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal.

(iii) The medical device does not have transitional pass-through payment status under § 419.66. In the case where a medical device otherwise meets the requirements under this section and has transitional pass-through payment status that expires during the calendar year, the medical device will qualify for separate payment as specified in paragraph (k)(2) of this section during such calendar year on the first day of the next calendar year quarter following the expiration of its pass-through status.

(iv) The medical device has payment that is packaged into a payment for a covered OPD service (or group of services) under a policy in this section.

(3) *Payment Amount.* From January 1, 2025, through December 31, 2027, the amount of payment for a qualifying non-opioid treatment for pain relief is as follows:

(i) For a qualifying drug or biological as defined in paragraph (k)(1) of this section, the amount of payment is the amount determined under section 1847A for the drug or biological that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological, subject to paragraph (k)(3)(iii) of this section.

(ii) For a qualifying medical device as defined in paragraph (k)(2) of this section, the amount of payment is the

amount of the hospital's charges for the device, adjusted to cost, that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the device, subject to paragraph (k)(3)(iii) of this section.

(iii) *Payment limitation.* The payment amounts in paragraph (k)(3)(i) and (ii) of this section shall not exceed the estimated average of 18 percent of the OPD fee schedule amount of the volume weighted average of the five OPD services with which the non-opioid treatment for pain relief is furnished most frequently.

■ 19. Section 419.46 is amended by revising paragraph (i)(2) and adding paragraph (j) to read as follows:

§ 419.46 Requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(i) * * *

(2) *Immediate measure suspension.* If CMS determines that the collection and reporting activities related to a measure potentially raise patient safety concerns, CMS will immediately suspend the measure from the Hospital OQR Program and will promptly notify hospitals and the public of the suspension of the measure. CMS will address the suspension and propose to retain, modify, or remove the measure in the next feasible rulemaking cycle.

* * * * *

(j) *Requirements for submission of electronic clinical quality measures (eQMs) under the Hospital OQR Program*

(1) Hospitals must utilize certified technology updated to be consistent with the Office of the National Coordinator for Health IT's (ONC) health IT certification criteria, as adopted and updated in 45 CFR 170.315.

(2) Hospitals must use electronic health record (EHR) technology certified to all eQMs that are available to report under the Hospital OQR Program.

(3) Hospitals must use the most recent version of the eCQM electronic measure specifications for the applicable reporting period available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: <https://ecqi.healthit.gov/> or another website as designated by CMS.

■ 20. Section 419.47 is amended by—

■ a. Revising the section heading;

■ b. Revising paragraph (a); and

■ c. Adding paragraphs (c) and (d).

The revisions and additions read as follows:

§ 419.47 Coding and Payment for Category B Investigational Device Exemption (IDE) Studies and Devices/Drugs Studied in a Clinical Trial with a Medicare Coverage with Evidence Development (CED) Designation.

(a) *Creation of a new HCPCS code for Category B IDE Studies that have a treatment arm and a placebo control arm.* CMS will create a new HCPCS code, or revise an existing HCPCS code, to describe a Category B IDE study, which will include both the treatment and placebo control arms, related device(s) of the study, as well as routine care items and services, as specified under § 405.201 of this chapter, when CMS determines that:

* * * * *

(c) *Creation of a new HCPCS code for devices/drugs and controls studied in clinical trials with the Medicare CED designation that have a study device/drug and a control arm.* CMS will create a new HCPCS code, or revise an existing HCPCS code, to describe a device/drug and a control arm studied in a clinical trial with the Medicare CED designation, which will include the study device/drug and control arm, when CMS determines that:

(1) The Medicare National Coverage Determination process determines that a coverage with evidence development is required to study a device/drug in a clinical trial; and

(2) A new or revised code is necessary to preserve the scientific validity of such a study, such as by preventing the unblinding of the study.

(d) *Payment for devices/drugs studied in clinical trials with the Medicare CED designation.* Where CMS creates a new HCPCS code or revises an existing HCPCS code under paragraph (c) of this section, CMS will:

(1) Make a single packaged payment for the HCPCS code that includes payment for the study device/drug and any control; and

(2) Calculate the single packaged payment rate for the HCPCS code based on an adjusted payment level representing the study device/drug and any control based on available pricing data and frequency of utilization of the study device/drug and any control in the study population.

■ 21. Section 419.82 is amended by revising paragraph (d)(1)(iii) to read as follows:

§ 419.82 Prior authorization for certain covered hospital outpatient department services.

* * * * *

(d) * * *

(1) * * *

(iii) The provisional affirmation or non-affirmation will be issued within 7

calendar days of receipt of the prior authorization request.

* * * * *

PART 435—ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

■ 22. The authority citation for part 435 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 23. Section 435.926 is amended by revising paragraphs (b) introductory text, (b)(1), (c)(1); and (d)(1) to read as follows:

§ 435.926 Continuous eligibility for children.

* * * * *

(b) *Eligibility.* The agency must provide continuous eligibility for the period specified in paragraph (c) of this section for an individual who is:

(1) Under age 19; and

* * * * *

(c) * * *

(1) The length of the continuous eligibility period is 12 months.

* * * * *

(d) * * *

(1) The child attains age 19;

* * * * *

PART 440—SERVICES: GENERAL PROVISIONS

■ 24. The authority citation for part 440 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 25. Section 440.90 is revised to read as follows:

§ 440.90 Clinic services.

Clinic services means preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients. The term includes the following services furnished to outpatients (services in paragraphs (a), (b), and (c) of this section are a mandatory part of clinic services, while services in paragraphs (d) and (e) of this section are optional):

(a) Services furnished at the clinic by or under the direction of a physician or dentist.

(b) Services furnished outside the clinic, by clinic personnel under the direction of a physician, to an individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address.

(c) Services furnished outside a clinic that is a facility of the Indian Health Service, whether operated by the Indian

Health Service or by a Tribe or Tribal organization (as authorized by the Indian Self-Determination and Education Assistance Act (ISDEAA), Pub. L. 93–638), by clinic personnel under the direction of a physician.

(d) Services furnished outside of a clinic that is primarily organized for the care and treatment of outpatients with behavioral health disorders, including mental health and substance use disorders, by clinic personnel under the direction of a physician.

(e) Services furnished outside of a clinic that is located in a rural area and is not a rural health clinic (as referenced in section 1905(a)(2)(B) of the Social Security Act and 440.20(b) of this subpart) by clinic personnel under the direction of a physician.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 26. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 27. Revise § 457.342 to read as follows:

§ 457.342 Continuous eligibility for children.

(a) A State must provide continuous eligibility for children under a separate CHIP in accordance with the terms of § 435.926 of this chapter, and subject to a child remaining ineligible for Medicaid, as required by section 2110(b)(1) of the Act and § 457.310 (related to the definition and standards for being a targeted low-income child) and the requirements of section 2102(b)(3) of the Act and § 457.350 (related to eligibility screening and enrollment).

(b) [Reserved]

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 28. The authority citation for part 482 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr, unless otherwise noted.

■ 29. Section 482.21 is amended by—

■ a. Adding paragraph (b)(4);

■ b. Redesignating paragraph (e) and (f) as (f) and (g), respectively; and

■ c. Adding new paragraph (e).

The additions read as follows:

§ 482.21 Condition of participation: Quality assessment and performance improvement program.

* * * * *

(b) * * *

(4) For hospitals that offer obstetrical services, the hospital must utilize its QAPI program to assess and improve health outcomes and disparities among

obstetrical patients on an ongoing basis. At a minimum, the hospital must:

(i) Analyze data and quality indicators collected for the QAPI program by diverse subpopulations as identified by the hospital among obstetrical patients.

(ii) Measure, analyze, and track data, measures, and quality indicators on patient outcomes and disparities in processes of care, services and operations among obstetrical patients.

(iii) Analyze and prioritize patient health outcomes and disparities, develop and implement actions to improve patient health outcomes and disparities, measure results, and track performance to ensure improvements are sustained among obstetrical patients.

(iv) Conduct at least one measurable performance improvement project focused on improving health outcomes and disparities among the hospital's population(s) of obstetrical patients annually.

* * * * *

(e) *Standard: Maternal Health QAPI activities.* For hospitals that offer obstetrical services, the following additional QAPI requirements apply:

(1) Obstetrical services leadership must engage in QAPI as specified in § 482.21 for obstetrical services, including but not limited to participating in data collection and monitoring as specified in § 482.21(b).

(2) If a maternal mortality review committee (MMRC) is available at the state or local jurisdiction in which the hospital is located, the facility leadership, obstetrical services leadership, or their designate(s) must further have a process for incorporating MMRC(s) data and recommendations into the hospital QAPI program as specified in § 482.21(b).

* * * * *

■ 30. Section 482.43 is amended by revising paragraphs (c) and adding paragraph (d) to read as follows:

§ 482.43 Condition of participation: Discharge planning.

* * * * *

(c) *Standard: Transfer protocols.* The hospital must have written policies and procedures for transferring patients under its care (inclusive of inpatient services) to the appropriate level of care (including to another hospital) as needed to meet the needs of the patient. The hospital must also provide training to relevant staff regarding the hospital policies and procedures for transferring patients under its care.

(d) *Standard: Requirements related to post-acute care services.* For those patients discharged home and referred for HHA services, or for those patients transferred to a SNF for post-hospital

extended care services, or transferred to an IRF or LTCH for specialized hospital services, the following requirements apply, in addition to those set out at paragraphs (a) and (b) of this section:

(1) The hospital must include in the discharge plan a list of HHAs, SNFs, IRFs, or LTCHs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, IRF, or LTCH, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available.

(i) This list must only be presented to patients for whom home health care post-hospital extended care services, SNF, IRF, or LTCH services are indicated and appropriate as determined by the discharge planning evaluation.

(ii) For patients enrolled in managed care organizations, the hospital must make the patient aware of the need to verify with their managed care organization which practitioners, providers or certified suppliers are in the managed care organization's network. If the hospital has information on which practitioners, providers or certified supplies are in the network of the patient's managed care organization, it must share this with the patient or the patient's representative.

(iii) The hospital must document in the patient's medical record that the list was presented to the patient or to the patient's representative.

(2) The hospital, as part of the discharge planning process, must inform the patient or the patient's representative of their freedom to choose among participating Medicare providers and suppliers of post-discharge services and must, when possible, respect the patient's or the patient's representative's goals of care and treatment preferences, as well as other preferences they express. The hospital must not specify or otherwise limit the qualified providers or suppliers that are available to the patient.

(3) The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of part 420, subpart C, of this chapter.

■ 31. Section 482.55 is amended by adding paragraph (c) to read as follows:

§ 482.55 Condition of participation: Emergency services.

* * * * *

(c) *Standard: Emergency services readiness.* In accordance with the complexity and scope of services offered, there must be adequate provisions and protocols to meet the emergency needs of patients.

(1) *Protocols.* Protocols must be consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions, including but not limited to patients with obstetrical emergencies, complications, and immediate post-delivery care.

(2) *Provisions.* Provisions include equipment, supplies, and medication used in treating emergency cases. Such provisions must be kept at the hospital and be readily available for treating emergency cases to meet the needs of patients. The available provisions must include the following:

(i) Drugs, blood and blood products, and biologicals commonly used in life-saving procedures;

(ii) Equipment and supplies commonly used in life-saving procedures; and

(iii) Each emergency services treatment area must have a call-in-system for each patient.

(3) *Staff training.* Applicable staff, as identified by the hospital, must be trained annually on the protocols and provisions implemented pursuant to this section.

(i) The governing body must identify and document which staff must complete such training.

(ii) The hospital must document in the staff personnel records that the training was successfully completed.

(iii) The hospital must be able to demonstrate staff knowledge on the topics implemented pursuant to this section.

(iv) The hospital must use findings from its quality assessment and performance improvement (QAPI) program, as required at § 482.21, to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.

■ 32. Section 482.59 is added to subpart D to read as follows:

§ 482.59 Condition of participation: Obstetrical services.

If the hospital offers obstetrical services, the services must be well organized and provided in accordance with nationally recognized acceptable standards of practice for the health care (including physical and behavioral health) of pregnant, birthing, and postpartum patients. If outpatient

obstetrical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(a) *Standard: Organization and staffing.* The organization of the obstetrical services must be appropriate to the scope of the services offered. As applicable, the services must be integrated with other departments of the hospital.

(1) Labor and Delivery rooms/suites (including labor rooms, delivery rooms (including rooms for operative delivery), and post-partum/recovery rooms whether combined or separate) must be supervised by an experienced registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a doctor of medicine or osteopathy.

(2) Obstetrical privileges must be delineated for all practitioners providing obstetrical care in accordance with the competencies of each practitioner. The obstetrical service must maintain a roster of practitioners specifying the privileges of each practitioner.

(b) *Standard: Delivery of service.* Obstetrical services must be consistent with needs and resources of the facility. Policies governing obstetrical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care and safety.

(1) The following equipment must be available to the labor and delivery room suites: call-in-system, cardiac monitor, and fetal doppler or monitor.

(2) There must be adequate provisions and protocols, consistent with nationally recognized and evidence-based guidelines, for obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the QAPI program (§ 482.21). Provisions include equipment (in addition to the equipment required under (b)(1)), supplies, and medication used in treating emergency cases. Such provisions must be kept on the hospital and be readily available for treating emergency cases.

(c) *Standard: Staff training.* The hospital must develop policies and procedures to ensure that relevant staff are trained on select topics for improving the delivery of maternal care.

(1) Training concepts must reflect the scope and complexity of services offered within the facility, including but not limited to:

(i) Facility-identified evidence-based best practices and protocols to improve the delivery of maternal care within the facility; and

(ii) The hospital must use findings from its quality assessment and performance improvement (QAPI) program, as required at § 482.21, to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.

(2) The governing body must identify and document which staff must complete annual training on the topics identified at § 482.59(c)(1).

(3) The hospital must document in the staff personnel records that the training was successfully completed.

(4) The hospital must be able to demonstrate staff knowledge on the topics identified at § 482.59(c)(1).

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 33. The authority citation for part 485 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395(hh).

■ 34. Section 485.618 is amended by—
■ a. Revising paragraph (e); and
■ b. Adding paragraph (f).

The revision and addition reads as follows:

§ 485.618 Condition of participation: Emergency Services.

* * * * *

(e) *Standard: Emergency services readiness.* In accordance with the complexity and scope of services offered, there must be adequate provisions (as required under paragraphs (b) and (c) of this section) and protocols to meet the emergency needs of patients.

(1) Protocols- Protocols must be consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions, including but not limited to patients with obstetrical emergencies, complications, and immediate post-delivery care.

(2) Staff training- Applicable staff, as identified by the CAH, must be trained annually on the protocols and provisions implemented pursuant to this section.

(i) The governing body must identify and document which staff must complete such training.

(ii) The CAH must document in the staff personnel records that the training was successfully completed.

(iii) The CAH must be able to demonstrate staff knowledge on such training.

(iv) The CAH must use findings from its quality assessment and performance improvement (QAPI) program, as required at § 485.641, to inform staff training needs and any additions,

revisions, or updates to training topics on an ongoing basis.

(f) *Standard: Coordination with emergency response systems.* The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.

■ 35. Section 485.641 is amended by—
■ a. Adding paragraph (d)(4); and
■ b. Revising paragraph (e).

The addition and revision reads as follows:

§ 485.641 Condition of participation: Quality assessment and performance improvement program.

* * * * *

(d) * * *

(4) For CAHs that offer obstetrical services, the following additional QAPI requirements apply:

(i) Obstetrical services leadership must engage in QAPI as specified in this section for obstetrical services, including but not limited to participating in data collection and monitoring as specified in paragraphs (d) and (e) of this section.

(ii) If a maternal mortality review committee (MMRC) is available at the state or local jurisdiction in which the CAH is located, the facility leadership, obstetrical services leadership, or their designate(s) must further have a process for incorporating MMRC(s) data and recommendations into the CAH QAPI program as specified in this section.

(e) *Standard: Program data collection and analysis.* The program must incorporate quality indicator data including patient care data, in order to achieve the goals of the QAPI program. For CAHs that offer obstetrical services, the CAH must utilize its QAPI program to assess and improve health outcomes and disparities among obstetrical patients on an ongoing basis. At a minimum, the CAH must:

(1) Analyze data and quality indicators collected for the QAPI program by diverse subpopulations as identified by the CAH among obstetrical patients.

(2) Measure, analyze, and track health equity data, measures, and quality indicators on patient outcomes and disparities in processes of care, services and operations, and outcomes among obstetrical patients.

(3) Analyze and prioritize identified patient health outcomes and disparities, develop and implement actions to

improve patient health outcomes and disparities, measure results, and track performance to ensure improvements are sustained when disparities exist among obstetrical patients.

(4) Conduct at least one measurable performance improvement project focused on improving health outcomes and disparities among the CAH's population(s) of obstetrical patients annually.

* * * * *

■ 36. Section 485.649 is added to subpart S to read as follows:

§ 485.649 Condition of participation: Obstetrical Services.

If the CAH offers obstetrical services, the services must be well organized and provided in accordance with nationally recognized acceptable standards of practice for the health care (including physical and behavioral health) of pregnant, birthing, postpartum patients. If outpatient obstetrical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(a) *Standard: Organization and staffing.* The organization of the obstetrical services must be appropriate to the scope of the services offered. As applicable, the services must be integrated with other departments of the CAH.

(1) Labor and Delivery rooms/suites (including labor rooms, delivery rooms (including rooms for operative delivery), and post-partum/recovery rooms whether combined or separate) must be supervised by an experienced registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a Doctor of Medicine or a Doctor of Osteopathy (MD/DO).

(2) Obstetrical privileges must be delineated for all practitioners providing obstetrical care in accordance with the competencies of each practitioner. The obstetrical service must maintain a roster of practitioners specifying the privileges of each practitioner.

(b) *Standard: Delivery of service.* Obstetrical services must be consistent with needs and resources of the CAH. Policies governing obstetrical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care and safety.

(1) The following equipment must be available to the labor and delivery room suites: call-in-system, cardiac monitor, and fetal doppler or monitor.

(2) There must be adequate provisions and protocols, consistent with nationally recognized and evidence-

based guidelines, for obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the QAPI program (§ 485.641). Provisions include equipment (in addition to the equipment required under (b)(1) of this section), supplies, and medication used in treating emergency cases. Such provisions must be kept on the CAH and be readily available for treating emergency cases.

(c) *Standard: Staff training.* The CAH must develop policies and procedures to ensure that relevant staff are trained on select topics for improving the delivery of maternal care.

(1) Training concepts must reflect the scope and complexity of services offered within the facility, including but not limited to:

(i) Facility-identified evidence-based best practices and protocols to improve the delivery of maternal care within the facility; and

(ii) The CAH must use findings from its quality assessment and performance improvement (QAPI) program, as required at § 485.641, to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.

(2) The governing body must identify and document which staff must

complete annual training on the topics identified at paragraph (c)(1) of this section.

(3) The CAH must document in the staff personnel records that the training was successfully completed.

(4) The CAH must be able to demonstrate staff knowledge on the topics identified at paragraph (c)(1) of this section.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–15087 Filed 7–10–24; 8:45 am]

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FEDERAL REGISTER

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Part III

The President

Executive Order 14124—White House Initiative on Advancing Educational Equity, Excellence, and Economic Opportunity Through Hispanic-Serving Institutions

Presidential Documents

Title 3—

Executive Order 14124 of July 17, 2024

The President

White House Initiative on Advancing Educational Equity, Excellence, and Economic Opportunity Through Hispanic-Serving Institutions

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to advance equity in economic and educational opportunities, strengthen the capacity of Hispanic-Serving Institutions (HSIs) to provide a high-quality education, increase opportunities for these institutions to participate in and benefit from Federal programs, and ensure that HSIs can continue to be engines of educational opportunity and economic mobility, it is hereby ordered as follows:

Section 1. Policy. Hispanic-Serving Institutions have a history of expanding educational opportunities for generations of Hispanic and Latino students. As defined in section 502(a)(5) of the Higher Education Act of 1965 (20 U.S.C. 1101a(a)(5)), HSIs are institutions of higher education that have an enrollment of at least 25 percent Hispanic undergraduate full-time-equivalent students and satisfy other criteria, including with respect to enrollment of needy students and expenditures per full-time-equivalent undergraduate student.

Today, more than 500 HSIs, located in 27 States, the District of Columbia, and Puerto Rico, serve more than 4.7 million students annually. Hispanic-Serving Institutions vary in size; support a range of academic interests; and serve urban, rural, and suburban communities. Over half of Hispanic and Latino postsecondary students in America attend an HSI, and nearly 40 percent of those students attend a 2-year HSI. Hispanic-Serving Institutions serve a significant number of students from low-income backgrounds. Students enrolled at HSIs account for approximately 30 percent of all Pell Grant recipients, even though these colleges and universities make up only 13 percent of all postsecondary degree-granting institutions. Further, HSIs can play a critical role in fostering diversity in science, technology, engineering, and mathematics fields. Notably, 69 percent of doctoral students in HSIs are enrolled in science- and engineering-related degrees, highlighting the significant role HSIs can play in ensuring a workforce that meets the Nation's evolving needs in technical fields.

As Hispanic and Latino college enrollment has grown to historic levels over the last few decades, so has the number of HSIs, making HSIs' success vital to the strength of the Nation. These institutions are creating and implementing evidence-based practices that lead to Hispanic and Latino student success.

Despite the fact that HSIs represent a large and fast-growing segment of the Nation's colleges and universities, per-student Federal funding at HSIs is 25 percent less than at other degree-granting institutions. Over the last 30 years, the number of HSIs has more than doubled and Hispanic or Latino student enrollment at HSIs has more than tripled. But per-student Federal funding at HSIs remains low compared to degree-granting institutions generally, and many HSIs report having unmet physical and digital infrastructure needs. This scarcity of resources often leaves HSIs at a disadvantage when compared with better-resourced institutions. Students, faculty, and staff at under-resourced HSIs often face challenges in accessing the resources they need to excel.

Despite these funding disparities, research has shown that HSIs tend to do more for Hispanic and Latino student success than non-HSI colleges and universities—and do so with fewer resources. Many HSIs are leaders in promoting economic mobility for Hispanic and Latino students, including by closing college access, completion, and success gaps. Hispanic-Serving Institutions could further improve outcomes for students if they were adequately funded. The Federal Government must strengthen the capacity of HSIs to improve and expand their reach, while recognizing that HSIs face discrete challenges and opportunities that reflect their history and the communities they serve.

As set forth in Executive Order 14045 of September 13, 2021 (White House Initiative on Advancing Educational Equity, Excellence, and Economic Opportunity for Hispanics), the Federal Government must collaborate with Hispanic and Latino communities to ensure their long-term success, including by eliminating barriers to Federal funding and strengthening the capacity of HSIs. This order builds on those policies by establishing the White House Initiative on Advancing Educational Equity, Excellence, and Economic Opportunity Through Hispanic-Serving Institutions and the President's Board of Advisors on Hispanic-Serving Institutions.

It is the policy of my Administration to advance educational equity, excellence, and economic opportunity through strong partnerships with HSIs to ensure that they have access to Federal resources to help current and future generations of students succeed. The Federal Government must collaborate with HSIs and the students, families, and communities they serve to address and overcome barriers that may impede educational attainment and upward economic mobility. Strengthening the capacity of the Nation's HSIs is critical to fulfilling that objective.

Sec. 2. *White House Initiative on Advancing Educational Equity, Excellence, and Economic Opportunity Through Hispanic-Serving Institutions.* (a) In furtherance of the policy set forth in section 1 of this order, there is established within the Department of Education (Department) the White House Initiative on Advancing Educational Equity, Excellence, and Economic Opportunity Through Hispanic-Serving Institutions (Initiative), of which the Secretary of Education (Secretary) shall serve as Chair. The Secretary shall designate an Executive Director for the Initiative (Executive Director). The Executive Director shall manage the day-to-day operations of the Initiative, in consultation with the Assistant to the President and Director of the White House Office of Public Engagement, as appropriate, and coordinate with senior officials in the Executive Office of the President, who shall lend their expertise and advice to the Initiative.

(b) The Initiative shall advance educational equity, excellence, and economic opportunity through HSIs by focusing on the following goals:

- (i) identifying and promoting the availability of Federal programs and resources to enhance HSIs' educational capacity, including with respect to research and infrastructure development, while also breaking down barriers and expanding pathways for HSIs to access such programs and resources;
- (ii) identifying best practices for HSIs on developing, implementing, expanding, and sustaining strategies, programs, and initiatives that support the educational success and economic mobility of their students;
- (iii) improving the ability of HSIs to align their program offerings with the Nation's economic needs and promote opportunities for careers in critical professions, with an emphasis on increasing the number of students preparing for careers in in-demand and high-wage fields, such as science, technology, engineering, and math, as well as teaching, including bilingual and multilingual education;
- (iv) coordinating efforts to improve the fiscal security of HSIs;
- (v) developing new relationships, and fostering collaboration, among HSIs and philanthropic organizations, public- and private-sector organizations,

elementary and secondary education providers, labor unions, and other entities to improve postsecondary affordability and degree attainment, pathways for students to enroll in HSIs, career preparation at HSIs, and employment opportunities that advance economic mobility for HSI students and graduates;

(vi) strengthening Federal recruitment activities at HSIs to build accessible and equitable pathways into Federal career opportunities for HSI students, faculty, staff, and alumni;

(vii) encouraging HSIs, as institutions that provide students with degrees that lead to upward economic mobility, to participate in Federal policy-making processes;

(viii) encouraging the development of highly qualified, diverse, multilingual, and culturally responsive educators who support and instruct HSI students and contribute to effectively meeting those students' social, emotional, and academic needs; and

(ix) providing data, tools, and analytics to support HSIs in improving educational equity, excellence, and economic opportunity for students.

(c) On an annual basis, the Executive Director, in consultation with the Assistant to the President for Domestic Policy, shall report to the President on the Initiative's progress in carrying out its mission and function under this order.

(d) The Executive Director shall meet regularly with HSI students, leaders, and other representatives to discuss matters related to the Initiative's mission and function.

(e) The Department shall provide funding and administrative support for the Initiative to the extent permitted by law and within existing appropriations. To the extent permitted by law, including the Economy Act (31 U.S.C. 1535), and subject to the availability of appropriations, other executive departments and agencies (agencies) and offices may detail personnel to the Initiative to assist the Department in meeting the objectives of this order.

(f) To advance shared priorities and policies that advance educational equity, excellence, and economic opportunity through HSIs, the Initiative shall collaborate and coordinate with other White House Initiatives, including by sharing best practices on improving student success—including the success of Hispanic and Latino students—between HSIs and other institutions of higher education.

Sec. 3. *President's Board of Advisors on Hispanic-Serving Institutions.* (a) In furtherance of the policy described in section 1 of this order, there is established within the Department the President's Board of Advisors on Hispanic-Serving Institutions (Board).

(b) The Board shall consist of not more than 21 members, appointed by the President, and may include individuals who serve as representatives of their respective organizations and institutions, such as educational institutions, educational advocacy organizations, labor organizations, research institutions, public and private philanthropic organizations, private-sector organizations, nonprofit organizations, and community-based organizations. Members of the Board should be knowledgeable about the experiences of those who attend, work for, and work to strengthen HSIs.

(c) The President shall designate one member of the Board to serve as its Chair, and may designate another member of the Board to serve as Vice Chair. The Chair, in consultation with the Executive Director of the Initiative, shall convene regular meetings of the Board, determine the Board meeting agenda, and support the work of the Board consistent with this order.

(d) The Department shall provide funding and administrative support for the Board to the extent permitted by law and within existing appropriations. Members of the Board shall serve without compensation, but may

be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in the Government service (5 U.S.C. 5701–5707). Insofar as chapter 10 of title 5, United States Code (commonly known as the Federal Advisory Committee Act), may apply to the Board, any functions of the President under that Act, except that of reporting to the Congress, shall be performed by the Secretary, in accordance with guidelines issued by the Administrator of General Services.

(e) The Board shall provide advice to the President through the Secretary on how to advance the policy goals set forth in section 2(b) of this order, including with respect to:

(i) increasing the visibility of and participation by HSIs in Federal policy-making, including participation in Federal grant review processes;

(ii) providing HSIs, including those that have newly satisfied the criteria for the statutory definition, information about and access to Federal programs and Federal resources;

(iii) supporting the development of institutions on an enrollment trajectory to become an HSI, such as through mentorship with existing HSIs and sharing of best practices on how to improve the fiscal security of HSIs; and

(iv) establishing partnerships between HSIs and philanthropic organizations, public- and private-sector organizations, elementary and secondary education schools and their school districts, and labor unions.

(f) The Board shall periodically report to the President, through the Secretary and after consulting with the Executive Director, on the Board's progress in carrying out its mission and function under this order.

Sec. 4. Administrative Provisions. (a) As used in this order, the terms “Hispanic-Serving Institutions” and “HSIs” mean those institutions that meet the definition of “Hispanic-serving institution” in section 502(a)(5) of the Higher Education Act of 1965 (20 U.S.C. 1101a(a)(5)).

(b) The heads of agencies shall assist and provide information to the Initiative and the Board established in this order, consistent with applicable law, as may be necessary to carry out the functions of the Initiative and the Board.

(c) Each agency shall bear its own expenses of participating in the Initiative established in this order.

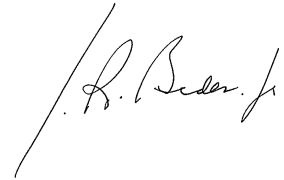
Sec. 5. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
July 17, 2024.

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