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U.S. GOVERNMENT
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FEDERAL REGISTER

Vol. 91 Friday,

No. 214 November 6, 2026

Pages 69955–70768

OFFICE OF THE FEDERAL REGISTER

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 270, 275, and 279

[Release Nos. IA–7035; IC–36380; File No. S7–2026–01]

RIN 3235–AN39

Amendments to the ''Small Business'' and ''Small Organization'' Definitions for Investment Companies and Investment Advisers for Purposes of the Regulatory Flexibility Act

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (the ''Commission'' or the ''SEC'') is amending the definitions of ''small business'' and ''small organization'' (collectively, ''small entities'') that are used in connection with Commission rulemaking under the Investment Company Act of 1940 (the ''Investment Company Act'') and the Investment Advisers Act of 1940 (the ''Advisers Act''). These definitions concern regulatory requirements applicable to registered investment companies and business development companies (collectively, ''funds'') as well as investment advisers. The definitions are used specifically for purposes of the Regulatory Flexibility Act (the ''RFA''), which requires the Commission to consider the impact of its regulations on small entities. The amendments are designed to modernize the definitions, by increasing certain asset-based thresholds, including a mechanism for periodic future inflation adjustments, and eliminating the threshold based on total assets for advisers. In connection with these amendments, the Commission is making conforming amendments to Form ADV as well as the rule that allows certain small SEC-registered advisers to apply for a continuing hardship exemption from making Advisers Act filings electronically.

DATES: This final rule was published in the **Federal Register** on November 6, 2026.

- Final amendments to 17 CFR 270.0–10 (''rule 0–10'') and 17 CFR 275.0–7 (''rule 0–7'') are effective February 4, 2027.
- Final amendments to 17 CFR 275.203–3 (''rule 203–3'') and 17 CFR 279.1 (''Form ADV'') are effective, and have a compliance date of, February 4, 2027.

FOR FURTHER INFORMATION CONTACT: Alexis Palascak, Senior Counsel, Sirimal R. Mukerjee, Senior Special Counsel, or Robert Holowka, Assistant Director, Investment Adviser Regulation Office, at (202) 551–6787, or Andrew Deglin, Senior Counsel, or Brian McLaughlin Johnson, Assistant Director, Investment Company Regulation Office, at (202) 551–6792, Division of Investment Management, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–8549.

SUPPLEMENTARY INFORMATION: The Commission is adopting amendments to the following rules and form:

CFR Citation (17 CFR)	Commission Reference	
17 CFR 270.0-10	Rule 0-10	Investment Company Act[1]
17 CFR 275.0-7	Rule 0-7	Advisers Act[2]
17 CFR 275.203-3(b)	Rule 203-3(b)	
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[1] 15 U.S.C. 80a–1 *et seq.*

[2] 15 U.S.C. 80b–1 *et seq.*

I. Introduction

We are adopting amendments to Commission rules that define a ''small entity'' under the RFA for funds and investment advisers by raising the asset thresholds contained in both definitions.[3] Specifically, the amendments to the Investment Company Act rule (rule 0–10) will increase the net asset threshold for

[3] Unless otherwise specified, the term ''investment companies'' or ''funds'' in this release refers collectively to registered investment companies and business development companies but not entities excluded from the definition of investment company under the Investment Company Act such as private funds.

funds to be considered ''small'' from $50 million to $10 billion and replace the ''group of related investment companies'' definition in the rule with ''family of investment companies,'' as that term is currently used in Form N–CEN. We are also adopting amendments to the Advisers Act rule (rule 0–7) that will increase the amount of regulatory assets under management (''RAUM'') below which an adviser is considered small from $25 million to $1 billion, eliminate the $5 million total assets threshold provision from the definition, and make conforming amendments to the adviser control relationship threshold to reflect the increased adviser RAUM threshold in the definition. Additionally, the amendments to Investment Company Act rule 0–10 and Advisers Act rule 0–7 will provide a mechanism for future inflation adjustments to the thresholds. Finally, the Commission is making conforming amendments to Form ADV and Advisers Act rule 203–3(b) for hardship exemptions to implement the amended adviser RAUM threshold. The final rules reflect comments the Commission received on amendments it proposed in January 2026 and will help the Commission more appropriately promote the effectiveness and efficiency of its regulations, with the goal of minimizing significant economic impact on small entities, consistent with the RFA.[4]

A. Background

The Commission has a longstanding commitment to understanding and addressing the concerns of small entities and has established the Office of Small Business Policy in the Division of Corporation Finance, the Office of the Advocate for Small Business Capital Formation, and the Small Business Capital Formation Advisory Committee to be responsive to such concerns.[5] In the context of rulemaking, the Commission tailors its regulations to the relevant characteristics of regulated entities and weighs the impact of its rules on small entities, including through performing analyses under the RFA.[6] A purpose of the RFA is to promote the effectiveness and efficiency of regulations, including through consideration of alternative regulatory approaches, with the goal of minimizing the significant economic impact on small entities consistent with the stated objectives of applicable statutes.[7] The Commission is required to determine if a rulemaking is likely to have a ''significant economic impact on a substantial number of small entities'' under the RFA.[8] Unless the Commission certifies that the rulemaking will not have such an impact, the Commission is required to conduct a regulatory flexibility analysis both during the proposal and final stages of adopting a rule.[9]

The Small Business Act gives the Administrator of the U.S. Small Business Administration (the ''SBA'') authority to establish small business size standards for all Federal agencies, in the absence of other specific statutory authority.[10] An agency may nevertheless prescribe its own small business size standard pursuant to section 601(3) of the RFA if, as described in 13 CFR 121.903(c), the agency consults with the SBA Office of Advocacy and the size standard will be used for the sole purpose of performing an RFA analysis.[11] Allowing agencies to establish their own definitions for the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction'' for purposes of the RFA analyses gives agencies flexibility in applying the provisions of the RFA.[12]

In 1982, the Commission adopted rule 0–10 for investment companies and rule 0–7 for investment advisers to define ''small business'' and ''small organization'' for purposes of Commission rulemakings under the Investment Company Act and Advisers Act, respectively.[13] These definitions were last amended in 1998[14] and, in connection with outreach to small entities, the Commission has subsequently received requests to update the definitions.[15]

Under rule 0–10, an investment company is deemed a small entity if it, together with other investment companies in the same group of related investment companies, has net assets of $50 million or less as of the end of its most recent fiscal year.[16] A group of related investment companies is defined, with respect to management companies, as two or more management companies (including series thereof) that (i) hold themselves out to investors as related companies for purposes of investment and investor services; and (ii) either (1) have a common investment adviser or have investment advisers that are affiliated persons of each other; or (2) have a common administrator.[17] Under rule 0–7, an investment adviser is deemed a small entity if it: (i) has RAUM[18] of less than $25 million (the ''RAUM Threshold'');[19] (ii) did not have total assets[20] of $5 million or more on the last day of the most recent fiscal year (the ''Total Assets Threshold''); and (iii) does not control, is not controlled by, and is not under common control with (a ''control relationship'') another investment adviser that has assets under management of $25 million or more, or

[4] *See* Amendments to the ''Small Business'' and ''Small Organization'' Definitions for Investment Companies and Investment Advisers for Purposes of the Regulatory Flexibility Act, Investment Company Act Release No. 35864 (Jan. 7, 2026) [91 FR 1107 (Jan. 12, 2026)] (the ''Proposing Release''). The comment letters on the Proposing Release (File No. S7–2026–01) are available at *https://www.sec.gov/rules-regulations/public-comments/s7-2026-01*. *See also* Enhancement of Emerging Growth Company Accommodations and Simplification of Filer Status for Reporting Companies, Release No. 33–11419 (May 19, 2026) [91 FR 30086 (May 21, 2026)] (''2026 Filer Status Release'') (among other things, proposing amendments to the ''small entity'' definitions for purposes of the Securities Act of 1933 and the Securities Exchange Act of 1934 (the ''Exchange Act'')).

[5] *See* Proposing Release, at n.1 (discussing the history of these Commission offices and the committee).

[6] *See* Proposing Release, at section I.A.1.

[7] Public Law 96–354, 2, Sept. 19, 1980, 94 Stat. 1164; 5 U.S.C. 601–612.

[8] *See* 5 U.S.C. 605(b). The RFA does not define ''significant economic impact'' or ''substantial number of small entities.''

[9] *See* 5 U.S.C. 603–604; *see also* 5 U.S.C. 605(b).

[10] 15 U.S.C. 632(a)(2). 15 U.S.C. 632(a)(1) sets forth the default standard for a ''small business concern'' as ''one which is independently owned and operated and which is not dominant in its field of operation.''

[11] 13 CFR 121.903(c); *see also* Small Business Size Regulations; Size Standards for Programs of Other Agencies, 67 FR 13714 (Mar. 26, 2002).

[12] 5 U.S.C. 601. Under the RFA, the term ''small entity'' has the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction'' as defined under the RFA, unless the agency has established a definition of such term. In the latter case, the definition of the term is instead what was established by the agency.

[13] *See* Final Definitions of ''Small Business'' and ''Small Organization'' for Purposes of the Regulatory Flexibility Act, Investment Company Act Release No. 12194 (Jan. 28, 1982) [47 FR 5215 (Feb. 4, 1982)] (''1982 Adopting Release''); *see also* Proposing Release, at section I.A.2 and I.A.3 (explaining the history of the Commission's investment company and investment adviser size standards).

[14] *See* Definitions of ''Small Business'' or ''Small Organization'' Under the Investment Company Act of 1940, Investment Advisers Act of 1940, the Securities Exchange Act of 1934, and the Securities Act of 1933, Investment Company Act Release No. 23272 (June 24, 1998) [63 FR 35508 (June 30, 1998)] (''1998 Adopting Release'').

[15] *See* Proposing Release, at n.10.

[16] *See* 17 CFR 210.6–04 (Regulation S–X section generally applicable to balance sheets filed by registered investment companies and business development companies, including requirements for disclosure of net assets).

[17] 17 CFR 270.0–10(a). In the case of unit investment trusts (''UITs''), a group of related investment companies is defined as two or more UITs (including series thereof) that have a common sponsor.

[18] RAUM are securities portfolios for which the adviser provides continuous and regular supervisory or management services. *See* Form ADV, Instructions for Part 1A, Instruction 5(b).

[19] *See* Proposing Release, at n.11 (discussing the basis for the use of the term ''regulatory assets under management'').

[20] *See* 17 CFR 275.0–7(b)(2); 1998 Adopting Release at n.42 (describing ''total assets'').

any person (other than a natural person) that had total assets of $5 million or more on the last day of the most recent fiscal year (the ''Control Relationship Threshold'').

In January 2026, the Commission proposed amendments to the investment company and investment adviser ''small entity'' definitions. Specifically, the Commission proposed to:

- Amend rule 0–10 for funds to: (i) increase the net asset threshold for funds from $50 million to $10 billion; and (ii) refer, for purposes of aggregating the net assets of related funds, to a ''family of investment companies'' as that term is used in Item B.5 of Form N–CEN rather than to a ''group of related investment companies'' as used in the current rule;
- Amend rule 0–7 for investment advisers to increase the RAUM Threshold below which an investment adviser is considered to be a ''small entity'' from $25 million to $1 billion and to conform the assets under management threshold in the Control Relationship Threshold with the revisions made to the RAUM Threshold;
- Amend Form ADV to revise the instructions and Item 12 of Part 1A of Form ADV, including through making conforming changes to Form ADV, and amend rule 203–3 providing a continuing hardship exemption from electronic filing requirements; and
- Amend rule 0–10 and rule 0–7 to allow the Commission to make subsequent inflation adjustments to the asset thresholds in these rules by order every 10 years in accordance with an inflation adjustment mechanism.

The Commission also requested comment on whether to amend the Total Assets Threshold, as well as the total assets threshold contained in the Control Relationship Threshold, in rule 0–7.

The Commission received approximately 20 comments on the proposed amendments. Commenters generally supported the proposal's goal to modernize the ''small entity'' definitions.[21] These commenters noted that the current rules are out of date and stated that the proposed amendments would help calibrate the Commission's analysis of the regulatory and compliance costs for small entities under the RFA.[22] Some commenters suggested modifications to the proposal, such as a higher fund net asset threshold, alternative non-RAUM Thresholds, different mechanisms for future threshold adjustments, elimination of the adviser Total Assets Threshold, or different treatment of certain entities.[23] Some commenters expressed concern that the proposal would diminish investor protections and suggested lower asset thresholds.[24] After consideration of the comments received, and as discussed in more detail below, the Commission is adopting the amendments largely as proposed but with some modifications in response to comments.

B. Overview of the Final Amendments

We are amending the definitions of ''small business'' and ''small organization'' under the Investment Company Act and the Advisers Act for purposes of the RFA, largely as proposed, but with modifications:

- Raising the Fund Net Asset Threshold. As proposed, the Commission is raising the net asset threshold for funds from $50 million to $10 billion.[25]
- Amending the Fund Group Definition. As proposed, the Commission is, for purposes of aggregating the net assets of related funds, replacing the term ''group of related investment companies'' with ''family of investment companies'' as that term is used in Item B.5 of Form N–CEN.
- Raising the Adviser RAUM Threshold. As proposed, the Commission is raising the RAUM Threshold from $25 million to $1 billion, and making conforming amendments to the Control Relationship Threshold to reflect the increased RAUM Threshold.[26] In a change from the proposal, the Commission is amending the Control Relationship Threshold to help advisers understand how to calculate the threshold.
- Eliminating the Adviser Total Assets Threshold. In a change from the proposal, the Commission is eliminating the $5 million Total Assets Threshold, and making conforming amendments to the Control Relationship Threshold to reflect that the Commission is eliminating the Total Assets Threshold.
- Periodic Inflation Adjustments. As proposed, the Commission is amending rule 0–10 and rule 0–7 to allow the Commission to make subsequent inflation adjustments to the asset thresholds by order every 10 years in accordance with the inflation adjustment mechanism set forth in section II.C below (the ''Inflation Adjustment Mechanism'').
- Conforming Amendments to Form ADV and the Hardship Exemption Rule. As proposed, the Commission is making conforming amendments to Form ADV, the uniform application for investment adviser registration and report form by exempt reporting advisers, and rule 203–3(b), which sets forth conditions for certain small SEC-registered advisers to apply for a continuing hardship exemption from the requirement to make Advisers Act filings electronically with the Investment Adviser Registration Depository (the ''IARD'').[27] The amendments are designed to reflect the Commission's amendments to the RAUM Threshold, the Control Relationship Threshold, and their corresponding periodic Inflation Adjustment Mechanism. In a change from the proposal, the Commission is also making additional conforming amendments to Form ADV and rule 203–3(b) to reflect the determination at adoption to eliminate the Total Assets Threshold.

Smaller firms play an important role in the asset management industry.[28] We are mindful that smaller firms may face disproportionate compliance burdens compared to larger firms.[29] For example, compliance costs—such as staff time, recordkeeping, cybersecurity costs, and reliance on outside expertise or market data—often do not scale with firm size,[30] and have increased, while client fees have decreased.[31] We also are mindful that failure to consider the impact of regulations on small entities could risk reducing innovation, competitiveness, and new market

[21] *See, e.g.,* Comment Letter of the Investment Company Institute (Mar. 13, 2026) (''ICI Comment Letter''); Comment Letter of MFA (Mar. 13, 2026) (''MFA Comment Letter''); Comment Letter of the Independent Directors Council (Mar. 13, 2026) (''IDC Comment Letter'').

[22] *See, e.g.,* Comment Letter of the National Venture Capital Association (Mar. 11, 2026) (''NVCA Comment Letter''); Comment Letter of the Small Business Investor Alliance (Mar. 16, 2026) (''SBIA Comment Letter'').

[23] *See, e.g.,* ICI Comment Letter; Comment Letter of Proskauer Rose LLP (Mar. 13, 2026) (''Proskauer Comment Letter''); Comment Letter of the Committee of Annuity Insurers (Mar. 10, 2026) (''CAI Comment Letter'').

[24] *See, e.g.,* Comment Letter of the Public Investors Advocate Bar Association (Mar. 16, 2026) (''PIABA Comment Letter''); Comment Letter of Better Markets (Mar. 13, 2026) (''Better Markets Comment Letter'').

[25] Final 17 CFR 270.0–10.

[26] Final 17 CFR 275.0–7.

[27] *See infra* footnote 127, and accompanying text (defining ''exempt reporting advisers'').

[28] Commenters agreed and stated, for example, that smaller funds offer innovation, and smaller advisers employ diverse investment philosophies and portfolio construction approaches, which broadens investor choice. *See, e.g.,* ICI Comment Letter.

[29] *See, e.g.,* Comment Letter of the Investment Adviser Association (Mar. 13, 2026) (''IAA Comment Letter'').

[30] *See, e.g.,* MFA Comment Letter.

[31] *See, e.g.,* Comment Letter of Garcia Hamilton & Associates, L.P. (Mar. 12, 2026) (''Garcia Hamilton Comment Letter'').

participants.[32] The Commission tailors its regulations to the relevant characteristics of regulated entities and weighs the impact of its rules on small entities, including through performing regulatory flexibility analysis under the RFA.

The final amendments are designed to help ensure the Commission's RFA analyses capture a more meaningful population of ''small entities'' so the Commission can continue to address the special concerns of small businesses. Updating the definitions of ''small business'' and ''small organization'' is appropriate to reflect the substantial growth in, and distribution of, regulatory assets under management and net assets over the decades since these thresholds were set.[33] The updates to the definitions reflect more reliable and consistent metrics for whether an adviser or fund is small, compared to those in the current rules.

Some commenters stated that the proposed amendments would classify too many funds or advisers as small (effectively leading the Commission to prioritize benefits of large funds and advisers instead of truly small funds and advisers),[34] or otherwise could result in regulatory arbitrage between investment advisers and broker-dealers [35] and diminish investor protections.[36] As explained below, the final amendments will not classify too many funds or advisers as small. The final amendments also will not diminish investor protections. Designating an entity as a small entity does not reduce investor protection. Investor protection is a concern regardless of the size of an entity. The purpose of the small entity definition is, in part, to ensure that the Commission considers whether its rules are appropriately calibrated so that smaller entities are not subject to regulations that may be disproportionately burdensome relative to the benefits or improvements in investor protection. The final amendments will enhance the Commission's rulemaking process by helping ensure the RFA analyses reflect current economic realities by incorporating the evolution of adviser and fund growth since the rules were first adopted, as other commenters stated.[37]

One commenter stated that the proposal did not appear to evaluate the investor-protection consequences of the proposed amendments and asserted the proposal focused primarily on industry size, rather than regulatory risk or compliance capacity. It outlined certain areas that the Commission should quantify and analyze in this regard, in particular to focus any regulatory relief on genuinely small entities and in a risk-based manner.[38] Because the final amendments primarily affect the process by which the Commission considers potential impacts on small entities, including benefits and costs of future rulemaking on small entities, the final amendments will not have any immediate impact on investor protection. Rather, the final amendments will require the Commission to consider and address the potential impacts of future rulemaking on small entities, including effects on investor protection.

Separately, the methodology for the proposed thresholds reflects that advisory fees are generally scaled with an adviser's assets under management, where greater advisory fees can support an increased compliance capacity. The updated thresholds also will allow the Commission to more appropriately address in future rulemakings, in a risk-based manner, concerns that are unique to those entities that should be deemed small entities in view of the growth in assets since the rules were adopted and the appropriateness of any regulatory accommodations that may be provided to small entities.

While conducting RFA analyses in future rulemakings, the Commission can take into account any potential for regulatory arbitrage between broker-dealers and investment advisers and adjust its future rules accordingly. The Commission carefully weighs the economic impact of its rules on all regulated entities, including small businesses, and tailors its regulations to the relevant characteristics of the particular entities regulated. In this way, the Commission works to meet its mandate under the Federal securities laws while at the same time considering any potentially disproportionate costs and regulatory burdens for small entities. The Commission intends to continue this careful, measured regulation that addresses small business concerns within the protections of the Federal securities laws.

II. Discussion

A. Amendments to Rule 0–10 Under the Investment Company Act

1. Raising the Net Asset Threshold

The Commission is amending the net asset threshold for small funds, as proposed. The final rule will amend paragraph (a) of rule 0–10 to increase the net asset threshold from $50 million to $10 billion and, as discussed in more detail in section II.C below, establish a mechanism to inflation-adjust this figure every ten years. The increase accounts for the overall growth in the fund industry since the $50 million threshold was originally set in 1982.[39] At that time, 62.4% of funds were deemed ''small entities,'' but by 2024, the share of funds deemed ''small entities'' had fallen to 0.6%.[40] Raising the net asset threshold in rule 0–10 to reflect growth in the investment company industry over the past decades will improve the utility of RFA analyses by more closely reflecting the population of funds that does not have the same competitive advantages as larger fund families (for instance, due to economies of scale when these larger families perform certain compliance and other operational functions in-house).[41] It also will more closely reflect the population of funds that does not have the same negotiating power as larger

[32] *See, e.g.,* Comment Letter of the CFP Board, Financial Planning Association, *et al.* (Mar. 13, 2026) (''CFP Board Comment Letter'').

[33] *See infra* section II.A.1 and section II.B.1.

[34] *See, e.g.,* PIABA Comment Letter.

[35] Comment Letter of the Securities Industry and Financial Markets Association (Mar. 13, 2026) (''SIFMA Comment Letter'') (noting the differences between the regulatory frameworks applicable to broker-dealers and investment advisers and stating that regulatory arbitrage is a contributing factor driving the shift from broker-dealer to registered investment adviser frameworks).

[36] PIABA Comment Letter.

[37] *See e.g.,* IAA Comment Letter. One commenter expressed concern that the proposal would be inconsistent with an Executive Order and other Federal efforts to make housing affordable. This commenter expressed concern that reclassifying billion-dollar advisers and multi-billion-dollar fund families as ''small'' for securities rulemaking works at cross purposes with efforts to curb large institutional purchases of single-family homes. *See* Comment Letter of Angela Dowell (Feb. 26, 2026) (''Dowell Comment Letter'') (citing, for example, ''Stopping Wall Street From Competing with Main Street Homebuyers,'' Donald J. Trump Executive Order, Jan. 20, 2026, *available at https://www.whitehouse.gov/presidential-actions/2026/01/stopping-wall-street-from-competing-with-main-street-homebuyers/*). We disagree that the final amendments will be inconsistent with the Executive Order or other Federal efforts to make housing affordable. The plain language of the current and final rules limits the application of the definitions, stating that the definitions of ''small business'' and ''small organization'' are for purposes of Commission rulemaking in accordance with the provisions of Chapter Six of the Administrative Procedure Act, unless otherwise defined for purposes of a particular rulemaking.

[38] Comment Letter of James E. Scarborough (Mar. 12, 2026) (''Scarborough Comment Letter'') (requesting analysis of investor exposure, regulatory relief consequences, risk-based threshold alternatives, and regulatory gap risk).

[39] *See* Proposing Release, at nn.50–55 and accompanying text.

[40] *See* 1982 Adopting Release; Proposing Release, at n.55 (85 small entities/13,630 total registered investment companies and BDCs = 0.6%).

[41] Unless stated otherwise, the use of the term ''fund family'' or ''fund families'' in this release has the same meaning as ''family of investment companies.''

fund families when retaining service providers to perform compliance and operational functions.

In determining how to calibrate the amended threshold, the Commission considered the distribution of assets across individual funds and fund families, with the goal of ensuring that the proportion of funds that may face greater challenges in complying with Commission regulations due to their size be included in the small entity definition. Specifically, the Commission analyzed data reported on Form N–CEN to sort families of investment companies into percentiles according to their cumulative average total net assets. The Commission further analyzed this data to determine the percentage of individual funds and the percentage of average total net assets represented by each percentile.[42] At proposal, the Commission estimated that, as of December 2024, fund families at or below the 80th percentile threshold of $10.04 billion in net assets accounted for 22.91% of individual funds and only 2.13% of fund assets.[43] The analysis that formed the basis for the proposed threshold reflects that the assets of the investment company industry are heavily concentrated at the largest fund families, and these largest fund families not only manage a large majority of assets in the industry, but also account for a majority of the individual funds.[44]

Most commenters supported generally raising the net asset threshold from the current level to account for growth in the industry.[45] Several commenters supported raising the net asset threshold to $10 billion in particular, stating that this threshold appropriately reflects current market size and structure.[46] One of the commenters specifically expressed its support for the distribution-based methodology used to reach the proposed $10 billion threshold for funds.[47] This commenter, while supporting the proposal, further encouraged the Commission to adjust the threshold to $12 billion to account for growth in the industry since the date of the data underlying the proposal. Some other commenters expressed concerns that $10 billion is too high, one of whom requested that the Commission quantify and analyze the investor-protection consequences of the higher threshold and another expressed concerns about the effects of entities with billions of dollars in assets being deemed to be ''small'' (*i.e.,* very large firms could receive regulatory accommodations intended for smaller firms with limited regulatory capacity, which the commenter indicated could cause smaller firms to lose the advantages the RFA provides them and have negative investor protection consequences).[48] One commenter suggested adjusting the thresholds adopted in the 1998 amendments for inflation, resulting in a $100 million threshold, or alternatively using the SBA's small entity standard based on $40 million in gross receipts.[49] Another commenter, asserting that the proposed threshold is too high, suggested defining ''small entities'' as those at or below the 20th percentile of aggregate fund family net assets using a distribution methodology based on Form N–CEN data.[50]

After considering these comments, we are, as proposed, raising the net asset threshold to $10 billion for funds. We agree with commenters' statements that the increased threshold would better reflect the growth in the fund industry and aid the Commission's analysis of regulatory and compliance costs on small funds.[51] Based on analysis of the distribution of data discussed above, we are adopting a ''small entity'' definition that incorporates a $10 billion net asset threshold, which continues to correspond to the 80th percentile threshold in that distribution-based analysis.[52] While the amended threshold will deem some relatively large individual funds ''small'' for purposes of the RFA, such an outcome is consistent with the economies of scale rationale for aggregating funds within a family. A single large fund with no other related funds will bear similar regulatory costs to several smaller, related funds that collectively represent a similar level of net assets. Therefore, aggregating assets across fund families reflects the Commission's understanding that funds within a complex typically use the same administrative, management, and compliance systems to oversee all the funds within the complex, so fees imposed on the fund by the adviser or administrator typically reflect economies of scale that the adviser or administrator achieves from managing other funds.

While the Commission seeks to ensure that funds and fund families that may face greater challenges with regulatory compliance due to their size be deemed small entities, we are also mindful that setting the threshold too high has the potential to be counterproductive and to undermine the purpose of the Commission's RFA analyses. A higher threshold would result in a larger pool of small entities and therefore would increase the number of small entities needed to be affected by a rule for the rule to ''have a significant economic impact on a substantial number of small entities,'' which could lead to fewer RFA analyses being performed.[53] Setting the threshold too high might also inadvertently lead to the Commission overlooking issues that concern the smallest entities when the Commission attempts to tailor its rules, and instead focusing primarily on issues of more general concern to the industry. Such an outcome might have the potential to perpetuate larger funds' advantages in the market, to the detriment of the smaller funds that the RFA was designed to protect.[54] Accordingly, the Commission's amended threshold is meant to identify a level below which a meaningful proportion of funds would be deemed small entities, but above which the size of, and concentration of assets in, fund families increases to such an extent that treating individual funds within those families as small entities would not be consistent with the goals of the RFA. We are therefore not adopting a smaller threshold than the proposed $10 billion threshold. We are also therefore not adopting a threshold of $12 billion as one commenter suggested. We do not believe this change from the proposed

[42] *See* Proposing Release, at section II.A.1.

[43] *See* Proposing Release, at n.60; Table 1 and accompanying text. The data the Commission presented in the proposing release continues to represent the distribution of fund families, individual funds, and fund assets. *See also infra* footnote 52 and accompanying text.

[44] The SBA considers economic characteristics composing the structure of an industry such as degree of competition, average firm size, start-up costs and entry barriers, and distribution of firms by size in establishing size standards. *See* 13 CFR 121.102. We have focused our analysis on the distribution of firms by size, as that is the metric for which we have the best available data.

[45] *See e.g.,* Comment Letter of Federated Hermes, Inc. (Mar. 12, 2026) (''Federated Hermes Comment Letter''); CAI Comment Letter; Proskauer Comment Letter.

[46] *See e.g.,* IDC Comment Letter; Comment Letter of the American Securities Association (Mar. 13, 2026) (''ASA Comment Letter'').

[47] ICI Comment Letter.

[48] *See e.g.,* Better Markets Comment Letter; Scarborough Comment Letter.

[49] Better Markets Comment Letter.

[50] Dowell Comment Letter.

[51] *See e.g.,* IDC Comment Letter.

[52] Based on Form N–CEN data as of December 2025, fund families at or below the 80th percentile threshold of $10.59 billion in net assets similarly accounted for 22.6% of individual funds and 2.1% of fund assets.

[53] *See* 5 U.S.C. 605(b); *see also, e.g.,* 1982 Adopting Release, *supra* footnote 13, at n.41 and accompanying text (stating, in the context of the AUM threshold for investment advisers, ''the bigger the class, the greater the number of entities within it that must be adversely affected by a particular rulemaking before it can be said that the rulemaking affects a 'substantial' number of the class'').

[54] *See* discussion at *supra* footnotes 7–9 and accompanying text.

approach, based on one-year market movements, would be appropriate, as the proposed threshold was designed to be stable and flexible enough to guide Commission analysis for the next 10 years and not to reflect short-term market fluctuations.

We are not adjusting the current threshold for inflation, as some commenters suggested, but rather are retaining the proposed distribution-based methodology as the basis for the final rules' threshold adjustment. A net asset threshold of $100 million (the result of inflation-adjusting the current rule's threshold) would cover less than 3% of funds and less than .03% of fund assets and would constrain future Commission analysis of small entity issues to this limited group.[55] Further, we are not adopting a threshold based on a gross receipts analysis. As discussed in the Proposing Release, gross receipts are not well suited to the fund industry, primarily because the Commission does not have or collect data for gross receipts of registered investment companies.[56] As the Proposing Release also discussed, funds primarily generate revenue through capital appreciation and other investment returns rather than receipts from the sale of goods or services, and a fund's investment returns may be attributable primarily to its particular investment strategy, meaning that two funds of identical size but pursuing different investment strategies may produce vastly different returns.[57] Commenters did not address or dispute these rationales for using an approach other than a gross receipts analysis.

We are also not adopting an approach that defines small entities as fund families with net assets at or below the 20th percentile as determined annually. The $10 billion net asset threshold and corresponding percentile we are adopting were derived from a distribution analysis particular to that data and set of facts and, therefore, is not necessarily indicative of the proportion of funds that should be deemed small entities in the future. A fixed percentile may become stale over time as the size and distribution of fund family net assets changes. Additionally, as discussed above, we continue to believe that a lower net asset threshold would not appropriately define ''small entities'' for future Commission analysis.[58]

Some commenters recommended aligning the adviser and fund thresholds so that if either a fund or an adviser qualifies as small, both would be treated as small.[59] These commenters expressed concerns that a mismatch between the fund and adviser thresholds could produce anomalous outcomes where, for example, an adviser managing a few billion dollars is not considered ''small,'' while the funds it manages are. We continue to believe that independent asset thresholds for advisers and funds are appropriate. Advisers and funds are separate industries with different regulatory requirements and resources available to comply with these requirements. Therefore, the status of a fund as small and not dominant in its field is not indicative of its adviser being similarly situated, or vice versa.

2. Group Definition Amendments

As proposed, we are amending rule 0–10 to replace the term ''group of related investment companies'' with ''family of investment companies,'' as that term is used in Item B.5 of Form N–CEN.[60] Currently, while the ''small entity'' designation applies to individual funds, whether any individual fund is deemed small depends upon the aggregate net assets of all funds within its respective ''group of related investment companies.'' The change from using the term ''group of related investment companies'' to using ''family of investment companies'' in the small entity definition will enable the Commission to rely on information that is already reported on Form N–CEN to identify small entities for purposes of RFA analyses and to more efficiently consider whether future adjustments to the net asset threshold are warranted. For comparison, the table below provides the existing definition of ''group of related investment companies'' from rule 0–10 alongside the existing definition of ''family of investment companies'' from Form N–CEN:

[55] Proposing Release, at n.59 and accompanying text (table showing the distribution of assets across funds and fund families by percentile).

[56] Proposing Release, at n.63 and accompanying text.

[57] *See id.*

[58] *See supra* footnotes 52, 54–55 and accompanying text.

[59] *See* Federated Hermes Comment Letter; ICI Comment Letter; IDC Comment Letter.

[60] *See* final 17 CFR 270.0–10(a)–(b); proposed 17 CFR 270.0–10(a)–(b). Item B.5 of Form N–CEN requires investment companies to report whether they are part of a ''family of investment companies'' and, if so, to disclose the full name of the family of investment companies.

Table 1

"Group of Related Investment Companies"	"Family of Investment Companies"
(a) . . . (1) In the case of a management company, ***group of related investment companies*** means two or more management companies (including series thereof) that: (i) Hold themselves out to investors as related companies for purposes of investment and investor services; and (ii) Either: (A) Have a common investment adviser or have investment advisers that are affiliated persons of each other; or (B) Have a common administrator **(2)** In the case of a unit investment trust, the term ***group of related investment companies*** shall mean two or more unit investment trusts (including series thereof) that have a common sponsor. **(b)** ***Special rule for insurance company separate accounts.*** In determining whether an insurance company separate account is a *small business* or *small entity* pursuant to paragraph (a) of this section, the assets of the separate account shall be cumulated with the assets of the general account and all other separate accounts of the insurance company.	"Family of investment companies" means, except for insurance company separate accounts, any two or more registered investment companies that: (i) share the same investment adviser or principal underwriter; and (ii) hold themselves out to investors as related companies for purposes of investment and investor services. Insurance company separate accounts that may not hold themselves out to investors as related companies (products) for purposes of investment and investor services should consider themselves part of the same family if the operational or accounting or control systems under which these entities function are substantially similar.

Commenters expressed support for the proposed changes.[61] They agreed that the Commission should leverage data that is already collected in Form N–CEN, so as not to impose the additional burden of a new reporting requirement related to the ''group of related investment companies'' definition.[62] Some commenters, while expressing support for the proposed changes, also offered views on how the ''family of investment companies'' definition in Form N–CEN might be improved.[63]

After considering commenters' input, we are adopting a final definition that uses ''family of investment companies,'' as proposed. As described in the Proposing Release, the definition of ''family of investment companies'' serves a substantially similar purpose to the definition of ''group of related investment companies'' in seeking to group together funds that hold themselves out to investors as related (the ''holding out prong'') and that share an investment adviser or key service provider (an administrator for a ''group of related investment companies'' or underwriter for a ''family of investment companies'').[64] We acknowledge that specific differences from the ''group of related investment companies'' concept may produce different outcomes at the margins, such as the extent to which an insurance company's separate account is aggregated (with the insurance company's general account, as well as with other separate accounts) to determine whether individual separate accounts are small entities.[65] Notwithstanding the differences between the two terms, we continue to anticipate, as discussed in the Proposing Release, that funds that are part of the same ''family of investment companies'' are likely to experience similar economies of scale as those funds that are part of the same ''group of related investment companies.'' Examples of potential cost savings due to economies of scale might include complex-wide policies and procedures and recordkeeping systems, a shared chief compliance officer or board members, and one legal and compliance function that services the whole complex.

We are not amending the current definition of ''family of investment companies'' in Form N–CEN as some commenters have suggested. One commenter suggested amending the Form N–CEN definition so that it does not aggregate funds based on a shared principal underwriter, stating that funds that share an underwriter do not necessarily share compliance infrastructure.[66] This commenter, however, did not address the second prong of the Form N–CEN definition that requires registered investment companies to hold themselves out as related companies for purposes of investment and investor services in order to be grouped in the same family of investment companies, which in our view is likely indicative that two funds share compliance and operational infrastructure. Another commenter suggested that the Form N–CEN definition should aggregate separate accounts if they have the same insurance company sponsor or depositor, similar to the current ''group of related investment companies'' definition that aggregates assets of the general account and all other separate

[61] *See, e.g.,* ICI Comment Letter; CAI Comment Letter; IDC Comment Letter.

[62] *Id. See also* Proposing Release, at n. 77 and accompanying text.

[63] *See* Comment Letter of Rohan Sharma (Jan. 27, 2026) (''Sharma Comment Letter''); CAI Comment Letter.

[64] Proposing Release, at nn.69–71 and accompanying text.

[65] Proposing Release, at nn.74–75 and accompanying text (discussing the treatment of insurance company separate accounts under the current and proposed definitions); *see also* Proposing Release, at nn.72–73 and accompanying text (discussing the treatment of UITs under the current and proposed definitions).

[66] Sharma Comment Letter.

accounts of the insurance company.[67] While this commenter stated that this approach would be appropriate because the financial guarantees of variable contracts issued by the same insurance company are backed by the financial strength and claims-paying ability of the same general account, regardless of whether those contracts are supported by different separate accounts, the commenter did acknowledge that the suggested change would likely not significantly change how separate accounts are grouped for small entity definitional purposes.

As other commenters have noted, leveraging data from an existing definition does not impose an additional burden on registrants of having to amend their filings. If we were to amend Form N–CEN as these two commenters suggest, registrants would have to review and possibly amend their filings, reducing or eliminating the benefit of using existing data. Our final approach reflects a view that the burden on other registrants of amending Form N–CEN would not provide commensurate benefits in any incremental improvements to the Commission's analysis of small entities. Further, the ''family of investment companies'' definition from Form N–CEN and associated data collection have long been used in assisting the Commission's analysis of multiple funds across the same family of investment companies.[68]

B. Amendments To Rule 0–7 Under the Advisers Act

1. The RAUM Threshold

As proposed, the final amendments will raise the RAUM Threshold from $25 million to $1 billion and add the Inflation Adjustment Mechanism.[69] Rule 0–7 currently provides that an adviser is a small entity if it has assets under management of less than $25 million ''or such higher amount as the Commission may by rule deem appropriate under Section 203A(a)(1)(A) of the Act.'' [70] As proposed, the final amendments remove the phrase ''or such higher amount as the Commission may by rule deem appropriate under Section 203A(a)(1)(A) of the Act (15 U.S.C. 80b–3a(a)(1)(A)).'' [71] The final amendments are designed to update the RAUM Threshold to reflect the growth of advisers' assets under management over time.[72]

a. Consideration of Alternative Non-RAUM Thresholds

As proposed, the final amendments use an RAUM-based metric for threshold purposes. In the Proposing Release, we discussed feedback the Commission received suggesting alternatives to an asset-based approach to identifying small advisers and requested comment on alternatives to the RAUM Threshold.[73] Some commenters suggested the Commission should replace the RAUM Threshold with a non-RAUM threshold, such as a threshold based on revenue,[74] number of employees,[75] officers, owners, clients, non-accredited investors, or a combination thereof.[76] These commenters expressed concern that RAUM may not reflect the breadth of compliance resources that advisers may or may not have available.[77] According to these commenters, certain other non-RAUM-based thresholds would better evidence compliance burdens and risks of small advisers.[78] Other commenters opposed replacing the RAUM Threshold with a non-RAUM-based threshold.[79]

After considering comments, we are not persuaded to replace the RAUM Threshold with a non-RAUM-based threshold.[80] The Commission has long used RAUM to appropriately differentiate between small and other advisers to identify a universe of entities that are not dominant in the field, a principal element of the small entity status under the RFA.[81] As some commenters stated, RAUM is a meaningful proxy for business scale and compliance capacity,[82] and RAUM metrics directly correlate to the financial resources available for compliance.[83]

In contrast, a non-RAUM-based threshold would not be as reliable a metric to determine whether an adviser is small for RFA purposes as an RAUM-based threshold. An employee-based standard raises implementation challenges in appropriately addressing the use of service providers and outsourcing by investment advisers, which could distort the extent to which the number of an adviser's own employees reflects its actual resources and size. A commenter agreed, stating that an employee-based metric would penalize operational efficiency and outsourcing.[84] This commenter cautioned that moving to an employee-based metric would incentivize the misclassification of staff as contractors to maintain ''small entity'' status. Similarly, a threshold based on the number of clients or non-accredited investors also would not necessarily reflect an adviser's ability to devote resources towards compliance.[85] For example, while an adviser could have only one fund as a client, that fund could be large both by RAUM and number of investors resulting in the adviser maintaining the capacity to devote significant resources towards compliance-related matters. Conversely, an adviser may have a large number of clients, but those clients' assets could represent a small amount of RAUM, so that the adviser would not have economies of scale comparable to a larger adviser with significantly more RAUM. Likewise, we are not persuaded

[67] CAI Comment Letter. *See also* 17 CFR 270.0–10.

[68] *See* Proposing Release, at n.71 and accompanying text (explaining that this definition has been used by the Commission and registrants since 1985).

[69] We discuss the Inflation Adjustment Mechanism in section II.C; final 17 CFR 275.0–7(a)(1).

[70] 17 CFR 275.0–7(a)(1).

[71] In a change from the proposal, we are correcting an erroneous cite in 17 CFR 275.0–7(a)(1), so instead of erroneously citing to 15 U.S.C. 80b–3a(a)(2), it correctly cites to 15 U.S.C. 80b–3a(a)(3), which defines ''assets under management'' under the Advisers Act.

[72] Proposing Release at section II.B.1 for a discussion of the growth of advisers' assets under management over time.

[73] Proposing Release at section II.B.1.

[74] Garcia Hamilton Comment Letter (supporting a revenue-based threshold); *but see, e.g.,* IAA Comment Letter (opposing a revenue-based threshold).

[75] *See e.g.,* CFP Board Comment Letter (supporting an employee-based threshold), *but see, e.g.,* Sharma Comment Letter (opposing an employee-based threshold).

[76] *See e.g.,* Comment Letter of Neil Patrick Murphy (Feb. 8, 2026) (''Murphy Comment Letter'') (supporting a flexible non-RAUM-based threshold), *but see, e.g.,* Sharma Comment Letter (supporting an RAUM-based threshold). A commenter recommended that the Commission should consider ''risk-based threshold alternatives'' such as ''investor exposure,'' and appeared to define ''investor exposure'' as ''total investor assets managed by firms.'' *See* Scarborough Comment Letter. While it appears the commenter was recommending an RAUM-based threshold, given that the commenter suggested the Commission analyze investor exposure, which it defined as ''total investor assets managed by firms,'' the Commission also has considered a total assets based threshold, as well as other types of investor exposure-based thresholds, and we continue to believe that an RAUM-based threshold is the most reliable indicator of whether an adviser is small, for the reasons discussed in this release.

[77] *See e.g.,* CFP Board Comment Letter.

[78] *See e.g.,* CFP Board Comment Letter.

[79] *See e.g.,* Sharma Comment Letter.

[80] Given that the Commission is maintaining an RAUM-based threshold, we are not persuaded to impose additional reporting requirements such as data concerning revenue, as one commenter recommended. *See* Garcia Hamilton Comment Letter.

[81] *See* Proposing Release at section II.B.1.

[82] Proskauer Comment Letter (stating that for advisers, RAUM is a much more meaningful proxy for business scale and compliance capacity, not the amount of assets carried on the adviser's balance sheet).

[83] Sharma Comment Letter.

[84] Sharma Comment Letter.

[85] Murphy Comment Letter.

that a threshold based on the number of officers or owners would be a meaningful measure of adviser size for RFA purposes, because those metrics do not directly relate to how an adviser would scale resources in connection with compliance. A revenue-based threshold also would not provide as meaningful a measure of adviser size for RFA purposes as an RAUM-based threshold. Advisers have diverse fee structures, and as a result, annual receipts may not correlate with firm scale, operational complexity, or available compliance resources. A commenter agreed, stating that revenue recognition practices may differ among firms depending on their accounting methods, further reducing comparability and administrative simplicity.[86]

The Commission has ready access to RAUM data for the types of advisers that are generally subject to our rules, not just those registered with us.[87] Commenters agreed, with one commenter stating that it supported the RAUM-based threshold, in part, because it was readily available to the Commission.[88] For example, while the Commission collects RAUM information from both SEC-registered advisers and exempt reporting advisers, it does not collect revenue information from either type of adviser, and it does not collect employee counts from exempt reporting advisers.[89]

Using RAUM to distinguish between advisers is an approach that is broadly consistent with size standards generally under the Advisers Act and the rules thereunder, as well as advisers' existing reporting and compliance obligations. Congress has repeatedly differentiated the regulations to which an adviser is subject by using assets under management thresholds as size standards under the Advisers Act. For example, Advisers Act section 203(m) sets forth an assets under management threshold for the private fund adviser exemption from registration, and Advisers Act section 203A(a)(2) sets forth an assets under management threshold for mid-sized advisers. Some commenters agreed.[90] For example, one commenter stated that it appreciated the Commission's explanation for proposing to maintain an RAUM-based threshold, including the view that RAUM aligns with existing regulatory frameworks.[91] Another commenter supported maintaining an RAUM metric, in part, because it is well understood and widely used.[92]

A commenter recommended that, no matter the approach, the Commission should establish a structured methodology that grounds any definition of ''small entity'' in empirical data.[93] The final amendments to the RAUM Threshold address this comment because they help ensure that rule 0–7 continues to use a structured methodology that grounds the definition of ''small entity'' in empirical data, namely RAUM, as discussed more fully in section II.B.1.b.

b. The $1 Billion RAUM Threshold

As proposed, we are raising the RAUM Threshold from $25 million to $1 billion. Commenters generally agreed that the current RAUM Threshold is too low.[94] Most commenters supported raising the RAUM Threshold to correct the misalignment between the current threshold and the current economic reality created by decades of industry growth,[95] the fact that capital has become concentrated among a small number of advisers,[96] and the structural changes in the investment management industry since the 1998 amendments, including that in 2010, the Dodd-Frank Act raised the SEC-registration threshold, resulting in fewer smaller advisers registering with the Commission.[97] In contrast, one commenter asserted it is counterintuitive that advisers' significantly increased RAUM supports their designation as small entities.[98] Another commenter stated that the Commission should not base the RAUM Threshold on the fact that there are some very large advisers.[99]

We continue to believe that the current RAUM Threshold is too low. The final RAUM Threshold is designed to capture the types and numbers of investment advisers that the Commission now considers to be ''small'' in light of industry growth since the 1998 amendments.[100] We disagree that industry asset growth or the presence of very large advisers undermines basing ''small entity'' status on an RAUM Threshold or the particular RAUM Threshold we are adopting.[101] It is appropriate to consider the size of the investment management industry as a whole, as well as how the size is distributed across advisers, in determining adviser size thresholds under the RFA, because it helps ensure that such size thresholds are relevant to the adviser industry. What is ''small'' is an inherently relative exercise, and in an industry that ranges to very large advisers managing trillions of dollars in assets, even small advisers may manage sizeable amounts of assets. As discussed below, the distribution of advisory assets skewing heavily towards large advisers only exacerbates this effect.

Most commenters supported raising the adviser RAUM Threshold specifically from $25 million to $1 billion, saying that the proposed threshold would better reflect current market realities.[102] Others expressed concern that the proposed threshold would be too high because it would classify too many advisers as small.[103] One commenter cautioned that the Commission should not raise the adviser RAUM Threshold any higher than the proposed $1 billion threshold because it would obscure the impacts of rulemaking on small entities and deprive the public of a clear articulation of, and opportunity to comment on, those impacts.[104]

Some commenters recommended increasing the RAUM Threshold by a lesser amount than proposed.[105] For example, a commenter recommended that the Commission should increase the current RAUM Threshold for inflation since the 1998 amendments, instead, raising it to about $50 million.[106] Another commenter recommended amending the RAUM Threshold to align with the lowest 20th

[86] IAA Comment Letter.

[87] *See* Proposing Release at section II.B.1.

[88] *See, e.g.,* ICI Comment Letter.

[89] *See* Form ADV, General Instruction 3; Item 2 of Part 1A; Item 5 of Part 1A; section 7.B. of Schedule D of Part 1A; Proposing Release at n.82 (describing exempt reporting adviser reporting).

[90] *See, e.g.,* IAA Comment Letter.

[91] IAA Comment Letter.

[92] ICI Comment Letter.

[93] *See* CFP Board Comment Letter.

[94] *See, e.g.,* ASA Comment Letter. Some commenters appeared to confuse the adviser RAUM Threshold with the SEC's adviser registration threshold, and opposed the proposed increase on that basis. *See, e.g.,* Comment Letter of Gallatin & Company, LLC (Feb. 19, 2026) (''Gallatin Comment Letter''). Most commenters, however, appeared to understand the distinction between the RAUM Threshold and the SEC-registration threshold. *See, e.g.,* SIFMA Comment Letter. Some commenters also cautioned the Commission to not raise the SEC-registration threshold. *See, e.g.,* CFP Board Comment Letter. The Commission did not propose to increase the SEC-registration threshold in the Proposing Release, and the Commission is not amending the SEC-registration threshold.

[95] *See, e.g.,* Comment Letter of Logos Research Centre (Mar. 13, 2026) (''Logos Comment Letter'').

[96] *See, e.g.,* NVCA Comment Letter.

[97] *See, e.g.,* MFA Comment Letter.

[98] PIABA Comment Letter.

[99] Better Markets Comment Letter.

[100] *See* Proposing Release at section II.B.1.

[101] PIABA Comment Letter (stating that the Commission's reasoning is circular); Better Markets Comment Letter (stating that the Commission should not base its threshold for deeming entities small on the fact that there are some very large investment companies and investment advisers).

[102] *See, e.g.,* Sharma Comment Letter.

[103] *See, e.g.,* Better Markets Comment Letter.

[104] MFA Comment Letter.

[105] *See, e.g.,* Better Markets Comment Letter, Dowell Comment Letter.

[106] Better Markets Comment Letter.

percentile of advisers.[107] We are not persuaded to increase the RAUM Threshold by a lesser amount than proposed because we are concerned that the commenters' recommended thresholds would not account for the fact that the distribution of RAUM across all advisers is highly uneven. As discussed in the Proposing Release, some advisers report having virtually zero RAUM, while a significant amount of the total RAUM is concentrated at the top 5 percent of advisers.[108] As discussed in the Proposing Release, the proposed $1 billion RAUM Threshold would represent 75 percent of advisers, but only under 3 percent of the total RAUM in the industry.[109] Therefore, we continue to believe that in light of the significant concentration of RAUM with the very largest advisers, the $1 billion RAUM Threshold will strike an appropriate balance between the level of RAUM per small adviser and the proportion of total RAUM in the industry.[110]

Some commenters recommended that the Commission provide certain data to support its proposal.[111] For example, a commenter recommended the Commission provide data concerning investor exposure, which the commenter appeared to define as total investor assets managed by firms that would newly qualify as small entities.[112] Another commenter expressed concern that the proposal did not provide details about why the RAUM Threshold should be $1 billion and not another number.[113] This commenter expressed concern that the Commission described the proposed amendment as seeking to separate those who are ''dominant in their field'' from those who are ''not dominant in'' their field, but did not explain the ''dominance'' test or why that test would be appropriate in this circumstance.

Other commenters, however, expressed appreciation that the Commission chose the $1 billion figure based on data, which demonstrated industry concentration.[114] Another commenter stated that it appreciated the Commission's thoughtful and well-reasoned analysis supporting the proposed $1 billion RAUM Threshold.[115] This commenter discussed how the Proposing Release carefully considered both the significant concentration of assets among the largest advisers and the RFA's requirement that a small entity be one that is not ''dominant in its field.'' The commenter stated that although the proposal would classify a substantial proportion of advisers as small entities, the Commission explained why this result would be appropriate given the comparatively modest amount of assets managed by these firms relative to the largest advisers.

The Commission proposed the $1 billion RAUM Threshold in light of the RFA's default definitions of the terms ''small business'' and ''small organization,'' which define such entities as those that are independently owned and operated and are not dominant in their field.[116] The RFA provides that an agency may establish its own definitions of ''small business'' and ''small organization'' under certain circumstances.[117] Rule 0–7's Control Relationship Threshold is designed to address the element of the RFA's default definitions that require the ''small business'' or ''small organization'' to be independently owned and operated,[118] whereas the Commission proposed the $1 billion RAUM Threshold to address the requirement that a ''small business'' or ''small organization'' not be dominant in its field.[119]

As discussed in the Proposing Release, the Commission used Form ADV reporting data from SEC-registered advisers and exempt reporting advisers to analyze the distribution of investment advisers and RAUM, including data concerning the percentile of advisers, individual RAUM of advisers at the percentile, the total number of all advisers at or below the percentile, and the total RAUM of all advisers at or below the percentile in millions and as a percent.[120] The Commission estimated that the proposed $1 billion RAUM Threshold would still represent under 3 percent of total RAUM in the industry.[121] The Commission published these summary statistics in the Proposing Release, showing the distribution of assets across firms, and the proportion of entities that would qualify under the proposed and other potential thresholds.[122] As discussed in the Proposing Release, these data revealed that the distribution of RAUM across all advisers is highly uneven, in part due to some advisers reporting zero or virtually zero RAUM, and more significantly because of the concentration of RAUM with the very largest advisers in the industry. The Commission compared data concerning the proposed RAUM Threshold to historical definitions, noting that the proposed RAUM Threshold would not result in the same proportion of advisers that were ''small entities'' as a result of the 1998 amendments.[123]

After considering comments, and in light of the RFA's default definitions and our data analysis, we continue to believe that a $1 billion RAUM Threshold is appropriate, and we do not believe that the final rules would inappropriately afford larger firms RFA accommodations that are intended for small entities.[124] A size standard threshold that is set too high could inadvertently cause Commission RFA analysis to mistakenly focus on issues of more general concern to the industry, instead of on issues that particularly impact smaller entities, as required by the RFA. Conversely, we are concerned that setting the RAUM Threshold too low would not be consistent with the RFA's default definition of ''small business'' and ''small organization,'' because it would exclude advisers that are not dominant in their field. We believe such advisers may have fewer compliance resources, and therefore, would benefit from being considered a ''small business'' or ''small organization'' under the RFA. Although using $1 billion as the RAUM Threshold would classify a large proportion of investment advisers as small, this is a reasonable and appropriate result for purposes of our analyses under the RFA, in part due to the relative amount of

[107] Dowell Comment Letter.

[108] Proposing Release at Table 3, and accompanying text.

[109] Proposing Release at section II.B.1.

[110] Proposing Release at section II.B.1.

[111] *See, e.g.,* Scarborough Comment Letter.

[112] Scarborough Comment Letter.

[113] CFP Board Comment Letter.

[114] *See, e.g.,* MFA Comment Letter (stating that MFA appreciated the Commission's consideration of a threshold above that 75th percentile, given industry concentration).

[115] IAA Comment Letter.

[116] 5 U.S.C. 601(3); 5 U.S.C. 601(4); 15 U.S.C. 632(a)(1).

[117] 5 U.S.C. 601(3); 5 U.S.C. 601(4).

[118] Proposing Release at n.85.

[119] Proposing Release at II.B.1.

[120] *See* Proposing Release at n.82–83; Table 3 and accompanying text. The data the Commission presented in the Proposing Release continues to represent the distribution of investment advisers and RAUM.

[121] *See* Proposing Release at section II.B.1; Table 3 and accompanying text; *See* Scarborough Comment Letter, which requested such quantification and analysis. This commenter recommended the Commission should quantify and analyze investor exposure, which the commenter appeared to define as total investor assets managed by firms that would newly qualify as small entities. Therefore, it appears the commenter was recommending analysis of an RAUM-based threshold, which the Proposing Release analyzed.

[122] *See* Proposing Release at n.82–83; Table 3 and accompanying text; *see also* Logos Comment Letter, which requested such summary statistics.

[123] *See* Proposing Release at n.82–83; Table 3 and accompanying text; *see also* Logos Comment Letter, which requested such comparative historical analysis.

[124] Scarborough Comment Letter (requesting such analysis).

assets managed by these advisers compared to the largest advisers, *i.e.,* those dominant in their field. We continue to believe that a $1 billion RAUM Threshold strikes an appropriate balance between the level of RAUM per small adviser and the proportion of total RAUM in the industry captured by the new threshold.[125]

A commenter recommended that ''exempt reporting advisers'' should have a higher adviser RAUM Threshold than SEC-registered advisers.[126] An ''exempt reporting adviser'' is an investment adviser that qualifies for the exemption from registration under section 203(l) of the Advisers Act because it is an adviser solely to one or more venture capital funds, or under rule 203(m)–1 of the Advisers Act because it is an adviser solely to private funds and has assets under management in the United States of less than $150 million.[127] According to this commenter, Congress has chosen to subject exempt reporting advisers to different and generally less burdensome regulatory obligations and it would be inconsistent with the logic underlying the RFA and the Advisers Act to not assess the burden on exempt reporting advisers independently in recognition of Congress's intent to subject these businesses to different regulatory regimes. We are not persuaded to raise the RAUM Threshold higher for exempt reporting advisers than for SEC-registered advisers, because, in our experience, we do not believe exempt reporting advisers and SEC-registered advisers would be subject to different economies of scale that should impact their status as a small adviser. For example, in our experience, both types of advisers could have similar business models or operational structures that could allow them to achieve similar economies of scale to implement certain rules. If a future rulemaking, however, would have a different impact on exempt reporting advisers than on SEC-registered advisers, the Commission could address that in the future rulemaking.

As discussed above, some commenters recommended aligning the adviser and fund thresholds so that if either a fund complex or its adviser qualifies as small, both would be treated as small for purposes of the RFA.[128] We are not persuaded to implement this recommendation, for the reasons discussed above.

The current rule provides that an adviser is a small entity if it has assets under management of less than $25 million ''or such higher amount as the Commission may by rule deem appropriate under Section 203A(a)(1)(A) of the Act.'' Advisers Act section 203A(a)(1)(A) prohibits advisers from registering with the SEC if they have assets under management below a certain amount. The Commission originally adopted the phrase in 1998 so the RAUM Threshold could increase in tandem with any increase in the minimum threshold for SEC registration.[129] That has not happened in practice, however, despite the SEC registration threshold increasing in 2010.[130] Accordingly, we proposed to remove ''or such higher amount as the Commission may by rule deem appropriate under Section 203A(a)(1)(A) of the Act (15 U.S.C. 80b–3a(a)(1)(A)),'' because the revised RAUM Threshold would exceed and thus not align with the minimum threshold for adviser registration. The Commission did not receive any comments on this proposed change and is removing the phrase, as proposed.

2. The Total Assets Threshold

The final amendments eliminate the Total Assets Threshold, which currently excludes from the definition of small entity any adviser that has total assets of $5 million or more.[131] The Commission requested comment on whether to adjust or eliminate the Total Assets Threshold and proposed to amend the Total Assets Threshold to include an Inflation Adjustment Mechanism.[132]

The Total Assets Threshold was designed to enable the Commission to differentiate between small advisers and non-small advisers that may not have significant RAUM but do have significant assets related to a non-advisory line or component of their business.[133] The Total Assets Threshold also worked in concert with the Control Relationship Threshold in capturing common types of advisory industry affiliations.[134] The Commission had stated that an adviser in a control relationship with a large broker-dealer or other large financial services firm typically benefits from the financial and technical resources of the large firm, and that the large firm may handle much of the administrative and compliance needs of its affiliated adviser using resources not reflected in the adviser's client assets or business assets.[135]

Some commenters recommended eliminating the Total Assets Threshold, stating that total assets are not a reliable indicator of whether an adviser should be considered a small entity.[136] A commenter stated that total assets reflected on an adviser's balance sheet do not necessarily correlate with operational complexity, staffing levels, compliance capacity, or the scope of its advisory business.[137] This commenter stated that advisers may hold assets unrelated to their core advisory operations, including assets tied to non-advisory activities, temporary capital arrangements, or organizational structure, that do not meaningfully reflect firm size for RFA purposes. Another commenter stated that a balance sheet test can exclude advisers that are operationally small, while failing to meaningfully differentiate among advisers' ability to bear incremental compliance costs associated with Commission rulemakings.[138] According to this commenter, where an adviser has *de minimis* RAUM but substantial non-advisory assets, the adviser's investment advisory business is, by definition, not a meaningful component of the firm as a whole. The commenter indicated that in that circumstance, total assets may reflect the scale of the firm, taken as a whole, but does not reflect the resources that the firm is willing or able to allocate to an immaterial advisory business line. This commenter stated that when new adviser-specific requirements increase fixed compliance costs, an enterprise with substantial non-advisory assets but minimal RAUM may rationally choose to exit the advisory business rather than

[125] *See* Proposing Release at section II.B.1.

[126] *See* Proskauer Comment Letter.

[127] Form ADV, Glossary of Terms.

[128] *See supra* footnote 59 and accompanying text.

[129] 1998 Adopting Release at n.48; Proposing Release at n.79.

[130] *Id.*

[131] To implement this amendment, the Commission is removing 17 CFR 275.0–7(a)(2), which sets forth the Total Assets Threshold. The Commission is redesignating the Control Relationship Threshold from 17 CFR 275.0–7(a)(3) to 17 CFR 275.0–7(a)(2) and making conforming amendments to remove references to total assets. The Commission also is removing 17 CFR 275.0–7(b)(2), which defines ''total assets,'' and redesignating the subparagraphs of 17 CFR 275.0–7(b), to account for that removal.

[132] Proposed 17 CFR 275.0–7(a)(2); Proposing Release at section II.B.2.

[133] Proposing Release at section II.B.2.

[134] *Id.*

[135] Definitions of ''Small Business'' or ''Small Organization'' Under the Investment Company Act of 1940, the Investment Advisers Act of 1940, the Securities Exchange Act of 1934, and the Securities Act of 1933, Securities Act Release No. 7383 (Jan. 22, 1997), [62 FR 4106 (Jan. 28, 1997)] (''1997 Proposing Release''), at text following n.51.

[136] Some commenters recommended that if the Commission retains the Total Assets Threshold, it should raise it to be commensurate with the proposed RAUM Threshold. *See e.g.,* Proskauer Comment Letter.

[137] IAA Comment Letter.

[138] Proskauer Comment Letter.

devote incremental resources to comply with the rules affecting an immaterial portion of its overall operations.

After considering comments, we are eliminating the Total Assets Threshold. It is not necessary to maintain the Total Assets Threshold, because the RAUM Threshold and Control Relationship Threshold, as amended, are more reliable indicators of whether an adviser is a small entity for purposes of the RFA. Balance sheet assets, such as leases and equipment, do not reflect the scope of an advisory business as well as regulatory assets under management.[139] Furthermore, we understand an adviser that has *de minimis* RAUM, but significant assets related to a non-advisory business may not be willing or able to allocate resources from the non-advisory line to an immaterial advisory business if the non-advisory line does not share comparable compliance requirements. For example, while advisers and broker-dealers may have some comparable compliance requirements under the Advisers Act and the Exchange Act, respectively, other compliance requirements are not easily scalable for both. For example, both advisers and broker-dealers must deliver 17 CFR 279.1, Part 3 and 17 CFR 249.641, respectively (''Form CRS'') to retail investors under the Advisers Act and the Exchange Act, respectively,[140] but only advisers must file Form ADV Part 1A, as applicable.[141] Therefore, a large broker-dealer under common control with an adviser with *de minimis* RAUM may be able to scale certain resources to the adviser concerning Form CRS, but not Form ADV Part 1A, because that requirement only concerns the adviser.

The RFA defines a ''small business'' and ''small organization'' as entities that are ''not dominant in their field.'' [142] The final rules will continue to be consistent with the Commission's efforts to take into account the structure of business concerns and organizations in the securities industry when defining the terms ''small business'' and ''small organization'' and to preclude entities with significant economic or financial resources from obtaining potential regulatory benefits under the RFA.[143] The Control Relationship Threshold will continue to prevent affiliates of large advisers from obtaining potential regulatory benefits under the RFA. Currently and under the final rules, the Control Relationship Threshold precludes advisers from being considered small if they have *de minimis* RAUM, but control, are controlled by, or are under common control with another adviser that has assets under management equal to or greater than the RAUM Threshold. In such a case, the adviser with *de minimis* RAUM would appropriately continue to be precluded from obtaining potential regulatory benefits under the RFA.

Although the Commission originally aligned the Total Assets Threshold with the total assets test used in the ''small entity'' definition in 17 CFR 240.0–10 (''Exchange Act rule 0–10''), it is not necessary to continue to align them through a total assets metric, as a commenter discussed.[144] Currently, Exchange Act rule 0–10(a) provides, among other things, that when used with reference to an ''issuer'' or a ''person,'' other than an investment company, the term ''small business'' or ''small organization'' means an ''issuer'' or ''person'' that, on the last day of its most recent fiscal year, had total assets of $5 million or less.[145] The Commission stated that it aligned the values of the ''small entity'' definitions under the Advisers Act and the Exchange Act in view of financial industry affiliations between advisers and other large financial services firms to which the Exchange Act definition would apply.[146] However, as discussed above, the RAUM Threshold is a more reliable indicator of whether an adviser is a small entity for purposes of the RFA. As indicated by a commenter, RAUM is a more meaningful proxy for business scale and compliance capacity for advisers, rather than the amount of assets carried on the adviser's balance sheet.[147] The ''small entity'' definitions under the Advisers Act and the Exchange Act will continue to be aligned in other ways, including by both having thresholds that concern control relationships.[148]

The Commission receives limited information regarding advisers' total assets that would allow it to analyze with specificity the impact of potential changes to the Total Assets Threshold over the distribution of investment advisers. The Commission only receives information in Item 1.O. of Part 1A of Form ADV regarding investment advisers with $1 billion or more in total assets as well as information in Item 12 from registered investment advisers with less than $25 million in RAUM regarding whether they have less than $5 million in total assets. Commenters did not support adopting additional reporting requirements to preserve this element of the definition of ''small entity.'' [149] Given that the RAUM Threshold and Control Relationship Threshold are more meaningful thresholds to determine whether an adviser is small for purposes of the RFA than the Total Assets Threshold, we are not persuaded that imposing new reporting burdens to calibrate the Total Assets Threshold would be justified.

3. The Control Relationship Threshold

The Commission is amending the Control Relationship Threshold, with modifications from the proposal. Currently, the Control Relationship Threshold disqualifies an adviser from being considered small if it is in a control relationship with an affiliated adviser exceeding an assets under management test that mirrors the current RAUM Threshold of $25 million.[150] To continue to maintain a consistent threshold between the Control Relationship Threshold and the RAUM Threshold, the Commission is amending the value of the Control Relationship Threshold to conform it to the revised $1 billion RAUM Threshold, including its corresponding Inflation Adjustment Mechanism, as proposed.[151] Also, as proposed, the Commission is removing ''(or such higher amount as the Commission may deem appropriate)'' to further conform the Control Relationship Threshold with the revised RAUM Threshold, for which the Commission removed a similar phrase.[152] In a change from the proposal, the Commission is removing from the Control Relationship Threshold the elements that concern the Total Assets Threshold, namely that an

[139] *See* 1998 Adopting Release at n.42 (stating that ''total assets'' includes leases and equipment).

[140] *See* 17 CFR 275.204–5 and 17 CFR 240.17a–14.

[141] *See* 17 CFR 275.203–1 and 17 CFR 275.204–1.

[142] 5 U.S.C. 601(3); 5 U.S.C. 601(4); 15 U.S.C. 632.

[143] Proposed Definitions of ''Small Business'' and ''Small Organization'' for Purposes of the Regulatory Flexibility Act, Securities Act Release No. 6302 (Mar. 20, 1981), 46 FR 19251 (Mar. 30, 1981) (''1981 Proposing Release'') (stating that the Commission believes that it is appropriate to take into account the structure of business concerns and organizations in the securities industry when defining the terms ''small business'' and ''small organization'' and to preclude entities with significant economic or financial resources from obtaining potential regulatory benefits under the RFA).

[144] Proskauer Comment Letter.

[145] In separate rulemaking, the Commission proposed to revise Exchange Act rule 0–10 (17 CFR 240.0–10) to raise the total assets threshold in the definition of small entity issuer (other than an investment company) from $5 million to $35 million. *See* 2026 Filer Status Release.

[146] Proposing Release at section II.B.2.

[147] Proskauer Comment Letter.

[148] Final 17 CFR 275.0–7(a)(2) and 17 CFR 240.0–10(i).

[149] *See e.g.,* Proskauer Comment Letter.

[150] 17 CFR 275.0–7(a)(3).

[151] Final 17 CFR 275.0–7(a)(2).

[152] *See* section II.B.1.b of this release.

adviser is disqualified from being considered a small entity if it has a control relationship with any person (other than a natural person) that had total assets of $5 million or more on the last day of the most recent fiscal year (as well as the proposed inflation adjustment to this amount).[153] As discussed above, an RAUM threshold is a more reliable indicator of whether an adviser is a small entity than a total assets threshold.[154] In another change from the proposal, the Commission is further amending the Control Relationship Threshold, after considering comments, to help advisers understand how to calculate the assets under management referenced in the Control Relationship Threshold, as discussed more fully below.[155] As a result, under the final amendments, an adviser would meet the Control Relationship Threshold if it does not control, is not controlled by, and is not under common control with another investment adviser that has assets under management equal to or greater than the RAUM Threshold.

The Control Relationship Threshold is designed to preclude entities with significant economic or financial resources from obtaining potential regulatory benefits under the RFA.[156] We continue to believe that Congress did not intend affiliates of large businesses to receive benefits under the RFA.[157] Only those businesses and organizations that are ''independently owned'' may qualify as small entities pursuant to the definitions contained in the RFA.[158] The final amendments to the Control Relationship Threshold are designed to help ensure the Control Relationship Threshold continues to preclude entities with significant economic or financial resources from their large business affiliates from obtaining potential regulatory benefits under the RFA.

Commenters supported the Commission's proposal to make conforming amendments to the Control Relationship Threshold to reflect the revised $1 billion RAUM Threshold, with its corresponding Inflation Adjustment Mechanism.[159] Commenters also offered recommendations concerning the Control Relationship Threshold. A commenter requested that the Commission confirm that RAUM as reported on Form ADV is the operative metric for adviser small entity status.[160] Under the current rule, the RAUM Threshold sets forth how to calculate assets under management: as defined under Advisers Act section 203A(a)(3) and reported on an adviser's annual updating amendment to Form ADV.[161] The current Control Relationship Threshold, however, only discusses assets under management, without detailing the calculation method.[162]

After considering the comments, the Commission is confirming that advisers must calculate assets under management for the Control Relationship Threshold using the same method as the RAUM Threshold: as defined under Advisers Act section 203A(a)(3) and reported on the adviser's annual updating amendment to Form ADV. In this regard, in a change from the proposal, the Commission is amending the Control Relationship Threshold so that instead of specifying the amount of assets under management of an affiliated investment adviser to surpass the threshold, as it currently does, it instead references rule 0–7 paragraph (a)(1), which sets forth the RAUM Threshold, including its corresponding Inflation Adjustment Mechanism and the calculation method.[163] This amendment does not change how the Control Relationship Threshold operates as compared to the current rule. Instead, it is designed to ensure that advisers understand how to calculate the assets under management in the Control Relationship Threshold.

A commenter recommended the Commission amend the Control Relationship Threshold to provide a special rule for insurance companies, so that an insurance company's affiliated institutional advisers would not be cumulated with an insurance company's affiliated retail advisers.[164] This commenter stated that institutional advisers and retail advisers involve substantially different infrastructures, systems, and regulatory requirements, they do not share management or advisory personnel, they have distinct costs and burdens, and there are few opportunities for economies of scale between them. The commenter expressed concern that a retail adviser may be disproportionately and unfairly impacted by changes in Commission regulation if its assets under management are cumulated with an institutional adviser merely due to common control.

We are not persuaded to provide a special rule for insurance companies, so that an insurance company's affiliated institutional advisers would not be cumulated with an insurance company's affiliated retail advisers. Currently, the requirements in rule 0–7 do not distinguish between retail advisers and institutional advisers. We are not persuaded that advisers should be treated differently under rule 0–7 solely based on the fact that they are affiliated with an insurance company. We disagree with this commenter's assertion that an adviser's retail and institutional advisory businesses involve substantially different regulatory requirements. Retail and institutional advisory businesses involve substantially similar regulatory requirements, because both are subject to the Advisers Act, and the rules thereunder, among other things which do not generally differentiate between the type of client. Even if affiliated advisers choose different infrastructures, systems, management, or advisory personnel, there remain opportunities for economies of scale concerning compliance with and operation under the Advisers Act and the rules thereunder, even if some particular provisions do not apply to each adviser. Therefore, we disagree with the commenter's assertion that a retail adviser would be disproportionately or unfairly impacted by changes in Commission regulation if its assets under management are cumulated with an institutional adviser due to common control.

4. Conforming Amendments to Form ADV and the Adviser Hardship Exemption Rule

The Commission is making conforming amendments to Form ADV, General Instruction 17, and Item 12 of Part 1A, as well as Advisers Act rule 203–3(b), with modifications from the proposal. Form ADV is the uniform application for investment adviser registration and report form by exempt reporting advisers. General Instruction 17 summarizes the conditions for certain small advisers to apply for an

[153] A commenter requested the Commission provide examples illustrating the application of the Control Relationship Threshold to common dual-registrant and holding company structures, stating that it was concerned large broker-dealer operations of dual registrants would cause an adviser to no longer be a small entity. This request appears to concern the element of the current Control Relationship Threshold that concerns total assets that we are removing, because only the total asset analysis considered non-advisory assets. Therefore, this request does not appear to be applicable to the final rules. *See* ASA Comment Letter; 17 CFR 275.0–7(a)(3); final 17 CFR 275.0–7(a).

[154] *See* section II.B.2 of this release.

[155] Final 17 CFR 275.0–7(a)(2).

[156] Proposing Release at section II.B.3.

[157] 1997 Proposing Release, at text accompanying n.52.

[158] 1981 Proposing Release at text accompanying n.32; Proposing Release at text accompanying n.111.

[159] *See, e.g.,* ASA Comment Letter.

[160] ASA Comment Letter.

[161] 17 CFR 275.0–7(a)(1).

[162] 17 CFR 275.0–7(a)(3).

[163] Final 17 CFR 275.0–7(a)(2).

[164] CAI Comment Letter.

exemption from filing Form ADV electronically with the IARD. Item 12 of Part 1A requires an eligible SEC-registered adviser to report how it qualifies as a ''small business'' or ''small organization'' under rule 0–7. It is designed to provide information to the public and the Commission about advisers, including information that enables the Commission to consider the effect of its regulations on small entities, as required by the RFA.[165] Rule 203–3(b) sets forth conditions for certain small SEC-registered advisers to apply for a continuing hardship exemption from the requirement to make Advisers Act filings electronically with the IARD, among other things.

As proposed, the Commission is making conforming amendments to Form ADV, including General Instruction 17 and Item 12, as well as rule 203–3(b) to reflect the final amendments to the RAUM Threshold, the Control Relationship Threshold, and their corresponding inflation adjustments. Currently, General Instruction 17 states, in part, that an adviser is a small business, and may be eligible for a continuing hardship exemption, if it is required to answer Item 12 of Part 1A ''(because you have assets under management of less than $25 million)'' and it is able to respond ''no'' to each question in Item 12. As proposed, the Commission is removing the parenthetical ''(because you have assets under management of less than $25 million).'' This parenthetical is implicit, given that the sentence also directs advisers to Item 12, which provides the relevant instructions. Removing this phrase will avoid requiring the Commission to update it periodically, as the Commission adjusts the RAUM Threshold for inflation. Also, as proposed, the Commission is revising General Instruction 17 and rule 203–3(b) so they explicitly apply to an adviser that is either a ''small business'' or ''small organization,'' as Item 12 does, rather than just a ''small business.''

In a change from the proposal, the Commission is making additional conforming amendments to Form ADV, Item 12 of Part 1A to remove references to the Total Assets Threshold, to reflect that the Commission is eliminating the Total Assets Threshold from rule 0–7. In connection with this change, the Commission also is amending rule 203–3(b)(5) to remove the phrase ''that you were required to answer'' because it is no longer relevant in light of the amendments to Item 12. In another change from the proposal, the Commission is revising the language of Form ADV Item 12, so that it refers to rule 0–7, rather than re-stating the threshold, as proposed. This amendment does not change the substance of Item 12 as compared to the proposal. The purpose of this amendment is to help ensure Item 12 remains operative, without additional rulemaking, in light of future Commission orders that may adjust rule 0–7's threshold for inflation.

One commenter supported the proposed amendments to Form ADV, discussing that the proposed amendments would help ensure internal consistency across Commission rules.[166] This commenter, along with another commenter, recommended not imposing any additional reporting requirements.[167] The Commission did not propose additional reporting requirements, and is not adopting additional reporting requirements at this time. A commenter requested the Commission quantify and analyze regulatory relief consequences, which the commenter described as Commission reporting, compliance, or procedural accommodations that would become newly available once firms qualify as small entities.[168] We are confirming that rule 203–3(b) provides such an accommodation and its continuing hardship accommodation will become newly available once firms qualify as small entities.[169]

C. Periodic Future Adjustments

The final amendments to rules 0–10 and 0–7 will, as proposed, provide an Inflation Adjustment Mechanism for periodic future adjustments of the asset-based thresholds used in these rules' small entity definitions.[170] Specifically, the amendments provide that the Commission will issue an order every ten years adjusting: (i) the net asset threshold in the investment company small entity definition; and (ii) in the investment adviser small entity definition, the RAUM Threshold (which will also now have the effect of adjusting the Control Relationship Threshold). As proposed, the final amendments to rule 0–10 and rule 0–7 will require that the adjustment of the asset-based thresholds be calculated by reference to the Personal Consumption Expenditures Chain-Type Price Index (the ''PCE Index'').[171] The final amendments providing the Inflation Adjustment Mechanism will require rounding the investment company small entity net asset threshold to the nearest multiple of $1,000,000,000 and rounding the investment adviser small entity RAUM Threshold (and thus the Control Relationship Threshold) to the nearest multiple of $100,000,000.[172]

In order to adjust the asset-based thresholds for the ''small entity'' definitions as discussed above, the Commission considered an analysis of the distribution of fund and adviser assets and the growth in these assets over time. As described in the Proposing Release, however, these amended thresholds may become less useful over time due to growth in markets and any subsequent changes in the fund and adviser industries. The proposed Inflation Adjustment Mechanism was designed to ensure that the thresholds are adjusted every ten years, because the adjustment would be required by rule and effected through a Commission order.

Some commenters supported the proposed inflation adjustments.[173] Other commenters supported the goal of periodic adjustments, but expressed concern about the details of the proposal.[174] For example, some commenters recommended the Commission use a shorter cadence for adjustments, such as five or seven years, to ensure that the thresholds remain reasonable.[175] Some commenters recommended using an adjustment mechanism they consider more relevant than inflation, such as a broad-based index of asset prices,[176] or the proposal's own asset-based distribution

[165] *See* Form ADV, Item 12 of Part 1A.

[166] IAA Comment Letter.

[167] IAA Comment Letter; Proskauer Comment Letter.

[168] *See* Scarborough Comment Letter.

[169] Currently, the Commission's definition of ''small entity'' under the RFA is incorporated into the Commission's other rules and regulations only in connection with an adviser's responses to Form ADV (and this release is implementing corresponding amendments to the form) and rule 203–3(b). *See infra* footnote 189, and accompanying text.

[170] Final 17 CFR 270.0–10(c); final 17 CFR 275.0–7(c).

[171] *See id.*

[172] Final 17 CFR 275.0–7(c)(2) and final 17 CFR 270.0–10(c)(2). Final 17 CFR 270.0–10 will require the net asset threshold for small entities be adjusted for inflation by dividing the year-end value of the PCE Index for the calendar year preceding the calendar year in which the order is being issued, by the year-end value of the PCE Index for the calendar year in which any final rule that is adopted becomes effective, multiplying $10 billion (*i.e.,* the final amendments' net asset threshold) by that quotient, and rounding the product to the nearest multiple of $1 billion. Final 17 CFR 275.0–7(c)(2) will adjust the RAUM Threshold (and thus the Control Relationship Threshold) by starting with the same quotient but will multiply that by $1 billion, rounded to the nearest multiple of $100 million.

[173] *See, e.g.,* NVCA Comment Letter.

[174] *See, e.g.,* Federated Hermes Comment Letter.

[175] *See, e.g.,* Sharma Comment Letter (recommending a five-year cadence); Federated Hermes Comment Letter and ICI Comment Letter (each recommending a seven-year cadence).

[176] Proskauer Comment Letter.

analysis for RAUM and net asset percentiles.[177]

After considering comments, we are adopting the Inflation Adjustment Mechanism substantially as proposed.[178] Adjustments that the Commission makes mechanically by order could help maintain the thresholds at levels that reflect the buying power of money over time, without the need for Commission action through rulemaking.[179] We expect, as discussed in the Proposing Release and by commenters, that the Inflation Adjustment Mechanism will prevent the thresholds in the small entity definitions from becoming less meaningful over time on account of anticipated changes in dollar value.[180] Specifically, because a fund's or adviser's size is related to its ability to bear compliance costs, adjusting the asset-based thresholds is designed to account for potential increases in those compliance costs.

While certain comments recommended a shorter adjustment cadence, the final amendments' Inflation Adjustment Mechanism reflects the same ten-year cadence as proposed. Given the distributions of different-sized entities for funds and investment advisers, inflationary changes over shorter periods would generally not result in a meaningfully different set of funds and investment advisers being considered small entities under their respective definitions.[181]

Likewise, after considering comments recommending an adjustment mechanism based on a metric other than inflation, we are adopting this aspect of the Inflation Adjustment Mechanism as proposed. We acknowledge that inflation may not perfectly represent growth in the fund and adviser industries. Nevertheless, as discussed above, our view continues to be that inflation adjustment is the most appropriate mechanism for periodically and mechanically adjusting the asset thresholds and implementing the adjustments by order. Inflation, unlike the asset-based distribution analysis mechanisms described by commenters, is a known factor for which a precise value can reliably be derived from a defined index. Periodically adjusting the thresholds to a set percentile from a distribution analysis would similarly be inappropriate. The percentile that resulted from the distribution analysis performed in the Proposing Release is particular to that data and set of facts and, therefore, is not necessarily indicative of the proportion of funds or advisers that should be deemed small entities in the future. In addition, performing the same or similar analysis to determine a future percentile based on then-current data would involve a level of analysis that would require a future rulemaking rather than an adjustment by Commission order. Similarly, we do not consider using a broad-based index of asset prices as the basis for adjustment as suggested by commenters to be appropriate in light of the breadth of fund and adviser strategies. Any one particular index of asset prices would not be appropriate for certain strategies, and if multiple indexes were used, this could result in different levels of adjustment depending on the index, as well as operational complexity.

It is possible, but less predictable, that the asset-based thresholds may become less useful over time even taking the Inflation Adjustment Mechanism we are adopting into account (for example, with the advent of market events, changes in the makeup or distribution of size of the fund or adviser markets, or other industry changes). In this case, the Commission could consider performing appropriate analyses to propose amendments to the thresholds again in the future independent of the Inflation Adjustment Mechanism. Similarly, in the future, the Commission also could consider proposing a periodic adjustment approach using analysis other than one based on the Inflation Adjustment Mechanism.

D. Effective Date and Compliance Date

The effective dates and compliance dates are as follows:

- Final amendments to rule 0–10 and rule 0–7 are effective February 4, 2027, which is 90 days from the date of publication in the **Federal Register**.
- Final amendments to rule 203–3 and Form ADV are effective, and have a compliance date of, February 4, 2027, which is 90 days from the date of publication in the **Federal Register**.

One commenter recommended an implementation period of 180 days, so advisers can reassess their ''small entity'' status, update internal Form ADV filing procedures, train compliance and personnel on the revised Form ADV Item 12 logic and hardship exemption eligibility, and coordinate updates with third-party compliance vendors or filing service providers where applicable.[182] We are not persuaded to provide an implementation period of 180 days. While additional SEC-registered advisers will have to update their small entity status in Item 12 of Form ADV and will be newly eligible for the hardship exemption under rule 203–3(b), the information required to comply with the final amendments is readily available to advisers and the additional cost of the final amendments would be minimal. Also, as a practical matter, most advisers will have additional time to update their Form ADV because Form ADV does not require advisers to file an other-than-annual amendment to update Item 12; most advisers will update Item 12 as part of their regularly scheduled annual amendments.[183] The compliance period for rule 203–3 and Form ADV is designed to provide the Financial Industry Regulatory Authority (''FINRA'') sufficient time to update the IARD to reflect revised Item 12.[184]

In the event that FINRA is unable to update the IARD by the end of the compliance period, until the IARD is updated, advisers should leave Item 12 blank, and provide responses to revised Item 12 in the miscellaneous section of Schedule D of Form ADV.

We are adopting an effective date for rule 0–7, rule 203–3, and Form ADV that matches the compliance date for rule 203–3 and Form ADV, because these rules and form are connected to each other. We are adopting the same effective date for rule 0–10 for consistency.

III. Economic Analysis

The Commission is mindful of the economic effects, including the costs and benefits, of its rules. The Commission has a long-held focus on small entities when engaged in rulemaking. A purpose of the RFA is to promote the effectiveness and efficiency of regulations, including through consideration of alternative regulatory approaches, with the goal of minimizing

[177] *See, e.g.,* Proskauer Comment Letter; ICI Comment Letter.

[178] As discussed above, for advisers, we are removing the Total Assets Threshold and its corresponding inflation adjustment, and we are revising the Control Relationship Threshold to refer to the RAUM Threshold and its inflation adjustment in establishing the threshold under which an affiliated adviser may affect an adviser's small entity status. *See* sections II.B.2 and II.B.3.

[179] The Commission has historically incorporated periodic and mechanical adjustments to certain dollar-based thresholds in regulations affecting funds and investment advisers. These adjustments reflect that some level of change in dollar value is reasonably anticipated to occur in the future and help ensure that the rules' intended application remains consistent and relevant over time. *See, e.g.,* 17 CFR 270.3c–7; 17 CFR 275.205–3; *see also* Proposing Release, at n.128 (discussing Commission releases that have used the PCE Index for inflation adjustment).

[180] *See* Proposing Release at section II.C; *see also, e.g.,* CAI Comment Letter; IAA Comment Letter.

[181] *See, e.g., supra* footnotes 42–43 and 52 and accompanying text; *supra* footnotes 108–110 and accompanying text.

[182] Comment Letter of Charles Schwab & Co. (Mar. 13, 2026) (''Schwab Comment Letter'').

[183] *See* Form ADV, General Instruction 4.

[184] FINRA operates the IARD.

the significant economic impact on small entities consistent with the stated objectives of applicable statutes.[185] The Commission is required to determine if a rulemaking is likely to have a ''significant economic impact on a substantial number of small entities'' under the RFA.[186] In applicable rulemakings, the Commission's definitions of ''small entities'' determine the scope of the regulatory flexibility analyses conducted at the proposal and final stages. The updated definitions are expected to better tailor the Commission's analyses of the specific regulatory challenges faced by small entities by expanding the scope of the analyses that the Commission conducts under the RFA. These analyses, in turn, are expected to better inform the Commission of the regulatory impacts faced by small entities so that it may consider adapting its rulemaking accordingly.[187] To the extent such adaptations to future rulemakings will occur, the use of the amended definitions of ''small entities'' in RFA analyses could result in different benefits and costs of such rulemakings.[188] For example, if the Commission, informed by the more tailored RFA analyses, determined to scope fewer small entities into future rulemakings or tailor obligations imposed by such rulemakings differently for small entities, there could be lower compliance costs imposed on such entities.

In addition to these indirect effects, the final rule will have direct economic effects arising in situations where the updated small entity definitions affect the application of existing Commission rules and regulations. Currently, the Commission's definition of ''small entity'' under the RFA is incorporated into the Commission's other rules and regulations only in connection with an adviser's responses to Form ADV (and this release is implementing corresponding amendments to the form) and to rule 203–3(b). We thus consider the effects of the updated definition as it relates to the use of that definition in Form ADV, as well as the effects of the other associated changes to the form and to rule 203–3(b).[189]

First, we are amending Form ADV to revise General Instruction 17, which currently permits registered or registering investment advisers to receive a continuing hardship exemption from Form ADV electronic filing requirements, pursuant to rule 203–3(b), if such investment adviser is a small business and can demonstrate that filing Form ADV electronically would impose an undue hardship.[190] As proposed, we are revising General Instruction 17 to define an investment adviser as a ''small business'' or ''small organization'' if it is required to answer Item 12 (which itself relies on the definition in rule 0–7) and if it is able to respond ''no'' to each question in Item 12. Since the amendments to Item 12, in conformity with rule 0–7, reflect the removal of the Total Assets Threshold and that the RAUM Threshold is increasing from $25 million to $1 billion, General Instruction 17 will similarly reflect these changes for the availability of the continuing hardship exemption.

As a result, 10,180[191] additional registered investment advisers may be eligible for the exemption under the revised definition, as reflected in the amended General Instruction 17, before any future adjustment for inflation. However, we expect that the increased availability of the continuing hardship exemption to registered investment advisers meeting the updated definition will have minimal economic impact. Due to the ubiquity of inexpensive access to computers and the internet—both to advisers themselves and to the service providers they may employ—any newly eligible advisers are unlikely to be able to demonstrate that filing Form ADV electronically would impose an undue hardship.[192] We therefore anticipate that few, if any, additional advisers will be able to rely on the exemption.

Second, as proposed, we are amending Item 12 of Part 1A of Form ADV to align the RAUM threshold for completing the questions in that item with the final amendments to the definitions of ''small business'' and ''small organization'' under rule 0–7.[193] In a departure from the proposal, we are revising Item 12 and rule 203–3(b)(5) to reflect that the final amendments eliminate the Total Assets Threshold from rule 0–7.

As a result of the final amendments, approximately 10,180[194] additional registered investment advisers will be required to complete Item 12 of Part 1A (before any future adjustment for inflation). These advisers may incur costs associated with training their compliance personnel, updating internal procedures, and coordinating updates with third-party service

[185] *See supra* footnote 7.

[186] *See supra* footnote 8.

[187] Many commenters agreed that the updated definitions will better inform the Commission of the regulatory impacts faced by small entities. *See, e.g.,* IAA Comment Letter, MFA Comment Letter, Schwab Comment Letter. Other commenters stated that the updated definitions, as proposed, would not better inform the Commission in this regard. *See, e.g.,* Better Markets Comment Letter and PIABA Comment Letter. These and other comments received on the substance of the proposed changes to the definitions are discussed throughout *supra* section II.

[188] One commenter argued that the revised definitions may lengthen the rulemaking process. *See* Logos Comment Letter (stating that ''[b]roader inclusion may also increase frequency with which [RFA] analyses are required. This could lengthen the rulemaking process and require administrative resources. While these procedural costs are relatively modest compared to potential regulatory impacts on smaller firms, they represent an operational trade off.'') Our experience with conducting RFA analyses has been that they have not significantly lengthened the rulemaking process.

[189] The scope of the economic analysis therefore addresses the request by one commenter stating that the Commission ''should quantify and analyze [. . .] which SEC reporting, compliance, or procedural accommodations become newly available once firms qualify as small entities.'' *See* Scarborough Comment Letter.

[190] Also, as proposed, the Commission is revising General Instruction 17 and rule 203–3(b) so they explicitly apply to an adviser that is either a ''small business'' or ''small organization,'' as Item 12 does, rather than just a ''small business.''

[191] This estimate captures the number of registered investment advisers with RAUM equal to or above $25 million but below $1 billion. The estimate does not account for the number of such advisers in a control relationship with an affiliated adviser managing $1 billion or more, who would be disqualified from being eligible for the exemption. This estimate also excludes advisers with RAUM below $25 million who may newly qualify as small entities because the amendments eliminate the total-assets tests and increase the RAUM threshold for affiliated advisers.

[192] The Commission has not received applications for the continuing hardship exemption in recent years. In addition, registered advisers or advisers registering with the Commission may still be eligible for the temporary hardship exemption under 17 CFR 275.203–3(a), regardless of whether they are a small business or small organization, if they experience certain unanticipated technical difficulties. However, we acknowledge that any advisers that may consider applying for the exemption may incur costs to train their compliance personnel on the revised exemption eligibility. *See* Schwab Comment Letter (stating that ''the proposed updates will require advisors to [. . .] [t]rain their compliance and personnel on the revised [. . .] hardship exemption eligibility.'').

[193] *See supra* section II.B.4. In another change from the proposal, the Commission is revising the language of Form ADV Item 12, so that it refers to rule 0–7, rather than re-stating the threshold, as proposed. This amendment would help ensure Item 12 remains operative, without additional rulemaking, in light of future Commission orders that may adjust rule 0–7's threshold for inflation. This amendment thus does not have independent economic effects.

[194] *See supra* footnote 191.

providers,[195] and will incur costs associated with preparing the disclosure. Because the information needed to complete the corresponding questions will be readily available to advisers, we estimate the cost increase for each affected adviser will be minimal, averaging approximately $91 per adviser per year,[196] or $928,925 per year for the industry as a whole.[197]

Consistent with the requirements of Executive Order 12866, the Commission reports estimated total monetized benefits and costs for all affected entities in two additional ways specified in OMB Circular A–4.[198] The two presentations are intended to address the fact that the various benefits and costs of the final amendments will not accrue at the same point in time; rather, benefits and costs that accrue sooner are generally more valuable than those that occur later in time.[199] The following discussion focuses on the monetized costs presented in the Economic Analysis, given that the principal benefits of the final rule depend on future Commission action and are thus impossible to predict.

We report (1) the present values of expected costs that are monetized in our Economic Analysis, aggregated across all affected entities, over a 10-year time horizon, starting in 2026, as well as (2) the annualized values over the same time horizon that are derived from the present values. This time horizon represents the period over which the principal costs that are monetized in the Economic Analysis are expected to accrue.[200] The present values and annualized values account for the timing of costs through discounting, which is a procedure that accounts for the time value of money.[201]

Table 2 reports the present values of the aggregate monetized annual costs described above.[202] The analysis uses annual real discount rates of 3 percent and 7 percent over a 10-year time horizon, starting in 2026.[203] We estimate that the present value of total monetized costs is $7,126,602 using a 3 percent discount rate and $5,850,846 using a 7 percent discount rate.

Table 2: Present Value of Aggregate Monetized Benefits and Costs over 10 years from 2026 to 2035 (2026 Dollars)

Estimated Effects[a]	3% real discount rate	7% real discount rate
Benefits	not quantified	not quantified
Costs	$7,126,602	$5,850,846

Notes:

[a] For each discount rate, the present value calculations are based on the assumption that recurring annual monetized costs begin to accrue in 2027, which is the year in which affected entities first comply with the amendments to Form ADV. We further assume that monetized costs occur in a steady stream, and we use a mid-year discount rate. Monetized costs are $928,925 per year for the industry as a whole. (*See supra* footnote 198 and accompanying text.)

Table 3 reports annualized aggregate monetized costs using real discount rates of 3 percent and 7 percent over a 10-year horizon.[204] The lump sum present values of aggregate costs reported in Table 2 are converted in Table 3 into a constant stream of annualized costs over a 10-year time horizon, starting in 2026.[205] We estimate that annualized total monetized costs are $823,198 per year using a 3 percent discount rate and $805,319 per year using a 7 percent discount rate.

[195] *See* Schwab Comment Letter (stating that ''the proposed updates will require advisors to: [r]eassess their 'small entity' status using new thresholds; [u]pdate internal form ADV filing procedures; [t]rain their compliance and personnel on the revised Item 12 logic [. . .]; and [c]oordinate updates with third-party compliance vendors or filing service providers where applicable.'')

[196] The $91 is based on the following calculations: hourly rate of a Management Analyst in the securities industry at $365 for 0.25 hours ≈ $91. *See infra* Table PRA–1 and accompanying footnotes 5 and 7.

[197] $928,925 = $91.25 per adviser × 10,180 advisers.

[198] *See* E.O. 12866 (Sept. 30, 1993), 58 FR 51735, 51741 (Oct. 4, 1993) (requiring agencies to provide an analysis of benefits, costs, and regulatory alternatives to OIRA for significant regulatory actions); OMB, Circular A–4, at 31–34, 45 (Sept. 17, 2003) (providing guidance to agencies regarding compliance with E.O. 12866); *see also* E.O. 14215 (Feb. 18, 2025), 90 FR 10447, 10448 (Feb. 24, 2025) (requiring all Federal agencies, including the Securities and Exchange Commission to comply with E.O. 12866). In addition, E.O. 14192 requires agencies to provide their best approximation of the total costs or savings associated with each new regulation or repealed regulation consistent with the analyses required by E.O. 12866. *See* E.O. 14192 (Jan. 31, 2025), 90 FR 9065, 9066 (Feb. 6, 2025). For purposes of approximating the total cost savings and costs under E.O. 14192, the Commission uses the annualized monetized benefits and costs using a real discount rate of 7 percent. *See* Table 3 and accompanying discussion.

[199] *See* Circular A–4, at 32.

[200] *See id.* at 31 (stating that ''[t]he ending point should be far enough in the future to encompass all the significant benefits and costs likely to result from the rule''). The analysis uses a 2026–2035 analytical horizon and expresses monetary amounts in constant 2026 dollars. Present values are measured as of the beginning of 2026. We assume that recurring monetized compliance costs begin in 2027 and occur at mid-year in each year from 2027 through 2035. The analysis uses calendar years and accounts for the compliance periods included in the release (*see* note a in Table 2).

[201] *See id.* at 32 (''The Rationale for Discounting'') & 45 (''Treatment of Benefits and Costs over Time''); *see also* OIRA, Regulatory Impact Analysis: A Primer, at 11 (Aug. 15, 2011), *available at https://www.reginfo.gov/public/jsp/Utilities/circular-a-4_regulatory-impact-analysis-a-primer.pdf* (''To provide an accurate assessment of benefits and costs that occur at different points in time or over different time horizons, an agency should use discounting. Agencies should provide benefit and cost estimates using both 3 percent and 7 percent annual discount rates expressed as a present value as well as annualized.''); Harvey S. Rosen & Ted Gayer, Public Finance 151 (8th ed. 2008) (defining present value as ''the value today of a given amount of money to be paid or received in the future'').

[202] *See supra* footnote 197 and accompanying text.

[203] This approach is consistent with OMB Circular A–4. *See* Circular A–4, at 31–34 (stating that, ''[f]or regulatory analysis, [agencies] should provide estimates of net benefits using both 3 percent and 7 percent'' discount rates and discussing why those rates are reasonable default rates). Also, we use a mid-year discount rate. *See OMB, Circular* A–94, at 21–22 (Oct. 29, 1992) (stating that, ''When costs and benefits occur in a steady stream, applying mid-year discount factors is more appropriate.'').

[204] This approach is consistent with the recommended treatment of benefits and costs over time in Circular A–4. *See* Circular A–4 at 45 (''You should present annualized benefits and costs using real discount rates of 3 and 7 percent'').

[205] For each discount rate, the annualized monetized costs in Table 3 represent the constant annual stream of costs whose present value over the time horizon equals the corresponding present value in Table 2. *See* note a, Table 3 for additional calculation details. The annualized monetized costs present these values over the 10-year time horizon, starting in the year 2026.

Table 3: Annualized Aggregate Monetized Benefits and Costs
over 10 years from 2026 to 2035
(2026 Dollars)

Estimated Effects[a]	3% real discount rate	7% real discount rate
Benefits	not quantified	not quantified
Costs	$823,198	$805,319

Notes:

[a] For each discount rate, the annualized values are calculated by dividing the corresponding present values in Table 2 by the sum of discount factors over the time horizon. The discount factor in year *t* of the time horizon is equal to $1/(1 + discount\ rate)^{(t-0.5)}$.

We do not anticipate that the amendments will have any significant direct effects on efficiency, competition, or capital formation because, as discussed above, they will have minimal direct economic impact. But to the extent that the amended definitions of ''small entities'' contribute to the Commission better tailoring its rulemaking to account for the regulatory challenges faced by small entities, they could have indirect effects on efficiency, competition, and capital formation resulting from future rulemakings.[206] For example, if the Commission, informed by the more tailored RFA analyses, determined to tailor future rulemakings to reduce compliance costs for small entities, there could be benefits to competition.[207]

Lastly, the Commission considered alternatives to the amendments to Form ADV to align the form with the amended definition.[208] Specifically, we considered replacing Item 12 of Part 1A of Form ADV with a single question that would ask advisers to indicate whether they fall under the amended small entity definition, instead of providing the information in each question in Item 12 that would allow the Commission to continue to make that determination, under the amended definition. While the alternative may streamline the information reported in that item, we expect that it would not materially reduce costs for advisers because an adviser would still have to gather from its own records the information needed to apply the small entity definition.[209] In addition, the alternative may impose some transition costs for some advisers that would complete the item.[210] Finally, maintaining the requirement for advisers to report the information needed to apply the ''small entity'' definition will continue to provide the Commission with insight into the class of small entity advisers and how the individual parts of the definition affect whether advisers qualify as a small entity.

IV. Paperwork Reduction Act

A. Introduction

The final amendments revise part of an existing ''collection of information'' within the meaning of the Paperwork Reduction Act of 1995 (the ''PRA'').[211] The title for the collection of information is ''Form ADV'' (OMB control number 3235–0049).[212] An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The Commission solicited comments on the proposed revision to the collection of information and submitted it to OMB for review, in accordance with PRA requirements.[213] The Commission did not receive any comments on the PRA. The Commission is submitting the final collection of information to the OMB for review and approval in accordance with the PRA.[214]

B. Final Amendments

The final amendments in this release that will affect the collection of information titled ''Form ADV'' are the conforming amendments to Form ADV, Item 12 of Part 1A. Item 12 requires an SEC-registered adviser that is a ''small business'' or ''small organization'' to report how it qualifies as a ''small business'' or ''small organization'' under rule 0–7. Item 12 is designed to provide information to the public and the Commission about advisers, including information that enables the Commission to consider the effect of its regulations on small entities, as required by the RFA.[215] The final amendments affect a sub-set of respondents of the ''Form ADV'' collection of information, namely SEC-registered advisers that qualify as ''small businesses'' or ''small organizations'' under rule 0–7. Responses are mandatory and are not kept confidential.

As proposed, the Commission is making conforming amendments to Item 12 to reflect the final amendments to rule 0–7 concerning the amended RAUM Threshold, the amended Control Relationship Threshold, and their

[206] Some commenters agreed that the updated definitions may have indirect effects on competition and capital formation. *See, e.g.,* SBIA Comment Letter, IDC Comment Letter, and Logos Comment Letter.

[207] One commenter stated that '' . . . [T]he proposed amendments prioritize the hypothetical efficiencies, capital formation, and competitive benefits supposedly gained by mislabeling large advisers as 'small' entities. Historically, rules that focus on reducing industry costs harm investors.'' *See* PIABA Comment Letter. As noted above, we do not anticipate that the amendments will have any direct effects on efficiency, competition, or capital formation. Further, the Economic Analysis cannot predict the economic impact, including the impact on efficiency, competition, and capital formation, of any future rulemakings based on whether or how the Commission may adapt its policy choices as a result of the revised small entity definition; and thus such economic analysis of any future rulemakings is outside of the scope of the analysis in this rulemaking.

[208] Given the scope and context for this rulemaking, the Commission does not believe there are specific reasonable alternatives to the final conforming changes to the instruction for the continuing hardship exemption because these changes merely align the language in the instruction with the amended small entity definition and related changes to Item 12.

[209] While we anticipate that advisers would generate the necessary records in the ordinary course of their advisory businesses, we acknowledge that the alternative would impose some transition costs on advisers.

[210] *See* IAA Comment Letter (stating that ''Even incremental additions to Form ADV can require operational changes, compliance review, and ongoing monitoring.'')

[211] 44 U.S.C. 3501 *et seq.*

[212] The PRA is not applicable to the final amendments to 17 CFR 275.0–7, 17 CFR 270.0–10, or the amendments to 17 CFR 275.203–3(b) because they do not contain a ''collection of information'' requirement within the meaning of the PRA; they do not create any new filing, reporting, recordkeeping, or disclosure requirements. 44 U.S.C. 3502(3).

[213] 44 U.S.C. 3507(d); 5 CFR 1320.11; Proposing Release at section IV.

[214] 44 U.S.C. 3507(d); 5 CFR 1320.12.

[215] *See* Form ADV, Item 12 of Part 1A.

corresponding inflation adjustments.[216] In a change from the proposal, the Commission is making conforming amendments to Item 12 to reflect the removal of the Total Assets Threshold in final rule 0–7.

C. Estimated Burdens

Below is a table explaining the Commission's estimated annual burdens for the final amendments.

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Table PRA-1: Estimated Annual Burdens for the Final Amendments to Form ADV, Item 12 of Part 1A

	Proposed[1]	Final[3]	Difference[10]
Respondents	10,051 respondents[2]	10,180 respondents[4]	129 respondents
Aggregate Responses	10,051 responses	10,180 responses	129 responses
Time Burden Per Response	0.25 hours	0.25 hours[5]	No change
Aggregate Time Burden	2,512.75 hours	2,545 hours[6]	32.25 hours
Monetized Time Burden Per Response	$94.50	$91.25[7]	($3.25)
Aggregate Monetized Time Burden	$949,819.50	$928,925[8]	($20,894.50)
Aggregate Cost Burden	$0	$0[9]	No change

Notes:

[216] *See supra* section II.B.4.

1. *See* Proposing Release at section IV, based on IARD data as of December 31, 2024.

2. The Commission estimated that 10,850 advisers would complete Item 12 under the proposed amendments – 799 estimated advisers that already complete Item 12 = approximately 10,051 advisers that would newly complete Item 12 under the proposed amendments.

3. Estimates of respondents and aggregate responses are based on IARD data as of December 31, 2025. We continue to estimate one response per respondent.

4. We estimate that 11,017 advisers would complete Item 12 under the final amendments – 837 estimated advisers that already complete Item 12 = approximately 10,180 advisers that would newly complete Item 12 under the final amendments.

5. Although, in a change from the proposal, the final amendments remove requirements concerning the Total Assets Threshold, we continue to estimate that final Item 12 as a whole would take approximately 0.25 hours, as we estimated in the proposal.

6. Aggregate responses x time burden per response = aggregate time burden.

7. We expect a management analyst in the securities industry would complete Item 12, at an hourly wage rate of $365 per hour. 0.25 hours per response x $365 per hour wage rate = $91.25. To calculate the occupational hourly rate, the Commission uses the May 2025 occupational mean hourly wage data from the Occupational Employment and Wage Statistics (OEWS) program of the Bureau of Labor Statistics (BLS) for "Securities, Commodity Contracts, and Other Financial Investments and Related Activities" (NAICS 523). *See* Occupational Employment and Wage Statistics, U.S. BUREAU OF LABOR STATISTICS, https://www.bls.gov/oes/; *see also* Standard Occupational Classification, U.S. BUREAU OF LABOR STATISTICS, https://www.bls.gov/soc/ (describing occupational classification system used by BLS); EXEC. OFF. OF THE PRESIDENT, OFF. OF MGMT. & BUDGET, NORTH AMERICAN INDUSTRY CLASSIFICATION SYSTEM (2022), *available at* https://www.census.gov/naics/reference_files_tools/2022_NAICS_Manual.pdf (describing the industry classification system used by BLS and other agencies). The mean hourly wage for each occupation is multiplied by an employment cost index (ECI) factor of 1.0227, calculated as one plus the percentage change in the seasonally adjusted ECI for wages and salaries of private industry workers from the second quarter of 2025 (ECI=173.563), which contains the May 2025 OEWS reference period, to the first quarter of 2026 (ECI=177.498), which is the date of the most recently available ECI observations when the occupational hourly rates used in this release were calculated. See Employment Cost Index, U.S. BUREAU OF LABOR STATISTICS, Seasonal Data 2001-Present, available at https://www.bls.gov/eci/tables.htm. The adjusted mean hourly wage is then multiplied by a nonwage cost adjustment factor of 5.734, which accounts for nonwage costs borne by employers, such as bonuses, benefits, and overhead. This factor is calculated as the average, over 2016-2025, of the ratio of the Bureau of Economic Analysis's gross output for NAICS 523 to total annual wages across all occupations for NAICS 523 in the OEWS data. See Gross Output by Industry, U.S. BUREAU OF ECONOMIC ANALYSIS, https://www.bea.gov/data/industries/gross-output-by-industry; Occupational Employment and Wage Statistics, U.S. BUREAU OF LABOR STATISTICS, https://www.bls.gov/oes/. The $365 occupational hourly rate for a management analyst is calculated as $62.16 x 1.0227 x 5.734, or approximately $365 (where $62.16 is the May 2025 mean hourly wage for management analysts in NAICS 523). The final product is the occupational hourly rate. *See generally* UPDATED METHODOLOGY FOR CALCULATING OCCUPATIONAL HOURLY RATES (Dec. 19, 2025), *available at* https://www.sec.gov/files/method-occupational-hourly-rates.pdf.

8. Aggregate responses x monetized time burden per response = aggregate monetized time burden.

9. We continue to estimate $0 external cost burdens for the final amendments, because we expect advisers would generate the necessary records in the ordinary course of their advisory business.

10. The differences between the proposed and final estimates are due to using updated data. We estimate that the changes from the proposal would not result in burden changes. *See* note 5 above.

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V. Regulatory Flexibility Act Certification

Pursuant to section 605(b) of the RFA, the Commission certified that the proposed amendments to the rules would not, if adopted, have a significant economic impact on a substantial number of small entities. The Commission included this certification in section V of the Proposing Release.

As discussed in the Proposing Release, for purposes of the Advisers Act and the Regulatory Flexibility Act, currently an investment adviser generally is a small entity if it: (1) has assets under management having a total value of less than $25 million; (2) did not have total assets of $5 million or more on the last day of the most recent fiscal year; and (3) does not control, is not controlled by, and is not under common control with another investment adviser that has assets under management of $25 million or more, or any person (other than a natural person) that had total assets of $5 million or more on the last day of its most recent

fiscal year.[217] Currently, for the purposes of the Investment Company Act and the Regulatory Flexibility Act, funds are considered small entities if they, together with other funds in the same group of related funds, have net assets of $50 million or less as of the end of their most recent fiscal year.[218]

The Commission stated that the proposed amendments would ultimately affect its analyses under the RFA in future rulemakings but would not themselves impose an economic impact on funds or advisers. The proposed amendments to Advisers Act rule 203–3(b) are clarifying in nature and would not impose a significant economic impact on advisers. While additional advisers would have to complete Item 12 of Form ADV, the information required by this Item is readily available to advisers and the additional cost of this change would be minimal.[219] The Commission, therefore, stated that there would be no significant economic impact on a substantial number of small entities as a result of the proposed amendments.

The Commission requested comments on the certification, but did not receive any comments on the certification. We are adopting the amendments, with certain modifications from the proposal, as discussed above in section II. Such changes do not alter the basis of the Commission's certification in the Proposing Release. Accordingly, the Commission certifies that the final amendments will not have a significant economic impact on a substantial number of small entities.[220]

VI. Congressional Review Act

For purposes of Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act),[221] the Commission must seek the determination of the Office of Management and Budget (the ''OMB'') as to whether a final regulation constitutes a ''major rule.'' OMB has determined the final rule is not a ''major rule.''

VII. Other Matters

The Office of Management and Budget has determined that this action is not a significant regulatory action under Executive Order 12866, and therefore it was not subject to Executive Order 12866 review. This rule is not an Executive Order 14192 regulatory action because this rule is not significant under Executive Order 12866.

Statutory Authority

The Commission is adopting the rule and form amendments contained in this document under the authority set forth in chapter 6 of title 5 of the United States Code (particularly section 601 thereof [5 U.S.C. 601]), the Investment Company Act, particularly section 38 thereof [15 U.S.C. 80a–37], and the Advisers Act, particularly section 211 thereof [15 U.S.C. 80b–11].

List of Subjects in 17 CFR Parts 270, 275, and 279

Investment companies, Investment advisers, Reporting and recordkeeping requirements, Administrative practice and procedure.

Text of Rule and Form Amendments

For the reasons set out in the preamble, the Commission is amending title 17, chapter II of the Code of Federal Regulations as follows:

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

■ 1. The authority citation for part 270 continues to read, in part, as follows:

Authority: 15 U.S.C. 80a–1 *et seq.,* 80a–34(d), 80a–37, 80a–39, 1681w(a)(1), 6801–6809, 6825, and Pub. L. 111–203, sec. 939A, 124 Stat. 1376 (2010), unless otherwise noted.

* * * * *

■ 2. Revise § 270.0–10 to read as follows:

§ 270.0–10 Small entities under the Investment Company Act for purposes of the Regulatory Flexibility Act.

(a) *General.* For purposes of Commission rulemaking in accordance with the provisions of Chapter Six of the Administrative Procedure Act (5 U.S.C. 601 *et seq.*) and unless otherwise defined for purposes of a particular rulemaking, the term *small business* or *small organization* for purposes of the Investment Company Act of 1940 shall mean an investment company that, together with other investment companies in the same family of investment companies, has net assets of $10 billion or less as of the end of its most recent fiscal year, or, following March 1, 2037, the dollar amount specified in the most recent order issued by the Commission in accordance with paragraph (c) of this section and as published in the **Federal Register**. For purposes of this section, family of investment companies has the same meaning and conditions as in Item B.5 of Form N–CEN.

(b) *Determination of net assets.* The Commission may calculate its determination of the net assets of a family of investment companies based on the net assets of each investment company in the family of investment companies as of the end of such company's fiscal year.

(c) *Future inflation adjustments.* The dollar amount specified in paragraph (a) of this section shall be adjusted by order of the Commission, issued on or about March 1, 2037, and approximately every ten years thereafter. The adjusted dollar amount established in such orders shall be computed by:

(1) Dividing the year-end value of the Personal Consumption Expenditures Chain-Type Price Index (or any successor index thereto), as published by the United States Department of Commerce, for the calendar year preceding the calendar year in which the order is being issued, by the year-end value of such index (or successor) for the calendar year 2027; and

(2) Multiplying $10 billion times the quotient obtained in paragraph (c)(1) of this section and rounding the product to the nearest multiple of $1 billion.

PART 275—RULES AND REGULATIONS, INVESTMENT ADVISERS ACT OF 1940

■ 3. The authority citation for part 275 continues to read, in part, as follows:

Authority: 15 U.S.C. 80b–2(a)(11)(G), 80b–2(a)(11)(H), 80b–2(a)(17), 80b–3, 80b–4, 80b–4a, 80b–6(4), 80b–6a, 80b–11, 1681w(a)(1), 6801–6809, and 6825, unless otherwise noted.

* * * * *

■ 4. Revise § 275.0–7 to read as follows:

§ 275.0–7 Small entities under the Investment Advisers Act for purposes of the Regulatory Flexibility Act.

(a) For purposes of Commission rulemaking in accordance with the provisions of Chapter Six of the Administrative Procedure Act (5 U.S.C. 601 *et seq.*) and unless otherwise defined for purposes of a particular rulemaking proceeding, the term *small business* or *small organization* for purposes of the Investment Advisers Act of 1940 shall mean an investment adviser that:

(1) Has assets under management, as defined under Section 203A(a)(3) of the Act (15 U.S.C. 80b–3a(a)(3)) and reported on its annual updating amendment to Form ADV (17 CFR 279.1), of less than $1 billion, or, following March 1, 2037, the dollar amount specified in the most recent order issued by the Commission in accordance with paragraph (c) of this

[217] 17 CFR 275.0–7.

[218] 17 CFR 270.0–10.

[219] *See* Proposing Release at n.140, and accompanying text.

[220] *See* 5 U.S.C. 605(b).

[221] *See* 5 U.S.C. chapter 8.

section and as published in the **Federal Register**; and

(2) Does not control, is not controlled by, and is not under common control with another investment adviser that has assets under management equal to or greater than the threshold in paragraph (a)(1) of this section.

(b) For purposes of this section, *control* means the power, directly or indirectly, to direct the management or policies of a person, whether through ownership of securities, by contract, or otherwise.

(1) A person is presumed to control a corporation if the person:

(i) Directly or indirectly has the right to vote 25 percent or more of a class of the corporation's voting securities; or

(ii) Has the power to sell or direct the sale of 25 percent or more of a class of the corporation's voting securities.

(2) A person is presumed to control a partnership if the person has the right to receive upon dissolution, or has contributed, 25 percent or more of the capital of the partnership.

(3) A person is presumed to control a limited liability company (LLC) if the person:

(i) Directly or indirectly has the right to vote 25 percent or more of a class of the interests of the LLC;

(ii) Has the right to receive upon dissolution, or has contributed, 25 percent or more of the capital of the LLC; or

(iii) Is an elected manager of the LLC.

(4) A person is presumed to control a trust if the person is a trustee or managing agent of the trust.

(c) The dollar amount specified in paragraph (a) of this section shall be adjusted by order of the Commission, issued on or about March 1, 2037, and approximately every ten years thereafter. The adjusted dollar amount established in such orders shall be computed by:

(1) Dividing the year-end value of the Personal Consumption Expenditures Chain-Type Price Index (or any successor index thereto), as published by the United States Department of Commerce, for the calendar year preceding the calendar year in which the order is being issued, by the year-end value of such index (or successor) for the calendar year 2027; and

(2) Multiplying $1 billion times the quotient obtained in paragraph (c)(1) of this section and rounding the product to the nearest multiple of $100 million.

■ 5. Amend § 275.203–3 by revising paragraphs (b)(1) and (5) to read as follows:

§ 275.203–3 Hardship exemptions.

* * * * *

(b) * * *

(1) *Eligibility for exemption.* If you are a ''small business'' or ''small organization'' (as described in paragraph (b)(5) of this section), you may apply for a continuing hardship exemption. The period of the exemption may be no longer than one year after the date on which you apply for the exemption.

* * * * *

(5) *Small business or small organization.* You are a ''small business'' or ''small organization'' for purposes of this section if you are required to answer Item 12 of Form ADV (17 CFR 279.1) and checked ''no'' to each question in Item 12.

* * * * *

PART 279—FORMS PRESCRIBED UNDER THE INVESTMENT ADVISERS ACT OF 1940

■ 6. The authority citation for part 279 continues to read as follows:

Authority: The Investment Advisers Act of 1940, 15 U.S.C. 80b–1, *et seq.,* Pub. L. 111–203, 124 Stat. 1376.

■ 7. Amend Form ADV (referenced in § 279.1) by:

■ a. In the General Instructions, revising the second bullet point paragraph of Instruction 17 related to continuing hardship exemptions; and

■ b. In Part 1A, revising Item 12.

Note: Form ADV is attached as Appendix A to this document. The text of Form ADV does not, and this amendment will not, appear in the Code of Federal Regulations.

By the Commission.

Dated: November 4, 2026.

Sherry R. Haywood,

Assistant Secretary.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix A

FORM ADV (Paper Version)

Uniform Application for Investment Adviser Registration and Report by Exempt Reporting Advisers

Form ADV General Instructions

* * * * *

17. What if I am not able to file electronically?

If you are required to file electronically but cannot do so, you may be eligible for one of two types of hardship exemptions from the electronic filing requirements.

* * * * *

• A *continuing hardship exemption* may be granted if you are a small business or small organization and you can demonstrate that filing electronically would impose an undue hardship. You are a small business or small organization, and may be eligible for a continuing hardship exemption, if you are required to answer Item 12 of Part 1A *and* you are able to respond ''no'' to each question in Item 12. See SEC rule 0–7.

If you have been granted a continuing hardship exemption, you must complete and submit the paper version of Form ADV to FINRA. FINRA will enter your responses into the IARD. As discussed in General Instruction 16, FINRA will charge you a fee to reimburse it for the expense of data entry.

* * * * *

Part 1A

* * * * *

Item 12 Small Businesses

The SEC is required by the Regulatory Flexibility Act to consider the effect of its regulations on small entities. In order to do this, we need to determine whether you meet the definition of ''small business'' or ''small organization'' under rule 0–7.

Answer this Item 12 only if you are registered or registering with the SEC *and* you indicated in response to Item 5.F.(2)(c) that you have regulatory assets under management of the thresholds provided in rule 0–7. You are not required to answer this Item 12 if you are filing for initial registration as a state adviser, amending a current state registration, or switching from SEC to state registration.

For purposes of this Item 12 only, *control* means the power to direct or cause the direction of the management or policies of a *person,* whether through ownership of securities, by contract, or otherwise. Any *person* that directly or indirectly has the right to vote 25 percent or more of the voting securities, or is entitled to 25 percent or more of the profits, of another *person* is presumed to *control* the other *person.*

	Yes	No
A. Do you *control* another investment adviser that had regulatory assets under management equal to or greater than the threshold provided in rule 0–7(a)(1) on the last day of its most recent fiscal year?	☐	☐
B. Are you *controlled* by or under common *control* with another investment adviser that had regulatory assets under management equal to or greater than the threshold provided in rule 0–7(a)(1) on the last day of its most recent fiscal year?	☐	☐

* * * * *

[FR Doc. 2026–22741 Filed 11–5–26; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

19 CFR Parts 110, 111, 141, 142 and 171

[USCBP–2026–1387; CBP Dec. 26–19]

RIN 1685–AA48

Heightened Requirements for Foreign Importers of Record

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Interim final rule; request for comments.

SUMMARY: This document amends the U.S. Customs and Border Protection (CBP) regulations, consistent with Section 2 of Executive Order 14411, ''Strengthening Customs Enforcement,'' by establishing new requirements for foreign importers of record (IORs) when making entry, and corresponding responsibilities for licensed customs brokers with regard to their clients. The new regulations also set forth consequences for foreign IORs and customs brokers who fail to comply with the new requirements.

DATES: This interim final rule is effective on January 5, 2027. As explained in Section VII, licensed customs brokers may submit requests for delayed compliance with the changes in § 111.29 of title 19 of the Code of Federal Regulations (19 CFR 111.29) prior to January 5, 2027. All customs brokers are expected to be in full compliance with the requirements of this rule no later than May 6, 2027.

Comment date: Comments on the rule must be received on or before January 5, 2027.

ADDRESSES: You may submit comments, identified by docket number, through the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments via docket number USCBP–2026–1387.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents and submitted comments, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Anita Rivera, Branch Chief, Revenue Enforcement Branch, Trade Modernization Division, Trade Programs Directorate, Office of Trade, at (771) 233–2939 or *ForeignIOR@cbp.dhs.gov.*

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I. Public Participation

Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments on any aspect of this rulemaking. U.S. Customs and Border Protection (CBP) also invites comments that relate to the economic or federalism effects that might result from this rule. If appropriate to a specific comment, the commenter should reference the specific portion of the rule, explain the reason for any recommended change, and include data, information, or authority that supports the recommended change.

II. Background

On June 3, 2026, the President signed Executive Order (E.O.) 14411 (Strengthening Customs Enforcement).[1] Section 1 of the E.O. emphasizes the importance of customs enforcement for purposes of national security, foreign policy, and the economy of the United States. It further states that effective customs enforcement prevents the importation of unlawful and dangerous goods, ensures importers of record (IORs) are correctly identified and held accountable for duties owed, and guarantees compliance with numerous Federal laws, including laws governing forced labor, rules of origin, origin marking, intellectual property, revenue collection, and product safety.

The E.O. calls for customs reform to remedy systemic inefficiencies, loopholes, insufficient enforcement mechanisms, and outdated processes that have created opportunities for malign actors to evade Federal law. IORs often use various arrangements and schemes to undervalue imports, withhold critical information about themselves and the goods being imported or its production process, and/or avoid payment of duties. These actions threaten national security, threaten product safety, undermine foreign relations, disadvantage domestic businesses, and harm Americans.

Sections 2(b) and (c) of E.O. 14411 direct the Secretary of the Department of Homeland Security, through the issuance or modification of relevant regulations, policy or guidance, to prohibit foreign IORs from making informal entry pursuant to 19 U.S.C. 1498 and to require foreign IORs who want to make formal entry to either be a Customs Trade Partnership Against Terrorism (CTPAT) validated participant or use a licensed customs broker who is a CTPAT validated participant. Section 10 of the E.O. provides definitions for certain terms, such as ''foreign IOR'' and ''U.S. IOR,'' that are intended to assist in the enforcement of the E.O.'s directives.

One of CBP's many critical mission sets is to facilitate legitimate trade that supports economic growth while shielding the American public and businesses from illicit trade, including unsafe products, intellectual property theft, and unfair trade practices. In particular, with respect to foreign IORs, CBP faces challenges enforcing their financial obligations to the U.S. government arising from lost revenue, such as from unpaid duties and taxes. In addition, CBP cannot easily ensure that foreign IORs are complying with U.S. customs and trade laws to prevent the importation of dangerous and

[1] 91 FR 35125 (June 10, 2026). A Fact Sheet accompanying the Executive Order, issued the same day, emphasizes the goal of comprehensive customs reform through various actions to be taken by the Department of Homeland Security (DHS) and CBP to strengthen the enforcement of U. S. customs laws and promote economic strength and national security by combatting customs fraud. *See https://www.whitehouse.gov/fact-sheets/2026/06/fact-sheet-president-donald-j-trump-strengthens-customs-enforcement/.*

unlawful goods. These challenges exist primarily because foreign IORs and their assets are primarily located outside the United States.

Consistent with the E.O. and governing statutes, this rulemaking addresses the challenges presented by foreign IORs. Section 2(b) of the E.O. instructs CBP to prohibit foreign IORs from filing informal entry because, among other reasons, such IORs are not similarly situated to U.S. IORs and may be less familiar with U.S. customs laws. Foreign IORs also present challenges when CBP pursues enforcement actions against them. Similarly, Section 2(c) of the E.O. instructs CBP to prohibit foreign IORs who have not been vetted by CBP through CTPAT validation from making formal entry, unless they rely on a CTPAT validated broker to file the entry. This is necessary to treat all IORs equally based on their individualized circumstances to protect the revenue and strengthen national security.

Through CTPAT validation of IORs, CBP is able to ensure proper vetting of foreign IORs that mitigates risks to revenue, domestic industry, American consumers, and national security—CTPAT validation allows CBP to pursue effective enforcement against foreign IORs and provides heightened visibility into their corporate structures and supply chains. Because CTPAT validation offers CBP stronger insight into foreign IORs, CBP is not prohibiting foreign IORs who are CTPAT validated from filing informal entry in this rulemaking. Similarly, CBP is not prohibiting foreign IORs from filing informal entry through a CTPAT validated broker in this rulemaking. However, as further detailed in section VI.G. below, CBP will be monitoring the informal entries filed by foreign IORs and their brokers following the effective date of the rule. If CBP determines that informal entries filed by foreign IORs present risks to the revenue, national security, or public health and safety, CBP will take action to fully prohibit foreign IORs from using informal entry to enter goods for consumption.

CBP will only allow a foreign IOR to enter goods for consumption [2] on its own behalf, *i.e.,* to serve as the IOR for the entry, whether an informal or formal entry,[3] if the foreign IOR is CTPAT validated. Further, consistent with Section (2)(c) of the E.O., the only way for a foreign IOR who is not CTPAT validated to secure the entry and release of goods is by designating a CTPAT validated and licensed customs broker to make entry on the foreign IOR's behalf.

This rulemaking implements these requirements for foreign IORs when filing entries pursuant to the authority in 19 U.S.C. 1484 and 1498. This rule will assist CBP in preventing foreign parties from evading U.S. customs and trade laws and will level the playing field for U.S. IORs by holding foreign IORs to the same standards and enforcement mechanisms to which U.S. IORs are currently held. Heightened requirements for foreign IORs will further CBP's mission to protect the American public and ensure the collection of revenue owed to the United States. With this rule, foreign IORs are prohibited from making informal entry of merchandise for consumption for which a CBP Form 3461 or 7501 must be filed unless the foreign IOR is either a CTPAT validated participant or uses a CTPAT validated and licensed customs broker. To make formal entry, a foreign IOR must also either be a CTPAT validated participant or use a CTPAT validated and licensed customs broker to enter merchandise for consumption. Foreign parties who are not CTPAT validated IORs must designate a licensed customs broker who is a CTPAT validated participant to file entry on their behalf. A designated licensed customs broker who is a CTPAT validated participant must act as the importer of record for the entry if such foreign parties are not the owner or purchaser of the merchandise being entered.

CBP is leveraging the CTPAT program to increase transparency as to foreign IORs transacting customs business in the United States and to better identify the merchandise they are importing. CTPAT validated participants have been vetted by CBP, have demonstrated that they are meeting certain security requirements, *i.e.,* the minimum security criteria (MSC), and have a known history of compliance, resulting in a higher degree of accountability and visibility into the foreign IOR's supply chain and security. Where a customs broker is acting on behalf of a foreign party, CBP is utilizing the existence of CTPAT validated and licensed brokers in the transaction to ensure transparency and accountability for a segment of the trade that presents higher risk than others.

III. Authority

Under section 66 of title 19 of the United States Code (19 U.S.C. 66), the Secretary of the Treasury [4] is authorized to prescribe regulations to be used in carrying out the provisions of laws relating to raising revenue from imports or to duties on imports, or to warehousing, and give directions to CBP officers and prescribe such rules and forms to be observed by them as may be necessary for the proper execution of the law. Section 1624 of title 19 (19 U.S.C. 1624) authorizes the Secretary of the Treasury to make such rules and regulations as may be necessary to carry out the provisions of the Tariff Act of 1930, codified at 19 U.S.C. 1001 *et seq.*

Section 4320 of title 19 (19 U.S.C. 4320) [5] authorizes the Secretary of the Department of Homeland Security (DHS) to establish, among other things, a program that ensures collection of sufficient information to allow CBP to verify the existence of an IOR (19 U.S.C. 4320(b)(1)(A)), sufficient information to allow CBP to identify linkages or other affiliations between importers (19 U.S.C. 4320(b)(1)(B)), and sufficient information to allow CBP to identify changes in address and corporate structure of an importer (19 U.S.C. 4320(b)(1)(C)). Section 4321 of title 19 (19 U.S.C. 4321) authorizes the Commissioner of CBP, as part of an importer risk assessment program, to develop risk assessment guidelines for

[2] Encompassing all entries for consumption (19 CFR 141.0a(f)), to include entries filed upon importation, and upon withdrawal from a bonded warehouse or a Foreign Trade Zone.

[3] As explained in more detail below, these requirements are applicable to merchandise for which an informal entry is required to be filed on CBP Form 3461 or 7501, or their electronic equivalents, and for which a formal entry is required to be filed.

[4] The Homeland Security Act of 2002 generally transferred the functions of the U.S. Customs Service from the Treasury Department to the Secretary of the Department of Homeland Security. *See* Public Law 107–296, 116 Stat. 2142; 6 U.S.C. 203 (''there shall be transferred to the Secretary [of Homeland Security] the functions . . . of (1) the United States Customs Service of the Department of the Treasury, including the functions of the Secretary of the Treasury relating thereto''). Nevertheless, pursuant to Section 412 of the HSA, the Treasury Department retained authority related to various customs revenue functions, including those functions found in the Tariff Act of 1930 [(Pub. L. 71–361, 46 Stat. 590, as amended (codified at 19 U.S.C. 1202 *et seq.*)). 6 U.S.C. 212(a)(1), (2). But the Secretary of the Treasury may delegate any such retained authority at the Treasury Secretary's discretion. 6 U.S.C. 212(a)(1). Consistent with this delegation authority, the Secretary of the Treasury issued Treasury Order 100–20 (available at *https://home.treasury.gov/about/general-information/orders-and-directives/treasury-order-100-20*), delegating the authorities contained in 6 U.S.C. 212 and 215 to the Secretary of Homeland Security. All further references to the ''Secretary of Treasury'' should be construed as referring to the Secretary of Homeland Security unless specified otherwise.

[5] On February 24, 2016, Congress enacted the Trade Facilitation and Trade Enforcement Act of 2015 (TFTEA), Public Law 114–125, 130 Stat. 122 (19 U.S.C. 4301 note). Sections 114 and 115 of TFTEA added sections 4320 (Importer of record program) and 4321 (Establishment of importer risk assessment program) to title 19 of the U.S. Code. Section 116 of TFTEA amended 19 U.S.C. 1641, adding paragraph (i) (Identification of importers).

IORs, including nonresident importers,[6] and procedures to ensure increased oversight of products imported by new nonresident importers relating to the enforcement of priority trade issues.[7] *See* 19 U.S.C. 4321(a) and (b). Section 4321(c) excludes validated Tier 2 and Tier 3 CTPAT participants from the requirements of 19 U.S.C. 4321.[8]

Sections 1484 and 1498 of title 19 (19 U.S.C. 1484 and 1498) authorize the Secretary of the Treasury to prescribe regulations for the declaration and entry of merchandise. All merchandise imported into the customs territory of the United States is subject to entry and clearance procedures, unless excepted. *See* section 141.4(a) of title 19 of the Code of Federal Regulations (19 CFR 141.4(a)). These procedures ensure the proper appraisement, valuation, and tariff classification of the merchandise for the purpose of collecting the lawful amount of duties owed, as well as ensuring compliance with all laws and regulations administered and enforced by CBP. Sections 1484 and 1498 provide for different procedures for the entry and clearance of merchandise depending upon the aggregate value of the shipment. There are ''formal entry'' procedures established by 19 U.S.C. 1484 and 1485, which are generally applicable to shipments of merchandise valued in excess of $2,500. Title 19 CFR part 142 implements 19 U.S.C. 1484, as amended, and prescribes formal entry procedures.

Section 1498 of title 19 (19 U.S.C. 1498) authorizes special rules and regulations for the entry of certain merchandise, which includes section 1498(a)(1)(A) concerning shipments of merchandise valued at $2,500 or less (referred to as ''informal entries''). Such entries may be, but are not required to be, subject to the requirements for formal entry prescribed at 19 U.S.C. 1484 and 1485. Informal entry regulations are found at 19 CFR part 143, subpart C. While informal entries are ''excepted'' from formal entry requirements, as noted, the Secretary of the Treasury may include any formal entry requirement in the rules and regulations governing informal entry. 19 U.S.C. 1498(b). The statutory framework of 19 U.S.C. 1498 authorizes, in effect, a less stringent entry process than under 19 U.S.C. 1484, which has developed into a process with fewer forms and procedures as compared to the formal entry process. As a result, informal entry procedures are generally less burdensome and complex than the formal entry procedures. However, CBP may require formal entry for any merchandise if deemed necessary for purposes of admissibility, revenue protection, or the efficient conduct of customs business. 19 CFR 143.22.

Section 1641 of title 19 (19 U.S.C. 1641) authorizes the Secretary of the Treasury to prescribe such regulations relating to the customs business of customs brokers as the Secretary considers necessary to protect importers and the revenue of the United States, including regulations relating to the furnishing of information to CBP, and to carry out the provisions of 19 U.S.C. 1641.

Section 1592 of title 19 (19 U.S.C. 1592) authorizes CBP to assess civil penalties against any person who, by fraud, gross negligence or negligence, enters or introduces, or attempts to enter or introduce, merchandise into commerce of the United States by means of a material false statement or omission.

The Security and Accountability for Every (SAFE) Port Act of 2006 (Pub. L. 109–347, 120 Stat. 1884 (2006), 6 U.S.C. 961 *et seq.*) authorizes the Secretary of DHS, acting through the Commissioner of CBP, to establish a voluntary government-business initiative to build cooperative relationships that strengthen and improve overall security of the international supply chain and U.S. border security, and facilitate the movement of secure cargo through the international supply chain, known as CTPAT. *See* 6 U.S.C. 962, 964 and 965. The CTPAT program plays a crucial role in safeguarding the economic and national security of the United States by acting as a vital component of CBP's multi-layered, risk-based security strategy. By securing international supply chains, the program helps prevent the entry of terrorist weapons, narcotics, and other contraband, thereby mitigating threats to national security. The CTPAT program contributes to the nation's prosperity by ensuring the free and fair flow of legitimate trade, preventing costly disruptions, and fostering a secure trade environment. The program's commitment to customs and trade enforcement provides an essential platform to combat trade fraud and protect American consumers and industries.

CBP encourages participation in this program by providing benefits to participants meeting or exceeding the CTPAT program requirements. An individual or company [9] that wishes to participate in the CTPAT program must complete an application in the CTPAT Portal [10] demonstrating that it meets the MSC [11] to establish eligibility for the program. Once a company is accepted into the program and receives ''certified'' status, the CTPAT participant will undergo a validation to verify the participant's supply chain security processes. 6 U.S.C. 964. At the conclusion of a successful validation, the participant will be granted ''certified—validated'' status. 6 U.S.C. 965. Upon becoming a participant in the CTPAT program, an individual or company enjoys a variety of benefits, which are listed on CBP's website at *https://www.cbp.gov/border-security/ports-entry/cargo-security/ctpat.*[12]

IV. Challenges Relating to Foreign Importers of Record

Unlike other countries that either do not allow foreign persons to act as an IOR or have strict processes for becoming a foreign IOR,[13] in the United

[6] Section 4321(e)(2) defines a ''nonresident importer'' as an importer who is (A) an individual who is not a citizen of the United States or an alien lawfully admitted for permanent residence in the United States; or (B) a partnership, corporation, or other commercial entity that is not organized under the laws of a jurisdiction within the customs territory of the United States (as such term is defined in General Note 2 of the Harmonized Tariff Schedule of the United States) or in the Virgin Islands of the United States.

[7] Section 4322 of title 19 (19 U.S.C. 4322) established seven ''priority trade issues,'' including import safety and revenue, and provided procedures for future changes to the list of priority trade issues.

[8] In this interim final rule, CBP is referring to the tier system of the CTPAT program only in the context of 19 U.S.C. 4321. Although initially referred to as Tier 1, Tier 2, and Tier 3 for CTPAT program participants, CBP has transitioned to using the terms ''certified,'' ''certified—validated,'' and ''certified—exceeding'' when referring to the various levels of the CTPAT program.

[9] *See* 6 U.S.C. 962. Businesses eligible to apply for CTPAT partnership include U.S. importers of record; non-resident Canadian importers; U.S./Canada highway carriers; U.S./Mexico highway carriers; air, rail and sea carriers; licensed U.S. customs brokers; U.S. marine port authority/terminal operators; certain third-party logistics providers (3PLs); U.S. freight consolidators; ocean transportation intermediaries and non-vessel operating common carriers (NVOCCs); Mexican and Canadian manufacturers; and Mexican long-haul highway carriers. In addition, CBP is conducting a pilot (90 FR 52690), Nov. 21, 2025)) for certain types of asset-based and non-asset-based 3PLs that are currently not eligible to participate in the CTPAT program, pursuant to the Customs Trade Partnership Against Terrorism Pilot Program Act of 2023 (Pub. L. 118–98, 138 Stat. 1575).

[10] *See trade.cbp.dhs.gov/ctpat/ctpat-portal-ui.*

[11] *See* 6 U.S.C. 963. *See also https://www.cbp.gov/border-security/ports-entry/cargo-security/ctpat-customs-trade-partnership-against-terrorism/apply/security-criteria.*

[12] This list may change as benefits are updated to improve the program.

[13] For example, Mexico, Brazil, India, South Korea, Vietnam, and China do not allow foreign persons to act as IORs. The European Union (EU) allows foreign IORs, however, the importer must obtain a unique identification number and in many EU Member States must obtain a local Value-Added Tax (VAT) registration. Japan requires all non-resident importers to utilize an attorney for customs procedure when importing into Japan to ensure proper compliance with customs rules.

States, a foreign individual or entity may become an IOR and make entry in the United States solely by submitting CBP Form 5106 (Create/Update Importer Identity Form) to request a CBP-assigned number, or by using an Internal Revenue Service (IRS) Employer Identification Number (EIN), which provides only basic contact and business information to CBP. Many of the foreign individuals and entities who become IORs appear to be U.S.-based in the Automated Commercial Environment (ACE) because they list a U.S. address, which may be the address of an agent or post office box for mail. In reality, these foreign individuals or entities have no physical presence and no assets beyond a mailing address in the United States and are considered shell companies. These shell companies obscure the real identity and corporate structure of their owner,[14] as well as ownership of the entity's assets, enabling tax evasion, financial fraud and other financial crimes. Due to the anonymity of a shell company's identity and the identity of its owner(s), it is difficult to track and verify the company's financial transactions, including customs entries, and to prevent the importation of potentially unsafe merchandise, such as counterfeit goods and precursor chemicals for the purposes of manufacturing illicit substances, into the United States. Thus, these shell companies pose a significant threat to national security, economic security, and public safety.

These shell companies may also engage in misclassification, undervaluation, or other duty evasion schemes, knowing that CBP's options for enforcement are limited when assets and individuals are located outside of the United States and that it is more difficult for CBP to detect linkages and affiliations. In such cases, when detected by CBP, these shell company IORs may be placed on live entry pursuant to 19 CFR 142.13(a)(3), which mandates the filing of an entry summary and deposit of all estimated duties, taxes, and fees owed to obtain the merchandise's release from CBP custody, and may have their immediate delivery privileges discontinued pursuant to 19 CFR 142.25(a). However, the shell company IOR may export the shipment rather than pay the estimated duties, taxes, and fees at that time, making collection efforts fruitless, and later attempt to re-enter the goods under a different shell company. Enforcement actions against shell companies are challenging because the foreign entity may simply shut down an existing shell company and begin importing as a new shell company. When an IOR is registered with CBP by submitting CBP Form 5106, CBP is only aware that the entity is a foreign IOR if the IOR lists its foreign address.[15] Once the IOR has begun importing and becomes liable for the payment of duties, penalties, or liquidated damages, CBP may later learn through its investigations and enforcement actions that an IOR who listed a U.S. address was in reality a shell company set up on behalf of a foreign company to avoid paying CBP debts that become due or evade other enforcement consequences. By this point, the economic damage undercutting U.S. domestic industry has already been completed.

The United States faces substantial challenges when seeking to enforce U.S. customs and trade laws against foreign IORs. One of these challenges is the enforcement of financial obligations to the U.S. government, including duties. Pursuing the collection of duties, penalties, and liquidated damages is often ineffective because these entities' operations are outside U.S. jurisdiction, and their assets and key individuals are located outside U.S. jurisdiction. While CBP can use tools such as ''live entry'' [16] and discontinuance of immediate delivery privileges pursuant to 19 CFR 142.13 and 142.25 to secure future obligations, amounts already owed to CBP often go uncollected if the entity is unwilling to pay. Data collected from October 2020 through the beginning of February 2026 shows that the unpaid bill amount per entry is $29.16 for foreign IORs as compared to $22.57 for U.S. IORs, which is 29% lower for U.S. IORs.[17] As of February 6, 2026, the total principal bill amount (not including interest) owed by non-CTPAT foreign IORs for uncollected bills that were opened on or after October 1, 2020, and remained unpaid, was $1.01 billion. After CBP audits uncovered $1.16 billion in lost revenue from foreign IORs between January 1, 2020, and August 27, 2026, CBP was able to recoup only $35.7 million, implying a collection rate of 3.1% for the missed payments.[18] For U.S. IORs, that collection rate was 15.2%. Additionally, live entry and discontinuance of immediate delivery privileges are limited in their effectiveness where foreign IORs reconstitute their identities and create new fake companies. These new shell companies operate under a different name and exist solely to evade enforcement consequences for violations of U.S. law. While CBP's enforcement authority extends to any individual or entity importing merchandise into the United States, enforcement is often more effective against individuals and entities located within the United States. When an IOR's operations and the majority if not all of its financial assets are located outside the United States, CBP's ability to compel compliance with U.S. customs and trade laws, conduct investigations, collect owed revenue, identify linkages and affiliations, or enforce penalties is significantly reduced. Moreover, the government's ability to pursue legal action against, or collect duties from, these foreign entities is more complex because they are not subject to U.S. jurisdiction due to the revenue rule.

The revenue rule is a longstanding common law doctrine that permits the courts of one country to refuse to entertain lawsuits that are initiated by a foreign country to enforce the foreign country's revenue laws. *Her Majesty the Queen* v. *Gilbertson,* 597 F.2d 1161, 1164–1165 (9th Cir. 1979); *see also Holman* v. *Johnson,* (1775) 98 Eng. Rep. 1120–1121 (K.B. 1775) (stating that ''no country ever takes notice of the revenue laws of another''). The rationale behind the rule is threefold: first, the international principle of comity precludes the courts of one nation from scrutinizing (and potentially bringing embarrassment upon) the public laws of another nation; second, one nation's utilization of another nation's court system to enforce its own revenue laws is an extension of the former nation's sovereign power, and that assertion of sovereign power within the territory of another nation violates national sovereignty principles; and third, permitting the courts of one nation to interpret the complex revenue laws of a

[14] While CBP Form 5106 includes a section (3J) for information regarding the beneficial owner and company officer of an entity, it is optional and frequently, an entity does not provide this information when submitting the form. For example, from July 2021 through June 2026, only 2.88% of IORs who are registered as foreign in ACE provided the company position title of a company officer, 3.17% provided the name of a beneficial owner or company officer, 1.52% provided an email and phone number of a company officer or beneficial owner, and 0.38% provided passport details of a company officer or beneficial owner.

[15] Foreign individuals or entities may indicate in section 1E of CBP Form 5106 that they are requesting a CBP-assigned number because they are not a U.S. resident but are not required to do so, as the data elements in this section are optional.

[16] The term ''live entry'' colloquially refers to the requirement of filing of an entry summary, with payment of any estimated duties, taxes, and fees owed, as a prerequisite to obtaining the release of imported merchandise from CBP custody. 19 CFR 142.13(a).

[17] Source: CBP Office of Finance data, obtained on February 17, 2026.

[18] Source: received from CBP's Office of Trade (OT) on August 27, 2026. Obtained from Trade Regulatory Audit Management System.

foreign nation would result in great administrative difficulties at great expense to the interpreting nation. *Gilbertson,* 597 F.2d at 1164 (quoting *Moore* v. *Mitchell,* 30 F.2d 600, 604 (2nd Cir. 1929)); *Gov't of India* v. *Taylor,* (1955) A.C. 491, 511–514 (H.L. 1955). Thus, the revenue rule protects the independent sovereignty of each nation and prevents the courts of one country from becoming an extension of the judicial branch of another. Lawsuits to recover U.S. customs duties, penalties, and liquidated damages are all within the jurisdiction of the federal courts. *See, e.g.,* 28 U.S.C. 1331, 1582. However, enforcement of such a judgment from a federal court in a foreign jurisdiction would likely be precluded by that jurisdiction's observance of the revenue rule, or at least time-consuming and exceedingly difficult to pursue.

Verification of the accuracy of import and entry documentation, conducting audits, or performing site visits of a foreign IOR's premises are all considerably more difficult and resource intensive for foreign IORs. CBP also faces challenges in enforcing CBP recordkeeping requirements on foreign IORs. Although all importers, foreign and U.S., are subject to recordkeeping requirements under 19 U.S.C. 1508, it is much easier and more straightforward for CBP to conduct document verification and examination of records for domestic entities. Communication barriers and lack of understanding of U.S. laws and regulations can further hamper CBP's enforcement ability and result in delays, difficulty in resolving issues, and a higher incidence of errors and non-compliance.

Generally speaking, it is inherently more complex for CBP to ensure compliance by foreign IORs, as compared to U.S. IORs. Foreign IORs may exploit U.S. customs and trade laws and refuse to pay their customs debts, knowing the challenges posed by international enforcement of domestic customs laws and regulations. Because of these challenges in holding foreign IORs accountable, there is decreased incentive for foreign IORs to comply with U.S. laws and regulations intended to ensure the safety of imported merchandise and to secure the revenue; foreign IORs avoid the consequences that U.S. IORs face, because their assets and key individuals may be beyond the reach of CBP and the U.S. courts. Principles such as the revenue rule reinforce why it is important for the United States to impose heightened requirements on foreign IORs, who can more easily evade payment of amounts owed and other consequences for noncompliance with U.S. customs and trade laws. These challenges are unique in the context of foreign IORs.

V. Addressing the Challenges Relating to Foreign Importers of Record

It is critical that CBP be able to counter the challenges discussed above through meaningful and effective enforcement actions. Thus, pursuant to the authorities set forth above, and consistent with E.O. 14411, CBP is implementing additional requirements for foreign IORs to make entry. This rule will require foreign IORs to be CTPAT validated, or to use a CTPAT validated and licensed customs broker to make entry. These new requirements will promote compliance and accountability. Licensed customs brokers will have new responsibilities corresponding with the new foreign IOR requirements to verify and declare that their client meets the qualifications to be considered a U.S. IOR before reporting as a U.S. IOR. Lastly, this rule will impose a new requirement on U.S. IORs to declare their qualification as a U.S. IOR.

To implement these new requirements, CBP is establishing a new part 110 (Importers of Record) in title 19 of the CFR. This new part contains two sections laying out the qualifications to be considered a ''U.S. importer of record,'' or ''foreign importer of record,'' as well as a new definitions section defining the terms ''beneficial owner,'' and ''physical domestic assets.'' This new part 110 provides predictability and standardization for trade members which previously did not exist.

First, CBP establishes the requirements that must be met to be considered a U.S. IOR in new 19 CFR 110.2(a), to allow CBP, IORs, and customs brokers to know who qualifies as a U.S. IOR and who does not. Pursuant to this new provision, a U.S. IOR is an individual who is a United States citizen or lawful permanent resident, or an entity that is organized under the laws of the United States, is located in the United States, and maintains at all times: (i) at least 51% of beneficial owner(s) who are United States citizens or lawful permanent residents and have control of the entity; or (ii) direct ownership of a significant amount of unencumbered real property in the United States. With respect to real property ownership, the property can be subject to some encumberment, but the net unencumbered value of the real property must be of a significant amount. Whether an individual or entity qualifies as a U.S. IOR is subject to verification by CBP as set forth in a new § 110.2(b). A foreign IOR is defined as an IOR who does not meet the criteria of a U.S. IOR, pursuant to § 110.3.

In the new § 110.2(b), CBP has set forth a verification process for confirming that a party meets the requirements to be considered a U.S. IOR. The determination of whether an entity qualifies as a U.S. IOR or a foreign IOR will vary depending upon the circumstances in each instance. To verify that an entity is located in the United States for qualification as a U.S. importer of record, CBP will take into account, among other considerations, the size and scale of the overall operations of the entity and whether it is an instrumentality of a foreign manufacturer without a substantial presence in the United States. Criteria which CBP may consider in its discretion and to the extent relevant, include, but are not limited to, whether: (1) the entity's principal place of business is in the United States; (2) the entity has a physical presence in the United States where substantial business transactions are conducted, such as paying employees, generating revenue, or operating retail locations; (3) the entity maintains sufficient unencumbered physical domestic assets, as defined in § 110.1; (4) the entity directly owns a sufficient amount of unencumbered real property in the United States; (5) the entity's gross sales generally exceed its cost of goods sold and the entity is structured in a manner that it is anticipated to generate its own profit; and (6) the entity is sufficiently capitalized. As good governance, CBP is providing this non-exhaustive list of criteria that CBP will consider when verifying the identity and status of an IOR. These criteria are flexible as CBP cannot predict all possible circumstances that may be relevant for verification purposes. Having the newly created criteria available will allow CBP to verify that an entity's declaration meets the requirements under § 110.2, which in turn increases supply chain security, revenue protection, and compliance with the customs law of the United States.

In its verification, CBP may review records, such as, proof of citizenship or lawful permanent residence, corporate charters, financial statements and records, purchase receipts, or documents of title, provided at the request of CBP. Pursuant to 19 U.S.C. 1508, an IOR, or other party who imports merchandise into the customs territory of the United States, or an agent of an IOR or person whose activities require the filing of a declaration or entry, or both, must make, keep, and render for examination and inspection records which pertain to

any such activity and are normally kept in the ordinary course of business.[19] To ensure CBP can adequately verify the status of IORs, the IOR must, pursuant to 19 U.S.C. 1508, comply with statutory recordkeeping and production requirements, and CBP retains the authority to request proof from the IOR as to its qualification as a U.S. IOR.

CBP is taking a comprehensive approach to distinguish the level of risk associated with foreign and U.S. IORs, to establish requirements commensurate with that risk, thus putting all importers (including nonresident importers as described in 19 U.S.C. 4321) on equal footing. These new regulatory provisions require consideration of both substance (such as ownership, physical presence, and U.S.-based assets) and form (such as place of incorporation or organization and address) as indicators of whether an individual or entity is a U.S. or foreign IOR. The existing references to a ''nonresident importer'' in CBP regulations (found in subparts B and C of part 141) capture importers who are not U.S. citizens or lawful permanent residents or not entities organized under the laws of the United States or its territories; that is, importers who have met a low threshold to qualify as nonresident importers. A nonresident importer could simply be an importer who is not incorporated within the customs territory of the United States (§ 141.18), whereas a foreign IOR is an individual or entity who has not satisfied a variety of specific criteria, such as at least 51% beneficial ownership or direct ownership of a significant amount of unencumbered real property in the United States. The existing references to a ''nonresident importer'' within CBP regulations are not in conflict with the new regulations for U.S. IORs and foreign IORs, as these new regulations create additional requirements for importers. The regulatory changes implemented by this rule that distinguish a U.S. IOR from a foreign IOR present a clearer framework for importers and a higher threshold to qualify as a U.S. IOR. Central to these new definitions is ensuring that physical assets of the importer are located in the United States, increasing the likelihood that CBP can collect revenue owed from all IORs and enabling CBP to better identify potential linkages and affiliations when an importer's assets are transferred.

In support of § 110.2(a)(2)(iii)(A) regarding U.S. IORs, CBP is defining the term ''beneficial owner'' in new § 110.1. CBP is including the ''beneficial owner'' condition in the requirements for a U.S. IOR because illicit actors often use corporate structures, such as shell companies, to conceal their identities, which undermines U.S. national security and threatens the domestic economy. Shell companies can shield identities of the beneficial owners, enabling them to transact business in the United States without facing legal consequences and evading enforcement mechanisms, creating an uneven playing field for U.S. businesses engaged in legitimate trade. Including a definition of ''beneficial owner'' enables CBP to identify the true individual or individuals exercising control over the entity responsible for the importation of goods. Also, by defining ''beneficial owner,'' CBP is providing clarity and transparency to trade members as to CBP's understanding of who qualifies as a beneficial owner. At the same time, CBP is facilitating compliance and revenue collection as a clear definition will reduce the ability of bad actors to use shell companies to evade duties and other customs and trade law requirements.

The term ''beneficial owner'' means, with respect to an entity, an individual who is a natural person, and directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise, either exercises substantial control over the entity, or owns or controls not less than 25 percent of the ownership interests of the entity. The ''beneficial owner'' definition includes circumstances where multiple layers of entity ownership exist between the natural person and the entity, such as a corporation that is owned by another corporation that is owned by a natural person, in which case the natural person is the beneficial owner despite the layers of entity ownership. The definition specifically excludes: (1) a minor child, as defined in the State in which the entity is formed, or in the case of an entity that was not formed in the United States an individual who has not yet attained the age of 18, if the parent or guardian of the minor child meets the definition of a beneficial owner; (2) an individual acting as a nominee, intermediary, custodian, or agent on behalf of another individual; (3) an individual acting solely as an employee of a corporation, limited liability company, or other similar entity and whose control over or economic benefits from such entity are derived solely from the employment status of the person, provided that such a person is not a senior officer; (4) an individual whose only interest in a corporation, limited liability company, or other similar entity is through a right of inheritance; or (5) a creditor of a corporation, limited liability company, or other similar entity, unless the creditor meets the requirements of an individual who, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise exercises substantial control over the entity or owns or controls not less than 25 percent of the ownership interests of the entity. For purposes of this definition, an individual might be a beneficial owner through substantial control, ownership interest, or both. Substantial control can be exercised by an individual who is either a senior officer (*e.g.,* the entity's president, or chief executive officer), has the authority to appoint or remove certain officers of the entity, or is an important decision-maker regarding the entity's business, finances and structure. Ownership interests that establish ownership rights in the entity include shares of equity, stock voting rights, or any other mechanism used to establish ownership. As all entities are substantially controlled by one or more individual(s), every entity must have at least one beneficial owner for purposes of determining as to whether an entity is a U.S. IOR. An entity may have multiple beneficial owners and there is no maximum number of beneficial owners.

To develop this definition, CBP reviewed a preexisting Financial Crimes Enforcement Network (FinCEN) definition (31 CFR 1010.380(d)), established by statute [20] to provide further consistency for the overall understanding of ''beneficial owner'' and expectations for trade members. This definition expands on the FinCEN definition by adding a paragraph to account for instances where an entity is incorporated/formed in the United States and is owned entirely by one or more other entities that are also incorporated/formed in the United States, but the natural persons who ultimately own the various layers of entities are not U.S. citizens or lawful permanent residents. This additional language is intended to clarify that natural persons must be identified as the beneficial owners, even where multiple layers of entity ownership exist

[19] *See* also 19 CFR part 163 for the recordkeeping requirements applicable to IORs, among other persons, listed in § 163.2.

[20] The Corporate Transparency Act, title LXIV of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Public Law 116–283 (Jan. 1, 2021), established a definition for ''beneficial owner'' as part of the reporting requirement to FinCEN for U.S. and foreign entities, which was implemented in the regulation at 31 CFR 1010.380(d).

and that such multiple layers of entity ownership do not diminish the obligation to report the natural person beneficial owners. It is noteworthy that ''beneficial owner'' is defined in this document for the purpose of this rulemaking and CBP is not bound by FinCEN's interpretation of that term in other contexts, nor are these regulations impacted by whether FinCEN requires submission of beneficial ownership information.

Lastly, CBP is adding a definition of ''physical domestic assets,'' which becomes relevant when CBP verifies whether an IOR qualifies as a U.S. IOR pursuant to new § 110.2(b)(3). ''Physical domestic assets'' are defined as cash deposited in a U.S. bank account, U.S. Treasury bonds, and real property, inventory, machinery, and/or equipment that is physically located in the United States. It is important to note that CBP did not use the term ''tangible'' in this context as tangible assets may include accounts receivable which CBP purposefully excluded from this definition. Assets identified as physical domestic assets in CBP's definition are more readily capable of being traced and seized, which increases the likelihood of successful collection of customs debts. The physical nature of the assets is important for serving the purpose of these regulations. Valuation of intangible assets is often speculative and subject to manipulation, particularly in the context of IORs who may be structured as a separate entity from a retailer ultimately selling the product to the public. Additionally, receivables may be due from foreign parties, creating the potential for manipulation of their valuation and diminishing the likelihood of collection.

This definition of ''physical domestic assets'' covers a limited universe of assets that are relevant for the purpose of determining affiliations of entities. CBP needs to understand affiliations because foreign IORs can easily evade CBP requirements and verifications by creating new companies. By considering the types of assets covered under this definition, CBP is better able to identify shell companies that foreign actors use to evade U.S. customs laws. In addition, CBP's ability to pursue collection from successor companies, alter egos [21] or other parties when piercing the corporate veil [22] is increased, potentially reaching physical domestic assets improperly transferred to individuals tied to the shell company, such as corporate officers or shareholders.

CBP is adding two new sections to subpart B of part 141 (§ 141.21 and § 141.22), pertaining to the right to make entry and declarations on entry. Pursuant to paragraph (a) of new § 141.21, a foreign IOR, as defined in § 110.3, may not enter merchandise for consumption unless specific requirements are met. This restriction is applicable to merchandise entered for consumption (§ 141.0a(f)) for which a formal entry is required to be filed or, if an informal entry is filed, for which an informal entry is required to be filed on CBP Form 3461 and/or CBP Form 7501, or their electronic equivalents.[23]

Pursuant to § 141.21(b)(1), if the foreign IOR is CTPAT validated and has the right to make entry pursuant to § 143.26 for informal entry or 19 U.S.C. 1484(a)(2)(B) for formal entry, the foreign IOR may enter merchandise for consumption or designate a customs broker to make entry. A CTPAT validated foreign IOR choosing to hire a customs broker may elect to hire a CTPAT validated broker, or a non-CTPAT validated broker.

Pursuant to § 141.21(b)(2), a foreign IOR who is not CTPAT validated must designate a customs broker licensed under 19 U.S.C. 1641 who is validated through the CTPAT program to either make entry or to act as the importer of record on the entry.[24] If a customs broker acts as the importer of record for the entry on behalf of a principal on the power of attorney (§ 141.46) who is not an importer of record, and that principal would qualify as a foreign importer of record pursuant to § 110.3 of this chapter, the broker must also be validated through the CTPAT program. The designated customs broker who is validated through the CTPAT program must act as the IOR for the entry if the principal on the power of attorney (§ 141.46) is not the owner or purchaser of the merchandise.

It is important to note that, upon the effective date of this rule (January 5, 2027), being a licensed customs broker alone is not sufficient to file entry on behalf of a foreign IOR or a foreign principal on a broker's power of attorney, unless that foreign IOR is itself a CTPAT validated IOR. CBP has limited visibility into the information pertaining to a foreign party when a customs broker is filing the entries on behalf of the foreign party. A CTPAT validated broker has demonstrated to CBP that it has controls in place to give the broker insight into its client and the client's supply chain. As a result, CBP is requiring that a customs broker acting on behalf of a non-CTPAT validated foreign IOR be CTPAT validated, to ensure that a trusted party is filing the entry and entry summary. This places CBP in a better position to protect the revenue, ensure supply chain security, and guarantee the safety of the American public.

CTPAT is highly effective in securing international supply chains by requiring its participants to implement stringent security measures for their cargo, personnel, and facilities. This program encourages companies to proactively identify and mitigate risks such as terrorism, smuggling, and other illicit activities within their supply chains. By partnering with the private sector, CTPAT enables CBP to enhance cargo security and streamline legitimate trade, allowing enforcement resources to focus on higher-risk shipments. CTPAT's primary focus is on security and trade compliance, and its operational model inherently promotes transparency. The program requires participants to submit detailed security profiles and engage in a rigorous validation process with CBP to confirm compliance with established MSC, fostering a clear understanding of security practices between the government and the trade community. In addition, CBP is more likely to collect debt from CTPAT validated participants than from non-CTPAT participants. The analysis in section VIII.B. below shows that, on average, the uncollected bill amount per entry summary for CTPAT validated foreign IORs is much lower than for non-CTPAT foreign IORs, who more easily evade payment of outstanding bills, penalties, or claims for liquidated damages.

New § 141.22 regulates entry by a U.S. IOR and addresses the declaration requirement for U.S. IORs, including verification of the declaration by CBP. Pursuant to paragraph (a), a party who has the right to make entry and meets the requirements to be considered a U.S.

[21] *See* Black's Law Dictionary (12th ed. 2024) (defining ''*alter ego*'' as ''A corporation used by an individual or a subservient corporation in conducting personal business, the result being that a court may impose liability on the individual or subservient corporation by piercing the corporate veil when someone dealing with the corporation is a victim of fraud, illegality, or injustice.'').

[22] *See* Black's Law Dictionary (12th ed. 2024) (defining ''*piercing the corporate veil*'' as ''the judicial act of imposing personal liability on otherwise immune corporate officers, directors, or shareholders for the corporation's wrongful acts.''). This doctrine disregards the corporate entity's separate legal existence, treating corporate officers, directors, or shareholders as liable for corporate debts.

[23] Operationally, this new requirement is applicable to informal entry types 11, 12, and 13, and all formal entry types. For more information on entry types, please see *https://www.cbp.gov/trade/automated/catair.*

[24] Use of a CTPAT validated broker does not confer CTPAT benefits on the IOR or the principal on the broker's power of attorney.

IOR, as defined in § 110.2, may continue to enter merchandise without the need for CTPAT validation, subject to the existing requirements and applicable procedures for formal entry and informal entry in 19 CFR parts 142 and 143. U.S. IORs may also elect to designate a customs broker who is not CTPAT validated. At the time of filing an entry (§ 141.0a(a)) and entry summary (§ 141.0a(b)), qualification as a U.S. IOR must be declared. Before filing, the IOR, or the broker on behalf of the IOR, must review the requirements in § 110.2, as well as the definitions for ''beneficial owner,'' and ''physical domestic assets,'' and assess whether all the criteria of a U.S. IOR are met. If the party satisfies the criteria, the IOR or the broker on behalf of the IOR must select the checkbox [25] on CBP Forms 3461 and 7501, declaring the qualification as a U.S. IOR. CBP updated CBP Forms 3461 and 7501, and their electronic equivalents, by adding a checkbox for IORs (or customs brokers filing an entry on their behalf) to declare that the IOR or principal on the power of attorney (§ 141.46) meets the criteria of a U.S. IOR. Foreign IORs and principals who do not meet the requirements to be considered a U.S. IOR under § 110.2 should leave this checkbox blank, to indicate that they are instead covered by § 110.3. Beginning January 5, 2027 these updated forms, and their electronic equivalents, must be used for each entry and entry summary filing.

If a designated customs broker who is not CTPAT validated acts as the IOR for the entry on behalf of a client, § 141.22(a)(2) requires that the customs broker identify the principal on the power of attorney at the time of filing an entry (§ 141.0a(a)) and entry summary (§ 141.0a(b)). As a result, the principal must have a CBP Form 5106 on file with CBP. On the updated CBP Forms 3461 and 7501, and their electronic equivalents, the customs broker will select the checkbox indicating that the broker is acting as the IOR on behalf of a principal, and provide the principal's IOR number, if applicable, or other identifier linked to the CBP Form 5106 on file, if no IOR number exists. If the broker is not making entry on behalf of a principal and is instead identified as the IOR to make entry on their own behalf, no principal need be identified.

New § 141.22(b) states that for purposes of a verification conducted under § 110.2(b), the decision as to whether an individual or entity qualifies as a U.S. IOR will be made by the appropriate Center of Excellence and Expertise (Center) Director.[26] The appropriate Center is the importer's assigned Center, or if an importer has not yet been assigned to a Center, the appropriate Center is the Center that most closely aligns with the Harmonized Tariff Schedule of the United States classification of the highest in total value commodity imported by that importer.

In addition to these new provisions, CBP is also updating § 141.46, regarding the requirement to obtain an executed power of attorney before transacting customs business on behalf of a principal. CBP is amending § 141.46 to clarify that a power of attorney must be executed whenever a customs broker is transacting customs business on behalf of a client, even when the broker is acting as the IOR for an entry.[27]

CBP is also updating § 142.13 which sets forth the conditions under which CBP may require live entry and § 142.25 which sets forth the conditions under which CBP may discontinue immediate delivery privileges. Live entry conditions the release of merchandise upon the filing of an entry summary with a deposit of all estimated duties, taxes, and fees—release thus cannot occur until payment is tendered. Section 142.13 currently lists various conditions when CBP may require live entry, and § 142.25 currently lists various conditions when CBP may discontinue immediate delivery privileges. In this interim final rule, CBP is adding another condition for when live entry may be required and when immediate delivery privileges may be discontinued: when the IOR, including a broker acting as the IOR on behalf of a principal on the power of attorney, inaccurately declares to CBP its qualification as a U.S. IOR as required under § 141.22. *See* new § 142.13(a)(5) and § 142.25(a)(5). If the IOR inaccurately declares that it qualifies as a U.S. IOR, CBP now has the ability to require live entry and discontinue immediate delivery privileges. In addition to the changes in §§ 142.13(a) and 142.25(a), CBP is also adding a new paragraph (e) to § 142.13 and a new paragraph (c) to § 142.25 that state that CBP may impose the requirement of live entry and discontinue immediate delivery privileges pursuant to §§ 142.13(a) and 142.25(a) on importers making formal and informal entry under the provisions of either part 142 or part 143.

Finally, CBP is making changes to regulations in part 111 and in Appendix B to part 171 pertaining to a customs broker's responsibilities with respect to its clients and the consequences for failing to meet those responsibilities. Current § 111.29(a) sets forth a customs broker's responsibility to exercise due diligence in making financial settlements and answering correspondence, among other responsibilities. CBP is adding a new § 111.29(a)(2) to include the responsibility of a customs broker to verify that a client meets the qualifications to be considered a U.S. IOR, after redesignating existing paragraph (a) as paragraph (a)(1). A customs broker, prior to filing a declaration on behalf of a client pursuant to § 141.22, must verify that the client qualifies as a U.S. IOR. Verification requires a customs broker to request and review client records establishing that the criteria specified in the definition of U.S. IOR are met. As mentioned above, the client records may include, but are not limited to, proof of citizenship or lawful permanent residence, corporate charters, financial statements and records, purchase receipts, or documents of title. If a customs broker determines during the review of the client records that the client is not a U.S. IOR, the broker must cease filing entries on behalf of the client if the broker is not CTPAT validated. CBP has also updated § 111.21(a) and 111.23, to require that the broker maintain records related to the broker's verification for five years from the date of the verification.

These new provisions are in line with the statutory mandate of section 116 of TFTEA (19 U.S.C. 1641(i)). Brokers must ensure that they are filing accurate information on behalf of their clients, and that their clients are who they say they are. CBP recommends, as a good business practice, that customs brokers obtain information from their client at the time of obtaining a power of attorney, to allow sufficient time for the broker to complete the verification process before filing entry.

For verification purposes under § 141.22, CBP must have the ability to request proof from the broker that the broker has verified that the client is in

[25] In the electronic versions of CBP Form 3461 and CBP Form 7501, the filer will not make this declaration using a checkbox, but will instead indicate ''Yes'' or ''No'' to declare whether the IOR is a U.S. IOR. For simplicity in this document, CBP will refer to this as a checkbox as it appears on CBP Form 3461 and CBP Form 7501.

[26] *See https://www.cbp.gov/trade/centers-excellence-and-expertise-information/cee-directory.*

[27] This amendment revokes by operation of law any prior ruling issued by CBP to the extent that it conflicts with this new requirement. *See* 19 CFR 177.12(d)(1). For example, this amendment revokes the holding in Headquarters Ruling Letter 223772, dated August 6, 1992, that ''[n[o power of attorney is required . . . [when b]rokers will make entry in [their] own name as the importer of record.''

fact a U.S. IOR, and the customs broker must comply with the recordkeeping and production requirements in 19 U.S.C. 1508, as discussed above.

Additionally, CBP is revising paragraph (K) in Appendix B to part 171 which contains guidelines for the imposition and mitigation of penalties for violations of 19 U.S.C. 1592. These guidelines are used by CBP in arriving at a just and reasonable assessment and disposition of liabilities arising under 19 U.S.C. 1592 within the stated limitations. Paragraph (K) states that if a customs broker commits a section 1592 violation and the violation involves fraud, or the customs broker commits a grossly negligent or negligent violation and shares in the benefits of the violation to an extent over and above customary brokerage fees, the customs broker will be subject to the mitigation guidelines of Appendix B. However, if the broker commits either a grossly negligent or negligent violation of section 1592 (without sharing in the benefits of the violation as described above), CBP may proceed against the customs broker pursuant to the limited remedies provided under 19 U.S.C. 1641 (monetary penalty, suspension or revocation of a license or permit). CBP is updating this language to state that subject to CBP's discretion, if a customs broker commits a violation of 19 U.S.C. 1592, the customs broker may be subject to penalties under 19 U.S.C. 1592 or any other enforcement actions available under the law, including 19 U.S.C. 1641.

Economic security is national security, and customs law enforcement is essential to protect the economy of the United States and the health and safety of the American people. Customs law enforcement requires the ability to assess stringent penalties to ensure an adequate deterrent effect on customs brokers that fail to comply with the law. Historically, CBP has penalized brokers pursuant to 19 U.S.C. 1641, which sets a maximum monetary penalty amount of $30,000 for violations. Moreover, pursuant to existing paragraph (K) in Appendix B to part 171, CBP has assessed penalties against customs brokers pursuant to 19 U.S.C. 1592 only in those cases where the broker was involved in a violation with a culpability level of fraud or where the agency could demonstrate the broker benefited from the violation. Although penalties up to $30,000 are available under 19 U.S.C. 1641, customs brokers still commit violations and repeatedly represent foreign IORs who fail to comply with U.S. laws. With this amendment to paragraph (K), CBP is enhancing its enforcement options against brokers to include broader applicability of penalties under 19 U.S.C. 1592, for which a maximum penalty may be assessed at the domestic value of the merchandise. As such, CBP envisions that higher penalties will have a greater deterrent effect on customs brokers that fail to comply with the law.

VI. Explanation of Amendments to the CBP Regulations

A. Amendments to Part 110

CBP is creating a new part 110 in title 19 of the CFR, and adding subparts A and B. In new § 110.1, CBP has added new definitions for the terms ''beneficial owner,'' and ''physical domestic assets.'' In new § 110.2, CBP has laid out the requirements to be considered a U.S. importer of record, and the verification requirements associated with that status. In new § 110.3, CBP has explained that any IOR not qualified to be considered a U.S. IOR is considered a foreign IOR. Subpart B is reserved.

B. Amendments to Part 111

CBP is amending part 111, in accordance with the requirements discussed above. Specifically, CBP is amending §§ 111.21 and 111.23 by adding the requirement that brokers maintain records related to verifying that the client meets the threshold for a U.S. IOR under § 110.2. CBP is also amending § 111.29 by redesignating paragraph (a) as a new paragraph (a)(1) and adding a new paragraph (a)(2) to include a customs broker's responsibility for verifying a client's qualification as a U.S. IOR.

C. Amendments to Part 141

CBP is amending part 141, in accordance with the requirements discussed above. Specifically, CBP is adding two new sections (§ 141.21 and § 141.22). New § 141.21 states that a foreign IOR may not enter merchandise for consumption unless it is a CTPAT validated IOR or designates a customs broker who is CTPAT validated, and lays out associated requirements. New § 141.22 states that a U.S. IOR must submit a declaration as to its qualification as a U.S. IOR at the time of filing an entry and entry summary. CBP has also amended § 141.46 to clarify that a power of attorney is required even when the broker is acting as the IOR for an entry. In addition, the general authority citation for part 141 is revised to include 19 U.S.C. 4320 and 4321.

D. Amendments to Part 142

CBP is amending part 142, in accordance with the requirements discussed above. Specifically, CBP is amending § 142.13 by adding a new paragraph (a)(5) that states that CBP may impose a live entry requirement if the importer inaccurately declares to CBP its qualification as U.S. IOR pursuant to § 141.22. CBP is also adding a new § 142.13(e) to clarify that CBP may impose a live entry requirement on formal and informal entries under the provisions of part 142 and part 143.

E. Amendments to Part 171

CBP is amending Appendix B to part 171, which sets forth guidelines for the imposition and mitigation of penalties for violations under 19 U.S.C. 1592. Specifically, CBP is revising paragraph (K) in Appendix B, as discussed above.

F. Severability

CBP intends for the provisions contained in this rulemaking to be severable from each other and to be given effect to the maximum extent possible, such that if a court holds that any provision is invalid or unenforceable—whether in its entirety or as to a particular person or circumstance—the other provisions will remain in effect as to any other person or circumstance.[28] The various provisions in this IFR are designed to function sensibly without the others, and CBP intends for them to be severable so that each can operate independently.

G. Alternative and Request for Comments

As noted in Section II, above, although Section 2(b) of the E.O. directs CBP to prohibit foreign IORs from filing informal entry, CBP has not implemented that prohibition in this interim final rule. However, CBP will continue to monitor informal entries for consumption filed by CTPAT validated foreign IORs and CTPAT validated brokers on behalf of foreign IORs. If CBP determines that requiring that informal entries for foreign IORs be filed by a CTPAT validated party is insufficient to protect the revenue, national security, and the health and safety of the American people, CBP may prohibit informal entries for consumption filed by a foreign IOR or a broker acting on their behalf. CBP welcomes public comment on this alternative, in addition to the approach implemented by this interim final rule.

[28] Courts have uniformly held that the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.*, 5 U.S.C. 706(2), authorizes courts to sever and set aside ''only the offending parts of the rule.'' *Carlson* v. *Postal Regulatory Comm'n,* 938 F.3d 337, 351 (D.C. Cir. 2019); *see, e.g., K Mart Corp.* v. *Cartier, Inc.,* 486 U.S. 281, 294 (1988).

VII. Delayed Compliance Date

In consideration of the business process changes needed for licensed customs brokers to verify whether a client meets the requirements to be considered a U.S. IOR, CBP will accept requests from brokers to delay compliance with the new verification requirement for customs brokers in § 111.29. Brokers who are currently subject to any of the following enforcement actions are ineligible for delayed compliance: removal from the CTPAT program, revocation of CBP Form 5106 filing privileges, suspension or debarment by a Federal agency and identified with an exclusion record in the System for Award Management Exclusions List on SAM.gov, entry filer code suspension, or broker license revocation proceedings. Such requests must be submitted by January 5, 2027 and must include an explanation of the need for delayed compliance. For additional details on how to submit a request for delayed compliance, see *www.cbp.gov/trade/strengthening-customs-enforcement/delayed-compliance*. If delayed compliance is approved, customs brokers must continue to make satisfactory progress toward compliance by demonstrating a good faith effort to comply with this rule to the extent of the broker's current ability during the compliance period. All customs brokers are expected to be in full compliance with the requirements of this rule no later than May 6, 2027.

VIII. Statutory and Regulatory Requirements

A. Administrative Procedure Act

The Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.,* generally requires agencies to publish a notice of proposed rulemaking in the **Federal Register**, and to provide interested persons the opportunity to submit comments prior to issuance of a final rule. As an initial matter, the requirements of the APA do not apply to the extent that the rulemaking involves a foreign affairs function of the United States. 5 U.S.C. 553(a)(1).[29]

This interim final rule addresses challenges resulting from importations by foreign IORs. Securing America's borders, regulating and vetting foreign actors, and protecting its citizens from external threats is a foreign affairs function of the United States. Importations into the United States across America's borders can pose threats to U.S. citizens, including threats from contraband and harmful materials that can flow across the border, as well as narcotics trafficking and other destabilizing or unlawful activities, including the flow of dangerous drugs, weapons, and technology. Further, ensuring foreign parties abide by U.S. trade law is a core foreign affairs function. Unchecked importations by foreign actors into the United States can undermine domestic markets and supply chains—for instance, foreign government assistance and subsidies, such as tax breaks to foreign manufacturers, enable them to sell cheaper goods and disadvantage domestic companies. In response, the U.S. may establish antidumping and/or countervailing duties to counteract foreign government assistance and subsidies. Tracking and vetting foreign importers is critical to counteracting bad actors in the trade space, preventing evasion of U.S. trade law, and upholding the integrity of domestic markets and supply chains. If customs and trade laws cannot be adequately enforced against foreign importers of record, it leaves American citizens vulnerable to foreign actors and foreign governments. Accordingly, this rule is clearly and directly involved in a core foreign affairs function.[30] Moreover, proceeding without notice and comment will allow the Department to timely address sensitive foreign-policy and national-security matters that affect relations with foreign governments. This rule directly impacts foreign actors, including foreign importers, manufacturers, and businesses. Foreign governments, especially those whose citizens and businesses this rule most affect, may seek to retaliate against the United States or United States exporters. Bypassing notice and comment will reduce the risk the United States suffers retaliation from foreign governments based on this rule. Therefore, this interim final rule involves the foreign affairs function of the United States and is not subject to notice and comment under the APA.[31]

Further, as discussed above, the revenue rule permits a court of one country to refuse to allow lawsuits initiated by another country to enforce the foreign country's revenue laws, absent an agreement between the two countries to enforce the collection of a foreign IOR's debt. The revenue rule is a means to avoid interfering with foreign relations and a country's national sovereignty by preventing another country from enforcing its own laws within the borders of another country. Therefore, this interim final rule involves the foreign affairs function of the United States.

Further, the APA provides an exception to advance notice and comment requirements ''when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest.'' 5 U.S.C. 553(b)(B). The good cause exception ''excuses notice and comment in emergency situations . . . or where delay could result in serious harm.'' [32]

Notice and comment is impracticable when the due and required execution of agency functions would be unavoidably prevented by undertaking public rulemaking proceedings.[33] Impracticability can occur when there is an imminent hazard to persons or property within the United States, or when immediate implementation of a rule might directly affect public safety.[34]

The public interest prong of the good cause exception applies when ordinary procedures of notice and comment, generally presumed to serve the public interest, would actually harm the public interest.[35] These interests include public safety and public health.[36] This prong is distinct from the need for immediacy under the impracticability prong and is ''appropriately invoked when the timing and disclosure requirements of the usual procedures would defeat the purpose of the proposal.'' [37]

CBP finds that good cause exists to issue this rule as an interim final rule. Delaying the publication of this interim final rule for purposes of providing public notice and comment would be impracticable. As mentioned above, non-CTPAT foreign IORs are importing

[29] *Mast Indus., Inc.* v. *Regan,* 96 F.Supp. 1567, 1582 (finding the foreign affairs exception applies when the regulation is ''clearly and directly'' involved in a foreign affairs function).

[30] *Id.*

[31] *See Am. Ass'n of Exps. & Imps.-Textile & Apparel Grp.* v. *United States,* 751 F.2d 1239, 1249 (Fed. Cir. 1985) (noting that foreign affairs exception covers agency actions ''linked intimately with the Government's overall political agenda concerning relations with another country'').

[32] *Jifry* v. *FAA,* 370 F.3d 1174, 1179 (D.C. Cir. 2004) (citations omitted).

[33] *See* S. Doc. No. 248, 79th Cong., 2d Sess. 200 (1946).

[34] *See Jifry* v. *FAA,* 370 F.3d 1174, 1179 (D.C. Cir. 2004); *NRDC* v. *Nat'l Highway Traffic Safety Admin.,* 894 F.3d 95, 114 (2d Cir. 2018).

[35] *Mack Trucks, Inc.* v. *EPA,* 682 F.3d 87, 95 (D.C. Cir. 2012).

[36] See *United States* v. *Dean,* 604 F.3d 1275, 1279 (11th Cir. 2010) (to delay regulations would harm the public interest because it would delay the registration of sex offenders who would evade registration requirements during the notice and comment period, putting the public's safety at risk).

[37] *See Mack Trucks, Inc.* v. *EPA,* 682 F.3d 87, 95 (D.C. Cir. 2012).

goods that may be dangerous to the American public, such as narcotics and counterfeits. In the past, CBP has seized unsafe merchandise for failure to meet Consumer Product Safety Commission standards, unsafe merchandise that is not compliant with the Food and Drug Administration's regulations, and other imports such as counterfeit merchandise that threatens public safety. Data ranging from October 2020 through the beginning of February 2026 shows that the rate of seizure incidents is higher for non-CTPAT foreign IORs, which have 6.38 seizures per million entry summaries, than for CTPAT validated foreign IORs, which have 1.14 seizures per million entry summaries, as discussed in the analysis below. In recent years, CBP has seen an increase in the number of seizures of violative goods attempted to be imported by foreign IORs. Thus, CBP must act now to avoid further harm to persons and property in the United States.

Furthermore, under the ''contrary to public interest'' prong, advance notice of new requirements would significantly increase the incentive on the part of foreign IORs to ''flood the market'' by importing high volumes of illicit merchandise during a notice and comment period before the rule takes effect, thereby compounding the very challenges that CBP is addressing with this interim final rule. IOR accounts are being created with false or incomplete information, likely by shell companies who are attempting to disguise their identity. CBP's records show that between March 2019 and the end of September 2025, individuals and entities created approximately 55,000 accounts with fake phone numbers, such as 123456789, and 45,000 accounts with fake email addresses, such as emails beginning with ''noemail,'' or *abc@abc.com,* etc., hindering CBP's ability to contact an IOR for validation of entry information and enforcement and revenue collection purposes. If CBP provides notice and comment before implementing these new requirements, CBP anticipates a significant increase in new IOR accounts created with false information, further complicating CBP's enforcement efforts against IORs that are disguising their identity as a foreign IOR and attempting to import illicit merchandise prior to a final rule taking effect.

CBP is only able to identify IORs as foreign if they list a foreign address on CBP Form 5106, but there are likely many more foreign persons and entities using incorrect U.S. addresses or shell companies to import goods, preventing CBP from knowing the true importer's identity and location. Recently, CBP discovered over 870 unique CBP Form 5106 accounts sharing a single physical address, most of which were found to be linked to foreign entities. Because foreign IORs cannot be held accountable through the same mechanisms as U.S. IORs, CBP's debt collection and enforcement efforts can be frustrated as foreign IORs have less incentive to comply with U.S. law. If CBP provides advance notice of new requirements for foreign IORs, those foreign importers may create shell companies, and already existing shell companies may create new shell companies, to evade U.S. laws and the new requirements established by this interim final rule. Due to technological advances pertaining to duty collection and targeting, enforcement, and processing, CBP is now equipped to address the challenges relating to foreign IORs. Waiting to counter the above-mentioned challenges would harm CBP's ability to collect lawful revenue owed and take effective enforcement action to address violations of U.S. customs and trade laws, disadvantage the domestic industry, and would allow a gap that invites the importation of illegal and dangerous merchandise into the United States.

As discussed above, this interim final rule establishes new requirements for foreign IORs and U.S. IORs when making entry in the United States. Requiring CTPAT validated status of foreign IORs and customs brokers lowers the risk associated with foreign IORs as CBP has more visibility into CTPAT validated participants and assurances regarding the security of their supply chains compared to foreign IORs and customs brokers who are not CTPAT validated participants. These new requirements will allow CBP to more effectively focus its efforts on higher risk importers to interdict illicit drugs, intellectual property violative goods, misclassified merchandise, and other goods that pose risks to public safety. The new requirements will also enable CBP to better ensure the collection of duties, taxes, and fees from foreign IORs. Data ranging from October 2020 through the beginning of February 2026 shows, on average, that CTPAT foreign IORs owe CBP $1.21 in uncollected bills per entry summary, compared to non-CTPAT foreign IORs who owe $34.08 per entry summary. A prolonged rulemaking process would create uncertainty that would undermine the credibility and effectiveness of CBP's actions to limit entry by foreign IORs to CTPAT validated participants.

However, CBP recognizes that IORs and customs brokers need time to make adjustments to comply with this rule. Therefore, CBP is publishing this interim final rule with a 60-day delayed effective date to give IORs and brokers time to modify the relevant business processes that are affected by this interim final rule. Customs brokers are provided additional time to comply with the new due diligence responsibility of verifying a client's qualification as a U.S. IOR and maintaining the associated records. CBP is also soliciting public comments on this interim final rule and will consider all timely submitted comments in determining whether and how to revise the rule in a subsequent final rule. Given the public safety and revenue implications of continued imports by foreign IORs into the United States, CBP has attempted to strike a balance between its need to address these urgent requirements while still providing sufficient time for IORs and customs brokers to comply with the regulatory changes involved in this rulemaking, as well as providing for an opportunity to comment. For the reasons discussed above, this rule is exempt from the prior public notice and comment requirements of the APA under both the foreign affairs exception and the good cause exception.

B. Executive Orders 12866, 13563, and 14192

Executive Orders 12866 (Regulatory Planning and 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. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 14192 (Unleashing Prosperity Through Deregulation) directs agencies to significantly reduce the private expenditures required to comply with Federal regulations and provides that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.''

The Office of Management and Budget (OMB) has designated this rule a ''significant regulatory action'' under section 3(f) of Executive Order 12866, although not economically significant under section 3(f)(1). Accordingly, the rule has been reviewed by the Office of Management and Budget.

This rule is not an Executive Order 14192 regulatory action because it is being issued with respect to a national

security or homeland security function of the United States. The benefit-cost analysis demonstrates that the regulation is anticipated to improve national or homeland security as its primary direct benefit or is issued with respect to foreign affairs related functions of the United States and OIRA and the promulgating agency agree the regulation qualifies for a 'good cause' exception under 5 U.S.C. 553(b)(B). See OMB Memorandum M–25–20, ''Guidance Implementing Section 3 of Executive Order 14192, titled 'Unleashing Prosperity Through Deregulation' '' (Mar. 26, 2025). Additionally, this proposed rule is exempt from Executive Order 14192 under section 5(c) of Executive Order 14192. Table 1 shows an accounting statement for the effects of the rule.

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Table 1: A-4 Accounting Statement for the Rule

Category	Annualized Estimate (in 2026 USD) over 2027 to 2036	
Benefits	**3% Discount Rate**	**7% Discount Rate**
Monetized benefits	None	None
Quantified, non-monetized benefits	None	None
Qualitative (unquantified) benefits	Stricter enforcement of duties, penalties, and liquidated damages, stronger protections against prohibited goods such as illicit drugs, and safer supply chains resulting from increased CTPAT participation or use of CTPAT brokers by foreign IORs.	
Costs	**3% Discount Rate**	**7% Discount Rate**
Monetized costs	$1,233,253 resulting from programming changes, the cost to CBP of increased CTPAT participation, and the burdens of submitting and processing brokers' delayed compliance requests.	$1,257,478 resulting from programming changes, the cost to CBP of increased CTPAT participation, and the burdens of submitting and processing brokers' delayed compliance requests.
Quantified, non-monetized costs	None	None
Qualitative (unquantified) costs	Costs to brokers and foreign IORs of increased CTPAT applications and participation. Cost to brokers and U.S. IORs of gathering documentation and maintaining records of U.S. IOR status. Cost to some foreign IORs of switching to CTPAT validated brokers.	
Cost Savings	**3% Discount Rate**	**7% Discount Rate**
Monetized cost savings	None	None
Quantified, non-monetized cost savings	None	None
Qualitative (unquantified) cost savings	None	None
Transfers	**3% Discount Rate**	**7% Discount Rate**
Monetized budgetary transfers	None	None
Other monetized transfers	None	None
Unquantified transfers	Transfers from foreign IORs to U.S. government resulting from improved collection rates of duties, penalties, and liquidated damages. Transfers from non-CTPAT validated brokers to CTPAT validated brokers.	
Distributional Effects	**3% Discount Rate**	**7% Discount Rate**

Effects on State, local, and/or tribal governments	Not anticipated	Not anticipated
Effects on small businesses	Because a general notice of proposed rulemaking was not necessary for this rule, CBP did not prepare a regulatory flexibility analysis to analyze the effects on small businesses.	
Effects on wages	Not anticipated	Not anticipated
Effects on growth	Not anticipated	Not anticipated

BILLING CODE 9111–14–C

Background

To fulfill its mission, CBP must ensure that importers of record (IORs) pay the applicable duties, taxes, and fees for their imports as well as any monetary penalties issued by CBP. Sometimes, CBP discovers that an IOR underpaid its duties through misrepresentations such as undervaluation, false country of origin, transshipment, misclassification, or false invoices. Other times, an IOR will simply refuse to pay any duties in the first place. Upon discovery of underpayment, CBP can issue a penalty to the IOR, but the IOR may not cooperate in paying. CBP can collect on the basic importation and entry bond, but sometimes the bond saturates, meaning that it does not cover the full amount owed. In that case, CBP can try to seize the IOR's assets. This option can be difficult when the IOR is foreign, as a foreign IOR may have few if any real assets in the United States, and whatever assets the foreign IOR has in its home country may be unreachable to the U.S. government. CBP can require the IOR to file live entry and suspend immediate delivery privileges for all future importations until that IOR makes any outstanding payments to CBP, but foreign IORs may be able to evade these requirements through creation of shell companies. When an IOR is based outside the United States, CBP has less visibility into the IOR's operations and assets than it does with U.S. IORs, making it easier for the foreign IOR to conceal its identity and harder for CBP to hold the IOR and its affiliates accountable. As a result, foreign IORs that receive or anticipate enforcement or collection actions by CBP will sometimes switch to a new name to evade consequences for past actions. Foreign IORs can therefore avoid payments to CBP and other consequences more easily than U.S. IORs can, giving the former an unfair advantage.

While CBP has limited visibility into many foreign IORs' operations, IORs that are CTPAT validated are generally more transparent and trustworthy in their transactions and dealings with CBP. The CTPAT program ensures that participants meet minimum security criteria and abide by best practices. It also creates more visibility into the participants' supply chain and operations because the CTPAT participant must be in communication with its contact in CBP to show that it is continuing to meet the requisite standards. The CTPAT participant must also have visibility into the operations of businesses that it interacts with to ensure the supply chain is secure, as represented to CBP upon validation. Hence, if an IOR is not CTPAT validated, but uses a CTPAT validated broker, that broker will have obtained more information about the IOR's business than a non-CTPAT validated broker would have, and CBP will be better able to obtain information regarding the IOR from the broker if necessary. Requiring foreign IORs to be CTPAT validated or use CTPAT validated brokers will therefore strengthen CBP's ability to enforce collections on foreign IORs by increasing transparency into the foreign IORs' business and supply chain practices.

Purpose of the Rule

CBP faces challenges in enforcing collection of duties, penalties, and liquidated damages against foreign IORs because these IORs often have few, if any, physical assets in the United States and their bond does not fully cover amounts lawfully owed to CBP. This rule requires foreign IORs to either be CTPAT validated or to use a CTPAT validated broker so that the foreign IORs meet stricter standards of security and transparency. CTPAT validated brokers have more information about their clients' supply chains, and this information could improve CBP's ability to collect payments from the foreign IOR and identify other non-compliance with U.S. customs and trade laws. Furthermore, foreign entities will have more incentive to avoid exporting prohibited goods to the United States or otherwise violate CBP requirements if they are trying to maintain their CTPAT validated status. U.S. IORs will also have to provide documentation proving that they are a U.S. IOR at CBP's request, which will help CBP to determine which IORs claiming to be U.S. IORs are in fact foreign shell companies.

Baseline for the Rule

In this regulatory impact assessment (RIA), CBP analyzes the effects of the rule by comparing a baseline and an alternative scenario. Currently, foreign IORs import shipments into the United States without being CTPAT validated or using a CTPAT validated broker. Under this rule, foreign IORs would have to be CTPAT validated or use CTPAT validated brokers to enter merchandise into the United States. The effects of the rule are therefore the differences between the world under the current baseline and the world under this rule.

Population Affected

For the purposes of this analysis, CBP assessed whether IORs were foreign or U.S. based on the physical address provided on CBP Form 5106. However, there could be IORs that listed a U.S. address but who would more accurately be classified as foreign. Some of these IORs might be foreign shell companies being intentionally dishonest, while others might be self-labeling as U.S. IORs in good faith but not meet the standard to be considered a U.S. IOR that is laid out in this rule. As a result, this analysis may underestimate the true number of foreign IORs. There could also be some businesses that have given CBP a foreign address but could meet the standard to be considered a U.S. entity under the rule. To the extent that the number of foreign IORs differs from the estimates below, the true effects of the rule would differ from CBP's estimates. If more IORs are foreign than CBP estimates, then the true benefits and costs of the rule will both be higher than expected. The benefits would be

higher than CBP's estimate because CBP would be strengthening its enforcement capabilities for an even greater number of IORs than estimated, while the costs would be higher because a greater number of non-CTPAT validated foreign IORs would be disallowed from using a non-CTPAT validated broker than estimated.

IORs and brokers will be the main entities affected by the rule. Table 2 shows the number of IORs who made an entry summary between October 1, 2020, and February 6, 2026. Of those IORs, 16% were foreign, and 84% were U.S. IORs. CTPAT validated IORs are a small percentage of both foreign and U.S. IORs. Only 0.4% of foreign IORs are CTPAT validated, but, as shown in Table 3, 68% of foreign IORs already use CTPAT validated brokers. The remaining 32% of foreign IORs will not be able to continue importing into the United States unless they switch brokers or become CTPAT validated themselves.

Table 2: Number of Active IORs

	Count
Non-CTPAT validated foreign IORs	187,127
CTPAT validated foreign IORs	744
Non-CTPAT validated U.S. IORs	995,389
CTPAT validated U.S. IORs	4,549
Total	**1,187,809**

*Importers were counted as active if they made any entry summaries between October 1, 2020, and February 6, 2026. Source: Based on trade data from October 1, 2020, to February 6, 2026, from the CBP Automated Commercial Environment (ACE), obtained on February 17, 2026.

Table 3: Active Foreign IORs That Are CTPAT Validated or Using CTPAT Validated Brokers

	Count	Share of All Foreign IORs
Foreign IORs that are CTPAT validated	744	0.40%
Foreign IORs that used a CTPAT validated broker	127,691	67.97%
Foreign IORs that are CTPAT validated and/or used a CTPAT validated broker	127,724	67.98%

*Importers were counted as active if they made any entry summaries between October 1, 2020, and February 6, 2026. Source: Based on trade data from October 1, 2020, to February 6, 2026, from ACE, obtained on February 17, 2026. Note: the figures in the bottom row are less than the sum of the upper rows because some foreign IORs both have CTPAT validation and use a CTPAT validated broker.

Table 4 shows the number of active brokers, of which 21% are CTPAT validated, 1% are CTPAT certified, and 78% are not CTPAT validated. About two-thirds of brokers have submitted an entry summary for a foreign IOR.

Table 4: Number of Active Brokers

	Number of active* brokers		Number of active* brokers that filed entries for foreign IORs	
	Count	Share of Total	Count	Share of Total
Validated	643	21%	622	30%
Certified	29	1%	28	1%
Non-CTPAT	2,428	78%	1,401	68%
Total	**3,100**	**100%**	**2,051**	**100%**

*Brokers were counted as active if they submitted any entry summaries between October 1, 2020, and February 6, 2026. Source: Based on trade data from October 1, 2020, to February 6, 2026, from ACE, obtained on February 17, 2026.

As shown in Table 4, there were 3,100 brokers that filed entry summaries between October 1, 2020, and February 6, 2026. CBP uses this number as its estimate for the number of brokers that will make entry and be affected by the rule in the 5 years following the rule's effective date. The number of currently permitted brokers, as of October 2, 2026, is 2,600, but this figure underestimates the number of brokers who will be affected by the rule because it does not include brokers who are not yet permitted but will be in the future.[38] For the purposes of estimating the number of submissions of the Broker Delayed Compliance Request Form, however, CBP uses the number of currently permitted brokers, 2,600, because that form will only be accepted for a limited time.

Benefits

Under the rule, CBP will be better equipped to enforce payments for duties, penalties, and liquidated damages from foreign IORs, and CBP will have more knowledge of which IORs are foreign or domestic. One of CBP's many critical mission sets is to facilitate legitimate trade that supports economic growth while shielding the American public and businesses from illicit trade, including unsafe products, intellectual property theft, and unfair trade practices. However, CBP cannot easily ensure that foreign IORs are complying with U.S. customs and trade laws to prevent the importation of dangerous and unlawful goods, potentially unsafe merchandise, such as counterfeit goods and precursor chemicals for the purposes of manufacturing illicit substances, into the United States. This program encourages companies to proactively identify and mitigate these risks within their supply chains, and these new requirements will allow CBP to more effectively focus its efforts on higher risk importers to interdict illicit drugs, intellectual property violative goods, misclassified merchandise, and other goods that pose risks to public safety.

CBP

The rule will aid CBP in enforcing duty payments by foreign IORs. At present, foreign IORs are difficult to collect payments from, as a foreign IOR may have no physical offices, bank accounts, or assets in the United States that CBP can seize. Moreover, without a physical presence in the country, a foreign shell company may import merchandise and disappear—before a demand for payment is even issued. Therefore, when CBP discovers unpaid duties, fees, penalties, and liquidated damages, it is typically more successful at collecting from U.S. IORs than foreign IORs. From January 1, 2020, to August 27, 2026, CBP audits uncovered a loss of revenue from U.S. IORs totaling $4.3 billion and from foreign IORs totaling $1.16 billion.[39] The loss of revenue was higher for U.S. IORs because U.S. IORs imported roughly 10 times more by value than foreign IORs over that period.[40] Thus, proportionally, the loss of revenue as compared to total value of imports was 0.06% for foreign IORs, as compared to 0.02% for U.S. IORs.[41] Moreover, as discussed below, in terms of CBP's ability to collect, the gap becomes even wider. After identifying unpaid duties and other unpaid amounts owed to CBP, CBP was able to collect a portion of what the IORs owed. As shown in Table 4, CBP collected $654 million from U.S. IORs after identifying the loss of revenue, implying a collection rate of 15.2% for what had gone unpaid. For foreign IORs, CBP collected $35.7 million, a collection rate of only 3.1%.

Table 4: Total Identified Loss of Revenue and Subsequent Collections, January 2020 - July 2026

IOR Type	Amount Reported	Discovered Loss of Revenue	Collected Amount	Percent Collected
Domestic	Total	$4.3 billion	$654 million	15.2%
Foreign	Total	$1.16 billion	$35.7 million	3.1%
Domestic	Average annual	$645.6 million	$98.2 million	15.2%
Foreign	Average annual	$174.2 million	$5.4 million	3.1%

Note: CBP identified all audits of IORs from January 1, 2020, to August 27, 2026, and compiled the total identified loss of revenue and collections stemming from those audits.
Note: The top two rows of figures show the total amounts that accumulated over the full time period. The bottom two rows show the average annual amounts implied by the upper rows.
Source: received from OT on August 27, 2026. Obtained from Trade Regulatory Audit Management System.

Open bill statistics show that foreign IORs that are CTPAT validated are much more likely to pay what they owe. Many IORs have open bills with CBP, meaning that they have unpaid duties, taxes, and fees that are past due. Some of these IORs may be slow and untimely in making payments, while others have no intention of ever paying. Open bills are a more common problem for entries made by non-CTPAT validated IORs than by CTPAT validated IORs, possibly because CBP has more leverage and information when dealing with CTPAT validated IORs. By requiring non-CTPAT validated foreign IORs to either become CTPAT validated or use a CTPAT validated broker, the rule will increase visibility into the foreign IORs' supply chains and thereby help CBP enforce payment. The transparency gained through this interim final rule concerning an IOR's foreign IOR status is also anticipated to assist with CBP's

[38] Source for number of permitted brokers: CBP Office of Trade, October 2, 2026.

[39] Source: received from OT on August 27, 2026. Obtained from Trade Regulatory Audit Management System.

[40] Source: based on trade data from October 1, 2020, to February 6, 2026, from ACE and open bill data from Office of Finance, obtained on February 17, 2026.

[41] CBP scaled the total import values from October 1, 2020, to February 6, 2026 by 2,431/1,955 to estimate the total import values from January 1, 2020, to August 27, 2026, so that CBP could compare the total import values with the total loss of revenue over the same time period.

identification and enforcement against shell companies and to enhance CBP's understanding of linkages and affiliations among foreign IORs, and shell companies. Moreover, stricter penalty enforcement by CBP could motivate foreign IORs to give more accurate information, including classification and valuation, for their imports in the first place, reducing the need for CBP to issue penalties.

CTPAT validated foreign IORs are much more compliant in making payments to CBP than non-CTPAT validated foreign IORs are, as shown by open bill statistics. To calculate the amount owed by different categories of IORs, CBP looked at bills that were opened between October 1, 2020, and February 6, 2026, and that were still open on February 6, 2026.[42] As of February 6, 2026, the total amount owed by non-CTPAT validated foreign IORs for open bills was $1,015,627,712. CBP excluded interest when calculating the amount owed for the open bills. To compare CTPAT validated and non-CTPAT validated foreign IORs, CBP divided each group's total uncollected bill amount by the number of entry summaries made during that same period to calculate the average uncollected bill amount per entry summary. On average, CTPAT validated foreign IORs owe CBP $1.21 in uncollected bills per entry summary, while non-CTPAT validated foreign IORs owe $34.08 per entry summary. A comparison of non-CTPAT validated and CTPAT validated U.S. IORs yields similar results, shown in Table 5.

Table 5: Average Uncollected Bill Amount per Entry Summary

CTPAT Status of IOR	Foreign IORs	U.S. IORs	All IORs
Non-CTPAT validated	$34.08	$29.83	$30.55
CTPAT validated	$1.21	$3.48	$3.29

Calculated by dividing total uncollected bill amount by entry summary count for each category.
Source: Based on trade data from October 1, 2020, to February 6, 2026, from ACE and open bill data from Office of Finance, obtained on February 17, 2026.

The difference between CTPAT validated and non-CTPAT validated foreign IORs' average uncollected bill amount per entry can be decomposed into the difference between the average amount owed on an open bill and the number of open bills per entry summary. These different components are shown in Table 6. One can see that the number of open bills per 10,000 entry summaries[43] is only slightly higher for non-CTPAT validated foreign IORs, but the average open bill is much larger for non-CTPAT validated foreign IORs ($68,763) than for CTPAT validated foreign IORs ($2,501).

Table 6: Decomposition of Foreign IORs' Uncollected Bill Amount per Entry Summary

CTPAT Status	Total Uncollected Bill Amount/Entry Summaries	Total Uncollected Bill Amount/Open Bill	Open Bills/10,000 Entry Summaries
Non-CTPAT validated	$34.08	$68,763	4.96
CTPAT validated	$1.21	$2,501	4.85

Source: Based on trade data from October 1, 2020, to February 6, 2026, from ACE and open bill data from Office of Finance, obtained on February 17, 2026.

The above tables focus on the average open bill amount per entry summary. One could instead look at the average open bill amount per IOR. Dividing the total uncollected bill amount by the number of IORs in each category reveals that CTPAT validated foreign IORs actually have a larger uncollected bill amount per IOR than non-CTPAT validated foreign IORs do. To understand why, CBP decomposed the open bill amount per IOR into two statistics: (1) the open bill amount per IOR with an open bill and (2) the share of IORs with open bills. Table 7 shows that non-CTPAT validated foreign IORs with open bills have an open bill amount of $978,447, which is larger than CTPAT validated foreign IORs' average of $192,979. However, dividing the total number of open bills by the number of IORs, one sees that CTPAT validated foreign IORs have more open bills (4.44 per 100 IORs) than non-CTPAT validated foreign IORs (0.55 per 100 IORs).

[42] An open bill is created when an entry liquidates for an increase, and an open bill is considered delinquent at 31 days old and unpaid. If a bill is only partially paid, it remains open and delinquent until the remaining amount is paid in full or otherwise resolved.

[43] The number of open bills per entry summary is a very low number, and so CBP reports the number of open bills per 10,000 entry summaries for readability, even though the total uncollected bill amount per entry summary equals the total uncollected bill amount per open bill times the number of open bills per entry summary, not per 10,000 entry summaries.

Table 7: Decomposition of Foreign IORs' Uncollected Bill Amount per Foreign IOR

CTPAT Status	Total Uncollected Bill Amount/All IORs	Total Uncollected Bill Amount/IORs with Open Bills	Open Bills/100 IORs
Non-CTPAT validated	$5,427	$978,447	0.55
CTPAT validated	$8,560	$192,979	4.44

Source: Based on trade data from October 1, 2020, to February 6, 2026, from ACE and open bill data from Office of Finance, obtained on February 17, 2026.

One likely reason that CTPAT validated foreign IORs have more open bills than non-CTPAT validated foreign IORs is that CTPAT validated foreign IORs make many more entries. Between October 1, 2020, and February 6, 2026, the average CTPAT validated foreign IOR made 7,053 entry summaries, while the average non-CTPAT validated foreign IOR made 159 entry summaries. It is reasonable for CTPAT validated foreign IORs to have 8 times more open bills per IOR than non-CTPAT validated foreign IORs when the CTPAT validated foreign IORs also make 44 times more entry summaries per IOR than the non-CTPAT validated foreign IORs. Therefore, open bills per entry summary are a more reliable indicator of CBP's collection difficulties than open bills per IOR when comparing different categories of IORs. Once again, the average open bill per entry summary is starkly higher for non-CTPAT validated IORs ($34.08) than CTPAT validated IORs ($1.21).

Table 8: Foreign IORs' Entry Summaries per IOR

CTPAT Status	Entry Summaries per IOR
Non-CTPAT validated	159
CTPAT validated	7,053

Source: Based on trade data from October 1, 2020, to February 6, 2026, from ACE, obtained on February 17, 2026.

Not only is there a clear correlation between open bills and CTPAT validation, but there are also reasons why CTPAT validation actually causes IORs to have lower open bills. Most importantly, one of the requirements for CTPAT validation is that the importer ''maintain no evidence of financial debt to CBP for which the responsible party has exhausted all administrative and judicial remedies for relief, a final judgment or administrative disposition has been rendered, and the final bill or debt remains unpaid at the time of the initial application or annual renewal.'' [44] Moreover, participation in the CTPAT program gives CBP more visibility into the IOR's business, helping CBP to contact and enforce collections from the CTPAT validated IOR. Meeting the security requirements of CTPAT may also prevent the IOR from doing something (such as undervaluing imports) that would lead to a large duty increase in the first place.

CBP expects to collect more revenue under the rule as a result of stricter enforcement of duties, penalties, and liquidated damages. CBP cannot estimate the revenue increase because CBP cannot assume that the rule will lead to a 100% collection rate or that the foreign IORs that switch to using CTPAT validated brokers under the rule will become exactly as compliant as CTPAT validated IORs. Whatever the increase in revenue, part of that revenue will be a benefit of the rule, and part will be a transfer. While the increased revenue collected by the U.S. government would come directly from foreign IORs, those foreign IORs could pass on some share of the burden to U.S. individuals through price adjustments. To the extent that the revenue ultimately comes from U.S. individuals, the revenue is a transfer, not a benefit of the rule, as the gain to the U.S. government would equal the loss to the individuals. To the extent that the foreign IORs themselves bear the burden of increased payments to CBP, that share of the increased revenue is a benefit of the rule, as it entails a transfer from foreign entities to the U.S. government. However, revenue aside, the fact that CBP will be more strictly enforcing payments is a benefit in itself. Some IORs are already cooperative in paying what they owe, while other IORs try to avoid paying duties and other obligations. Hence, without strict enforcement, the cooperative IORs are at a disadvantage, especially against foreign IORs with no assets in the United States that try to evade payments. By helping CBP compel foreign IORs to pay duties, penalties, and liquidated damages, the rule will make the playing field more level between U.S. and foreign IORs.

The rule will help CBP with the collection of payments from foreign IORs because more foreign IORs will be using CTPAT validated brokers, who are more knowledgeable about their clients than non-CTPAT validated brokers are.[45] Foreign shell companies are

[44] Source: U.S. Customs and Border Protection, *Importers,* accessed August 20, 2025. Available at: *https://www.cbp.gov/border-security/ports-entry/cargo-security/ctpat/importers.*

[45] Some foreign IORs will become CTPAT validated themselves, which would also help with revenue collection, but this effect will be limited to a fraction of Canadian IORs, who are the only foreign IORs eligible for CTPAT validation.

particularly difficult for CBP to collect revenue from because they can disappear and reappear later with a new name and contact information. However, CTPAT validated brokers have additional information on their clients besides the bare contact information, as the CTPAT minimum security criteria require CTPAT validated brokers to screen new business partners and monitor current partners. The minimum security criteria suggest the following to CTPAT validated brokers as vetting elements that can help determine if a company is legitimate: verifying the company's business address and how long it has been at that address; conducting research on the internet on both the company and its principals; checking business references; and requesting a credit report.[46] CBP could request this information from the brokers if the foreign IOR gave it to them. Alternatively, if the foreign IOR refuses to give any information to CTPAT validated brokers for screening purposes, then the brokers may refuse to do business with the foreign IOR, which, under the rule, would prevent the foreign IOR from importing.

Besides increasing CBP's collection of revenue, the rule could also help prevent the shipment of prohibited goods to the United States. The number of seizures per million entries is over five times larger for non-CTPAT validated foreign IORs (6.38) than CTPAT validated foreign IORs (1.14). By requiring foreign IORs to either become CTPAT validated or use a CTPAT validated broker, the rule will increase transparency into foreign IORs' operations, making it more difficult for bad actors to export prohibited goods to the United States.

Table 9: Foreign IORs' Seizures per Million Entry Summaries

CTPAT Status	Seizures per Million Entry Summaries
Non-CTPAT validated	6.38
CTPAT validated	1.14

Source: Based on trade data from October 1, 2020, to February 6, 2026, from ACE and seizure data from SEACATS, obtained on February 17, 2026.

The rule will also help to keep the supply chain safer from terrorist threats. Under the rule, more brokers will choose to become CTPAT validated so that they can continue serving non-CTPAT validated foreign IORs, and some foreign IORs may choose to become CTPAT validated so that they are not required to hire a CTPAT validated broker, though only foreign IORs that are Canadian are currently eligible for CTPAT validation. The increase in CTPAT validated entities will make the supply chain safer because an entity seeking CTPAT validation must work with CBP to identify security gaps and implement specific security measures and best practices. If the entity does not meet the minimum security criteria, CBP will recommend that the company address specific weaknesses as a condition to obtain CTPAT validation. The entity must also develop an internal validation process that preserves the security measures documented in its supply chain security profile. Therefore, entities that become CTPAT validated will make their supply chains less vulnerable to intrusion by terrorists or terrorist organizations. Besides increasing the number of CTPAT validated entities, the rule will also make the supply chain more secure by causing more non-CTPAT foreign IORs to use CTPAT validated brokers. One of the minimum security criteria for CTPAT validated customs brokers is that personnel ''must review the information included in import/export documents to identify or recognize suspicious cargo shipments.'' CTPAT validated brokers are therefore more vigilant than non-CTPAT validated brokers with regard to the cargo that their clients are importing.

Costs

CBP

The increased participation in CTPAT under the rule will result in costs to CBP. When a company applies for CTPAT validation, CBP must review the company's application and security profile. If CBP certifies the company, CBP then conducts a validation to verify that the company's stated security measures are implemented. This process may include interviews, document review, and site visits to domestic or foreign locations. During a site visit, CBP supply chain security specialists (SCSS) review in detail the entity's import supply chain security procedures to determine whether the security procedures in place meet CTPAT standards. The SCSS later document their findings from the visit in a validation report. Even after a company receives CTPAT validation, CBP continues to incur costs from the company's CTPAT participation, such as the costs of revalidation. CBP estimates that the increase in CTPAT participation will result in costs to CBP totaling $10.9 million, including the costs of additional staffing, travel, equipment, and automation.[47] For this analysis, CBP assumes that the $10.9 million will be spread evenly across the regulatory period, implying an annual cost of $1.09 million per year.

The rule will also result in programming costs for CBP. Under the rule, CBP Forms 3461 and 7501 and their electronic equivalents will need to be updated to include two checkboxes. One checkbox would be checked if the broker is acting as the IOR on behalf of the principal on the power of attorney, with a field for identifying the principal by IOR number or other identifier tied to CBP Form 5106. The second

[46] Source: U.S. Customs and Border Protection, *Minimum Security Criteria—U.S. Customers Brokers,* accessed August 20, 2025. Available at: *https://www.cbp.gov/sites/default/files/assets/documents/2022-May/CTPAT%20U.S.%20Customs%20Brokers%20MSC%20October%202021%20%28508%29.pdf.*

[47] Source: cost estimate obtained from CBP Office of Field Operations on August 24, 2026.

checkbox would be checked if the IOR (or principal, if the broker is acting as the IOR on behalf of the principal) is a U.S. IOR. CBP estimates that making these updates will result in programming costs of $1,222,871 for the government.[48] For this analysis, CBP assumes that the programming costs will be incurred in the first year of the regulatory period, 2027. Combining the programming costs with the costs of increased CTPAT participation, the total costs to CBP under the rule will equal an estimated $12,122,871. Under a discount rate of 3%, the annualized costs to CBP are $1,229,182 per year. In addition to these quantified costs, CBP will also incur time costs from enforcing the rule. When investigating a particular IOR claiming to be a U.S. IOR, CBP may ask the broker to supply documentation from the IOR to prove the IOR is a U.S. IOR. Obtaining and verifying this documentation will carry a time burden for CBP.

Finally, CBP will incur costs from processing brokers' delayed compliance requests in the first year of the rule. When the rule is published, brokers will have 60 days after the publishing date to verify that their clients claiming to be U.S. IORs are indeed U.S. IORs. Brokers that expect to have difficulty meeting this deadline may submit a Broker Delayed Compliance Request Form, containing the broker's identifying information along with the reason the broker is requesting an extension. If CBP approves the form, the broker will have 6 months instead of 60 days after the publication date to verify its clients and thereby come into compliance with the rule. CBP expects that all 2,600 currently permitted brokers will submit a form and that the average time burden for CBP to process a form will be 0.5 minutes. Hence, the total time burden for CBP to process Broker Delayed Compliance Request Forms will be 21.67 hours. The average hourly wage of a CBP Trade and Revenue employee is $95.34.[49] Therefore, the cost of CBP's time burden of processing the forms would be $2,066.

Brokers

Non-CTPAT Validated Brokers

Under the rule, brokers that are not CTPAT validated will no longer be allowed to make entry for foreign IORs that are not CTPAT validated. This restriction will lead to a decrease in customers for those brokers, but CBP does not count those brokers' loss of business as a cost to society. CBP assumes non-CTPAT validated foreign IORs will switch to using CTPAT validated brokers and that the non-CTPAT validated brokers' loss will therefore equal the CTPAT validated brokers' gain. Thus, from a societal perspective, the shift in clients from some brokers to others is a transfer, not a cost, of the rule. CBP discusses this effect further in the Transfers section below.

Under the rule some non-CTPAT validated brokers will seek to become CTPAT validated and will incur costs in doing so. The costs of CTPAT validation do not come in the form of any fees that the applicants have to pay to CBP, but rather in the additional labor hours it takes for the applicants to complete the validation process and to meet and maintain the high standards of security required of CTPAT validated companies. Becoming and remaining CTPAT validated generally requires a company to apply to CBP's CTPAT program, implement the applicable minimum security criteria, complete a security profile, train personnel, maintain program eligibility and participate in CBP validation and revalidation activities.

Broadly, the minimum security criteria for CTPAT validation require a company to assess security risks across its international supply chain, including business partners, facilities, conveyances, cargo handling, personnel, cybersecurity, and procedural controls. To manage these risks, the company must vet and monitor relevant supply chain partners and encourage or require appropriate security practices. The company must keep its security profile current, address identified weaknesses, and cooperate with CBP reviews, validations, and revalidations. To ensure that its business practices will continue to meet the minimum security criteria, the company must maintain a documented supply chain security program aligned to CTPAT minimum security criteria for its business type.

After reviewing the minimum security criteria, an applicant for CTPAT validation must submit an application through the CTPAT portal and provide required company and supply chain information. The applicant then completes and submits a detailed security profile describing how the company meets CTPAT criteria. CBP reviews the application and security profile. If accepted, the company may receive certified status before validation, depending on the business type and CBP review. CBP then conducts a validation to verify that the company's stated security measures are implemented. This process may include interviews, document review, and site visits to domestic or foreign locations. If CBP identifies gaps, the company must take corrective action within required timeframes. To maintain CTPAT validation, the company must update its profile as operations change, perform periodic reviews, maintain records, and participate in CBP revalidation, typically on a recurring cycle.

CBP does not currently charge a direct application or membership fee for CTPAT participation. However, companies seeking CTPAT validation should expect indirect costs, which may include: staff time to prepare the application, security profile, risk assessments, and documentation; security upgrades, such as facility access controls, seals, cargo tracking, lighting, fencing, CCTV, cybersecurity controls, or personnel screening procedures; training for employees and relevant business partners; travel or hosting costs associated with validation or revalidation visits; consultant or third-party support costs, if the company chooses to use outside assistance; and ongoing program management costs to monitor partners, update procedures, maintain documentation, and respond to CBP findings. The companies that will choose to seek CTPAT validation under the rule will include foreign IORs and U.S. brokers.

CTPAT validation is not a one-time event but an ongoing supply chain security commitment. Therefore, being CTPAT validated entails both the upfront cost to become CTPAT validated and the recurring cost to maintain the high security standards. CBP estimates that the average time burden of applying for CTPAT validation is 20 hours.[50] Based on an hourly wage of $38.88,[51] CBP estimates

[48] Source: obtained from CBP Trade Transformation Office on August 27, 2026.

[49] CBP bases this wage on the FY 2025 salary and benefits of the national average of CBP Revenue Positions. Source: Email correspondence with CBP's Office of Finance on June 11, 2026.

[50] U.S. Customs and Border Protection. *Supporting Statement for Paperwork Reduction Act Submission OMB Number 1651–0077: Customs-Trade Partnership against Terrorism (CTPAT) and Trade Compliance.*

[51] To calculate this loaded wage rate CBP multiplied the Bureau of Labor Statistics' (BLS) 2025 median hourly wage rate for Cargo and Freight Agents ($25.13), which CBP assumes best represents the wage for brokers, by the ratio of BLS' Q4 2025 total compensation to wages and salaries for Office and Administrative Support occupations (1.497), the assumed occupational group for brokers, to account for non-salary employee benefits, ($37.62 in 2025 dollars). To adjust to 2026 dollars, CBP assumes an annual increase of 3.36% based on the December 2025 12-month percent change in the Employment Cost Index. Source of median wage rate: U.S. Bureau of Labor Statistics. Occupational Employment and Wage Statistics, 2025 National Occupational Employment and Wage Estimates United States, OCC_code 43–5011.

that the average cost of this time burden equals $777.60. Though CBP can estimate the average application cost, it cannot quantify the total cost of CTPAT validation applications under the rule because CBP cannot predict the number of applications that would be made. Regarding post-application costs, CBP is unable to quantify the costs of maintaining high security standards after the application but believes these costs could be significant for the brokers that choose to become CTPAT validated. Some brokers have more clients or deal with more complex supply chains than others, and these differences could create significant differences across brokers in the amount of labor required to maintain high security standards, which makes quantification difficult. Brokers may recover some of these costs from their clients in the form of higher fees for services. Hence, the rule could lead to higher broker fees as newly validated CTPAT brokers pass at least a portion of the costs on to their clients.

The number of non-CTPAT validated brokers is shown in Table 10. From October 1, 2020, to February 6, 2026, 1,401 non-CTPAT brokers served a foreign IOR. Some of those brokers may be motivated to become CTPAT validated as a result of this rule. There are also 28 brokers that are CTPAT certified but not CTPAT validated, and the additional cost of becoming CTPAT validated for them is probably much smaller than for the non-CTPAT brokers.

Table 10: Number of Active Brokers

CTPAT Status	Number of Active* Brokers	Number of Active* Brokers That Filed Entries for Foreign IOR
Validated	643	622
Certified	29	28
Non-CTPAT	2,428	1,401
Non-CTPAT validated's share	79%	70%

*Brokers were counted as active if they submitted any entry summaries between October 1, 2020, and February 6, 2026.
Source: Based on trade data from October 1, 2020, to February 6, 2026, from ACE, obtained on February 17, 2026.

Brokers Who Serve U.S. IORs

All brokers, both CTPAT validated and non-CTPAT validated, who serve U.S. IORs will incur additional costs under the rule because those brokers will need to obtain records from the U.S. IORs to confirm their domestic status. Such records may include, but are not limited to, proof of citizenship or lawful permanent residence, corporate charters, financial statements, purchase receipts, or documents of title. If circumstances suggest the IOR may be orchestrating U.S. assets simply for purposes of attaining U.S. IOR status without an intention for those assets to remain in the United States, then the broker should ask additional follow-up questions and request additional information. Ultimately, if the broker's concerns are not allayed, it should refuse to certify or re-certify the IOR as a U.S. IOR. The brokers will also need to present the documentation they obtain from U.S. IORs to CBP upon request. Therefore, brokers will be required to retain the documents for 5 years from the date the verification is conducted so that the information will be accessible to CBP when debt arises. All brokers are U.S.-based, per CBP regulations.[52]

As shown in Table 11, almost 1 million U.S. IORs were active between October 1, 2020, and February 6, 2026. These U.S. IORs made up the majority of IORs and were responsible for the majority of entries. Table 12 shows that there are 323 U.S. IORs per broker, meaning that the average broker will have to obtain documentation for about 323 IORs as a result of the rule. CBP cannot estimate the cost of collecting and maintaining this documentation but believes these costs could be substantial. The precise cost is difficult to quantify because there will be large variation in how long it takes brokers to verify that their U.S. IOR clients are U.S. IORs. An IOR can qualify as a U.S. IOR based either on its beneficial owners' status or on the IOR's U.S. assets, and some IORs will have more complex corporate structures or asset holdings than others. Therefore, providing documentation of one's status as a U.S. IOR to a broker will be straightforward for some IORs and laborious for others.

As discussed above, brokers will be required to verify their U.S. clients' status as U.S. IORs within 60 days of the rule's publication date, but they may submit a Broker Delayed Compliance Request Form to request an extension. If CBP approves the request, the broker will have 6 months after the rule's publication date to verify its clients. CBP estimates that the average time burden to submit the form will be 20 minutes and that all 2,600 currently permitted brokers will submit a form.[53] The total time burden will therefore be 866.67 hours. At an average hourly wage of $38.88, the cost of this time burden will equal $33,696.

Finally, two checkboxes and a field to provide the IOR number of the principal, if applicable, will be added to CBP Form 3461, CBP Form 7501, and their electronic equivalents. However, CBP expects the cost of simply checking the boxes and entering the IOR number of the principal to be negligible, as discussed in the PRA section below.

Updated May 15, 2026. Available at *https://www.bls.gov/oes/special-requests/oesm25nat.zip*. Accessed May 21, 2026. The total compensation to wages and salaries ratio is equal to the total compensation cost per hour worked for Office and Administrative Support occupations ($37.47) divided by the wages and salaries cost per hour worked for the same occupation category ($25.03). See ''Table 2. Employer Costs for Employee Compensation for civilian workers by occupational and industry group.'' Bureau of Labor Statistics, ''Employer Costs for Employee Compensation—December 2025.'' Released March 20, 2026. Available at *https://www.bls.gov/news.release/archives/ecec_03202026.pdf*. Accessed May 21, 2026. Source of Employment Cost Index: Bureau of Labor Statistics ''Employment Cost Index, Continuous data.'' Data used was for civilian workers, total compensation for all industries all occupations current dollar index number. December 2025 Index (173.64), December 2024 Index (168.0). CBP estimates a 3.36% (173.64/168.0)-1) increase in 2025. Updated April 30, 2026. Available at *https://www.bls.gov/eci/tables.htm*. Accessed May 21, 2026.

[52] *See* 19 CFR part 111.

[53] Source: obtained from CBP Office of Trade on October 2, 2026.

Table 11: Entry Summary Statistics for U.S. IORs

	IORs	Entry Summaries	Entry Summary Value
Amount	999,938	202,395,488	$16,122,143,579,287
% of all IORs	84.2%	85.2%	91.3%

Based on trade data from October 1, 2020, to February 6, 2026, from ACE, obtained on February 17, 2026.

Table 12: U.S. IORs per Broker

	Count
U.S. IORs	999,938
Brokers	3,100
U.S. IORs/broker	323

Source: Based on trade data from October 1, 2020, to February 6, 2026, from ACE, obtained on February 17, 2026.

Importers of Record

All IORs Who Use Brokers

The rule could increase the workload for CTPAT validated brokers, since some foreign IORs will need to switch from their current non-CTPAT validated broker to a CTPAT validated broker. If CTPAT validated brokers struggle to take on so many new clients in a short period of time, then IORs of all kinds could be negatively affected. CBP therefore examined whether CTPAT validated brokers are likely to have the capacity to handle the additional workload under the rule. Based on entry summary statistics, CBP expects that CTPAT validated brokers will be able to accommodate the new demand for their services, even in the short term, because foreign IORs make up a relatively small portion of the overall trade volume. The top row of Table 13 shows the number of non-CTPAT validated foreign IORs who did not use a CTPAT validated broker, as well as the number and value of entry summaries made by those IORs. The next two rows show those figures as a percentage of all foreign IORs and as a percentage of all IORs, respectively. About a third of foreign IORs are non-CTPAT validated IORs who use non-CTPAT validated brokers, meaning the rule will affect a significant share of foreign IORs. However, only 16% of IORs are foreign. Therefore, the share of all IORs who are non-CTPAT validated participants and use non-CTPAT validated brokers is much smaller than a third. As shown in the bottom row, these IORs make up only 5.4% of the total market and are responsible for 2.6% of entry summaries. Table 14 shows the number and share of IORs who used CTPAT validated brokers, as well as the number and value of the entry summaries. Using the numbers in these two tables, CBP estimated the percentage increase in broker services for CTPAT validated brokers if all of the non-CTPAT validated foreign IORs that currently use non-CTPAT validated brokers switch to CTPAT validated brokers under the rule. In that scenario, CTPAT validated brokers would see a 9.3% increase in clients and a 3.1% increase in the number of entries. If this increase in the quantity demanded for broker services were to be distributed evenly across all CTPAT validated brokers, CBP expects that the brokers would not have much difficulty handling the increase in business. Therefore, the overall broker market will probably be able to provide the same total amount of broker services under the rule as in the baseline. The relative increase in revenue for CTPAT validated brokers will most likely be close to the relative increase in entries handled by them, which is an estimated 3.1%. All brokers that do U.S. customs business are U.S.-based.

Table 13: Entry Summary Statistics for Non-CTPAT validated Foreign IORs Using Non-CTPAT Validated Brokers

	IORs	Entry Summaries	Entry Summary Value
Count	63,577	6,113,277	$293,340,970,604
Share of all foreign IORs	33.8%	17.4%	26.9%
Share of all IORs	5.4%	2.6%	2.3%

Source: Based on trade data from October 1, 2020, to February 6, 2026, from ACE, obtained on February 17 and March 25, 2026.

Table 14: Entry Summary Statistics for IORs Facilitated by CTPAT Validated Brokers

	IORs	Entry Summaries	Entry Summary Value
Amount	680,928	196,594,700	$12,942,269,979,145
Share of all IORs	76.2%	82.1%	80.9%

Source: Based on trade data from October 1, 2020, to February 6, 2026, from ACE, obtained on February 17 and March 25, 2026.

Table 15: Estimated Increase in Business for CTPAT Validated Brokers

IORs	Entry Summaries	Entry Summary Value
9.3%	3.1%	3.2%

Source: Based on trade data from October 1, 2020, to February 6, 2026, from ACE, obtained on February 17 and March 25, 2026.

Non-CTPAT Validated Foreign IORs Using Non-CTPAT Validated Brokers

CBP expects that non-CTPAT validated foreign IORs using non-CTPAT validated brokers in the baseline will switch to a CTPAT validated broker under the rule. While there are plenty of CTPAT validated brokers available, this switch will not be frictionless. Each IOR will probably research different CTPAT validated brokers and perhaps contact several of them to get quotes for services. This process of searching for a new broker will take time. Moreover, these CTPAT validated brokers will have stricter information requirements for their customers than non-CTPAT validated brokers do, on average. CBP assumes that some if not most of the cost of the extra work done by the CTPAT validated brokers to maintain CTPAT compliance is passed on to the customers in the form of higher broker fees. Therefore, most of the cost of the extra work will fall on the IORs, and these costs will equal the difference between the new rates charged by the CTPAT validated brokers and the old rates charged by the non-CTPAT validated brokers, though CBP lacks an estimate for this rate difference.

There may also be foreign IORs under the rule that decide to apply for CTPAT validation so that they are not required to hire a CTPAT-validated broker, though only foreign IORs that are Canadian are currently eligible for CTPAT validation. Becoming and remaining CTPAT validated generally requires a company to apply to CBP's CTPAT program, implement the applicable minimum security criteria, complete a security profile, and participate in CBP validation and revalidation activities. While there is no fee charged for participation in the CTPAT program, obtaining CTPAT validation entails many indirect costs, which are discussed in more detail above in the subsection regarding the costs of the rule to non-CTPAT validated brokers. Per the discussion above, the cost of the average time burden of applying for CTPAT validation is $777.60,[54] but CTPAT validation entails post-application time burdens of maintaining high security standards as well.

U.S. IORs

Just as the brokers for U.S. IORs will incur the cost of obtaining documentation from U.S. IORs proving their U.S. residence, the U.S. IORs will incur the cost of gathering and providing the documentation to the brokers and keeping records afterward. While CBP is unable to estimate this cost, it could be substantial on aggregate. From October 1, 2020, to February 6, 2026, there were almost 1 million U.S. IORs who made entry. These IORs were 84.2% of IORs and responsible for 85.2% of entry summaries, as shown in the table below.

Table 16: Entry Summary Statistics for U.S. IORs

	IORs	Entry Summaries
Count	999,938	202,395,488
Share of all IORs	84.2%	85.2%

Source: Based on trade data from October 1, 2020, to February 6, 2026, from ACE, obtained on February 17, 2026.

[54] CBP assumes that IORs have the same average wage as brokers, and therefore the average value of the time burden would be the same for both parties.

Transfers

Under the rule, non-CTPAT validated foreign IORs who were previously using non-CTPAT validated brokers will need to switch to CTPAT validated brokers to continue importing into the United States. This movement in clients will result in a decrease in revenue for non-CTPAT validated brokers and an increase in revenue for CTPAT validated brokers. Any increased revenue received by CTPAT validated brokers would therefore constitute a transfer from non-CTPAT validated brokers. CBP discusses that transfer in this section.

As shown in Table 17, non-CTPAT validated brokers make up 79% of brokers that have filed an entry summary and 70% of brokers that have filed an entry summary for a foreign IOR.

Table 17: Number of Active Brokers

CTPAT Status	Number of Active Brokers	Number of Active Brokers That Filed Entries for Foreign
Validated	643	622
Non-CTPAT validated	2,457	1,429
Non-CTPAT validated's share of total	79%	70%

Note: We counted brokers as active if they filed an entry summary between October 1, 2020, and February 6, 2026. Source: Based on trade data from ACE, obtained on February 17, 2026.

Table 18 shows the number of IORs with entry summaries facilitated by non-CTPAT validated brokers, as well as the number of such entry summaries and their value. Though non-CTPAT validated brokers make up a majority of brokers, they are responsible for only 17.2% of entry summaries. Combining Table 18 and Table 13 from the Costs Section, CBP calculates that, overall, non-CTPAT validated brokers will see a decrease in clients of 12.5% and a decrease in entry summaries of 15.0%.

Table 18: Entry Summary Statistics for IORs Facilitated by Non-CTPAT Validated Brokers, October 1, 2020, to February 6, 2026

	IORs	Entry Summaries	Entry Summary Value
Total Amount	506,881	40,850,898	$4,715,794,152,360
Share of all IORs	42.7%	17.2%	26.7%

Source: Based on trade data from October 1, 2020, to February 6, 2026, from ACE, obtained on February 17 and March 25, 2026.

Table 19: Estimated Decrease in Business for Non-CTPAT Validated Brokers

IORs	Entry Summaries	Entry Summary Value
12.5%	15.0%	8.8%

Source: Based on trade data from October 1, 2020, to February 6, 2026, from ACE, obtained on February 17 and March 25, 2026.

The negative effect of the rule on non-CTPAT validated brokers will not be evenly distributed. Some non-CTPAT validated brokers serve mostly U.S. IORs and will therefore not lose many clients under the rule, while other brokers get a larger share of their business from foreign IORs and will see a larger reduction in clients. To estimate the distribution of the rule's impact on non-CTPAT validated brokers, CBP took a random sample of 300 non-CTPAT brokers who made an entry summary between September 1, 2025, and February 6, 2026.[55] [56] For each broker, CBP calculated the share of the broker's clients that were foreign IORs, the share of entry summaries that were for foreign IORs, and the share of entry summary value for foreign IORs. For each of these three variables, CBP took the 1st through 9th deciles, plus the 95th, 98th, and 99th percentiles. These distribution statistics are shown in Table 20. The total number of active non-CTPAT validated brokers is 2,428, and CBP estimates in the second column the total number of brokers that are at or above the percentile in the first column.

[55] September 1 was chosen as the start because it was shortly after the *de minimis* exemption was suspended, which may have had an effect on demand for broker services.

[56] Choosing a sample size of 300 allowed us to construct a 95% confidence interval of the share of brokers for whom at least a fifth of their clients are foreign IORs with a margin of error of less than 5 percentage points. CBP calculates this share in the sample to be 9.47%, with a margin of error of 4.32%, yielding a 95% confidence interval of (13.34%, 21.99%). However, the main focus in this subsection is on the distribution of the share of IOR clients who are foreign across brokers, rather than a single proportion.

Looking at the 50th percentile in Table 20, one sees that more than half of non-CTPAT brokers rely very little on foreign IORs. These brokers will not be seriously affected by the rule. Further down the table, non-CTPAT brokers in the 90th percentile get about a quarter of their business from foreign IORs. CBP estimates that 243 brokers are at or above this level of reliance on foreign IORs as clients. Finally, the 2% of brokers (or approximately the top 50) who get the greatest share of business from foreign IORs file 72% of their entry summaries for foreign IORs. Under the rule, these brokers will need to either downsize significantly, find a new client base, or become CTPAT validated, which takes time. Once again, their loss will equal the CTPAT validated brokers' gain. As shown in Table 22 (borrowed from Table 14 in the Costs Section), CTPAT validated brokers will see an estimated increase of 3.1% in their entry summaries under the rule. The overall percentage increase for CTPAT validated brokers will be smaller than the percentage decrease for non-CTPAT validated brokers, as the former do more business in the baseline.

Table 20: Sample Distribution of Non-CTPAT Brokers' Share of Business from Foreign IORs.

Percentile	Estimated Number of Brokers at or above Percentile	Foreign IORs' Share of Brokers' IOR Clients	Foreign IORs' Share of Brokers' Total Entry Summaries	Foreign IORs' Share of Brokers' Total Entry Summary Value
10	2,185	0%	0%	0%
20	1,942	0%	0%	0%
30	1,700	0%	0%	0%
40	1,457	0%	0%	0%
50	1,214	3%	1%	0%
60	971	7%	3%	2%
70	728	14%	6%	7%
80	486	18%	11%	16%
90	243	29%	24%	32%
95	121	38%	37%	59%
98	49	45%	72%	81%
99	24	50%	90%	85%

Note: percentiles calculated based on the broker activity of a random sample of 300 non-CTPAT brokers who were active between September 1, 2025, and February 6, 2026. Source: Based on trade data from October 1, 2020, to February 6, 2026, from ACE, obtained on February 17, 2026.

Table 21: Entry Summary Statistics for IORs Facilitated by CTPAT Validated Brokers

	IORs	Entry Summaries	Entry Summary Value
Amount	680,928	196,594,700	$12,942,269,979,145
% of all IORs	57.3%	82.8%	73.3%

Source: Based on trade data from October 1, 2020, to February 6, 2026, from ACE, obtained on February 17 and March 25, 2026.

Table 22: Estimated Increase in Business for CTPAT Validated Brokers

IORs	Entry Summaries	Entry Summary Value
9.3%	3.1%	3.2%

Source: Based on trade data from October 1, 2020, to February 6, 2026, from ACE, obtained on February 17 and March 25, 2026.

Because the rule will improve CBP's ability to collect duties, penalties, and liquidated damages, the U.S. government will see some increase in revenue under the rule. The increase in government revenue will be in the form of payments made by foreign IORs. However, these foreign IORs will not necessarily shoulder the entire burden of the payments. Through price changes, the foreign IORs could offload some of the burden of these payments onto the U.S. individuals that buy from them. To the extent that U.S. individuals bear some of the burden of increased payments, the increase in revenue will be a transfer, not a benefit of the rule, as the gain to the U.S. government will equal the loss to the U.S. consumers. To the extent that the foreign IORs themselves bear the burden of the increased payments, that increased revenue to the U.S. government is a benefit, as the gain to the U.S. government would be coming from foreign entities.

Net Effect

The net effect of the rule is the difference between the total benefits and the total costs. In this analysis, CBP quantified the populations affected by the rule and discussed the effects of the rule qualitatively, but CBP lacked the information needed to estimate quantitatively either the total benefits or total costs of the rule. Therefore, CBP is unable to calculate the quantified net impact of the rule. In qualitative terms, the benefits of the rule will be to make CBP better positioned to collect revenue and penalties from foreign IORs and to prevent the importation of prohibited goods by foreign IORs. Revenue collection and screening of prohibited goods will improve because CBP will have more visibility into foreign IORs once they become CTPAT validated or begin using CTPAT validated brokers. The costs of the rule will be incurred by CBP, IORs, and brokers. CBP will incur a time cost from enforcing the rule, along with $12.2 million in costs resulting from programming updates, increased CTPAT participation, and processing brokers' requests for delayed compliance. Foreign IORs who are not CTPAT validated and who do not use a CTPAT validated broker will no longer be allowed to enter imported merchandise for consumption. These IORs will have to incur the cost of switching to a CTPAT validated broker and will likely bear the cost of the stricter informational standards set by CTPAT validated brokers, with this cost passed on to the IORs in the form of higher broker fees. In the long run, some of these foreign IORs may join CTPAT and become validated participants in the program, which is free to join but involves indirect costs to meet the requirements of the program, such as additional labor. The IORs who need to find new brokers will not be the only ones affected by the rule. U.S. IORs and the brokers who serve them will face the paperwork burden of proving that they are U.S. IORs. These IORs will need to provide documentation of their domestic status to the brokers, who will store the documentation and present it to CBP when asked for it. Non-CTPAT validated brokers will see a reduction in clients as foreign IORs shift to using CTPAT validated brokers. This effect is a transfer, not a cost to society, because from a societal perspective the loss to the non-CTPAT validated brokers will be offset by the CTPAT validated brokers' gain.

Alternatives

In this section, CBP discusses two regulatory alternatives that are stricter and an alternative that is less strict than the interim final rule. The first stricter alternative would require not only foreign IORs but also U.S. IORs to be CTPAT validated or use a CTPAT validated broker. This alternative would increase transparency and security in U.S. IORs' operations and save brokers from having to review their clients' records to verify their foreign or U.S. status. However, because U.S. IORs have a physical presence in the country, CBP is already better positioned to enforce payments for U.S. IORs than for foreign IORs. Therefore, the relative improvement in enforcement would not be as large for U.S. IORs as for foreign IORs. Moreover, this stricter alternative would cause greater disruption to U.S. imports than the interim final rule would. From October 1, 2020, to February 6, 2026, only 2.6% of entry summaries were made by foreign IORs that were neither non-CTPAT validated nor using a CTPAT validated brokers, and the interim final rule would only affect the entry summaries in that category.[57] In that same time period, 17.2% of entry summaries were made by foreign or U.S. IORs that were not CTPAT validated or using a CTPAT validated broker. Thus, the stricter regulatory alternative would affect a more significant share of entry summaries. Among active brokers, 78% are non-CTPAT validated and would therefore no longer be able to offer their services until they became CTPAT validated, which is a time intensive task. The share of IORs that would be ineligible to enter merchandise for consumption with their current CTPAT status and broker would increase from 5.4% under the interim final rule to 42.7% under the stricter regulatory alternative. The brokers that are CTPAT validated could have difficulty taking on so many clients. If the ineligible U.S. IORs all switched to CTPAT validated brokers, those brokers would see an increase in their IOR clients of 74.4% and an increase in entry summaries of 20.8%. Due to the higher costs and limited benefit of this scenario, CBP is not pursuing the stricter regulatory alternative.

CBP is considering a second stricter alternative that would prohibit foreign IORs from filing informal entries for consumption, regardless of whether they are a CTPAT member or use a CTPAT member broker. The most common informal entry types for consumption are ET11 entry and postal informal entry. Foreign IORs file approximately 9 percent of ET11 entry summaries and approximately 23 percent of the value of ET11 entry summaries. The practical effect of this stricter alternative would be that importers of informal entries would shift from filing informal entries to filing formal entries. Historically, there has been a difference in the entry requirements for informal entries and formal entries, but CBP is proposing to reduce this difference for ET11 and postal informal entries in a separate rule—CBP is publishing a Notice of Proposed Rulemaking related to Low Value Shipments that would impose stricter entry requirements on ET11 and postal informal entries to more closely match the requirements for formal entry. If that rule becomes effective, there would be little difference in the cost of making formal entry versus ET11 or postal informal entry. Therefore, if, during the final rule for this rulemaking, CBP adopts this stricter alternative, the effects of this alternative on ET11 and postal informal entries would be the additional entry requirements of switching to formal entry during the time period before the Low Value Shipment rule enters into effect. Without knowing the relative timing of future rulemakings, it is impossible to estimate for how long this provision might have costs that are attributable to this rule versus the Low Value Shipments rule. If the Low Value Shipments rule never finalizes, the additional costs to foreign IORs of switching from ET11 or postal informal

[57] Source: Information obtained from ACE on February 17 and March 25, 2026, based on entry summary data between October 1, 2020, and February 6, 2026. ''U.S. IORs'' are IORs with a physical address in the U.S. according to CBP Form 5106.

entry to formal entry would be attributable to this rule. For more information on changes being made to ET11 and postal informal entry, see the analysis for the Low Value Shipments Notice of Proposed Rulemaking.

The less strict alternative would reduce the costs of the interim final rule but also the benefits. In the interim final rule, importers will be required to report whether they are a foreign or U.S. IOR on CBP Form 3461 and CBP Form 7501. Brokers will be expected to obtain documentation from the IORs proving the domestic status of the IOR and to supply this documentation to CBP upon request. The purpose of this new information requirement is to allow CBP to know which IORs are foreign so that CBP can require those foreign IORs to use a CTPAT validated broker if the IOR is not CTPAT validated itself. However, the new information requirement about IORs' domestic status will apply to all brokers, including CTPAT validated brokers. As CTPAT validated brokers will be allowed to make entry for any IOR, foreign or U.S., CBP could waive the new information requirement for CTPAT validated brokers and still be able to implement the rule.

If CTPAT validated brokers did not have to state whether their clients were U.S. or foreign IORs, then those brokers would not have to obtain documentation proving the domestic status of their clients that are U.S. IORs. This alternative would affect a majority of U.S. IORs, as 56% of U.S. IORs already use CTPAT validated brokers, based on figures in the top row of Table 23. If CTPAT validated brokers did not have to state whether the IOR was a U.S. IOR, then those IORs could avoid the paperwork burden of proving they are U.S. IORs. Furthermore, the bottom row of Table 23 shows that the average CTPAT validated broker serves a much larger number of U.S. IORs than the average non-CTPAT validated broker. Therefore, the change would also limit the burden per broker. Without this proposed alternative, the average CTPAT validated broker would need to obtain documentation of domestic status from 866 U.S. IORs. With the proposed alternative, CTPAT validated brokers would not need to obtain this documentation. Only non-CTPAT validated brokers would need to do so, with the average non-CTPAT validated broker needing to obtain documentation from 180 U.S. IORs.

Table 23: U.S. IOR and Broker Statistics

	All	Using CTPAT validated Broker	Using non-CTPAT validated Broker*
U.S. IORs	999,938	556,667	443,271
Brokers	3,100	643	2,457
U.S. IORs/broker	323	866	180

Source: Information obtained from ACE on February 17 and March 25, 2026, based on entry summary data between October 1, 2020, and February 6, 2026. "U.S. IORs" are IORs with a physical address in the U.S. according to CBP Form 5106.

Note: The third column shows the number of U.S. IORs using CTPAT validated brokers and the number of such brokers. The fourth column shows the number of U.S. IORs using non-CTPAT validated brokers and the number of such brokers.

*CBP's estimate for the number of U.S. IORs using non-CTPAT validated brokers equals the total number of U.S. IORs minus the number of U.S. IORs using CTPAT validated brokers. This estimate therefore assumes that all IORs are using brokers of some kind and that each IOR only uses one broker.

Compared to the main regulatory scenario, this proposed alternative would have the drawback of hampering efforts by CTPAT validated brokers to obtain information about their clients. In the main regulatory scenario, brokers will be required by regulations to ''request and review a client's records establishing that the criteria specified in § 110.2 of this chapter, to be considered a U.S. importer of record, are satisfied. Such records may include, but are not limited to, proof of citizenship or lawful permanent residence, corporate charters, financial statements, purchase receipts, or documents of title.'' Because of this regulatory requirement, brokers will have the leverage to demand this information from their clients. In the alternative version of the rule, a CTPAT validated broker may still want to review a client's detailed records for the purposes of inspecting the supply chain and thereby maintaining its CTPAT validated status. However, if verifying the client's records were not a regulatory requirement for CTPAT validated brokers, then the clients claiming to be U.S. IORs may be reluctant to provide this documentation to the brokers. As a result, CTPAT validated brokers would have less visibility into their clients' supply chain, or the brokers would have to exert more effort to achieve the desired level of visibility.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 603(b)), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996 (SBREFA), 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 any proposed rule.'' Because this rule is being issued as an interim final rule, on the grounds set forth above, a regulatory flexibility analysis is not required under the RFA.

D. Paperwork Reduction Act

The Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3507) requires that CBP consider the impact of paperwork and other information collection burdens imposed on the public. An agency may not conduct, or sponsor, and an individual is not required to respond to, a collection of information unless the collection of information displays a valid Office of Management and Budget (OMB) control number. Implementing this IFR will require both CBP Form 3461 Entry/Immediate Delivery ACE and CBP Form 7501 Entry Summary (and their electronic

equivalents) to include two new checkboxes and a new field. One checkbox would be checked if the broker is acting as the IOR on behalf of the principal on the power of attorney. If the broker checks this box and the broker is not CTPAT validated, then the broker will also fill in a field for identifying the principal by IOR number or other identifier tied to CBP Form 5106. The second checkbox would be checked if the IOR (or principal, if the broker is acting as the IOR on behalf of the principal) is a U.S. IOR.

Customs brokers will also need to obtain documentation from their clients (IORs) proving that they are U.S. IORs. Customs brokers will incur costs in obtaining this information from U.S. IORs and keeping records, and U.S. IORs will also incur costs in gathering and providing the information to the customs brokers and keeping their own records.[58] However, CBP does not expect the time burden for CBP Form 3461, under OMB control number 1651–0024, or CBP Form 7501, under OMB control number 1651–0022, to increase. Once a customs broker has the needed documentation for a U.S. IOR, which is a one-time occurrence for that IOR, there is no additional time burden imposed on the public to submit an additional entry or entry summary form on behalf of the IOR. Furthermore, CBP does not anticipate any additional burden to the public for the time it takes to check the two checkboxes and provide the IOR number of the principal on the power of attorney, if applicable.

Brokers will be able to submit a Broker Delayed Compliance Request Form to request that the deadline to verify their U.S. clients be extended to 6 months after the publication date of this rulemaking. This form is being created for this rule, and the time burden estimates are as follows:

Broker Delayed Compliance Request Form

Estimated Number of Respondents: 2,600.

Estimated Number of Responses: 2,600.

Estimated Time per Response: 20 minutes (0.33 hours).

Estimated Total Annual Burden Hours: 867.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–38, UMRA) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed rule or final rule for which the agency published a proposed rule, which includes any Federal mandate that may result in a $100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector.

A written statement under UMRA is not required unless an agency has published a notice of proposed rulemaking. *See* 2 U.S.C. 1532(a). In addition, an action is exempt from UMRA if it is necessary for national security. *See* 2 U.S.C. 1503(5). As discussed under Section VIII.A., this rule is exempt from notice and comment rulemaking procedures and is necessary for national security. Accordingly, CBP has not prepared a written statement in connection with this rule.

IX. Signing Authority

In accordance with Treasury Order 100–20, the Secretary of the Treasury delegated to the Secretary of Homeland Security the authority related to the customs revenue functions vested in the Secretary of the Treasury as set forth in 6 U.S.C. 212 and 215, subject to certain exceptions. This regulation is being issued in accordance with DHS Delegation 07010.3, Revision 03.2, which delegates to the Commissioner of CBP the authority to prescribe and approve regulations related to customs revenue functions.

Rodney S. Scott, Commissioner, having reviewed and approved this document, has delegated the authority to electronically sign this document to Susan S. Thomas, Executive Assistant Commissioner, Office of Trade, for purposes of publication in the **Federal Register**.

List of Subjects

19 CFR Part 110

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

19 CFR Part 111

Administrative practice and procedure, Brokers, Penalties, Reporting and recordkeeping requirements.

19 CFR Part 141

Reporting and recordkeeping requirements.

19 CFR Part 142

Canada, Mexico, Reporting and recordkeeping requirements.

19 CFR Part 171

Administrative practice and procedure, Law enforcement, Penalties, Seizures and forfeitures.

Amendments to the CBP Regulations

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

■ 1. Add part 110 to read as follows:

PART 110—IMPORTERS OF RECORD

Sec.
110.0 [Reserved]

Subpart A—General Provisions

110.1 Definitions.
110.2 U.S. importer of record.
110.3 Foreign importer of record.

Subpart B—[Reserved]

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1484, 1498, 1623, 1624, 4320.

§ 110.0 [Reserved]

Subpart A—General Provisions

§ 110.1 Definitions.

Beneficial owner. The term ''beneficial owner'':

(1) Means, with respect to an entity, an individual who:

(i) Is a natural person; and

(ii) Directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise—

(A) Exercises substantial control over the entity; or

(B) Owns or controls not less than 25 percent of the ownership interests of the entity; and

(2) Includes circumstances where multiple layers of entity ownership exist between the natural person and the entity, such as a corporation that is owned by another corporation that is owned by a natural person, in which case the natural person is the beneficial owner of the entity despite the layers of entity ownership; and

(3) Does not include:

(i) A minor child, as defined in the State in which the entity is formed or, in the case of an entity that was not formed in the United States, an individual who has not yet attained the age of 18, if the parent or guardian of the minor child meets the definition of a beneficial owner;

(ii) An individual acting as a nominee, intermediary, custodian, or agent on behalf of another individual;

(iii) An individual acting solely as an employee of a corporation, limited liability company, or other similar entity and whose control over or

[58] *See* 19 CFR part 163 for the recordkeeping requirements applicable to IORs, among other persons, listed in section 163.2.

economic benefits from such entity are derived solely from the employment status of the person, provided that such a person is not a senior officer;

(iv) An individual whose only interest in a corporation, limited liability company, or other similar entity is through a right of inheritance; or

(v) A creditor of a corporation, limited liability company, or other similar entity, unless the creditor meets the requirements of paragraph (3)(i) of this definition.

(4) Beneficial ownership can be accomplished through substantial control, ownership interests, or both. Every entity must have at least one beneficial owner. An entity may have multiple beneficial owners.

Physical domestic assets. The term ''physical domestic assets'' means cash deposited in a U.S. bank account, U.S. Treasury bonds, and the following assets when physically located in the United States: real property, inventory, machinery, and/or equipment.

§ 110.2 U.S. importer of record.

(a) *Qualification as U.S. importer of record.* To be considered a U.S. importer of record, a party must be:

(1) An individual who is a United States citizen or lawful permanent resident; or

(2) An entity that meets the following requirements:

(i) The entity must be located in the United States;

(ii) The entity must be organized under the laws of the United States; and

(iii) Either:

(A) At all times, at least 51% of beneficial owner(s) of the entity, as defined in § 110.1, must be United States citizens or lawful permanent residents and have control of the entity; or

(B) The entity must maintain direct ownership of a significant amount of unencumbered real property in the United States at all times.

(b) *Verification.* Whether an individual or entity qualifies as a U.S. importer of record is subject to verification by CBP. The determination of whether an entity qualifies as a U.S. importer of record will vary depending upon the circumstances in each instance. To verify that an entity is located in the United States for qualification as a U.S. importer, CBP will take into account, among other considerations, the size and scale of the overall operations of the entity and whether it is an instrumentality of a foreign manufacturer without a substantial presence in the United States. Criteria that CBP may consider in its discretion and to the extent any are relevant, include, but are not limited to, the following:

(1) Whether the entity's principal place of business is in the United States;

(2) Whether the entity has a physical presence where substantial business transactions are conducted in the United States, including, but not limited to, paying employees, generating revenue, or operating retail locations;

(3) Whether the entity maintains sufficient unencumbered physical domestic assets, as defined in § 110.1;

(4) Whether the entity directly owns a significant amount of unencumbered real property in the United States;

(5) Whether the entity's gross sales generally exceed its cost of goods sold and the entity is structured in a manner that it is anticipated to generate its own profit; and

(6) Whether the entity is sufficiently capitalized.

§ 110.3 Foreign importer of record.

An importer of record who does not meet the criteria to be considered a U.S. importer of record pursuant to § 110.2 is a foreign importer of record.

Subpart B—[Reserved]

PART 111—CUSTOMS BROKERS

■ 2. The general authority citation for part 111 continues to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1624; 1641.

* * * * *

■ 3. Revise § 111.21(a) to read as follows:

§ 111.21 Record of transactions.

(a) Each broker must keep current in a correct, orderly, and itemized manner records of account reflecting all his financial transactions as a broker. He must keep and maintain on file copies of all his correspondence and other records relating to his customs business, including records related to verifications conducted pursuant to § 111.29(a)(2).

* * * * *

■ 4. Revise § 111.23(b) to read as follows:

§ 111.23 Retention of records.

* * * * *

(b) *Period of retention.* The records described in this section, other than powers of attorney, must be retained for at least five years after the date of entry. Records related to a verification conducted pursuant to § 111.29(a)(2) must be retained for five years from the date the verification is conducted. Powers of attorney must be retained until revoked, and revoked powers of attorney and letters of revocation must be retained for five years after the date of revocation or for five years after the date the client ceases to be an ''active client'' as defined in § 111.29(b)(2)(ii), whichever period is later. When merchandise is withdrawn from a bonded warehouse, records relating to the withdrawal must be retained for five years from the date of withdrawal of the last merchandise withdrawn under the entry.

■ 5. In § 111.29, revise the section heading and paragraph (a) to read as follows:

§ 111.29 Diligence in correspondence, paying monies, and verification of U.S. importers of record.

(a) *Due diligence by broker.* Each broker must exercise due diligence in:

(1) Making financial settlements, in answering correspondence, and in preparing or assisting in the preparation and filing of records relating to any customs business matter handled by him as a broker. Payment of duty, tax, or other debt or obligation owing to the Government for which the broker is responsible, or for which the broker has received payment from a client, must be made to the Government on or before the date that payment is due. Payments received by a broker from a client after the due date must be transmitted to the Government within five working days from receipt by the broker. Each broker must provide a written statement to a client accounting for funds received for the client from the Government, or received from a client where no payment to the Government has been made, or received from a client in excess of the Governmental or other charges properly payable as part of the client's customs business, within 60 calendar days of receipt. No written statement is required if there is actual payment of the funds by a broker.

(2) Verifying that a client meets the requirements to be considered a U.S. importer of record prior to making a declaration to CBP pursuant to § 141.22 of this chapter. A broker, prior to filing a declaration on behalf of a client pursuant to § 141.22 of this chapter, must verify that the client meets the requirements to qualify as a U.S. importer of record pursuant to § 110.2 of this chapter. Each broker must request and review a client's records to determine that the criteria to be considered a U.S. importer of record as specified in § 110.2 of this chapter, are satisfied. Such records may include, but are not limited to, proof of citizenship or lawful permanent residence, corporate charters, financial statements

and records, purchase receipts, or documents of title.

* * * * *

PART 141—ENTRY OF MERCHANDISE

■ 6. The general authority citation for part 141 is revised to read as follows:

Authority: 19 U.S.C. 66, 1448, 1484, 1498, 1624, 4320 and 4321.

* * * * *

■ 7. Add §§ 141.21 and 141.22 to read as follows:

§ 141.21 Entry by foreign importer of record.

(a) A foreign importer of record, as defined in § 110.3 of this chapter, may not enter merchandise for consumption except pursuant to the requirements in paragraph (b) of this section. This restriction is applicable to merchandise entered for consumption (§ 141.0a(f)) for which a formal entry is required to be filed or, if an informal entry is filed, for which an informal entry is required to be filed on CBP Form 3461 or CBP Form 7501, or their electronic equivalents.

(b) Entry of merchandise for consumption by a party meeting the qualifications for a foreign IOR, as defined in § 110.3 of this chapter, is restricted to the following:

(1) If the foreign importer of record is validated through the Customs Trade Partnership Against Terrorism (CTPAT) program (6 U.S.C. 961(a)), and has the right to make entry pursuant to § 143.26 of this chapter for informal entry or 19 U.S.C. 1484(a)(2)(B) for formal entry, the foreign importer of record may enter merchandise for consumption or hire a customs broker licensed under 19 U.S.C. 1641 to make entry.

(2) If the foreign importer of record is not validated through the CTPAT program, the foreign importer of record must designate a customs broker licensed under 19 U.S.C. 1641 who is validated through the CTPAT program (6 U.S.C. 961(a)) to make entry or act as the importer of record for the entry. If a customs broker acts as the importer of record for the entry on behalf of a principal on the power of attorney (see § 141.46 of this chapter) who is not an importer of record, and that principal would qualify as a foreign importer of record pursuant to § 110.3 of this chapter, the broker must also be validated through the CTPAT program. The designated customs broker who is validated through the CTPAT program must act as the importer of record for the entry if the principal on the power of attorney (§ 141.46) is not the owner or purchaser of the merchandise

§ 141.22 Entry by U.S. importer of record.

(a) A party meeting the requirements in § 110.2 of this chapter may enter merchandise for consumption, as follows:

(1) A U.S. importer of record who has the right to make entry pursuant to § 143.26 of this chapter for informal entry or 19 U.S.C. 1484(a)(2)(B) for formal entry, and who meets the requirements in § 110.2 of this chapter, may enter merchandise subject to the more specific requirements and procedures set forth elsewhere in this chapter. At the time of filing an entry (§ 141.0a(a)) and entry summary (§ 141.0a(b)), the importer of record must declare its qualification as a U.S. importer of record as defined in § 110.2 of this chapter.

(2) If a party meeting the requirements of § 110.2 of this chapter designates a customs broker licensed under 19 U.S.C. 1641 who is not validated through the Customs Trade Partnership Against Terrorism (CTPAT) program (6 U.S.C. 961(a)) to make entry as the importer of record, at the time of filing the entry (141.0a(a)) and entry summary (141.0a(b)), the customs broker must identify the principal on the power of attorney (§ 141.46) and must declare that the principal would meet the requirements to be considered a U.S. importer of record. In this instance, the principal on the power of attorney must have a CBP Form 5106 on file with CBP, pursuant to § 24.5 of this chapter.

(b) For purposes of a verification conducted pursuant to § 110.2(b) of this chapter of the declaration in paragraph (a) of this section, the decision as to whether an individual or entity qualifies as a U.S. importer of record, as defined in § 110.2 of this chapter, will be made by the appropriate Center Director.

■ 8. Revise § 141.46 to read as follows:

§ 141.46 Power of attorney retained by customhouse broker.

Before transacting customs business on behalf of a principal, to include acting as an importer of record on behalf of the principal, a customs broker is required to obtain a valid power of attorney to do so. The customs broker is not required to file the power of attorney with CBP. Brokers shall retain powers of attorney with their records (§ 111.1), and make them available for examination as provided in subpart C of part 111 of this chapter.

PART 142—ENTRY PROCESS

■ 9. The authority citation for part 142 continues to read as follows:

Authority: 19 U.S.C. 66, 1448, 1484, 1624.

■ 10. In § 142.13, add paragraphs (a)(5) and (e) to read as follows:

§ 142.13 When entry summary must be filed at time of entry.

(a) * * *

(5) Inaccurately declares to CBP, as determined by CBP, that the importer, or principal on the power of attorney where the broker acts as the importer of record, meets the requirements to be considered a U.S. importer of record pursuant to § 141.22 of this chapter.

* * * * *

(e) CBP may impose the requirement in paragraph (a) of this section on importers making entry under the provisions of this part or part 143 of this chapter.

■ 11. In § 142.25, add paragraphs (a)(5) and (c) to read as follows:

§ 142.25 Discontinuance of immediate delivery privileges.

(a) * * *

(5) Inaccurately declares to CBP that the importer, or principal on the power of attorney where the broker acts as the importer of record, meets the requirements to be considered a U.S. importer of record pursuant to § 141.22 of this chapter, as determined by CBP.

* * * * *

(c) CBP may impose the requirement in paragraph (a) of this section on importers making entry under the provisions of this part or part 143 of this chapter.

PART 171—FINES, PENALTIES, AND FORFEITURES

■ 12. The general authority citation for part 171 continues to read as follows:

Authority: 18 U.S.C. 983; 19 U.S.C. 66, 1592, 1593a, 1618, 1624; 22 U.S.C. 401; 31 U.S.C. 5321.

* * * * *

■ 13. In appendix B to part 171, revise section (K) to read as follows:

Appendix B to Part 171—Customs Regulations, Guidelines for the Imposition and Mitigation of Penalties for Violations of 19 U.S.C. 1592

* * * * *

(K) Subject to CBP's discretion, if a customs broker commits a violation of 19 U.S.C. 1592, the customs broker may be subject to a penalty under 19 U.S.C. 1592 or may be subject to any other enforcement action available under the law, including, but

not limited to, the remedies provided under 19 U.S.C. 1641.

* * * * *

Susan S. Thomas,

Executive Assistant Commissioner, Office of Trade, U.S. Customs and Border Protection.

[FR Doc. 2026–22735 Filed 11–5–26; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 571

[Docket No. FDA–2026–F–4956]

Food Additive Petitions; Change of Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is amending the regulations for food additive petitions (FAPs) to update addresses and simplify notification procedures. These technical amendments are being made to improve the accuracy of the Agency's regulations and are non-substantive.

DATES: This technical amendment is effective November 6, 2026.

FOR FURTHER INFORMATION CONTACT: Isabel Pocurull, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–5877, *Isabel.Pocurull@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is amending the animal food and drug regulations for food additive petitions (FAPs) at 21 CFR 571.1 to update addresses and Agency notification procedure. This technical amendment is being made to improve the accuracy of the Agency's regulations and is non-substantive.

Publication of this document constitutes final action on the changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical or non-substantive, ministerial changes to update addresses and Agency notification procedure.

List of Subjects in 21 CFR Part 571

Administrative practice and procedure, Animal feeds, Animal food additives, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 571 is amended as follows:

PART 571—FOOD ADDITIVE PETITIONS

■ 1. The authority citation for part 571 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371; 42 U.S.C. 241.

■ 2. Amend § 571.1 by:
■ a. Revising paragraph (a);
■ b. In paragraph (c), revising the undesignated text above item A; and
■ c. Revising paragraph (d).

The revisions read as follows:

§ 571.1 Petitions.

(a) Petitions to be filed under the provisions of section 409(b) of the Federal Food, Drug, and Cosmetic Act (the Act) can be submitted using both CVM's eSubmitter program, *https://www.fda.gov/industry/fda-esubmitter/cvm-esubmitter-programs,* to generate the submission and FDA's electronic submission gateway to submit, *https://www.fda.gov/industry/electronic-submissions-gateway-next-generation-esg-nextgen,* or on compact disk with paper cover letter. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state petitioner's mailing address and email address to which published notices or orders issued or objections filed pursuant to section 409 of the Act may be sent.

* * * * *

(c) * * *

(Date) _____

Name of petitioner _____

Post office address _____

Date _____

Name of food additive and proposed use _____

Food and Drug Administration, Center for Veterinary Medicine, *Director,* Division of Animal Food Ingredients, 5001 Campus Dr., College Park, MD 20740–3835

The undersigned, _____, submits this petition pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act with respect to _____ (Name of the food additive and proposed use)

Attached and constituting a part of this petition, are the following:

* * * * *

(d) The petitioner will be notified of the date on which the petition is filed or if an incomplete petition, it will usually be retained but not filed as a petition under section 409 of the Act. The petitioner will be notified in what respects the petition is incomplete.

* * * * *

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–22663 Filed 11–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. FDA–2026–N–12125]

Medical Devices; Ear, Nose, and Throat Devices; Classification of the External Mechanical Stimulator for the Relief of Congestion

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the external mechanical stimulator for the relief of congestion into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the external mechanical stimulator for the relief of congestion. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective November 6, 2026. The classification was applicable on December 4, 2023.

FOR FURTHER INFORMATION CONTACT: Payton Lin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1212, Silver Spring, MD 20993–0002, 240–402–6580, *Payton.Lin@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the external mechanical stimulator for the relief of congestion into class II (special controls), which we have determined will provide a reasonable assurance of the safety and effectiveness of the

device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On June 16, 2023, FDA received Sound Health Systems, Inc.'s request for De Novo classification of the Sonu device. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 4, 2023, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 874.6010.[1] We have named the generic type of device ''external mechanical stimulator for the relief of congestion,'' and it is identified as a device that delivers vibrations to the sinus and nasal areas to relieve congestion.

FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR EXTERNAL MECHANICAL STIMULATORS FOR THE RELIEF OF CONGESTION

Identified risks to health	Mitigation measures
Injury from mechanical overstimulation on the face causing one or more of the following: • Skin irritation or redness • Pain • Discomfort • Headache • Vertigo • Hearing loss • Tinnitus	Non-clinical performance testing; Human factors testing; Software verification, validation, and hazard analysis; Electrical safety testing; Electromagnetic compatibility testing; Battery safety testing; and Labeling.

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR EXTERNAL MECHANICAL STIMULATORS FOR THE RELIEF OF CONGESTION—Continued

Identified risks to health	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation.
Ineffective treatment leading to worsening congestion	Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for external mechanical stimulators for the relief of congestion. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 874

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 874 is amended as follows:

PART 874—EAR, NOSE, AND THROAT DEVICES

■ 1. The authority citation for part 874 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 874.6010 to subpart F to read as follows:

§ 874.6010 External mechanical stimulator for the relief of congestion.

(a) *Identification.* An external mechanical stimulator for the relief of congestion delivers vibrations to the sinus and nasal areas to relieve congestion.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including verification of specified mechanical stimulation parameters.

(2) Performance data must demonstrate the electromagnetic compatibility, battery safety, and electrical safety of the device.

(3) Software verification, validation, and hazard analysis must be performed.

(4) The patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Human factors testing must demonstrate that users can successfully use the device in the intended use environment based solely on its labeling and instructions for use.

(6) Labeling must include the following:

(i) Device specifications, including the frequency range, maximum output power, and power source; and

(ii) Explanation of the user interface.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–22657 Filed 11–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1768]

Specific Listing for 3-Chloromethcathinone, A Currently Controlled Schedule I Substance

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is establishing a specific listing and DEA Controlled Substances Code Number (drug code) for 1-(3-chlorophenyl)-2-(methylamino)propan-1-one (3-chloromethcathinone; 3–CMC) in schedule I of the Controlled Substances Act (CSA). Although 3-chloromethcathinone is not specifically listed in schedule I of the CSA with its own unique drug code, it is a schedule I controlled substances in the United States because it is a positional isomer of 4-chloromethcathinone, which is a schedule I hallucinogen. Therefore, DEA is simply amending the schedule I hallucinogenic substances list in its regulations to separately include 3-chloromethcathinone.

DATES: Effective November 6, 2026.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

3-Chloromethcathinone Control

3-Chloromethcathinone (also known as, 1-(3-chlorophenyl)-2-(methylamino)propan-1-one; and 3–CMC) is a chemical substance that is structurally related to 4-chloromethcathinone (also known as, 1-

(4-chlorophenyl)-2-(methylamino)propan-1-one; and 4–CMC). 4-Chloromethcathinone is listed as a hallucinogenic substance in schedule I at 21 CFR 1308.11(d)(106). As stated in subsection 21 CFR 1308.11(d), a listed hallucinogenic substance includes ''any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation,'' and the term ''isomer'' includes the ''optical, position[al], and geometric isomers.''

When compared to the chemical structure of 4-chloromethcathinone, 3-chloromethcathinone meets the definition of a ''positional isomer'' in 21 CFR 1300.01(b), which cross-references the term ''positional isomer'' in 21 CFR 1308.11(d). Both 4-chloromethcathinone and 3-chloromethcathinone possess the same molecular formula and core structure, and they have the same functional groups. 4-Chlorometh cathinone and 3-chloromethcathinone differ from one another by the position of the chloride atom on the same functional group (phenyl ring). This does not create new chemical functionalities or destroy existing chemical functionalities. Accordingly, under 21 CFR 1308.11(d), 3-chloro methcathinone, as a positional isomer of 4-chloromethcathinone, has been and continues to be a schedule I controlled substance.[1]

Legal Authority

This rule is prompted by a letter dated June 6, 2024, in which the Secretariat of the United Nations informed the United States government that 3-chlorometh cathinone have been added to Schedule II of the Convention on Psychotropic Substances of 1971 (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. This letter was prompted by decisions at the 67th Session of the Commission on Narcotic Drugs (CND) in March 2024 to schedule 3-chloromethcathinone under Schedule II of the 1971 Convention (CND Decision 67/2). Preceding these decisions, the Food and Drug Administration (FDA), on behalf of the Secretary of Health and Human Services and pursuant to 21 U.S.C. 811(d)(2), published two notices in the **Federal Register** with an opportunity to submit domestic information and opportunity to comment on this action.[2]

As discussed above in this final rule, 3-chloromethcathinone, by virtue of being a positional isomer of 4-chloro methcathinone, has been controlled in schedule I of the CSA since December 17, 2025.[3] Therefore, all regulations and criminal sanctions applicable to schedule I substances have been and remain applicable to 3-chloro methcathinone. Drugs controlled in schedule I of the CSA satisfy and exceed the required domestic controls of Schedule II under Article 2 of the 1971 Convention.

Effect of Action

As discussed above, this rule does not affect the continuing status of 3-chloromethcathinone as a schedule I controlled substances in any way. This action, as an administrative matter, merely establishes a separate, specific listing for 3-chloromethcathinone in schedule I of the CSA and assigns a DEA controlled substances code number (drug code) for this substance. This action will allow DEA to establish an aggregate production quota and grant individual manufacturing and procurement quotas to DEA-registered manufacturers of 3-chlorometh cathinone, who had previously been granted individual quotas for such purposes under the drug code for 4-chloromethcathinone.

Regulatory Analyses

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA) including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest.[4]

Pursuant to 5 U.S.C. 553(b)(B), DEA finds that notice-and-comment rulemaking is unnecessary, and that good cause exists to dispense with these procedures, as 3-chloromethcathinone is currently controlled in schedule I as a positional isomer of 4-chlorometh cathinone. The addition of a separate listing for 3-chloromethcathinone and its DEA controlled substances code number in the list of schedule I substances in 21 CFR 1308.11(d) makes no substantive difference in the status of this drug as a schedule I controlled substance, but instead is ''a minor or merely technical amendment in which the public is not particularly interested.''[5] This rule is a ''technical amendment'' to 21 CFR 1308.11(d) as it is ''insignificant in nature and impact, and inconsequential to the industry and public.'' Therefore, DEA finds that publishing a notice of proposed rulemaking and soliciting public comment are unnecessary and good cause exists to dispense with these procedures.

In addition, DEA is concerned that delaying the effective date of this rule potentially could cause confusion regarding the regulatory status of 3-chloromethcathinone. With 3-chloro methcathinone currently controlled under schedule I as a positional isomer, and with no additional requirements being imposed through this action, DEA finds good cause exists to make this rule effective immediately upon publication in accordance with 5 U.S.C. 553(d)(3).

Executive Orders 12866, 13563, 14192, and 14294 (Regulatory Review).

This regulation has been drafted and reviewed in accordance with the principles of Executive Orders (E.O.) 12866, 13563, and 14192. This rule is not a significant regulatory action under section 3(f) of E.O. 12866. 3-Chloro methcathinone is already a controlled substance in the United States under schedule I, as it is a positional isomer of the schedule I hallucinogen 4-chloromethcathinone. In this final rule, DEA is merely making an administrative change by amending its regulations to separately list 3-chloromethcathinone in schedule I and to assign a DEA controlled substances code number to this substance. A separate listing for 3-chloromethcathinone and its DEA controlled substances code number will not alter the status of this substance as a schedule I controlled substance. DEA scheduling actions are not subject to E.O. 14192, Unleashing Prosperity Through Deregulation, or E.O. 14294, Fighting Overcriminalization in Federal Regulations.

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[1] 4-Chloromethcathinone (and its isomers) has been subject to schedule I controls since December 17, 2025. *See Schedules of Controlled Substances: Placement of 4-Chloromethcathinone in Schedule I,* 90 FR 51102 (Nov. 11, 2025).

[2] *See International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Bromazolam; Flubromazepam; Butonitazene; 3-Chloromethcathinone (3–CMC); Dipentylone; 2-Fluorodeschloroketamine (2–FDCK); Nitrous Oxide (N2O); Carisoprodol; Request for Comments,* 88 FR 52179 (Aug. 7, 2023)*; International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; Butonitazene; 3-Chloromethcathinone; Dipentylone; 2-Fluorodesch loroketamine; Bromazolam; Request for Comments,* 89 FR 8683 (Feb. 8, 2024).

[3] *Schedules of Controlled Substances: Placement of 4-Chloromethcathinone in Schedule I,* 90 FR 51102 (Nov. 17, 2025).

[4] 5 U.S.C. 553(b)(B).

[5] *National Nutritional Foods Ass'n* v. *Kennedy,* 572 F.2d 377, 385 (2d Cir. 1978) (quoting S. Rep. No. 79–752, at 200 (1945)). *See also Utility Solid Waste Activities Group* v. *E.P.A.,* 236 F.3d 749, 755 (D.C. Cir. 2001) (the ''unnecessary'' prong ''is confined to those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and public'') (internal quotations and citation omitted).

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does 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.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not 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.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) applies to rules that are subject to the notice-and-comment requirements under the APA or other laws.[6] As noted in the above section regarding the applicability of the APA, DEA determined that there was good cause to exempt this final rule from notice and comment. Consequently, the RFA does not apply.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995.[7] This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. 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 Office of Management and Budget control number.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1532, DEA has determined that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year . . . .'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. Amend § 1308.11 by adding the new paragraph (d)(118) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

*	*	*	*	*	*	*
(118) 3-Chloromethcathinone (3-CMC, 1-(3-chlorophenyl)-2-(methylamino)propan-1-one)						1241
*	*	*	*	*	*	*

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on November 2, 2026, by DEA Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2026–22717 Filed 11–5–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2026–0562]

RIN 1625–AA09

Drawbridge Operation Regulation; Wishkah River, Aberdeen, WA

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the operating schedule that governs the Puget Sound and Pacific railroad bridge (PS&P) across the Wishkah River, mile 0.1 in Aberdeen, WA. This rule will change the PS&P railroad bridge draw position to the fully closed-to-navigation position. Furthermore, this rule requires 24-hour notice for all drawbridge openings and a bridge operator will no longer be required to be on site.

DATES: This rule is effective December 7, 2026.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov.* Type the docket number (USCG–2026–0562) in the ''SEARCH'' box and click ''SEARCH''. In

[6] 5 U.S.C. 601–612.

[7] 44 U.S.C. 3501–3521.

the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Danny McReynolds, Bridge Management Specialist, Northwest Coast Guard District Bridge Office; telephone 571–607–1520, email *smb-cgd-nw-bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
OMB Office of Management and Budget
NPRM Notice of Proposed Rulemaking (Advance, Supplemental)
§ Section
U.S.C. United States Code
GWRR Genesee & Wyoming Inc.
PS&P Puget Sound and Pacific railroad

II. Background Information and Regulatory History

On June 16, 2026, the Coast Guard published a Notice of Proposed Rule Making, with a request for comments, entitled ''Drawbridge Operation Regulation; Wishkah River, Aberdeen, WA'' in the **Federal Register** (91 FR 36105). There we stated why we issued the NPRM and invited comments on our proposed regulatory action related to this regulatory change. We received one unrelated comment during the comment period that ended July 16, 2026.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 33 U.S.C. 499. The PS&P railroad bridge across the Wishkah River, mile 0.1, at Aberdeen, WA operates in accordance with 33 CFR 117.1065(b). Bridge logs have shown a significant reduction in bridge opening requests for ten years and the bridge is mostly cycled for maintenance. This rule is necessary to balance the needs of the railroad by reducing the need to frequently cycle the draw closed for rail traffic and back open for marine traffic while maintaining the reasonable needs of navigation.

This regulatory action is based on the ability for the PS&P railroad bridge to open on signal after the GWRR has received at least 24-hour notice by telephone or VHF radio. This rule allows any vessel that needs a draw opening to transit through the subject bridge with the proper advance notice during clear visibility or reduced visibility.

IV. Discussion of Comments, Changes and the Final Rule

The Coast Guard provided a comment period of 31 days and received one unrelated comment regarding sea lions in California. No changes were made to the content of the rule since publication of the NPRM.

This rule amends the operating schedule of the PS&P railroad bridge found in 33 CFR 117.1065(b) by allowing the bridge to be maintained in the closed-to-navigation position and requiring GWRR to fully open the swing span with a minimum of 24-hours' notice. When the draw is to be opened or closed the drawtender must sound one prolonged blast followed by one short blast. We will remove the text in 33 CFR 117.1065(b), ''When the draw of the bridge is closed and the visibility at the drawtender' s station is less than one mile up or down the channel, the drawtender shall sound two prolonged blasts every minute.''

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders.

A. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rule. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities for the following reasons. While some owners or operators of vessels intending to transit the bridge may be small entities, the Coast Guard has not identified any vessel operators that will be caused significant economic impact as result of the proposed rule change. As noted earlier, only one or two vessels required openings of the drawbridge annually over the last 10 years. They would be able to continue to request openings of the drawbridge with a 24-hour notice.

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

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

B. Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

C. Federalism and Indian Tribal Government

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

D. Unfunded Mandates Reform Act

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

E. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, Rev.1, associated implementing instructions, and Environmental Planning Policy COMDTINST 5090.1 (series) which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f). The Coast Guard has determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule promulgates the operating regulations or procedures for drawbridges and is categorically excluded from further review, under paragraph L49, of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are required for this rule.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and DHS Delegation No. 00170.1, Revision No. 01.4.

■ 2. Amend 117.1065 by revising paragraph (b) to read as follows:

§ 117.1065 Wishkah River.

* * * * *

(b) The draw of the Puget Sound and Pacific railroad bridge, mile 0.1 at Aberdeen, shall be maintained in the closed-to-navigation position. Vessels requesting the bridge's draw to be opened for navigation shall make a request at least 24 hours in advance by telephone or VHF radio channel 13. Please refer to the Coast Pilot in the Grays Harbor, Washington section for updated contact requirements. When the draw is to be opened or closed the drawtender shall sound one prolonged blast followed by one short blast.

* * * * *

Michael E. Campbell,

Rear Admiral, U. S. Coast Guard,Commander, Northwest Coast Guard District.

[FR Doc. 2026–22677 Filed 11–5–26; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2026–0530; FXES11130900000–267–FF09E41000]

RIN 1018–BB21

Endangered and Threatened Wildlife and Plants; Technical Corrections for 43 Wildlife and Plant Species on the Lists of Endangered and Threatened Wildlife and Plants

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Direct final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce technical corrections for 43 wildlife and plant species under the Endangered Species Act of 1973, as amended (Act). For 7 wildlife species and 30 plant species that predominately occur in California and Nevada, we are revising the List of Endangered and Threatened Wildlife and the List of Endangered and Threatened Plants (''the Lists'') to reflect the current scientifically accepted taxonomy and nomenclature of these species. We are also making commensurate revisions to the applicable critical habitat sections. Further, for six wildlife species occurring within the United States and territories, we are correcting errors in the Lists made in previous publications. The taxonomic, nomenclatural, and orthographic revisions and the corrections of publication errors are editorial in nature and involve no substantive changes to the Lists or any applicable regulations.

DATES: This rule is effective February 4, 2027 without further action unless significant adverse comment is received by December 7, 2026. If significant adverse comment is received regarding taxonomic changes for any of these species, we will publish a timely withdrawal of the relevant portions of the rule in the **Federal Register**.

ADDRESSES: *Comment submission:* All submissions must include the docket number [FWS–R8–ES–2026–0530] for this document. You must submit comments using one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Search box, enter FWS–R8–ES–2026–0530, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, click on the Rule box to locate this document. You may submit a comment by clicking on ''Comment.''

(2) *By hard copy:* Submit comments by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R8–ES–2026–0530, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

Comments submitted through any method not authorized in this document, or sent to an address not listed here, will not be considered. We will not accept comments via email, fax, or hand delivery. We are not required to consider comments that are submitted after the comment period ends or that are submitted via a method outside of these instructions. Comments containing profanity, vulgarity, threats, or other inappropriate content will not be considered.

We will post all comments at *https://www.regulations.gov.* You may request that we withhold personal identifying information from public review; however, we cannot guarantee that we will be able to do so. See Public Comments, below, for more information.

FOR FURTHER INFORMATION CONTACT: Angela Picco, Threatened and Endangered Species Lead, Ecological Services, U.S. Fish and Wildlife Service, Pacific Southwest Regional Office, 2800 Cottage Way, Suite W–2606; telephone 916–414–6490. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

See Species-specific Inquiries and Information in **SUPPLEMENTARY INFORMATION**, below, for relevant names and contact information.

SUPPLEMENTARY INFORMATION:

Public Comments

You may submit your comments and materials regarding the taxonomic revisions, identified below in table 1, by one of the methods listed in **ADDRESSES**. Please include sufficient information with your comments to allow us to verify any scientific or commercial information you include. We will not consider comments sent by email or fax, or to an address not listed in **ADDRESSES**.

We will post all comments on *https://www.regulations.gov.* Before including your address, phone number, email address, or other personal information

in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documentation we use in preparing this direct final rule, will be available for public inspection on the internet at *https://www.regulations.gov*. Please note that comments posted to *https://www.regulations.gov* are not immediately viewable. When you submit a comment, the system receives it immediately. However, the comment will not be publicly viewable until we post it, which might not occur until several days after submission. Information regarding this rule is available in alternative formats upon request (see **FOR FURTHER INFORMATION CONTACT**).

Species-Specific Inquiries and Information

For information pertaining to specific species, please contact our Ecological Services field offices as follows:

Common name	Contact information
· Western snowy plover [Pacific Coast Distinct Population Segment (DPS)]. · Kneeland Prairie pennycress.	Vicky Ryan, Field Supervisor, U.S. Fish and Wildlife Service, Arcata Fish and Wildlife Office, 1655 Heindon Road, Arcata, California 95521, 707–825–5123.
· El Segundo blue butterfly · Del Mar manzanita. · Laguna Beach dudleya. · Otay tarplant. · Salt marsh bird's-beak.	Jonathan Snyder, Acting Field Supervisor, U.S. Fish and Wildlife Service, Carlsbad Fish and Wildlife Office, 2177 Salk Avenue, Suite 250, Carlsbad, California 92008, 760–309–7993.
· Bakersfield cactus · Clara Hunt's milk-vetch. · Coyote ceanothus. · Lake County stonecrop. · Layne's butterweed. · Palmate-bracted bird's-beak. · Pine Hill flannelbush. · Presidio manzanita. · San Mateo thornmint. · Soft bird's-beak.	Kim Turner-Olah, Acting Field Supervisor, U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office, 2800 Cottage Way, W–2606, Sacramento, California 95825, 916–414–6707.
· Ash Meadows gumplant · Ash-gray paintbrush. · Bear Valley sandwort. · Cushenbury oxytheca. · Desert slender salamander. · Eureka Valley dune grass. · Inyo California towhee. · San Bernardino kangaroo rat. · Santa Ana River woolly-star. · Southern mountain buckwheat. · Spring-loving centaury. · Stephens' kangaroo rat. · San Bernardino Mountains bladderpod.	Brian Croft, Field Supervisor, U.S. Fish and Wildlife Service, Palm Springs and Southern Nevada Fish and Wildlife Office, 4701 North Torrey Pines Drive, Las Vegas, Nevada 89130, 702–515–5244.
· Arroyo toad · Conejo dudleya. · Gambel's watercress. · Hoffmann's rockcress. · Island rush-rose. · Santa Monica dudleya. · Gowen cypress.	Cat Darst, Field Supervisor, U.S. Fish and Wildlife Service, Ventura Fish and Wildlife Office, 2493 Portola Rd., Suite B, Ventura, California 93003, 805–677–3333.

Background

The List of Endangered and Threatened Wildlife and the List of Endangered and Threatened Plants (''the Lists''), set forth in title 50 of the Code of Federal Regulations (CFR) at §§ 17.11 and 17.12, respectively, contain the names of endangered species and threatened species federally listed pursuant to the Act (16 U.S.C. 1531 *et seq.*). The regulations at 50 CFR 17.11(c) and 17.12(b) require us to use the most recently accepted scientific name of any wildlife or plant species, respectively, that we have determined to be an endangered or threatened species. As noted in 50 CFR 17.94(a), for species with critical habitat designations, the lists at §§ 17.11 and 17.12 refer to critical habitat designations presented in § 17.95 (fish and wildlife), § 17.96 (plants), and § 17.99 (plants on the Hawaiian Islands). For consistency in the references, the scientific and common names in critical habitat sections need to comport with the scientific and common names in the Lists.

Purpose of Direct Final Rule and Final Action

The purpose of this direct final rule is to notify the public that we are revising the Lists at 50 CFR 17.11(h) and 17.12(h) to reflect scientifically accepted taxonomy and nomenclature for 7 wildlife species and 30 plant species listed under section 4 of the Act. Changes to the Lists include one or both of the following: (1) revisions to certain entries in the scientific name columns to reflect the most recently accepted scientific names in accordance with 50

CFR 17.11(c) and 17.12(b), or (2) revisions to certain entries in the common name columns to better reflect current usage or to improve clarity. In some instances, changes in the Lists necessitate corresponding changes to the names used in 50 CFR 17.95, critical habitat for fish and wildlife, or 50 CFR 17.96, critical habitat for plants.

We are publishing this rule without a prior proposal because this is a noncontroversial action that is in the best interest of the public and should be undertaken in as timely a manner as possible. For the taxonomic and nomenclatural revisions provided below in table 1, this rule will be effective, as published in this document, on the effective date specified in **DATES**, unless we receive significant adverse comments on or before the comment due date specified in **DATES**. Significant adverse comments are comments that provide strong justifications as to why this rule should not be adopted for a particular species or why it should be changed to a name different from the one we have used.

If we receive significant adverse comments regarding the taxonomic changes for any of the species included in table 1, below, we will publish a document in the **Federal Register** withdrawing this rule for the appropriate species before the effective date, and we will publish a proposed rule to initiate promulgation of those changes to 50 CFR 17.11(h) and/or 17.12(h).

In addition, we are notifying the public that we have identified editorial errors in the Lists, and they will be corrected on the effective date of this rule (see **DATES**, above). The identified errors are provided below in table 2. While you may submit comments by one of the methods listed in **ADDRESSES** on the corrections provided below in table 2, we consider these corrections purely administrative, and we intend to make these editorial corrections on the effective date of this rule.

None of these changes are regulatory in nature; they are for accuracy and clarity. These revisions do not alter species' protections or status in any way, and this rule does not have a substantive effect on the public. Any actions altering a species' protection or status would require a separate rulemaking action following the procedures of 50 CFR part 424.

Brief Summary of Taxonomic and Nomenclatural Changes

Table 1 provides changes we are making to reflect the scientifically accepted taxonomy and nomenclature of 7 wildlife species and 30 plant species listed under section 4 of the Act. These changes reflect the most recently accepted scientific nomenclature in accordance with 50 CFR 17.11(c) and 17.12(b). We also provide updates to common names to conform with current usage, including the removal of synonyms that, per 50 CFR 17.11(b) and 17.12(c), are no longer needed for clarity.

TABLE 1—REVISIONS TO THE LISTS REFLECTING THE CURRENT SCIENTIFICALLY ACCEPTED TAXONOMY AND NOMENCLATURE FOR THESE SPECIES

Species name as currently listed	Corrected species name
§ 17.11 Endangered and Threatened Wildlife	
Common name (*scientific name*)	Common name (*scientific name*)
MAMMALS	
San Bernardino Merriam's kangaroo rat (*Dipodomys merriami parvus*) Stephens' kangaroo rat (*Dipodomys stephensi* (incl. *D. cascus*))	San Bernardino kangaroo rat (*Dipodomys merriami parvus*). Stephens' kangaroo rat (*Dipodomys stephensi*).
BIRDS	
Inyo California towhee (*Melozone crissalis eremophilus*) ..... Western snowy plover [Pacific Coast population DPS] (*Charadrius nivosus nivosus*).	Inyo California towhee (*Melozone crissalis eremophila*). Western snowy plover [Pacific coast DPS] (*Anarhynchus nivosus nivosus*).
AMPHIBIANS	
Arroyo (=arroyo southwestern) toad (*Anaxyrus californicus*) ..... Desert slender salamander (*Batrachoseps aridus*)	Arroyo toad (*Anaxyrus californicus*). Desert slender salamander (*Batrachoseps major aridus*).
INSECTS	
El Segundo blue butterfly (*Euphilotes battoides allyni*)	El Segundo blue butterfly (*Euphilotes allyni*).
§ 17.12 Endangered and Threatened Plants	
FLOWERING PLANTS	
Acanthomintha obovata ssp. *duttonii* (San Mateo thornmint) ..... *Arabis hoffmannii* (Hoffmann's rock-cress) ..... *Arctostaphylos glandulosa* ssp. *crassifolia* (Del Mar manzanita) ..... *Arctostaphylos hookeri* var. *ravenii* (Presidio manzanita) ..... *Arenaria ursina* (Bear Valley sandwort) ..... *Astragalus clarianus* (Clara Hunt's milk-vetch) ..... *Castilleja cinerea* (Ash-gray Indian paintbrush) ..... *Ceanothus ferrisae* (coyote ceanothus) ..... *Centaurium namophilum* (spring-loving centaury) ..... *Cordylanthus maritimus* ssp. *maritimus* (salt marsh bird's-beak) ..... *Cordylanthus mollis* ssp. *mollis* (soft bird's-beak) ..... *Cordylanthus palmatus* (palmate-bracted bird's-beak) ..... *Deinandra* (= *Hemizonia*) *conjugens* (Otay tarplant)	*Acanthomintha duttonii* (San Mateo thornmint). *Boechera hoffmannii* (Hoffmann's rockcress). *Arctostaphylos glandulosa* subsp. *crassifolia* (Del Mar manzanita). *Arctostaphylos montana* subsp. *ravenii* (Presidio manzanita). *Eremogone ursina* (Bear Valley sandwort). *Astragalus claranus* (Clara Hunt's milk-vetch). *Castilleja cinerea* (Ash-gray paintbrush). *Ceanothus ferrisiae* (coyote ceanothus). *Zeltnera namophila* (spring-loving centaury). *Chloropyron maritimum* subsp. *maritimum* (salt marsh bird's-beak). *Chloropyron molle* subsp. *molle* (soft bird's-beak). *Chloropyron palmatum* (palmate-bracted bird's-beak). *Deinandra conjugens* (Otay tarplant).

TABLE 1—REVISIONS TO THE LISTS REFLECTING THE CURRENT SCIENTIFICALLY ACCEPTED TAXONOMY AND NOMENCLATURE FOR THESE SPECIES—Continued

Species name as currently listed	Corrected species name
Dudleya abramsii ssp. *parva* (Conejo dudleya)	*Dudleya parva* (Conejo dudleya).
Dudleya cymosa ssp. *ovatifolia* (Santa Monica Mountains dudleya)	*Dudleya cymosa* subsp. *ovatifolia* (Santa Monica dudleya).
Dudleya stolonifera (Laguna Beach liveforever)	*Dudleya stolonifera* (Laguna Beach dudleya).
Eriastrum densifolium ssp. *sanctorum* (Santa Ana River woolly-star)	*Eriastrum densifolium* subsp. *sanctorum* (Santa Ana River woolly-star).
Eriogonum kennedyi var. *austromontanum* (southern mountain wild-buckwheat).	*Eriogonum kennedyi* var. *austromontanum* (southern mountain buck-wheat).
Fremontodendron californicum ssp. *decumbens* (Pine Hill flannelbush)	*Fremontodendron decumbens* (Pine Hill flannelbush).
Grindelia fraxino-pratensis (Ash Meadows gumplant)	*Grindelia fraxinipratensis* (Ash Meadows gumplant).
Helianthemum greenei (island rush-rose)	*Crocanthemum greenei* (island rush-rose).
Lesquerella kingii ssp. *bernardina* (San Bernardino Mountains bladderpod).	*Physaria kingii* subsp. *bernardina* (San Bernardino Mountains bladderpod).
Opuntia treleasei (Bakersfield cactus)	*Opuntia basilaris* var. *treleasei* (Bakersfield cactus).
Oxytheca parishii var. *goodmaniana* (Cushenbury oxytheca)	*Acanthoscyphus parishii* var. *goodmaniana* (Cushenbury oxytheca).
Parvisedum leiocarpum (Lake County stonecrop)	*Sedella leiocarpa* (Lake County stonecrop).
Rorippa gambellii (Gambel's watercress)	*Nasturtium gambelii* (Gambel's watercress).
Senecio layneae (Layne's butterweed)	*Packera layneae* (Layne's butterweed).
Swallenia alexandrae (Eureka dune grass, Eureka Valley dune grass, or Eureka dunegrass).	*Swallenia alexandrae* (Eureka Valley dune grass).
Thlaspi californicum (Kneeland Prairie penny-cress)	*Noccaea fendleri* subsp. *californica* (Kneeland Prairie pennycress).
CONIFERS AND ALLIES	
Cupressus goveniana ssp. *goveniana* (Gowen cypress)	*Hesperocyparis goveniana* (Gowen cypress).

Summary of Editorial Changes

Per 50 CFR 17.11(f)(2), entries in the ''Listing citations and applicable rules'' column in 50 CFR 17.11(h), should ''contain the volume, document starting page number, and publication date of the **Federal Register** publication(s) in which a species was given status, listed, or reclassified.'' The entries in this column are nonregulatory in nature and are provided for informational and navigational purposes only. For a given species on the Lists, it is helpful to have the citation for the earliest **Federal Register** publication that addressed the status of that species. We are changing the respective entries in the ''Listing citations and applicable rules'' column for six species to include ''34 FR 5034, 3/8/1969.'' The March 8, 1969, **Federal Register** publication was a notice from the Secretary of the Interior announcing the fish and wildlife species he had determined were threatened with extinction per the Endangered Species Preservation Act of 1966 (80 Stat. 926; 16 U.S.C. 668aa(c)). The list of species maintained under the Endangered Species Preservation Act served as the basis for the list of species maintained under the Endangered Species Conservation Act of 1969. This list, in turn, served as the basis for the list of species maintained under the Endangered Species Act of 1973. This provenance is helpful information, and this information was inadvertently omitted in previous iterations of the Lists. We are adding the citation for the March 8, 1969, **Federal Register** publication for the six species in table 2.

TABLE 2—EDITORIAL CORRECTIONS TO THE LISTS

Current listed name	Error	Correction
California least tern (*Sternula antillarum browni*)	Entry in the ''Listing citations'' column fails to include ''34 FR 5034, 3/8/1969''.	34 FR 5034, 3/8/1969; 35 FR 16047, 10/13/1970; 35 FR 8491, 6/2/1970.
Hawaiian coot (alae keokeo) (*Fulica alai*)	Entry in the ''Listing citations'' column fails to include ''34 FR 5034, 3/8/1969''.	34 FR 5034, 3/8/1969; 35 FR 16047, 10/13/1970.
Hawaiian stilt (*Himantopus mexicanus* (=*himantopus*) *knudseni*).	Entry in the ''Listing citations'' column fails to include ''34 FR 5034, 3/8/1969''.	34 FR 5034, 3/8/1969; 35 FR 16047, 10/13/1970.
Puerto Rican plain pigeon (*Patagioenas inornata wetmorei*).	Entry in the ''Listing citations'' column fails to include ''34 FR 5034, 3/8/1969''.	34 FR 5034, 3/8/1969; 35 FR 16047, 10/13/1970.
Puerto Rican boa (*Epicrates inornatus*)	Entry in the ''Listing citations'' column fails to include ''34 FR 5034, 3/8/1969''.	34 FR 5034, 3/8/1969; 35 FR 16047, 10/13/1970.
Houston toad (*Bufo houstonensis*)	Entry in the ''Listing citations'' column fails to include ''34 FR 5034, 3/8/1969''.	34 FR 5034, 3/8/1969; 35 FR 16047, 10/13/1970; 50 CFR 17.95(d).[CH]

Description of Taxonomic and Nomenclatural Revisions

Using the best available scientific information, this direct final rule documents taxonomic and nomenclatural changes to 7 entries on the List of Endangered and Threatened Wildlife (50 CFR 17.11(h)) and 30 entries on the List of Endangered and Threatened Plants (50 CFR 17.12(h)). The basis for these taxonomic changes is supported by the best scientific and commercial data available.

Accordingly, we revise the scientific names of five wildlife species under section 4 of the Act (16 U.S.C. 1531 *et seq.*) as follows: Stephens' kangaroo rat (*Dipodomys stephensi*), Inyo California towhee (*Melozone crissalis eremophila*), western snowy plover [Pacific coast DPS] (*Anarhynchus nivosus nivosus*), desert slender salamander (*Batrachoseps major aridus*), and El Segundo blue butterfly (*Euphilotes allyni*). We make these changes to the List of Endangered and Threatened Wildlife to reflect the most recently accepted scientific names in accordance with 50 CFR 17.11(c). Additionally,

common name entries for the following two wildlife species are revised to better reflect currently accepted usage: San Bernardino kangaroo rat (*Dipodomys merriami parvus*) and arroyo toad (*Anaxyrus californicus*).

Similarly, we revise the scientific names of the following 27 plant species under section 4 of the Act (16 U.S.C. 1531 *et seq.*) as follows: *Acanthomintha duttonii* (San Mateo thornmint), *Boechera hoffmannii* (Hoffmann's rockcress), *Arctostaphylos glandulosa* subsp. *crassifolia* (Del Mar manzanita), *Arctostaphylos montana* subsp. *ravenii* (Presidio manzanita), *Eremogone ursina* (Bear Valley sandwort), *Astragalus claranus* (Clara Hunt's milk-vetch), *Ceanothus ferrisiae* (coyote ceanothus), *Zeltnera namophila* (spring-loving centaury), *Chloropyron maritimum* subsp. *maritimum* (salt marsh bird's-beak), *Chloropyron molle* subsp. *molle* (soft bird's-beak), *Chloropyron palmatum* (palmate-bracted bird's-beak), *Deinandra conjugens* (Otay tarplant), *Dudleya parva* (Conejo dudleya), *Dudleya cymosa* subsp. *ovatifolia* (Santa Monica dudleya), *Eriastrum densifolium* subsp. *sanctorum* (Santa Ana River woolly-star), *Fremontodendron decumbens* (Pine Hill flannelbush), *Eriogonum kennedyi* var. *austromontanum* (southern mountain buckwheat), *Grindelia fraxinipratensis* (Ash Meadows gumplant), *Crocanthemum greenei* (island rush-rose), *Physaria kingii* subsp. *bernardina* (San Bernardino Mountains bladderpod), *Opuntia basilaris* var. *treleasei* (Bakersfield cactus), *Acanthoscyphus parishii* var. *goodmaniana* (Cushenbury oxytheca), *Sedella leiocarpa* (Lake County stonecrop), *Nasturtium gambelii* (Gambel's watercress), *Packera layneae* (Layne's butterweed), *Noccaea fendleri* subsp. *californica* (Kneeland Prairie pennycress), and *Hesperocyparis goveniana* (Gowen cypress). We make these changes to the List of Endangered and Threatened Plants to reflect the most recently accepted scientific names in accordance with 50 CFR 17.12(b).

Additionally, we revise the common names of the following eight plant species (including four of the above species) to better reflect currently accepted usage: *Boechera hoffmannii* (Hoffmann's rockcress), *Arctostaphylos montana* subsp. *ravenii* (Presidio manzanita), *Castilleja cinerea* (ash-gray paintbrush), *Dudleya cymosa* subsp. *ovatifolia* (Santa Monica dudleya), *Dudleya stolonifera* (Laguna Beach dudleya), *Eriogonum kennedyi* var. *austromontanum* (southern mountain buckwheat), *Swallenia alexandrae* (Eureka Valley dune grass), and *Noccaea fendleri* subsp. *californica* (Kneeland Prairie pennycress). All of these revisions are not regulatory in nature and do not alter the listed species as previously recognized.

Several species that are the subjects of the taxonomic or nomenclatural revisions in this direct final rule have designated critical habitat. For clarity and consistency, we are revising the text of the critical habitat at 50 CFR 17.95 where necessary to correct scientific or common names for the following two wildlife species: Inyo California towhee (*Melozone crissalis eremophila*) and western snowy plover [Pacific coast DPS] (*Anarhynchus nivosus nivosus*). We also revise the text of the critical habitat at 50 CFR 17.96 where necessary to correct scientific or common names for the following nine plant species: *Eremogone ursina* (Bear Valley sandwort), *Castilleja cinerea* (ash-gray paintbrush), *Zeltnera namophila* (spring-loving centaury), *Chloropyron molle* subsp. *molle* (soft bird's-beak), *Eriogonum kennedyi* var. *austromontanum* (southern mountain buckwheat), *Grindelia fraxinipratensis* (Ash Meadows gumplant), *Physaria kingii* subsp. *bernardina* (San Bernardino Mountains bladderpod), *Acanthoscyphus parishii* var. *goodmaniana* (Cushenbury oxytheca), and *Noccaea fendleri* subsp. *californica* (Kneeland Prairie pennycress). These revisions are not regulatory in nature and do not alter the boundaries of critical habitat or the protections of the Act in any way.

Specific Taxonomic and Nomenclatural Changes

We provide below, in the same sequence as in table 1, a species-by-species discussion supporting the changes in scientific name, common name, or both in the Lists.

In certain instances, in the following discussions, we address changes to a species' scientific name. Per 50 CFR 17.11(c) and 17.11(g) for wildlife and 50 CFR 17.12(b) and 17.12(g) for plants, to determine a species' scientific name, we are to rely, to the extent practicable, on the Integrated Taxonomic Information System (ITIS) (*https://www.itis.gov/*). ITIS is an online database used by the Service as a reference for Act-related taxonomic decisions. We have determined that, as a reviewer of current taxonomic literature, it maintains generally accepted lists of taxa that are both valid and verified (81 FR 51550 at 51555, August 4, 2016). However, ITIS is not a taxonomic authority; it compiles information from other sources. In our experience, the taxonomic treatment it recognizes for some taxa is not always consistent with the best scientific data available. We are required by the Act to use the best scientific and commercial data available. When conflict exists, we rely on our own best professional judgment, the expertise of the scientific community, and current taxonomic literature (especially, but not limited to, primary sources) to determine the most appropriate taxonomic treatment (see 81 FR 51550, August 4, 2016, citing 45 FR 13010 at 13012–13013, February 27, 1980).

Per section 3(16) of the Act (16 U.S.C. 1532(16)), the term ''species'' may include a taxon at the species rank, a taxon at the subspecies rank, or for vertebrates, a distinct population segment (DPS); a DPS is a non-taxonomic entity that is unique to the Act. In taxonomy, a species is indicated by the combination of two terms, the genus epithet and the species epithet, forming a binomial. A subspecies is a form of infraspecific taxon; that is, a taxon hierarchically below the species rank or level. In zoological nomenclature, a subspecies is indicated by the combination of three terms, the genus epithet, the species epithet, and the subspecies epithet, forming a trinomial. In botanical nomenclature, multiple forms of infraspecific taxa are used indicating various taxonomic ranks.

For our purposes implementing the Act with respect to plants, we focus on the infraspecific taxa of subspecies and variety. For the purposes of section 3(16) of the Act, we consider plant varieties to be equivalent to subspecies (43 FR 17910 at 17912, April 26, 1978). Consistent with the International Code of Nomenclature for algae, fungi, and plants (ICN), we use abbreviations to distinguish between the two categories. The ICN is the set of internationally agreed upon rules and recommendations that botanical taxonomists use in the naming of algae, fungi, and plants. As such, we use the abbreviation ''var.'' (punctuation included) to indicate a variety. However, the abbreviation for indicating a subspecies has changed in botanical nomenclature; it had long been ''ssp.'' (punctuation included), but the ICN now recommends ''subsp.'' (punctuation included). We note that ITIS currently uses ''ssp.'' as the abbreviation to indicate botanical subspecies. This contrasts with the recommendation of the ICN, and we consider the ICN to provide the best scientific information on this matter. Therefore, in instances where we are addressing subspecies of plants, we are shifting the abbreviation we use from ''ssp.'' to ''subsp.'' We are doing this on

a case-by-case basis, when appropriate, and not en masse.

Additionally, in certain instances in the following discussions, we address species that include synonyms. Per 50 CFR 17.11(b) for wildlife common names, 17.11(c) for wildlife scientific names, 17.12(b) for plant scientific names, or 17.12(c) for plant common names, we sometimes parenthetically include one or more synonyms as part of the common name or scientific name when confusion might arise from the use of different names for the same taxon. When there is little chance for confusion, we do not include synonyms.

San Bernardino Kangaroo Rat

We are changing ''San Bernardino Merriam's kangaroo rat'' to ''San Bernardino kangaroo rat.'' This is an editorial change, not a taxonomic change. The scientific name remains the same. We acknowledge that the listed entity is a subspecies of the associated species-level taxon, Merriam's kangaroo rat (*Dipodomys merriami*). We further acknowledge that by including ''Merriam's'' in the common name of the subspecies, it indicates a hierarchical taxonomic relationship with *Dipodomys merriami.* However, ''San Bernardino kangaroo rat'' is used much more widely in the scientific literature as the common name for *Dipodomys merriami parvus.* Because of this, we are changing the common name. This editorial change does not affect the range or the listing status of this subspecies; we continue to recognize the listed entity at the subspecies rank for the purposes of section 3(16) of the Act. Critical habitat has been designated for this species, but ''San Bernardino kangaroo rat'' is consistent with the common name we use in 50 CFR 17.95. As such, no changes are needed in that section.

Stephens' Kangaroo Rat

We are changing ''*Dipodomys stephensi* (incl. *D. cascus*)'' to ''*Dipodomys stephensi.*'' This is an editorial change, not a taxonomic change. The common name remains the same. We are removing the parenthetical synonym. The current scientific literature recognizes *Dipodomys stephensi* as the most appropriate name for this taxon; the name *Dipodomys cascus* was established later in time and does not have nomenclatural precedence (that is, it is a junior synonym, in part) (ITIS 2024r, unpaginated); it has not been used for many years. At this point, there is little chance for confusion. Therefore, for simplicity, we are removing the synonym. ITIS (2024s, unpaginated) recognizes *Dipodomys stephensi* as the current (valid) scientific name for this taxon. This editorial change does not affect the range or the listing status of the species; we continue to recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. A species-specific ''4(d)'' rule (a rule issued under the authority of section 4(d) of the Act) has been designated for this species, but it does not mention the parenthetical synonym; consequently, no changes are needed in 50 CFR 17.40(t). Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.95.

Inyo California Towhee

We are changing the scientific name from ''*Melozone crissalis eremophilus*'' to ''*Melozone crissalis eremophila.*'' This is an editorial change, not a taxonomic change. The common name remains the same. On July 31, 2023, we recognized the genus-level taxonomic realignment for this listed entity from *Pipilo* to *Melozone* (88 FR 49310). However, *Pipilo* is masculine, and *Melozone* is feminine (David and Gosselin 2002, p. 259). Consequently, the subspecific name or epithet (the third name in the trinomial) should be changed from *eremophilus* to *eremophila* to remain consistent with the grammatical gender of the newly recognized genus name (or genus epithet). Information in ITIS (2024ab, unpaginated) supports the feminine orthography; however, ITIS does not currently recognize the subspecies. As discussed in our 2024 5-year status review for the Inyo California towhee (Service 2024, pp. 5–7), we are continuing to recognize the subspecies at this time, contrary to ITIS. This nomenclatural revision does not affect the range or the listing status of this subspecies; we continue to recognize the listed entity at the subspecies rank for the purposes of section 3(16) of the Act. Critical habitat has been designated for this species, and we are making commensurate changes in the subspecies' scientific name in 50 CFR 17.95.

Western Snowy Plover [Pacific Coast DPS]

We are changing the scientific name from ''*Charadrius nivosus nivosus*'' to ''*Anarhynchus nivosus nivosus,*'' we are changing the common name ''western snowy plover [Pacific Coast population DPS]'' to ''western snowy plover [Pacific coast DPS],'' and we are changing the DPS's entry in the ''Where listed'' column in 50 CFR 17.11(h) from ''Pacific Coast population DPS—U.S.A. (CA, OR, WA), Mexico (within 50 miles of Pacific coast)'' to ''U.S.A. (CA, OR, WA), Mexico (Baja California, Baja California Sur); within 50 miles of Pacific coast.'' On April 21, 2006 (71 FR 20607 at 20618), we determined that the listed entity qualified as a DPS under our DPS policy (61 FR 4722, February 7, 1996). This DPS is a population of the western snowy plover, a taxon at the subspecies rank. We are changing the entry for the scientific name of the listed DPS to reflect a taxonomic change of the subspecies.

Analyses of molecular data and other characteristics indicate that *Charadrius* (broadly speaking) is paraphyletic (Barth et al. 2013, figure 1 therein; Dos Remedios et al. 2015, figure 1 therein; Černý and Natale 2022, figure 6 therein); that is, the genus, as it has been traditionally recognized, comprises more than one evolutionary lineage. To better reflect the snowy plover's evolutionary lineage, most authorities have transferred it (along with several other *Charadrius* species) to the genus *Anarhynchus* in their recent treatments (Clements et al. 2023, unpaginated; Medler 2023, unpaginated; Gill et al. 2024, unpaginated; but see Handbook of the Birds of the World (HBW) and BirdLife International 2024, unpaginated). Additionally, the North American Classification Committee (NACC) of the American Ornithological Society (AOS) (formerly the Committee on Classification and Nomenclature of the American Ornithologists' Union) also recently accepted the genus-level change for the snowy plover, recognizing the species as *Anarhynchus nivosus* (Chesser et al. 2024, p. 2). The AOS NACC is widely accepted as the leading authority of avian taxonomy in North America. While the AOS NACC no longer explicitly addresses taxa at the subspecies rank, because of the hierarchical structure of zoological taxonomy, changes at the genus level are also reflected at the species- and subspecies-levels as well. Thus, the best scientific information available indicates that the scientific name for the DPS's underlying taxon is now *Anarhynchus nivosus nivosus.*

The ITIS entry for the western snowy plover does not currently reflect the recent information in the scientific literature (ITIS 2024, unpaginated); the most recent references ITIS cites for this taxon are from 2022. We conclude that ITIS does not currently provide the best available scientific information for this subspecies. Based on our review of the scientific literature, we recognize *Anarhynchus nivosus nivosus* as the scientific name for the DPS. This taxonomic revision does not affect the range or the listing status of this DPS; we continue to recognize the listed

entity as a DPS of a vertebrate subspecies for the purposes of section 3(16) of the Act.

Additionally, as part of our review of the scientific name entry in 50 CFR 17.11, we reviewed the common name entry. We are changing two aspects of the common name. First, we conclude that it is not necessary to capitalize the ''c'' in ''coast.'' The ''Pacific Coast'' is not a widely recognized proper noun, and when it is used, it is typically equivalent to the ''West Coast,'' referring to the Pacific coastal region of the conterminous United States. The range of the DPS also includes a portion of the Pacific coastal region of the Baja California Peninsula, Mexico, and therefore, ''Pacific Coast'' does not adequately describe the DPS's range. Second, we conclude that including the word ''population'' in the common name for the DPS is redundant; clarity is diminished by including the first use of the term in the entity's common name when the DPS initialism is written out: western snowy plover [Pacific coast *population* distinct population segment]. We are removing the first instance of that word in that phrase. As such, we are changing the entry for the common name to ''western snowy plover [Pacific coast DPS].'' This common name revision does not affect the range or the listing status of this DPS. Critical habitat has been designated for this DPS, and we are making commensurate changes in the DPS's scientific name and common name in 50 CFR 17.95.

Moreover, as described in 50 CFR 17.11(d), the ''Where listed'' column in 50 CFR 17.11(h) sets forth the geographic area where the species is listed for purposes of the Act. Currently, the entry in this column for the DPS reads ''Pacific Coast population DPS—U.S.A. (CA, OR, WA), Mexico (within 50 miles of Pacific coast).'' This is somewhat unclear. We are changing it to ''U.S.A. (CA, OR, WA), Mexico (Baja California, Baja California Sur); within 50 miles of Pacific coast.'' This change addresses three potential sources of confusion. First, the phrase ''Pacific Coast population DPS—'' at the beginning of the entry is unnecessary. When similar phrases are used in the List of Endangered and Threatened Wildlife, they are used to distinguish between or among different DPSs of the same species. For example, compare with the various entries for DPSs of the humpback whale (*Megaptera novaeangliae*) or steelhead (*Oncorhynchus mykiss*). Second, the new wording better indicates that the ''within 50 miles of the Pacific coast'' phrase applies to California, Oregon, and Washington as well as the DPS's range in Mexico, including the Mexican States of Baja California and Baja California Sur. This clarification is consistent with how we have long considered the range of the DPS. For example, our description of the DPS's range in the recovery plan (Service 2007, p. 1) states, ''[t]he Pacific coast population [of the western snowy plover] is defined as those individuals that nest within 50 miles of the Pacific Ocean on the mainland coast, peninsulas, offshore islands, bays, estuaries, or rivers of the United States and Baja California, Mexico.'' While this definition is more complete, it is still not entirely accurate as written; it does not include the Mexican State of Baja California Sur. This oversight is inconsistent with mapped or described ranges in our earlier publications (71 FR 20607 at 20609, April 21, 2006; Service 2007, p. 2 (figure 1); Service 2019b, p. 2). Thus, to address the third potential source of confusion, we are also amending the ''Where listed'' column to explicitly include the Mexican States of Baja California and Baja California Sur. These editorial changes do not affect the range or the listing status of the DPS, and they have no bearing on 50 CFR 17.95.

Arroyo Toad

We are changing the common name ''arroyo (=arroyo southwestern) toad'' to ''arroyo toad.'' This is an editorial change, not a taxonomic change. We are removing the synonym in the common name entry. The scientific name remains the same. When we listed this species in 1994, it was recognized as the arroyo southwestern toad (*Bufo microscaphus californicus*) (59 FR 64859, December 16, 1994). With subsequent taxonomic revisions, as described in 74 FR 52612 (October 13, 2009), we now recognize the listed entity as the arroyo toad (*Anaxyrus californicus*). This combination is widely used in the scientific literature. At this point, there is little chance for confusion. Therefore, for simplicity, we are removing the synonym in the common name. This editorial revision does not affect the range or the listing status of the species; we continue to recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has been designated for this species; however, the synonym is not included and ''arroyo toad'' is consistent with the common name we use in 50 CFR 17.95. As such, no changes are needed in that section.

Desert Slender Salamander

We are changing the scientific name from ''*Batrachoseps aridus*'' to ''*Batrachoseps major aridus*.'' This reflects a taxonomic change. The common name remains the same. We provide the background for this change in our 2014 5-year review (Service 2014, pp. 5–6 and 14), which is updated in the following discussion. Southern California slender salamanders (genus *Batrachoseps*) show high genetic diversity and complex phylogenetic lineages, which results in taxonomic uncertainty in *Batrachoseps* taxa in this region, including the desert slender salamander (Jockusch et al. 2020, entire). Further, the extreme scarcity of desert slender salamanders has limited the extent to which the entity has been assessed by modern methods (Martínez-Solano et al. 2012, p. 147; Jockusch et al. 2015, p. 67). ITIS currently does not recognize the desert slender salamander as a taxon, either as a species or a subspecies (ITIS 2024g, unpaginated; 2024h, unpaginated); ITIS's treatment does not consider it distinguishable from the garden slender salamander (*B. major*) (ITIS 2024i, unpaginated). However, it is unclear how ITIS came to its conclusion because the references it cites are inconsistent. For example, one of its references, the Amphibian Species of the World online database (Frost 2024a, unpaginated; 2024b, unpaginated) currently notes that the distinguishability of the desert slender salamander is ambiguous, whether at the species level or subspecies level, but the Committee on Standard English and Scientific Names for Reptiles and Amphibians North of Mexico, another reference ITIS cites, has recognized *Batrachoseps major aridus* in the past three editions of its list, the first of which ITIS cites (Crother 2008, p. 15; Crother 2012, p. 25; Crother 2017, p. 27). We conclude that ITIS does not currently provide the best available scientific information for this taxon. In all, in our review of the scientific literature (primary sources and taxonomic authorities), we find no consensus in the taxonomic treatment. While few sources support recognizing the desert slender salamander at the species rank (*B. aridus*), some sources support recognizing it as a population of garden slender salamander (*B. major*) and not as distinguishable taxon, and other sources support recognizing it at the subspecies rank (*B. m. aridus*). Currently, we are recognizing the desert slender salamander as a subspecies, *B. m. aridus,* consistent with Crother et al. (2017, p. 27). This taxonomic revision does not affect the range or the listing

status of this entity; however, with this change, we now recognize the listed entity at the subspecies rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.95.

El Segundo Blue Butterfly

We are changing the scientific name from ''*Euphilotes battoides allyni*'' to ''*Euphilotes allyni.*'' This reflects a taxonomic change. The common name remains the same. As we noted in our 2021 5-year review (Service 2021a, pp. 2–3), an analysis of genetic data determined that the population of *Euphilotes battoides*-type butterflies sampled from coastal Los Angeles County was the most distinct of several populations of *Euphilotes battoides*-type butterflies sampled from within Southern California (Dupuis et al. 2020, p. 1911). This subsequently prompted recognition of the El Segundo blue butterfly at the species rank, *Euphilotes allyni* (Rubinoff et al. 2021, pp. 161–162). The genetic evaluation confirmed that the range of the El Segundo blue butterfly is limited to the area from the northern portion of the Palos Verdes Peninsula to the area near Ballona Lagoon (Service 2021a, p. 7). The genetic data also indicated that other populations of similar-looking blue butterflies elsewhere that were suspected to be El Segundo blue butterflies, are not *E. allyni* (see discussion in Dupuis et al. 2020, pp. 1899, 1914–1915). Currently, ITIS continues to recognize *Euphilotes battoides allyni* as the current (valid) scientific name for the El Segundo blue butterfly (ITIS 2024x, unpaginated). It appears that ITIS's entry for this taxon does not reflect the recent information in the scientific literature because the most recent reference it cites is from 2009. We conclude that ITIS does not currently provide the best available scientific information for this taxon.

We are recognizing the El Segundo blue butterfly as *Euphilotes allyni.* This taxonomic revision does not affect the range or the listing status of this entity; however, with this change, we now recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.95.

Acanthomintha duttonii (San Mateo thornmint)

We are changing the scientific name from ''*Acanthomintha obovata* ssp. *duttonii*'' to ''*Acanthomintha duttonii.*'' This reflects a taxonomic change. The common name remains the same. Based on a reevaluation of the species, Jokerst (1991, p. 278) elevated the taxon to species rank. This treatment was recognized and accepted in the Jepson eFlora (Miller and Jokerst 2012, unpaginated). The Jepson eFlora (Jepson Flora Project 2024, unpaginated) is the regularly updated online version of The Jepson Manual: Vascular Plants of California (Baldwin et al. 2012, entire). The Jepson Manual is the standard flora for California in which contributing authors provide systematic treatments of all the State's taxonomic groups; it is widely considered an authoritative source for botanical taxonomy in California. ITIS (2024a, unpaginated) also recognizes and accepts this combination. This taxonomic revision does not affect the range or the listing status of this entity; however, with this change, we now recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Boechera hoffmannii (Hoffmann's rockcress)

We are changing the scientific name from ''*Arabis hoffmannii*'' to ''*Boechera hoffmannii*'' and changing the common name from ''Hoffmann's rock-cress'' to ''Hoffmann's rockcress.'' The updated scientific name reflects a taxonomic change, and the common name change is to better reflect usage in the literature. As we discuss in our 2011 5-year review for this species (Service 2011a, p. 4), botanical taxonomists now recognize Hoffmann's rockcress in the genus *Boechera* (Al-Shehbaz 2003, p. 386). This treatment was recognized and accepted in the Jepson eFlora (Windham and Al-Shehbaz 2012, unpaginated). ITIS (2024j, unpaginated) also recognizes and accepts this combination. This taxonomic revision does not affect the range or the listing status of this entity; we continue to recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Arctostaphylos glandulosa subsp. crassifolia (Del Mar manzanita)

We are changing the scientific name from ''*Arctostaphylos glandulosa* ssp. *crassifolia*'' to ''*Arctostaphylos glandulosa* subsp. *crassifolia.*'' This is an editorial change. The common name remains the same. As discussed at the start of this section, we are changing ''ssp.'' to ''subsp.'' to be consistent with botanical nomenclatural norms. ITIS (2024c, unpaginated) has not adopted this convention at this time; we conclude that ITIS does not currently provide the best available scientific information for this taxon. This editorial revision does not affect the range or the listing status of this entity; we continue to recognize the listed entity at the subspecies rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Arctostaphylos montana subsp. ravenii (Presidio manzanita)

We are changing the scientific name from ''*Arctostaphylos hookeri* var. *ravenii*'' to ''*Arctostaphylos montana* subsp. *ravenii.*'' This reflects a taxonomic change that also corrects an earlier nomenclatural error. The current common name remains unchanged. The scientific and common names of this listed entity have been inconsistently applied in 50 CFR 17.12 (the List) over time. In 1979, we originally used ''*Arctostaphylos hookeri* ssp. *ravenii*'' for the scientific name and ''Raven's manzanita'' for the common name (44 FR 61910, October 26, 1979). In the 1986 edition of the Code of Federal Regulations, the scientific name in the List was ''*Arctostaphylos pungens* var. *ravenii* (=*A. hookeri* ssp. *ravenii*)'' and the common name was ''Presidio (=Raven's) manzanita''; however, it appears that there was no associated rule published in the **Federal Register** to explain these changes. In the 1995 edition, the scientific name in the List was ''*Arctostaphylos hookeri* (=*pungens*) var. *ravenii,*'' again, apparently without an associated published rule. Ignoring the inserted synonym ''(=*pungens*),'' the combination ''*Arctostaphylos hookeri* var. *ravenii*'' was incorrect; it should have been ''*Arctostaphylos hookeri* ssp. *ravenii*'' (indicating subspecies rather than variety). In the 2001 edition of the Code of Federal Regulations, the entity's scientific name in the List no longer included the ''(=pungens)'' synonym, and the common name lost the ''(=Raven's)'' synonym—again, apparently without a published explanation. While we used the correct scientific name combination in the 2003 multi-species recovery plan that included this species (Service 2003, entire), the scientific name in the List continued to refer to it as a variety.

Meanwhile, based on molecular work on the *Arctostaphylos hookeri* complex that included the listed entity, Markos et al. (1998, p. 194) determined that infraspecific taxa formerly included in *A. hookeri* were, in fact, not close relatives of that species. To

accommodate these findings, *A. montana* was returned to its original rank of species, and the Presidio manzanita was included as *A. montana* subsp. *ravenii* (Parker et al. 2007, p. 150). This treatment was recognized and accepted in the Jepson eFlora (Parker et al. 2023, unpaginated). ITIS (2024d, unpaginated) also recognizes and accepts this combination, although as previously noted, ITIS has not adopted the ''subsp.'' orthographic convention at this time. We are changing the scientific name in the List for the Presidio manzanita to ''*Arctostaphylos montana* subsp. *ravenii.*'' This taxonomic revision does not affect the range or the listing status of this entity; we continue to recognize the listed entity at the subspecies rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Eremogone ursina (Bear Valley sandwort)

We are changing the scientific name from ''*Arenaria ursina*'' to ''*Eremogone ursina.*'' This reflects a taxonomic change. The common name remains the same. As we discuss in our 2015 5-year review (Service 2015b, p. 10), portions of the genus *Arenaria* are now recognized as *Eremogone* (Harbaugh et al. 2010, p. 195). This treatment was recognized and accepted in the Jepson eFlora (Hartman and Rabeler 2012, unpaginated). ITIS (2024v, unpaginated) also recognizes and accepts this taxon. This taxonomic revision does not affect the range or the listing status of this entity; we continue to recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has been designated for this species, and we are making commensurate changes in 50 CFR 17.96. Additionally, when we designated critical habitat for this species, we did so in a rule that included two other co-occurring species (72 FR 73092, December 26, 2007). To distinguish the critical habitat units among the three species, we used species-specific identifiers; we used the four-letter code ''ARUR'' for ''*Arenaria ursina*'' (72 FR 73092 at 73097, December 26, 2007). To maintain consistency, we are adding text into the appropriate section of 50 CFR 17.96 indicating that ''ARUR'' remains the identifier for this species even though we are recognizing the species as ''*Eremogone ursina.*'' This clarifying text does not alter the critical habitat as it was designated.

Astragalus claranus (Clara Hunt's milk-vetch)

We are changing the scientific name from ''*Astragalus clarianus*'' to ''*Astragalus claranus.*'' This is an editorial change. The common name remains the same. Silva (1998, unpaginated) noted the orthographical error of the original spelling. Jepson (1925, p. 578) had originally published the species name with an incorrectly constructed specific epithet: *clarianus* should have been *claranus.* ITIS recognizes the taxon but uses the original spelling, *A. clarianus* (ITIS 2024e, unpaginated; 2024f, unpaginated); however, ITIS does not include any recent references for this taxon. The treatment with the corrected spelling was recognized and accepted in the Jepson eFlora (Wojciechowski and Spellenberg 2023, unpaginated). We conclude that ITIS does not currently provide the best available scientific information for this taxon. This editorial revision does not affect the range or the listing status of this entity; we continue to recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Castilleja cinerea (Ash-gray paintbrush)

We are changing the common name from ''Ash-gray Indian paintbrush'' to ''Ash-gray paintbrush.'' This is an editorial change. The scientific name remains the same. The revised common name is consistent with modern usage, including the Jepson eFlora (Wetherwax et al. 2012, unpaginated). This editorial revision does not affect the range or the listing status of this entity; we continue to recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has been designated for this species, and we are making commensurate changes in 50 CFR 17.96.

Ceanothus ferrisiae (Coyote ceanothus)

We are changing the scientific name from ''*Ceanothus ferrisae*'' to ''*Ceanothus ferrisiae.*'' This is an editorial change. The common name remains the same. Silva (1998, unpaginated) noted the orthographical error of the original spelling. McMinn (1933, p. 89) had originally published the species name with an incorrectly constructed specific epithet: *ferrisae* should have been *ferrisiae.* This treatment with the corrected spelling was recognized and accepted in the Jepson eFlora (Burge and Wilken 2020, unpaginated). ITIS (2024k, unpaginated) also recognizes and accepts this orthography. This editorial revision does not affect the range or the listing status of this entity; we continue to recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Zeltnera namophila (Spring-loving centaury)

We are changing the scientific name from ''*Centaurium namophilum*'' to ''*Zeltnera namophila.*'' This reflects a taxonomic change. The common name remains the same. As mentioned in our 2020 5-year review (Service 2020b, p. unpaginated), and based on a phylogenetic analysis of molecular data (Mansion and Struwe 2004, entire), Mansion (2004, p. 732) described a new genus, *Zeltnera,* for most North American species of *Centaurium,* forming the new combination *Zeltnera namophila* for this species. This treatment was recognized and accepted in the Jepson eFlora (Pringle 2012, unpaginated). ITIS (2024ai, unpaginated) also recognizes and accepts this combination. This taxonomic revision does not affect the range or the listing status of this entity; we continue to recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has been designated for this species, and we are making commensurate changes in 50 CFR 17.96.

Chloropyron maritimum subsp. maritimum (Salt marsh bird's-beak)

We are changing the scientific name from ''*Cordylanthus maritimus* ssp. *maritimus*'' to ''*Chloropyron maritimum* subsp. *maritimum.*'' This reflects a taxonomic change. The common name remains the same. As detailed in our 2009 5-year review (Service 2009b, pp. 13–14), Tank et al. (2009, p. 188) resurrected *Chloropyron,* forming the combination *Chloropyron maritimum,* which includes the nominate subspecies *C. m.* subsp. *maritimum.* This treatment was recognized and accepted in the Jepson eFlora (Wetherwax and Tank 2012a, unpaginated). ITIS (2024m, unpaginated) also recognizes the combination. However, it appears that ITIS did not correctly update the grammatical gender of the subspecies epithet when the genus epithet changed. *Cordylanthus* is masculine, *Chloropyron* is neuter. Specifically, the subspecific epithet *maritimus* should be *maritimum.* Additionally, as discussed at the start of this section, ITIS continues to use the ''ssp.'' abbreviation to indicate subspecies. We conclude that ITIS does not currently provide the

best available scientific information for this taxon. We are recognizing *Chloropyron maritimum* subsp. *maritimum.* This taxonomic revision does not affect the range or the listing status of this entity; we continue to recognize the listed entity at the subspecies rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Chloropyron molle subsp. molle (Soft bird's-beak)

We are changing the scientific name from ''*Cordylanthus mollis* ssp. *mollis*'' to ''*Chloropyron molle* subsp. *molle.*'' This reflects a taxonomic change. The common name remains the same. Like the preceding entity, this taxon reflects a nomenclatural change from *Cordylanthus* to *Chloropyron* and associated revisions in the species and subspecies epithets to reflect the difference in grammatical gender of the new genus epithet. The taxon is now recognized as *Chloropyron molle* subsp. *molle.* Details are presented in the Recovery Plan for Tidal Marsh Ecosystems of Northern and Central California (Service 2013, p. 68). This treatment was recognized and accepted in the Jepson eFlora (Wetherwax and Tank 2012b, unpaginated). ITIS also recognizes and accepts this combination (ITIS 2024n, unpaginated). However, as discussed at the start of this section, ITIS continues to use the ''ssp.'' abbreviation to indicate subspecies; we are using the ''subsp.'' abbreviation, *Chloropyron molle* subsp. *molle.* This taxonomic revision does not affect the range or the listing status of this entity; we continue to recognize the listed entity at the subspecies rank for the purposes of section 3(16) of the Act. Critical habitat has been designated for this species, and we are making commensurate changes in 50 CFR 17.96. Additionally, in the heading for the critical habitat description, the species' family is included; for this species, we are changing ''Scrophulariaceae'' to ''Orobanchaceae'' to be consistent with current treatments (Wetherwax and Tank 2012b, unpaginated; ITIS 2024n, unpaginated).

Chloropyron molle subsp. molle (Palmate-bracted bird's-beak)

We are changing the scientific name from ''*Cordylanthus palmatus*'' to ''*Chloropyron palmatum.*'' This reflects a taxonomic change. The common name remains the same. Similar to the preceding two entities, this taxon reflects a nomenclatural change from *Cordylanthus* to *Chloropyron* and the associated revision in the species epithet to reflect the difference in grammatical gender of the new genus epithet. The taxon is now recognized as *Chloropyron palmatum.* Details are presented in the 2009 5-year review for this species (Service 2009d, pp. 19–20). This treatment was recognized and accepted in the *Jepson eFlora* (Wetherwax and Tank 2012c, unpaginated). ITIS (2024o, unpaginated) also recognizes and accepts this combination. This taxonomic revision does not affect the range or the listing status of this entity; we continue to recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Deinandra conjugens (Otay tarplant)

We are changing the scientific name entry from ''*Deinandra* (= *Hemizonia*) *conjugens*'' to ''*Deinandra conjugens.*'' This is an editorial change, not a taxonomic change. The common name remains the same. The current scientific literature now recognizes *Deinandra conjugens;* it has been more than 20 years since this taxon was recognized under the genus *Hemizonia* in the scientific literature (see 67 FR 76030, December 10, 2002). At this point, there is little chance for confusion. Therefore, for simplicity, we are removing the synonym in the scientific name. Other than the parenthetical synonym, the species' scientific name remains unchanged and is consistent with the Jepson eFlora (Baldwin 2012, unpaginated) and ITIS (2024q, unpaginated). This editorial revision does not affect the range or the listing status of the species; we continue to recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has been designated for this species; however, the synonym is not included and ''*Deinandra conjugens*'' is consistent with the scientific name we use in 50 CFR 17.96. As such, no changes are needed in that section.

Dudleya parva (Conejo dudleya)

We are changing the scientific name from ''*Dudleya abramsii* ssp. *parva*'' to ''*Dudleya parva.*'' This reflects a taxonomic change. The common name remains the same. As described in our 2009 and 2015 5-year reviews (Service 2009c, p. 9; Service 2015a, p. 11), the taxon should not be considered within the circumscription of *Dudleya abramsii* and should best be considered at the species rank. This was also supported by an analysis of molecular phylogeny (Yost et al. 2013, figures 1 and 2 therein). This treatment was recognized and accepted in the Jepson eFlora (McCabe 2012b, unpaginated). ITIS (2024u, unpaginated) also recognizes and accepts this combination. This taxonomic revision does not affect the range or the listing status of this entity; however, with this change, we now recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Dudleya cymosa subsp. ovatifolia (Santa Monica dudleya)

We are changing the scientific name from ''*Dudleya cymosa* ssp. *ovatifolia*'' to ''*Dudleya cymosa* subsp. *ovatifolia,*'' and the common name from ''Santa Monica Mountains dudleya'' to ''Santa Monica dudleya.'' We recognize that the taxonomy of this subspecies complex is not fully resolved (Service 2021b, entire). We are not addressing the larger taxonomic questions currently; the current change is merely editorial. As we describe at the start of this section, the abbreviation ''subsp.'' is now preferred over ''ssp.,'' and we are using it even though ITIS has not adopted this orthography (ITIS 2024t, unpaginated). Additionally, we are adopting the common name that is consistent with usage in the Jepson eFlora (McCabe 2012a, unpaginated), although we recognize that the current common name is also widely used. This editorial revision does not affect the range or the listing status of the species; we continue to recognize the listed entity at the subspecies rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Dudleya stolonifera (Laguna Beach dudleya)

We are changing the common name from ''Laguna Beach liveforever'' to ''Laguna Beach dudleya.'' This is an editorial change. The scientific name remains the same. We are adopting the common name that is consistent with usage in the Jepson eFlora (McCabe 2012c, unpaginated), although we recognize that the current common name is also widely used. This editorial revision does not affect the range or the listing status of the species; we continue to recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Eriastrum densifolium subsp. sanctorum (Santa Ana River woolly-star)

We are changing the scientific name from ''*Eriastrum densifolium* ssp. *sanctorum*'' to ''*Eriastrum densifolium* subsp. *sanctorum*.'' This is an editorial change. The common name remains the same. As we describe at the start of this section, the abbreviation ''subsp.'' is now preferred over ''ssp.,'' and we are using it even though ITIS has not adopted this orthography (ITIS 2024w, unpaginated). This editorial revision does not affect the range or the listing status of the species; we continue to recognize the listed entity at the subspecies rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Eriogonum kennedyi var. austromontanum (southern mountain buckwheat)

We are changing the common name from ''southern mountain wild-buckwheat'' to ''southern mountain buckwheat.'' This is an editorial change. The scientific name remains the same. We are adopting the common name that is consistent with usage in the Jepson eFlora (Reveal and Rosatti 2012, unpaginated), although we recognize that the current common name is also widely used. This editorial revision does not affect the range or the listing status of the species; we continue to recognize the listed entity at the subspecies rank for the purposes of section 3(16) of the Act. Critical habitat has been designated for this species, and we are making commensurate changes in 50 CFR 17.96.

Fremontodendron decumbens (Pine Hill flannelbush)

We are changing the scientific name from ''*Fremontodendron californicum* ssp. *decumbens*'' to ''*Fremontodendron decumbens.*'' This reflects a taxonomic change. The common name remains the same. In a revision of the genus *Fremontodendron,* Kelman (1991, p. 16) elevated *F. californicum* subsp. *decumbens* to the species rank, *F. decumbens,* as it was originally described (Lloyd 1965, p. 382). This is supported by more recent work examining molecular markers of *F. decumbens* and *F. californicum* (Kelman et al. 2006, p. 383). This treatment was recognized and accepted in the Jepson eFlora (Preston et al. 2012, unpaginated). ITIS (2024y, unpaginated) also recognizes and accepts this combination. While we acknowledge that there is some taxonomic uncertainty associated with some flannelbush individuals that, if confirmed as this taxon, could result in a change in the taxon's range (Service 2019c, p. 3), the taxonomic treatment recognized herein, in and of itself, does not affect the range of the listed entity. This change does not affect the entity's listing status; however, with this change, we now recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Grindelia fraxinipratensis (Ash Meadows gumplant)

We are changing the scientific name from ''*Grindelia fraxino-pratensis*'' to ''*Grindelia fraxinipratensis.*'' This is an editorial change. The common name remains the same.

When Ash Meadows gumplant was described as a new species by Reveal and Beatley (1971, p. 334), they constructed an orthographically incorrect Latin specific epithet, *fraxino-pratensis.* Greenhouse (2007, unpaginated) subsequently noted that the specific epithet should have been spelled *fraxinipratensis.* This subsequent spelling was accepted by the Jepson eFlora (Moore 2012, unpaginated), and ITIS (2024z, unpaginated) also accepts this orthography. This editorial revision does not affect the range or the listing status of the species; we continue to recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has been designated for this species, and we are making commensurate changes in 50 CFR 17.96.

Crocanthemum greenei (Island rush-rose)

We are changing the scientific name from ''*Helianthemum greenei*'' to ''*Crocanthemum greenei.*'' This reflects a taxonomic change. The common name remains the same. As discussed in our 2019 5-year review (Service 2019a, pp. 2–3), several lines of evidence supported the segregation of *Helianthemum* species (broadly speaking) into two distinct genera, *Helianthemum* in the Old World and *Crocanthemum* in the New World, including *C. greenei.* This treatment was recognized and accepted in the Jepson eFlora (Sorrie and Rosatti 2013, unpaginated). ITIS (2024p, unpaginated) also recognizes and accepts this combination. This taxonomic revision does not affect the range or the listing status of the species; we continue to recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Physaria kingii subsp. bernardina (San Bernardino Mountains bladderpod)

We are changing the scientific name ''*Lesquerella kingii* ssp. *bernardina*'' to ''*Physaria kingii* subsp. *bernardina.*'' This reflects a taxonomic change. The common name remains the same. As discussed in our 2009 5-year review (Service 2009f, pp. 5–6), multiple lines of evidence indicated that the genus *Physaria* is nested within the genus *Lesquerella;* this necessitated the merger of the two genera and new nomenclatural combinations under the genus *Physaria* (Al-Shehbaz and O'Kane 2002, pp. 319–329). This treatment was recognized and accepted in the Jepson eFlora (Al-Shehbaz 2012c, unpaginated). ITIS (2024ag, unpaginated) also recognizes and accepts this combination. This taxonomic revision does not affect the range or the listing status of this entity; we continue to recognize the listed entity at the subspecies rank for the purposes of section 3(16) of the Act. Critical habitat has been designated for this species, and we are making commensurate changes in 50 CFR 17.96.

Opuntia basilaris var. treleasei (Bakersfield cactus)

We are changing the scientific name from ''*Opuntia treleasei*'' to ''*Opuntia basilaris* var. *treleasei.*'' This reflects a taxonomic change. The common name remains the same. As discussed in our 2011 and 2020 5-year reviews (Service 2011b, p. 16; 2020a, p. 2), available information suggests that the entity is best treated as an infraspecific taxon of *O. basilaris.* This treatment was recognized and accepted in the Jepson eFlora (Baker et al. 2019, unpaginated). ITIS (2024ae, unpaginated) also recognizes and accepts this combination. This taxonomic revision does not affect the range or the listing status of the species; however, with this change, we now recognize the listed entity at the subspecies rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Acanthoscyphus parishii var. goodmaniana (Cushenbury oxytheca)

We are changing the scientific name from ''*Oxytheca parishii* var. *goodmaniana*'' to ''*Acanthoscyphus parishii* var. *goodmaniana.*'' This reflects a taxonomic change. The

common name remains the same. As detailed in our 2009 5-year review (Service 2009a, p.6), several lines of evidence indicated that the taxonomy of the Cushenbury oxytheca did not align well with other *Oxytheca* species. Ultimately, Reveal (2004, p. 144) recognized the Cushenbury oxytheca under the combination *Acanthoscyphus parishii* var. *goodmaniana.* This treatment was recognized and accepted in the Jepson eFlora (Reveal and Rosatti 2012, unpaginated). ITIS (2024b, unpaginated) also recognizes and accepts this combination. This taxonomic revision does not affect the range or the listing status of this subspecies; we continue to recognize the listed entity at the subspecies rank for the purposes of section 3(16) of the Act. Critical habitat has been designated for this species, and we are making commensurate changes in 50 CFR 17.96.

Sedella leiocarpa (Lake County stonecrop)

We are changing the scientific name from ''*Parvisedum leiocarpum*'' to ''*Sedella leiocarpa.*'' This reflects a nomenclatural change. The common name remains the same. We mentioned the nomenclatural revision in our 2009 5-year review (Service 2009e, p. 10). It involves a perceived nomenclatural error in the genus *Sedella* that prompted Clausen (1946, p. 58) to describe the genus *Parvisedum* and to make the corresponding species combinations, including *Parvisedum leiocarpum.* However, it was later determined that the perceived error was incorrect and that the change to *Parvisedum* was unnecessary (Eggli 1992, p. 83). As such, *Sedella leiocarpa* was, in fact, valid under the rules of botanical nomenclature. The Jepson eFlora (Boyd 2012, unpaginated) recognized and accepted *Sedella leiocarpa.* ITIS (2024ah, unpaginated) also recognizes and accepts this combination. This nomenclatural revision (correction) does not affect the range or the listing status of the species; we continue to recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Nasturtium gambelii (Gambel's watercress)

We are changing the scientific name from ''*Rorippa gambellii*'' to ''*Nasturtium gambelii.*'' This reflects two changes, an editorial (orthographic) change and a taxonomic change. The common name remains the same. The incorrect spelling of the specific epithet can be traced to the original description of the species by Sereno Watson (Watson 1876, p. 147). Watson named the new species, *Cardamine gambelii,* in honor of its collector William Gambel, but Watson incorrectly spelled it as ''Gambell'' (Watson 1876, p. 147). Watson apparently caught and corrected this error by 1895 (Watson 1895, p. 158). However, the error has sporadically been carried through the botanical literature for many years, even as the taxon underwent several revisions under different but similar genera: *Cardamine, Nasturtium,* and *Rorippa* (see Al-Shehbaz and Rollins 1988, p. 69). Subsequently, molecular data prompted Al-Shehbaz and Price (1998, entire) to again recognize *Nasturtium* as distinct from *Rorippa,* including the listed entity. This taxonomic treatment and corrected spelling for the specific epithet were both recognized and accepted by the Jepson eFlora (Al-Shehbaz 2012a, unpaginated). ITIS (2024ac, unpaginated) also recognizes and accepts this combination. This taxonomic revision does not affect the range or the listing status of this species; we continue to recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Packera layneae (Layne's butterweed)

We are changing the scientific name from ''*Senecio layneae*'' to ''*Packera layneae.*'' This reflects a taxonomic change. The common name remains the same. Analyses of morphological, geographical, and cytological data yielded differences sufficient to segregate several species of *Senecio* into a genus, *Packera,* separate from other species of *Senecio* (Löve and Löve 1975, p. 520). This resulted in the combination *Packera layneae* for Layne's butterweed (Weber and Löve 1981, p. 47). This treatment was recognized and accepted in the Jepson eFlora (Trock 2012, unpaginated). ITIS (2024af, unpaginated) also recognizes and accepts this combination. This taxonomic revision does not affect the range or the listing status of the species; we continue to recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Swallenia alexandrae (Eureka Valley dune grass)

We are changing the common name from ''Eureka dune grass, Eureka Valley dune grass, or Eureka dunegrass'' to ''Eureka Valley dune grass.'' This is an editorial change. The scientific name remains the same. The List currently presents three common names for this species. Each name is applicable to the species and is regularly used. For simplicity and consistency, we are now using one name. Prior to 2018, when we reclassified the species from an endangered species to a threatened species (83 FR 8576, February 27, 2018), we had used ''Eureka Dune grass.'' The species is known to occur on the Eureka Dunes, a large dune system in the Eureka Valley. The species also occurs on two other nearby dune systems in the Eureka Valley. Therefore, we are choosing to use ''Eureka Valley dune grass'' as the common name. This is consistent with the common name used by the Jepson eFlora (Bell and Smith 2012, unpaginated). Although we are not explicitly including them on the List as such, we consider the other common names as synonyms for this species. This editorial revision does not affect the range or the listing status of the species; we continue to recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Noccaea fendleri subsp. californica (Kneeland Prairie pennycress)

We are changing the common name from ''Kneeland Prairie penny-cress'' to ''Kneeland Prairie pennycress''; the non-hyphenated orthography is more consistent with common usage (for example, Al-Shehbaz 2012b, unpaginated). We are also changing the scientific name from ''*Thlaspi californicum*'' to ''*Noccaea fendleri* subsp. *californica.*'' This reflects a taxonomic change. As discussed in our 2011 5-year review (Service 2011c, p. 7), a phylogenetic analysis of molecular data (Koch and Al-Shehbaz 2004, p. 379) indicated that North American representatives of genus *Thlaspi* should be reassigned to the genus *Noccaea* and that the Kneeland Prairie pennycress should be assigned as a subspecies under *Noccaea fendleri* (Koch and Al-Shehbaz 2004, p. 382). This treatment was recognized and accepted in the Jepson eFlora (Al-Shehbaz 2012b, unpaginated). ITIS (2024ad, unpaginated) also recognizes and accepts this combination. This taxonomic revision does not affect the range or the listing status of the taxon; however, with this change, we now recognize the listed entity at the subspecies rank for the purposes of section 3(16) of the Act. Critical habitat has been designated for this species, and

we are making commensurate changes in 50 CFR 17.96.

Hesperocyparis goveniana (Gowen cypress)

We are changing the scientific name from ''*Cupressus goveniana* ssp. *goveniana*'' to ''*Hesperocyparis goveniana*.'' This reflects a taxonomic change. The common name remains the same. When we listed the entity in 1998 (63 FR 43100, August 12, 1998), we recognized it at the subspecies rank (Bartel 1993, p. 112). Its taxonomic rank was based on a sister infraspecific taxon, *C. g.* subsp. *pigmaea* (Bartel 1993, p. 112). Subsequent phylogenetic analyses indicated that *C. g.* subsp. *pigmaea* was not closely related to *C. g.* subsp. *goveniana* (Bartel et al. 2003, p. 699; Adams et al. 2009, p. 182), and the entity previously recognized as *C. g.* subsp. *pigmaea* became recognized as a separate taxon at the species rank. Without a sister infraspecific taxon, the infraspecific epithet no longer applied to the Gowan cypress, and the entity previously recognized as *C. g.* subsp. *goveniana* became recognized at the species rank, *C. goveniana.* Additionally, as discussed in our 2012 5-year review (Service 2012, p. 4), Adams et al. (2009, pp. 179, 181) also found that the New World *Cupressus* species were sufficiently differentiated from Old World taxa to be recognized under a new, separate genus, *Hesperocyparis,* including *H. goveniana.* This treatment was recognized and accepted in the Jepson eFlora (Bartel 2012, unpaginated). ITIS (2024aa, unpaginated) also recognizes and accepts this combination. This taxonomic revision does not affect the range or the listing status of the species; however, with this change, we now recognize the listed entity at the species rank for the purposes of section 3(16) of the Act. Critical habitat has not been designated for this species, and no changes are needed in 50 CFR 17.96.

Required Determinations

Clarity of the Rule

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

(a) Be logically organized;

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

(c) Use clear language rather than jargon;

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

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To help us to revise this rule, your comments should be as specific as possible.

National Environmental Policy Act

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), need not be prepared in connection with regulations issued pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (43 FR 49244).

Government-To-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments''' (59 FR 22951), Executive Order 13175, and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We have determined that this rule will not affect Tribes or Tribal lands.

References Cited

A complete list of the referenced materials is provided in Docket No FWS–R8–ES–2026–0530 at *https://www.regulations.gov* or is available upon request from the U.S. Fish and Wildlife Service (see **FOR FURTHER INFORMATION CONTACT**).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Regulation Promulgation

For the reasons given in the preamble, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. In § 17.11, in paragraph (h), amend the List of Endangered and Threatened Wildlife, by:

■ a. Under MAMMALS, revising the entries for ''Kangaroo rat, San Bernardino Merriam's'' and ''Kangaroo rat, Stephens' '';

■ b. Under BIRDS, revising the entries for ''Coot, Hawaiian (alae keokeo)'', ''Pigeon, Puerto Rican plain'', ''Plover, western snowy [Pacific Coast population DPS]'', ''Stilt, Hawaiian'', ''Tern, California least'', and ''Towhee, Inyo California'';

■ c. Under REPTILES, revising the entry for ''Boa, Puerto Rican'';

■ d. Under AMPHIBIANS, revising the entries for ''Salamander, desert slender'', ''Toad, arroyo (=arroyo southwestern)'', and ''Toad, Houston''; and

■ e. Under INSECTS, revising the entry for ''Butterfly, El Segundo blue''.

The revisions read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
		Mammals		
*	*	*	*	*
Kangaroo rat, San Bernardino.	*Dipodomys merriami parvus.*	Wherever found	E	63 FR 3835, 1/27/1988; 63 FR 51005, 9/24/1988; 50 CFR 17.95(a).[CH]
Kangaroo rat, Stephens'	*Dipodomys stephensi*	Wherever found	T	53 FR 38465, 9/30/1988; 87 FR 8967; 2/17/2022; 50 CFR 17.40(t).[4d]

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
		Birds		
*	*	*	*	*
Coot, Hawaiian (alae keokeo).	*Fulica alai*	Wherever found	E	34 FR 5034, 3/8/1969; 35 FR 16047, 10/13/1970.
*	*	*	*	*
Pigeon, Puerto Rican plain.	*Patagioenas inornata wetmorei*.	Wherever found	E	34 FR 5034, 3/8/1969; 35 FR 16047, 10/13/1970.
*	*	*	*	*
Plover, western snowy [Pacific Coast DPS].	*Anarhynchus nivosus nivosus*.	U.S.A. (CA, OR, WA), Mexico (Baja California, Baja California Sur); within 50 miles of Pacific coast.	T	58 FR 12864, 3/5/1993; 50 CFR 17.95(b).[CH]
*	*	*	*	*
Stilt, Hawaiian	*Himantopus mexicanus (=himantopus) knudseni*.	Wherever found	T	34 FR 5034, 3/8/1969; 35 FR 16047, 10/13/1970.
*	*	*	*	*
Tern, California least	*Sternula antillarum browni*.	Wherever found	E	34 FR 5034, 3/8/1969; 35 FR 16047, 10/13/1970; 35 FR 8491, 6/2/1970.
*	*	*	*	*
Towhee, Inyo California	*Melozone crissalis eremophila*.	Wherever found	T	52 FR 28780, 8/3/1987; 50 CFR 17.95(b).[CH]
*	*	*	*	*
		Reptiles		
*	*	*	*	*
Boa, Puerto Rican	*Epicrates inornatus*	Wherever found	E	34 FR 5034, 3/8/1969; 35 FR 16047, 10/13/1970.
*	*	*	*	*
		Amphibians		
*	*	*	*	*
Salamander, desert slender.	*Batrachoseps major aridus*.	Wherever found	E	38 FR 14678, 6/4/1973.
*	*	*	*	*
Toad, arroyo	*Anaxyrus californicus*	Wherever found	E	59 FR 64859, 12/16/1994; 50 CFR 17.95(d).[CH]
*	*	*	*	*
Toad, Houston	*Bufo houstonensis*	Wherever found	E	34 FR 5034, 3/8/1969; 35 FR 16047, 10/13/1970; 50 CFR 17.95(d).[CH]
*	*	*	*	*
		Insects		
*	*	*	*	*
Butterfly, El Segundo blue.	*Euphilotes allyni*	Wherever found	E	41 FR 22041, 6/14/1976.
*	*	*	*	*

■ 3. Amend § 17.12, in paragraph (h), the List of Endangered and Threatened Plants, by:

■ a. Under FLOWERING PLANTS:

■ i. Revising the entry for ''*Acanthomintha obovata* ssp. *duttonii*'';

■ ii. Adding, in alphabetical order, an entry for ''*Acanthoscyphus parishii* var. *goodmaniana*'';

■ iii. Removing the entry for ''*Arabis hoffmannii*'';

■ iv. Revising the entries for ''*Arctostaphylos glandulosa* ssp. *crassifolia*'', and ''*Arctostaphylos hookeri* var. *ravenii*'';

■ v. Removing the entry for ''*Arenaria ursina*'';

■ vi. Revising the entry for ''*Astragalus clarianus*'';
■ vii. Adding, in alphabetical order, an entry for ''*Boechera hoffmannii*'';
■ viii. Revising the entries for ''*Castilleja cinerea*'', and ''*Ceanothus ferrisae*'';
■ ix. Removing the entry for ''*Centaurium namophilum*'',
■ x. Adding, in alphabetical order, entries for ''*Chloropyron maritimum* subsp. *maritimum*'', ''*Chloropyron molle* subsp. *molle*'', and ''*Chloropyron palmatum*'';
■ xi. Removing the entries for ''*Cordylanthus maritimus* ssp. *maritimus*'', ''*Cordylanthus mollis* ssp. *mollis*'', and ''*Cordylanthus palmatus*'';
■ xii. Adding, in alphabetical order, an entry for ''*Crocanthemum greenei*'';
■ xiii. Revising the entry for ''*Deinandra* (= *Hemizonia*) *conjugens*'';
■ xiv. Removing the entry for ''*Dudleya abramsii* ssp. *parva*'';
■ xv. Revising the entry for ''*Dudleya cymosa* ssp. *ovatifolia*'';
■ xvi. Adding, in alphabetical order, an entry for ''*Dudleya parva*'';
■ xvii. Revising the entry for ''*Dudleya stolonifera*'';
■ xviii. Adding, in alphabetical order, an entry for ''*Eremogone ursina*'';
■ xix. Revising the entries for ''*Eriastrum densifolium* ssp. *sanctorum*'', ''*Eriogonum kennedyi* var. *austromontanum*'', ''*Fremontodendron californicum* ssp. *decumbens*'', and ''*Grindelia fraxino-pratensis*'';
■ xx. Removing the entries for ''*Helianthemum greenei*'' and ''*Lesquerella kingii* ssp. *bernardina*'';
■ xxi. Adding, in alphabetical order, entries for ''*Nasturtium gambelii*'' and ''*Noccaea fendleri* subsp. *californica*'';
■ xxii. Revising the entry for ''*Opuntia treleasei*'';
■ xxiii. Removing the entry for ''*Oxytheca parishii* var. *goodmaniana*'';
■ xxiv. Adding, in alphabetical order, an entry for ''*Packera layneae*'';
■ xxv. Removing the entry for ''*Parvisedum leiocarpum*'';
■ xxvi. Adding, in alphabetical order, an entry for ''*Physaria kingii* subsp. *bernardina*'';
■ xxvii. Removing the entry for ''*Rorippa gambellii*'';
■ xxviii. Adding, in alphabetical order, an entry for ''*Sedella leiocarpa*'';
■ xxix. Removing the entry for ''*Senecio layneae*'';
■ xxx. Revising the entry for ''*Swallenia alexandrae*'';
■ xxxi. Removing the entry for ''*Thlaspi californicum*''; and
■ xxxii. Adding, in alphabetical order, an entry for ''*Zeltnera namophila*''.
■ b. Under CONIFERS AND ALLIES:
■ i. Removing the entry for ''*Cupressus goveniana* ssp. *goveniana*'';
■ ii. Adding, in alphabetical order, an entry for ''*Hesperocyparis goveniana*''.

The revisions and additions read as follows:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Scientific name	Common name	Where listed	Status	Listing citations and applicable rules
		Flowering Plants		
*	*	*	*	*
Acanthomintha duttonii	San Mateo thornmint	Wherever found	E	50 FR 37858, 9/18/1985.
*	*	*	*	*
Acanthoscyphus parishii var. *goodmaniana*.	Cushenbury oxytheca	Wherever found	E	59 FR 43652, 8/24/1994; 50 CFR 17.96(a).[CH]
*	*	*	*	*
Arctostaphylos glandulosa subsp. *crassifolia*.	Del Mar manzanita	Wherever found	E	61 FR 52370, 10/7/1996.
Arctostaphylos montana subsp. *ravenii*.	Presidio manzanita	Wherever found	E	44 FR 61910, 10/26/1979.
*	*	*	*	*
Astragalus claranus	Clara Hunt's milk-vetch ..	Wherever found	E	62 FR 54791, 10/22/1997.
*	*	*	*	*
Boechera hoffmannii	Hoffmann's rockcress	Wherever found	E	62 FR 40954, 7/31/1997.
*	*	*	*	*
Castilleja cinerea	Ash-gray paintbrush	Wherever found	T	63 FR 49006, 9/14/1998; 50 CFR 17.96(a).[CH]
*	*	*	*	*
Ceanothus ferrisiae	Coyote ceanothus	Wherever found	E	60 FR 6671, 2/3/1995.
*	*	*	*	*
Chloropyron maritimum subsp. *maritimum*.	Salt marsh bird's-beak ...	Wherever found	E	43 FR 44810, 9/28/1978.
Chloropyron molle subsp. *molle*.	Soft bird's-beak	Wherever found	E	62 FR 61916, 11/20/1997; 50 CFR 17.96(a).[CH]
Chloropyron palmatum	Palmate-bracted bird's-beak.	Wherever found	E	51 FR 23765, 7/1/1986.
*	*	*	*	*
Crocanthemum greenei ...	Island rush-rose	Wherever found	T	62 FR 40954, 7/31/1997.
*	*	*	*	*
Deinandra conjugens	Otay tarplant	Wherever found	T	63 FR 54938, 10/13/1998; 50 CFR 17.96(a).[CH]

Scientific name	Common name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
Dudleya cymosa subsp. *ovatifolia*.	Santa Monica dudleya	Wherever found	T	62 FR 4172, 1/29/1997.
*	*	*	*	*
Dudleya parva	Conejo dudleya	Wherever found	T	62 FR 4172, 1/29/1997.
*	*	*	*	*
Dudleya stolonifera	Laguna Beach dudleya	Wherever found	T	63 FR 54938, 10/13/1998.
*	*	*	*	*
Eremogone ursina	Bear Valley sandwort	Wherever found	T	63 FR 49006, 9/14/1998; 50 CFR 17.96(a).[CH]
*	*	*	*	*
Eriastrum densifolium subsp. *sanctorum*.	Santa Ana River woolly-star.	Wherever found	E	52 FR 36265, 9/28/1987.
*	*	*	*	*
Eriogonum kennedyi var. *austromontanum*.	Southern mountain buckwheat.	Wherever found	T	63 FR 49006, 9/14/1998; 50 CFR 17.96(a).[CH]
*	*	*	*	*
Fremontodendron decumbens.	Pine Hill flannelbush	Wherever found	E	61 FR 54346, 10/18/1996.
*	*	*	*	*
Grindelia fraxinipratensis	Ash Meadows gumplant	Wherever found	T	50 FR 20777, 5/20/1985; 50 CFR 17.96(a).[CH]
*	*	*	*	*
Nasturtium gambelii	Gambel's watercress	Wherever found	E	58 FR 41378, 8/3/1993.
*	*	*	*	*
Noccaea fendleri subsp. *californica*.	Kneeland Prairie pennycress.	Wherever found	E	65 FR 6332, 2/9/2000; 50 CFR 17.96(a).[CH]
*	*	*	*	*
Opuntia basilaris var. *treleasei*.	Bakersfield cactus	Wherever found	E	55 FR 29361, 7/19/1990.
*	*	*	*	*
Packera layneae	Layne's butterweed	Wherever found	T	61 FR 54346, 10/18/1996.
*	*	*	*	*
Physaria kingii subsp. *bernardina*.	San Bernardino Mountains bladderpod.	Wherever found	E	59 FR 43652, 8/24/1994; 50 CFR 17.96(a).[CH]
*	*	*	*	*
Sedella leiocarpa	Lake County stonecrop	Wherever found	E	62 FR 33029, 6/18/1997.
*	*	*	*	*
Swallenia alexandrae	Eureka Valley dune grass.	Wherever found	T	83 FR 8576, 2/27/2018.
*	*	*	*	*
Zeltnera namophila	Spring-loving centaury	Wherever found	T	50 FR 20777, 5/20/1985; 50 CFR 17.96(a).[CH]
*	*	*	*	*
Conifers and Allies				
*	*	*	*	*
Hesperocyparis goveniana.	Gowen cypress	Wherever found	T	63 FR 43100, 8/12/1998.
*	*	*	*	*

■ 4. Amend § 17.95, in paragraph (b), by

■ a. In the entry ''Inyo California Towhee (*Melozone crissalis eremophilus*)'', removing the word ''*eremophilus*'' in the heading and adding, in its place, the word ''*eremophila*''; and

■ b. In the entry ''Western Snowy Plover (*Charadrius nivosus nivosus*)—Pacific Coast Population'':

■ i. Revising the heading;

■ ii. Revising the introductory text of paragraph (2); and
■ iii. Revising the introductory text of paragraphs (6), (13), (26), and (53).

These revisions read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(b) * * *

* * * * *

Western Snowy Plover [Pacific Coast DPS] (*Anarhynchus nivosus nivosus*)

* * * * *

(2) Within these areas, the primary constituent elements of the physical or biological features essential to the conservation of the western snowy plover [Pacific coast DPS] are sandy beaches, dune systems immediately inland of an active beach face, salt flats, mud flats, seasonally exposed gravel bars, artificial salt ponds and adjoining levees, and dredge spoil sites, with:

* * * * *

(6) Index map of critical habitat units for the western snowy plover [Pacific coast DPS] (*Anarhynchus nivosus nivosus*) in Washington follows:

* * * * *

(13) Index map of critical habitat units for the western snowy plover [Pacific coast DPS] (*Anarhynchus nivosus nivosus*) in Oregon follows:

* * * * *

(26) Index map of critical habitat units for the western snowy plover [Pacific coast DPS] (*Anarhynchus nivosus nivosus*) in Northern California follows:

* * * * *

(53) Index map of critical habitat units for the western snowy plover [Pacific coast DPS] (*Anarhynchus nivosus nivosus*) in Southern California follows:

* * * * *

■ 5. Amend § 17.96, in paragraph (a), by:
■ a. In the entry ''Family Caryophyllaceae: *Arenaria ursina* (Bear Valley sandwort)'':
■ i. Removing the word ''*Arenaria*'' in the heading and adding, in its place, the word ''*Eremogone*'';
■ ii. Revising paragraph (1);
■ iii. Revising the introductory text of paragraph (2); and
■ iv. Revising the introductory text of paragraphs (5), (6)(iii), (7)(iii), (8)(ii), (9)(iii), (10)(iv), (11)(iii), (12)(iii), (13)(ii), and (14)(iii); and
■ b. In the entry ''Family Orobanchaceae: *Castilleja cinerea* (ash-gray Indian paintbrush)'', removing the word ''Indian'' in the heading; and
■ c. In the entry ''Family Gentianaceae: *Centaurium namophilum* (spring-loving centaury)'', removing the words ''*Centaurium namophilum*'' in the heading and adding, in their place, the words ''*Zeltnera namophila*''; and
■ d. In the entry ''Family Scrophulariaceae: *Cordylanthus mollis* ssp. *mollis* (soft bird's-beak)'':
■ i. Removing the words in the heading ''Scrophulariaceae: *Cordylanthus mollis* ssp. *mollis*'' and adding, in their place, the words ''Orobanchaceae: *Chloropyron molle* subsp. *molle*'';
■ ii. In the introductory text of paragraph (2), removing the words ''*Cordylanthus mollis* ssp. *mollis*'' and adding, in their place, the words ''*Chloropyron molle* subsp. *molle*'';
■ iii. In the introductory text of paragraph (5), removing the words ''*Cordylanthus mollis* ssp. *mollis*'' and adding, in their place, the words ''*Chloropyron molle* subsp. *molle*'';
■ iv. In paragraphs (6) introductory text, (6)(ii), (7) introductory text, (7)(ii), (8) introductory text, (8)(ii), (9) introductory text, (9)(ii), (10) introductory text, and (10)(ii), removing the words ''*Cordylanthus mollis* ssp. *mollis*'' and adding, in their place, the words ''*Chloropyron molle* subsp. *molle*''; and
■ e. In the entry ''Family Polygonaceae: *Eriogonum kennedyi* var. *austromontanum* (Southern mountain wild-buckwheat)'',
■ i. Removing the hyphenated word ''wild-buckwheat'' in the heading and adding, in its place, the word ''buckwheat''; and
■ ii. Revising the introductory text of paragraphs (5), (6)(iii), (7)(ii), (8)(iii), (9)(iv), (10)(iii), (11)(iii), and (12)(ii); and
■ f. In the entry ''Family Asteraceae: *Grindelia fraxino-pratensis* (Ash Meadows gumplant)'', removing the hyphenated word ''*fraxino-pratensis*'' in the heading and adding, in its place, the word ''*fraxinipratensis*''; and
■ g. In the entry ''Family Brassicaceae: *Lesquerella kingii* ssp. *bernardina* (San Bernardino Mountains bladderpod)'':
■ i. Removing the words ''*Lesquerella kingii* ssp.'' in the heading and adding, in their place, the words ''*Physaria kingii* subsp.'';
■ ii. In the introductory text of paragraph (2), removing the words ''*Lesquerella kingii* ssp.'' and adding, in their place, the words ''*Physaria kingii* subsp.''; and
■ iii. Revising the introductory text of paragraph (5)(iv); and
■ h. In the entry ''Family Polygonaceae: *Oxytheca parishii* var. *goodmaniana* (Cushenbury oxytheca)'':
■ i. Removing the words ''*Oxytheca parishii*'' in the heading and adding, in their place, the words ''*Acanthoscyphus parishii*'';
■ ii. In the introductory text of paragraph (2), removing the word ''*Oxytheca*'' and adding, in its place, the word ''*Acanthoscyphus*''; and
■ iii. Revising the introductory text of paragraph (4)(xxxi); and
■ i. In the entry ''Family Brassicaceae: *Thlaspi californicum* (Kneeland Prairie penny-cress)'':
■ i. Revising the heading;
■ ii. In the introductory text of paragraph (2), removing the words ''*Thlaspi californicum*'' and adding, in their place, the words ''*Noccaea fendleri* subsp. *californica*'';
■ iii. In paragraph (2)(iv), removing the words ''*Thlaspi californicum*'' and adding, in their place, the words ''*Noccaea fendleri* subsp. *californica*''; and
■ iv. Revising introductory text of paragraph (4)(ii).

The revisions read as follows:

§ 17.96 Critical habitat—plants.

(a) * * *

* * * * *

Family Caryophyllaceae: *Eremogone ursina* (Bear Valley sandwort)

(1) Critical habitat units for *Eremogone ursina* are found in San Bernardino County, California. The maps provided are for informational purposes only. *Note:* The critical habitat units include ''ARUR'' as a unique identifier; ''ARUR'' is the identifier for *Eremogone ursina.*

(2) The primary constituent elements of critical habitat for *Eremogone ursina* are the habitat components that provide:

* * * * *

(5) *Note:* The reference to ''*Arenaria ursina*'' on the map is equivalent to ''*Eremogone ursina*.'' Index map (Map 1) follows:

* * * * *

(6) * * *

(iii) *Note:* The reference to ''*Arenaria ursina*'' on the map is equivalent to ''*Eremogone ursina*.'' Map of Units ARUR 1 and ARUR 2 (Map 2) follows:

* * * * *

(7) * * *

(iii) *Note:* The reference to ''*Arenaria ursina*'' on the map is equivalent to ''*Eremogone ursina*.'' Map of Units ARUR 3 and ARUR 4 (Map 3) follows:

* * * * *

(8) * * *

(ii) *Note:* The reference to ''*Arenaria ursina*'' on the map is equivalent to ''*Eremogone ursina*.'' Map of Unit ARUR 5 (Map 4) follows:

* * * * *

(9) * * *

(iii) *Note:* The reference to ''*Arenaria ursina*'' on the map is equivalent to ''*Eremogone ursina*.'' Map of Units ARUR 6 and ARUR 7 (Map 5) follows:

* * * * *

(10) * * *

(iv) *Note:* The reference to ''*Arenaria ursina*'' on the map is equivalent to ''*Eremogone ursina*.'' Map of Units ARUR 8, ARUR 9, and ARUR 12 (Map 6) follows:

* * * * *

(11) * * *

(iii) *Note:* The reference to ''*Arenaria ursina*'' on the map is equivalent to ''*Eremogone ursina*.'' Map of Units ARUR 10 and ARUR 11 (Map 7) follows:

* * * * *

(12) * * *

(iii) *Note:* The reference to ''*Arenaria ursina*'' on the map is equivalent to ''*Eremogone ursina*.'' Map of Units ARUR 13 and ARUR 14 (Map 8) follows:

* * * * *

(13) * * *

(ii) *Note:* The reference to ''*Arenaria ursina*'' on the map is equivalent to ''*Eremogone ursina*.'' Map of Unit ARUR 15 (Map 9) follows:

* * * * *

(14) * * *

(iii) *Note:* The reference to ''*Arenaria ursina*'' on the map is equivalent to ''*Eremogone ursina*.'' Map of Units ARUR 16 and ARUR 17 (Map 10) follows:

* * * * *

Family Polygonaceae: *Eriogonum kennedyi var. austromontanum* (southern mountain buckwheat)

* * * * *

(5) *Note:* The reference to ''southern mountain wild-buckwheat'' on the map is equivalent to ''southern mountain buckwheat.'' Index map (Map 1) follows:

* * * * *

(6) * * *

(iii) *Note:* The reference to ''southern mountain wild-buckwheat'' on the map is equivalent to ''southern mountain buckwheat.'' Map of Units ERKA 1 and ERKA 2 (Map 2) follows:

* * * * *

(7) * * *

(ii) *Note:* The reference to ''southern mountain wild-buckwheat'' on the map is equivalent to ''southern mountain buckwheat.'' Map of Unit ERKA 3 (Map 3) follows:

* * * * *

(8) * * *

(iii) *Note:* The reference to ''southern mountain wild-buckwheat'' on the map is equivalent to ''southern mountain buckwheat.'' Map of Units ERKA 4 and ERKA 5 (Map 4) follows:

* * * * *

(9) * * *

(iv) *Note:* The reference to ''southern mountain wild-buckwheat'' on the map is equivalent to ''southern mountain buckwheat.'' Map of Units ERKA 6, ERKA 7, and ERKA 10 (Map 5) follows:

* * * * *

(10) * * *

(iii) *Note:* The reference to ''southern mountain wild-buckwheat'' on the map is equivalent to ''southern mountain buckwheat.'' Units ERKA 8 and ERKA 9 (Map 6) follows:

* * * * *

(11) * * *

(iii) *Note:* The reference to ''southern mountain wild-buckwheat'' on the map is equivalent to ''southern mountain buckwheat.'' Units ERKA 11 and ERKA 12 (Map 7) follows:

* * * * *

(12) * * *

(ii) *Note:* The reference to ''southern mountain wild-buckwheat'' on the map is equivalent to ''southern mountain buckwheat.'' Map of Unit ERKA 13 (Map 8) follows:

* * * * *

Family Brassicaceae: Physaria kingii subsp. *bernardina* (San Bernardino Mountains bladderpod)

* * * * *

(5) * * *

(iv) *Note:* The reference to ''*Lesquerella kingii* ssp. *bernardina*'' on the following map is equivalent to ''*Physaria kingii* subsp. *bernardina*.''

* * * * *

Family Polygonaceae: Acanthoscyphus parishii var. *goodmaniana* (Cushenbury oxytheca)

* * * * *

(4) * * *

(xxxi) *Note:* The reference to ''*Oxytheca parishii* var. *goodmaniana*'' on the following map is equivalent to ''*Acanthoscyphus parishii* var. *goodmaniana*'':

* * * * *

Family Brassicaceae: *Noccaea fendleri* subsp. *californica* (Kneeland Prairie pennycress)

* * * * *

(4) * * *

(ii) *Note:* The reference to ''*Thlaspi californicum*'' on the following map is equivalent to ''*Noccaea fendleri* subsp. *californica*'':

* * * * *

Brian Nesvik,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2026–22682 Filed 11–5–26; 8:45 am]

BILLING CODE 4333–15–P

Proposed Rules

Federal Register
Vol. 91, No. 214
Friday, November 6, 2026

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–13801; Project Identifier MCAI–2025–01538–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2024–19–03, which applies to certain Airbus SAS Model A350–941 and –1041 airplanes. AD 2024–19–03 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. Since the FAA issued AD 2024–19–03, the FAA has determined that new or more restrictive airworthiness limitations are necessary. This proposed AD would continue to require certain actions in AD 2024–19–03 and would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by December 21, 2026.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2026–13801; 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 NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this proposed AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.* It is also available at *regulations.gov* under Docket No. FAA–2026–13801.
- 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.

FOR FURTHER INFORMATION CONTACT: Camille Seay, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 817–222–5149; email: *camille.l.seay@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments using a method listed under the **ADDRESSES** section. Include ''Docket No. FAA–2026–13801; Project Identifier MCAI–2025–01538–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to regulations.gov, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Camille Seay, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 817–222–5149; email: *camille.l.seay@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2024–19–03, Amendment 39–22845 (89 FR 82493, October 11, 2024) (AD 2024–19–03), for Airbus SAS Model A350–941 and –1041 airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before November 30, 2023. AD 2024–19–03 was prompted by an MCAI originated by EASA, which is the Technical Agent for the Member States of the European Union. EASA issued EASA AD 2024–0005, dated January 5, 2024 (EASA 2024–0005), to correct an unsafe condition.

AD 2024–19–03 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA issued AD 2024–19–03 to address reduced structural integrity of the airplane. The unsafe condition, if not addressed, could result in loss of structural integrity of the airplane.

Actions Since AD 2024–19–03 Was Issued

Since the FAA issued AD 2024–19–03, EASA superseded EASA AD 2024–0005 with EASA AD 2025–0204, dated September 19, 2025 (EASA AD 2025–0204), for all Airbus SAS Model A350–941 and –1041 airplanes. EASA AD 2025–0204 states that new or more restrictive airworthiness limitations have been developed, as specified in Airbus A350 Airworthiness Limitations Section (ALS) Part 2, Damage Tolerant Airworthiness Limitation Items (DT–ALI), Revision 11, dated July 2, 2025.

EASA also issued EASA AD 2026–0034, dated February 23, 2026 (EASA AD 2026–0034), for all Airbus SAS Model A350–941 and –1041 airplanes. EASA AD 2026–0034 states that new or more restrictive airworthiness limitations have been developed, as specified in Airbus A350 ALS Part 2, Damage Tolerant Airworthiness Limitation Items (DT–ALI), Variation 11.1, dated December 1, 2025.

EASA AD 2026–0034 also specifies that it requires tasks (limitations) already required by EASA AD 2025–0204, and that incorporation of EASA AD 2026–0034 invalidates (terminates) prior instructions for those. Therefore, for this AD where EASA AD 2026–0034 affects the same airworthiness limitations as those in EASA AD 2025–0204, the airworthiness limitations referenced in EASA AD 2026–0034 prevail.

Airplanes with an original airworthiness certificate or original export certificate of airworthiness issued after December 1, 2025, must comply with the airworthiness limitations specified as part of the approved type design and referenced on the type certificate data sheet; this proposed AD therefore does not include those airplanes in the applicability.

The FAA is proposing this AD to address the unsafe condition on these products. You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2026–13801.

Material Incorporated by Reference Under 1 CFR Part 51

EASA AD 2025–0204 specifies new or more restrictive airworthiness limitations for airplane structures and safe life limits.

EASA AD 2026–0034 specifies additional new or more restrictive airworthiness limitations for airplane structures and safe life limits.

This proposed AD would also require EASA AD 2024–0005, which the Director of the Federal Register approved for incorporation by reference as of November 15, 2024 (89 FR 82493, October 11, 2024)..

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

FAA's Determination

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would retain certain requirements of AD 2024–19–03. This proposed AD would also require revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations, which are specified in EASA AD 2025–0204 and EASA AD 2026–0034 already described, as proposed for incorporation by reference. Any differences with EASA AD 2025–0204 and EASA AD 2026–0034 are identified as exceptions in the regulatory text of this proposed AD.

This proposed AD would require revisions to certain operator maintenance documents to include new actions (*e.g.,* inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance (AMOC) according to paragraph (m)(1) of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to retain the Incorporation by Reference (IBR) of EASA AD 2024–0005 and incorporate EASA AD 2025–0204 and EASA AD 2026–0034 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2024–0005, EASA AD 2025–0204, and EASA AD 2026–0034 through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2024–0005, EASA AD 2025–0204, or EASA AD 2026–0034 does not mean that operators need to comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this proposed AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2024–0005, EASA AD 2025–0204, or EASA AD 2026–0034. Material required by EASA AD 2024–0005 is available at *regulations.gov* by searching for and locating Docket No. FAA–2024–1694, and material required by EASA AD 2025–0204 and EASA AD 2026–0034 for compliance will be available at *regulations.gov* by searching for and locating Docket No. FAA–2026–13801 after the FAA final rule is published.

Airworthiness Limitation ADs Using the New Process

The FAA's process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents, such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes airworthiness limitations, the FAA requirements are unchanged. Operators must revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness limitations must be followed according to 14 CFR 91.403(c) and 91.409(e).

The previous format of the airworthiness limitation ADs included a paragraph that specified that no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions and intervals are approved as an AMOC in accordance with the procedures

specified in the AMOCs paragraph under ''Additional AD Provisions.'' This new format includes a ''New Provisions for Alternative Actions and Intervals'' paragraph that does not specifically refer to AMOCs, but operators may still request an AMOC to use an alternative action or interval.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 38 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

The FAA estimates the total cost per operator for the retained actions from AD 2024–19–03 to be $7,650 (90 work-hours × $85 per work-hour).

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

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

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would 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 this proposed regulation:

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

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

(3) Would 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 Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2024–19–03, Amendment 39–22845 (89 FR 82493, October 11, 2024); and

■ b. Adding the following new AD:

Airbus SAS: Docket No. FAA–2026–13801; Project Identifier MCAI–2025–01538–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 21, 2026.

(b) Affected ADs

This AD replaces AD 2024–19–03, Amendment 39–22845 (89 FR 82493, October 11, 2024) (AD 2024–19–03).

(c) Applicability

This AD applies to Airbus SAS Model A350–941 and –1041 airplanes, certificated in any category, with an original airworthiness certificate or original export certificate of airworthiness issued on or before December 1, 2025.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address reduced structural integrity of the airplane. The unsafe condition, if not addressed, could result in loss of structural integrity of the airplane.

(f) Compliance

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

(g) Retained Revision of the Existing Maintenance or Inspection Program, With a New Terminating Action

This paragraph restates the requirements of paragraph (n) of AD 2024–19–03, with a new terminating action. For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before November 30, 2023: Except as specified in paragraph (h) of this AD, comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2024–0005, dated January 5, 2024 (EASA AD 2024–0005). Accomplishing the revision of the existing maintenance or inspection program required by paragraph (j) of this AD terminates the requirements of this paragraph.

(h) Retained Exceptions to EASA AD 2024–0005, With No Changes

This paragraph restates the exceptions specified in paragraph (o) of AD 2024–19–03, with no changes.

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2024–0005.

(2) Paragraph (3) of EASA AD 2024–0005 specifies revising ''the approved AMP,'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after November 15, 2024 (the effective date of AD 2024–19–03).

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2024–0005 is at the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2024–0005, or within 90 days after November 15, 2024 (the effective date of AD 2024–19–03), whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (4) and (5) of EASA AD 2024–0005.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2024–0005.

(i) Retained Provisions for Alternative Actions and Intervals, With a New Exception

This paragraph restates the requirements of paragraph (p) of AD 2024–19–03, with a new exception. Except as required by paragraph (j) of this AD, after the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2024–0005.

(j) New Revision of the Existing Maintenance or Inspection Program

Except as specified in paragraph (k) of this AD: Comply with all required actions and compliance times specified in, and in

accordance with, EASA AD 2025–0204, dated September 19, 2025 (EASA AD 2025–0204); and EASA AD 2026–0034, dated February 23, 2026 (EASA AD 2026–0034). Where EASA AD 2026–0034 affects the same airworthiness limitations as those in EASA AD 2025–0204, the airworthiness limitations referenced in EASA AD 2026–0034 prevail. Accomplishing the revision of the existing maintenance or inspection program required by this paragraph terminates the requirements of paragraph (g) of this AD.

(k) Exceptions to EASA AD 2025–0204 and EASA AD 2026–0034

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2025–0204 and of EASA AD 2026–0034.

(2) Paragraph (3) of EASA AD 2025–0204 and EASA AD 2026–0034 specifies revising the approved aircraft maintenance program (AMP) within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2025–0204 and EASA AD 2026–0034 is at the applicable limitations and associated thresholds as incorporated by the requirements of paragraph (3) of EASA AD 2025–0204 and EASA AD 2026–0034, or within 90 days after the effective date of this AD, whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (4) and (5) of EASA AD 2025–0204.

(5) This AD does not adopt the provisions specified in paragraph (4) of EASA AD 2026–0034.

(6) This AD does not adopt the ''Remarks'' section of EASA AD 2025–0204 and EASA AD 2026–0034.

(l) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2025–0204 and EASA AD 2026–0034.

(m) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, AIR–520, Continued Operational Safety 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 Continued Operational Safety Branch, send it to the attention of the person identified in paragraph (n) of this AD and email to: *AMOC@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, AIR–520, Continued Operational Safety Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(n) Additional Information

For more information about this AD, contact Camille Seay, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 817–222–5149; email: *camille.l.seay@faa.gov*.

(o) Material Incorporated by Reference

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

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

(3) The following material was approved for IBR on [DATE 35 DAYS AFTER PUBLICATION OF THE FINAL RULE].

(i) European Union Aviation Safety Agency (EASA) AD 2025–0204, dated September 19, 2025.

(ii) EASA AD 2026–0034, dated February 23, 2026.

(4) The following material was approved for IBR on November 15, 2024 (89 FR 82493, October 11, 2024).

(i) EASA AD 2024–0005, dated January 5, 2024.

(ii) [Reserved]

(5) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu*. You may find this material on the EASA website at *ad.easa.europa.eu*.

(6) 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.

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

Issued on November 3, 2026.

Brian Knaup,

Acting Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2026–22665 Filed 11–5–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–13803; Project Identifier MCAI–2025–01036–T]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2024–15–04, which applies to certain Dassault Aviation Model FALCON 7X airplanes. AD 2024–15–04 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. Since the FAA issued AD 2024–15–04, the FAA has determined that new or more restrictive airworthiness limitations are necessary. This proposed AD would continue to require certain actions in AD 2024–15–04 and would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by December 21, 2026.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2026–13803; 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 NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this proposed AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.* It is also available at *regulations.gov* under Docket No. FAA–2026–13803.
- 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.

FOR FURTHER INFORMATION CONTACT: Christopher Spencer, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7332; email: *9-AVS-AIR-BACO-COS@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments using a method listed under the **ADDRESSES** section. Include ''Docket No. FAA–2026–13803; Project Identifier MCAI–2025–01036–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Christopher Spencer, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7332; email: *9-AVS-AIR-BACO-COS@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2024–15–04, Amendment 39–22795 (89 FR 73264, September 10, 2024) (AD 2024–15–04), for certain Dassault Aviation Model FALCON 7X airplanes. AD 2024–15–04 was prompted by an MCAI originated by EASA, which is the Technical Agent for the Member States of the European Union. EASA issued EASA AD 2024–0033, dated January 31, 2024 (EASA AD 2024–0033), to correct an unsafe condition.

AD 2024–15–04 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in Dassault Falcon 7X Maintenance Manual, Airworthiness Limitations, Chapter 5–40 (DGT 107838), Revision 12, dated June 2023. The FAA issued AD 2024–15–04 to address reduced structural integrity and reduced control of the airplane due to the failure of system components.

AD 2024–15–04 specifies that accomplishing the revision required by that AD terminates certain requirements of AD 2014–16–23, Amendment 39–17947 (79 FR 52545, September 4, 2014) (AD 2014–16–23). This proposed AD would therefore continue to allow that terminating action.

Actions Since AD 2024–15–04 Was Issued

Since the FAA issued AD 2024–15–04, EASA superseded EASA AD 2024–0033 with EASA AD 2025–0122, dated May 28, 2025, which in turn was superseded by EASA AD 2025–0229, dated October 20, 2025 (EASA AD 2025–0229). Subsequently, EASA superseded EASA AD 2025–0229 with EASA AD 2026–0171, dated September 4, 2026 (EASA AD 2026–0171) (also referred to as the MCAI), for all Dassault Aviation Model FALCON 7X airplanes. Airplanes with an original airworthiness certificate or original export certificate of airworthiness issued after September 1, 2026, must comply with the airworthiness limitations specified as part of the approved type design and referenced on the type certificate data sheet; this proposed AD therefore does not include those airplanes in the applicability. The MCAI states that new or more restrictive airworthiness limitations have been developed, as specified in Dassault Falcon 7X Maintenance Manual, Airworthiness Limitations, Chapter 5–40 (DGT 107838), Revision 15, dated June 2026.

The FAA is proposing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2026–13803.

Material Incorporated by Reference Under 1 CFR Part 51

EASA AD 2026–0171 specifies new or more restrictive airworthiness limitations for airplane structures and safe life limits.

This proposed AD would also require EASA AD 2024–0033, which the Director of the Federal Register approved for incorporation by reference as of October 15, 2024 (89 FR 73264, September 10, 2024).

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

FAA's Determination

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would retain certain requirements of AD 2024–15–04. This proposed AD would also require revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations, which are specified in EASA AD 2026–0171 already described, as proposed for incorporation by reference. Any differences with EASA AD 2026–0171 are identified as exceptions in the regulatory text of this proposed AD.

This proposed AD would require revisions to certain operator

maintenance documents to include new actions (*e.g.,* inspections) and Critical Design Configuration Control Limitations (CDCCLs). Compliance with these actions and CDCCLs is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance (AMOC) according to paragraph (n)(1) of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to retain the Incorporation by Reference (IBR) of EASA AD 2024–0033 and incorporate EASA AD 2026–0171 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2024–0033 and EASA AD 2026–0171 through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2024–0033 or EASA AD 2026–0171 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this proposed AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2024–0033 or EASA AD 2026–0171. Material required by EASA AD 2024–0033 is available at *regulations.gov* by searching for and locating Docket No. FAA–2024–1290, and material required by EASA AD 2026–0171 for compliance will be available at *regulations.gov* by searching for and locating Docket No. FAA–2026–13803 after the FAA final rule is published.

Airworthiness Limitation ADs Using the New Process

The FAA's process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents, such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes airworthiness limitations, the FAA requirements are unchanged. Operators must revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness limitations must be followed according to 14 CFR 91.403(c) and 91.409(e).

The previous format of the airworthiness limitation ADs included a paragraph that specified that no alternative actions (*e.g.,* inspections), intervals, or CDCCLs may be used unless the actions, intervals, and CDCCLs are approved as an AMOC in accordance with the procedures specified in the AMOCs paragraph under ''Additional AD Provisions.'' This new format includes a ''New Provisions for Alternative Actions, Intervals, and CDCCLs'' paragraph that does not specifically refer to AMOCs, but operators may still request an AMOC to use an alternative action, interval, or CDCCL action or interval.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 161 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

The FAA estimates the total cost per operator for the retained actions from AD 2024–15–04 to be $7,650 (90 work-hours × $85 per work-hour).

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

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

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would 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 this proposed regulation:

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

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

(3) Would 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 Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2024–15–04, Amendment 39–22795 (89 FR 73264, September 10, 2024); and

■ b. Adding the following new AD:

Dassault Aviation: Docket No. FAA–2026–13803; Project Identifier MCAI–2025–01036–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 21, 2026.

(b) Affected ADs

(1) This AD replaces AD 2024–15–04, Amendment 39–22795 (89 FR 73264, September 10, 2024) (AD 2024–15–04).

(2) This AD affects AD 2014–16–23, Amendment 39–17947 (79 FR 52545, September 4, 2014) (AD 2014–16–23).

(c) Applicability

This AD applies to Dassault Aviation Model FALCON 7X airplanes, certificated in any category, with an original airworthiness certificate or original export certificate of airworthiness issued on or before September 1, 2026.

Note 1 to paragraph (c): Model FALCON 7X airplanes with modification M1000 incorporated are commonly referred to as ''Model FALCON 8X'' airplanes as a marketing designation.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address reduced structural integrity and reduced control of the airplane due to the failure of system components.

(f) Compliance

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

(g) Retained Revision of the Existing Maintenance or Inspection Program, With a New Terminating Action

This paragraph restates the requirements of paragraph (j) of AD 2024–15–04, with a new terminating action. For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before September 7, 2023, except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2024–0033, dated January 31, 2024 (EASA AD 2024–0033). Accomplishing the revision of the existing maintenance or inspection program required by paragraph (j) of this AD terminates the requirements of this paragraph.

(h) Retained Exceptions to EASA AD 2024–0033, With No Changes

This paragraph restates the exceptions specified in paragraph (k) of AD 2024–15–04, with no changes.

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2024–0033.

(2) Paragraph (3) of EASA AD 2024–0033 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after October 15, 2024 (the effective date of AD 2024–15–04).

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2024–0033 is at the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2024–0033, or within 90 days after October 15, 2024 (the effective date of AD 2024–15–04), whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (4) and (5) of EASA AD 2024–0033.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2024–0033.

(i) Retained Restrictions on Alternative Actions, Intervals, and Critical Design Configuration Control Limitations (CDCCLs), With a New Exception

This paragraph restates the requirements of paragraph (l) of AD 2024–15–04, with a new exception. Except as required by paragraph (j) of this AD, after the maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections), intervals, or CDCCLs are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2024–0033.

(j) New Revision of the Existing Maintenance or Inspection Program

Except as specified in paragraph (k) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2026–0171, dated September 4, 2026 (EASA AD 2026–0171). Accomplishing the revision of the existing maintenance or inspection program required by this paragraph terminates the requirements of paragraph (g) of this AD.

(k) Exceptions to EASA AD 2026–0171

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2026–0171.

(2) Paragraph (3) of EASA AD 2026–0171 specifies revising the approved aircraft maintenance program (AMP) within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2026–0171 is at the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2026–0171, or within 90 days after the effective date of this AD, whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (4) and (5) of EASA AD 2026–0171.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2026–0171.

(l) New Provisions for Alternative Actions, Intervals, and CDCCLs

After the existing maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (*e.g.,* inspections), intervals, and CDCCLs are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2026–0171.

(m) Terminating Action for Certain Requirements of AD 2014–16–23

Accomplishing the actions required by paragraphs (g) or (j) of this AD terminates the requirements of paragraph (q) of AD 2014–16–23.

(n) Additional AD Provisions

The following provisions also apply to this AD:

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

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

(o) Additional Information

For more information about this AD, contact Christopher Spencer, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7332; email: *9-AVS-AIR-BACO-COS@faa.gov.*

(p) Material Incorporated by Reference

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

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

(3) The following material was approved for IBR on [DATE 35 DAYS AFTER PUBLICATION OF THE FINAL RULE].

(i) European Union Aviation Safety Agency (EASA) AD 2026–0171, dated September 4, 2026.

(ii) [Reserved]

(4) The following material was approved for IBR on October 15, 2024 (89 FR 73264, September 10, 2024).

(i) EASA AD 2024–0033, dated January 31, 2024.

(ii) [Reserved]

(5) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*

(6) 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.

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

Issued on November 3, 2026.

Steven W. Thompson,

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

[FR Doc. 2026–22664 Filed 11–5–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2026–12541; Airspace Docket No. 26–AWP–11]

RIN 2120–AA66

Establishment of Class E Airspace, Shelter Cove Airport, Shelter Cove, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish a Class E airspace area extending upwards from 700 feet above the surface of the earth at Shelter Cove Airport (K0Q5), Shelter Cove, CA. K0Q5 is transitioning from a visual flight rules (VFR) to an instrument flight rules (IFR) airport. Additionally, this action would establish a controlled airspace area for the airport, providing coverage to arriving IFR aircraft descending below 1,500 feet above the surface and departing IFR aircraft until reaching 1,200 feet above the surface.

DATES: Comments must be received on or before December 21, 2026.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2026–12541 and Airspace Docket No. 26–AWP–11 using any of the following methods:

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

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W58–213, West Building, 5th Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W58–213 of the West Building, 5th 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.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W58–213 of the West Building, 5th Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11M, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/*. You may also contact the Airspace Regulation Group, Policy Directorate, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Keith T. Adams, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–2428.

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 area for Shelter Cove Airport, Shelter Cove, CA.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy*.

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/*.

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the office of the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198.

Incorporation by Reference

Class E5 airspace areas 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 proposes to amend the current version of that order, FAA Order JO 7400.11M, dated July 30, 2026, and effective September 15, 2026. These updates would be published in the next update to FAA Order JO 7400.11. FAA Order JO

7400.11M, which lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points, is publicly available as listed in the **ADDRESSES** section of this document.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to establish a Class E airspace area extending upward from 700 feet above the surface of the earth at Shelter Cove Airport, Shelter Cove, CA.

K0Q5 is establishing an Area Navigation (RNAV) (Global Positioning System [GPS])-A approach procedure to allow IFR operations at the airport below basic VFR weather minimums. The FAA proposes to establish a Class E airspace area extending upward from 700 feet above the surface to assist IFR aircraft on the instrument approach procedure descending below 1,500 feet above the surface. The proposed Class E airspace area would also accommodate the RNAV (GPS)-A approach missed approach segment until the aircraft reaches 1,200 feet above the surface.

Additionally, K0Q5 is establishing an instrument obstacle departure procedure allowing IFR aircraft to depart between the northwest counterclockwise to the south of the airport. The FAA proposes to establish a Class E airspace area extending upwards from 700 feet above the surface to accommodate departing IFR aircraft climbing to 1,200 feet above the surface.

The establishment of the proposed K0Q5's Class E airspace area would assist IFR aircraft transitioning within the enroute and terminal environments of the national airspace system.

Regulatory Notices and Analyses

The FAA has determined that this proposed 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 Order 2100.6B, ''Rulemaking and Guidance Procedure'' (March 10, 2025); and (3) is expected to result in, at most, de minimis costs from compliance with applicable operating requirements or minor flight rerouting for operators choosing to navigate around the controlled airspace. Since these proposed amendments are routine and the expected impact to operators is de minimis, the FAA certifies that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1G, ''FAA National Environmental Policy Act Implementing Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 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 7400.11M, Airspace Designations and Reporting Points, dated July 30, 2026, and effective September 15, 2026, is amended as follows:

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

* * * * *

AWP CA E5 Shelter Cove, CA [New]

Shelter Cove Airport, CA
(Lat. 40°01′41″ N, long. 124°04′28″ W)

That airspace extending upward from 700 feet above the surface within a 3.7-mile radius of the airport, within a 5.8-mile radius between the airport's 149° bearing clockwise to 300° bearing, and within 1 mile north and 1.1 miles either side of the airport's 149° bearing extending 6.6 miles southeast.

* * * * *

Issued in Des Moines, Washington, on October 27, 2026.

B.G. Chew,

Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2026–22667 Filed 11–5–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2026–1338]

RIN 1625–AA09

Drawbridge Operation Regulation; Harlem River, Between the Boroughs of Manhattan and the Bronx, New York City, New York

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to temporarily modify the operating regulation that governs the Macombs Dam Bridge across the Harlem River, mile 3.2, between the Boroughs of Manhattan and the Bronx, New York City, New York. The bridge owner, New York City Department of Transportation (NYCDOT), submitted a request on August 31, 2026, to allow the bridge to remain in the closed position from February 1, 2027, through November 30, 2027, and facilitate rehabilitation of the bridge structure. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before December 7, 2026.

The Coast Guard anticipates that this proposed rule will be effective from 12:01 a.m. on February 1, 2027, through 11:59 p.m. on November 30, 2027.

ADDRESSES: You may submit comments identified by docket number USCG–2026–1338 at *https://www.regulations.gov.*

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments. This notice of proposed rulemaking with its plain-language, 100-word-or-less proposed rule summary will be available in this same docket.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Donna D. Leoce, Northeast Coast Guard District, Bridge Management Specialist, telephone number (571) 613–2415, email *Donna.D.Leoce@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
OMB Office of Management and Budget
NPRM Notice of Proposed Rulemaking
§ Section
U.S.C. United States Code

NYCDOT New York City Department of Transportation

II. Background, Purpose and Legal Basis

The Macombs Dam Bridge across the Harlem River, between the Boroughs of the Bronx and Manhattan, New York, at mile 3.2, owned and operated by NYCDOT, has a vertical clearance of 28.2 feet above mean high water when closed, unlimited when open, and a horizontal clearance of 164 feet. The proposed temporary regulation will allow the bridge to remain in the closed position from 12:01 a.m. February 1, 2027, through 11:59 p.m. November 30, 2027. The modification of the bridge schedule will allow NYCDOT to perform necessary rehabilitation to the structure of the 131-year-old bridge to ensure its safety.

Commercial vessels, including small passenger vessels and marine construction support vessels, and recreational vessels transit the Harlem River in the vicinity of the bridge. Under this proposed rule, commercial and recreational vessels that regularly use the Harlem River can still transit under the bridge in the closed position. Vessels requiring higher vertical clearance can also access the Harlem River through the waterway's confluences with the East River to the east and the Hudson River to the west. NYCDOT briefed their proposed modification of the bridge's operating schedule to the Port of New York and New Jersey Harbor Safety, Navigation, and Operations Committee. This committee, comprised of representatives of major segments of waterway users, did not object to NYCDOT's proposal.

The existing operating schedule is listed in 33 CFR 117.789(b)(1). Currently, the Macombs Dam Bridge opens on signal with at least a four-hour advance notice and does not need to open for the passage of vessel traffic from 6 a.m. to 9 a.m. and 5 p.m. to 7 p.m. Monday through Friday except federal holidays.

NYCDOT requests a modification of 33 CFR 117.789(b)(1) to allow the bridge to remain in the closed position from February 1, 2027, through November 30, 2027, while a work platform system is in place under the bridge deck to perform necessary structural rehabilitation. The work platform will reduce the vertical clearance of the bridge to no less than 24.5 feet above Mean High Water in the closed position. The platform will not obstruct the operation of the bridge's navigation lights.

III. Discussion of Proposed Rule

We propose to temporarily modify the drawbridge operating schedule in 33 CFR 117.789(b)(1) for the Macombs Dam Bridge, at mile 3.2. The proposed rule would allow the bridge to remain in the closed position from February 1, 2027, through November 30, 2027, while a work platform system is in place under the bridge deck to perform necessary structural rehabilitation. Commercial and recreational vessels that regularly use the Harlem River can still transit under the bridge given in the closed position. Vessels requiring higher vertical clearance can also access the Harlem River through the waterway's confluences with the East River to the east and the Hudson River to the west.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on these statutes and Executive Orders.

A. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities for the following reasons. Commercial and recreational vessels that regularly use the Harlem River can still transit under the bridge given in the closed position. Vessels requiring higher vertical clearance can also access the Harlem River through the waterway's confluences with the East River to the east and the Hudson River to the west.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

B. Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

C. Federalism and Indian Tribal Governments

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

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

D. Unfunded Mandates Reform Act

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

E. Environment

We have analyzed this rule under Department of Homeland Security

Management Directive 023–01, Rev.1, associated implementing instructions, and Environmental Planning Policy COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f). The Coast Guard has determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule promulgates the operating regulations or procedures for drawbridges. Normally such actions are categorically excluded from further review, under paragraph L49, of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are required for this rule. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2026–1338 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. Also, if you go to the online docket and sign up for email alerts through the ''Subscribe'' option, you will be notified when comments/updates are posted, or a final rule is published.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and DHS Delegation No. 00170.1. Revision No. 1.04.

■ 2. Revise § 117.789 by adding paragraph (e) to read as follows:

§ 117.789 Harlem River

* * * * *

(e) The draw of the Macombs Dam Bridge, mile 3.2, need not open for the passage of vessels from 12:01 a.m. on February 1, 2027, through 11:59 p.m. on November 30, 2027.

Matthew Lake,

Rear Admiral (lower half), U.S. Coast Guard, Commander, Northeast Coast Guard District.

[FR Doc. 2026–22734 Filed 11–5–26; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

RIN 0648–BO62

Fisheries of the Exclusive Economic Zone Off Alaska; Amendment 128 to the FMP for Groundfish of the Bering Sea and Aleutian Islands Management Area and Amendment 116 to the FMP for the Groundfish Fisheries of the Gulf of Alaska; Small Sablefish Release

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

ACTION: Notice of availability; request for comments.

SUMMARY: The North Pacific Fishery Management Council (Council) submitted amendment 128 to the Fishery Management Plan (FMP) for Groundfish of the Bering Sea and Aleutian Islands Management Area (BSAI FMP) and amendment 116 to the FMP for Groundfish fisheries of the Gulf of Alaska (GOA FMP) to the Secretary of Commerce for review. If approved, these amendments would increase operational flexibility to allow vessels fishing for sablefish with fixed gear under the Individual Fishing Quota (IFQ) Program or Western Alaska Community Development (CDQ) Program to release sablefish and would revise the annual allocation process to account for sablefish discards. This action is intended to promote the goals and objectives of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the BSAI and GOA FMPs, and other applicable laws.

DATES: Submit comments on or before January 5, 2027.

ADDRESSES: A plain language summary of this proposed action is available at *https://www.regulations.gov/docket/NOAA-NMFS-2026-2542.* You may submit comments on this document, identified by NOAA–NMFS–2026–2542, by either of the following methods:

- *Electronic Submission:* Submit electronic public comments via the Federal e-Rulemaking Portal. Visit *https://www.regulations.gov* and type NOAA–NMFS–2026–2542 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Gretchen Harrington, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

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), 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.

Electronic copies of amendment 128 to the BSAI FMP, amendment 116 to the GOA FMP, the Draft Environmental

Assessment/Regulatory Impact Analysis for Proposed Amendment 128 to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area and Proposed Amendment 116 to the Fishery Management Plan for Groundfish fisheries of the Gulf of Alaska Release of IFQ/CDQ Sablefish (referred to as the ''Analysis''), and the draft finding of no significant impact prepared for this action are available from *https://www.regulations.gov* with a search for 0648–BO62 or from the NMFS Alaska Region website at *https://www.fisheries.noaa.gov/region/alaska.*

FOR FURTHER INFORMATION CONTACT: Mason Smith, 907–586–7228, *mason.smith@noaa.gov*.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Act requires that each regional fishery management council submit any FMP amendment it prepares to NMFS for review and approval, disapproval, or partial approval by the Secretary of Commerce. The Magnuson-Stevens Act also requires that NMFS, after a council's transmittal of an FMP amendment, immediately publish a notice in the **Federal Register** announcing that the amendment is available for public review and comment. This notice announces that proposed amendment 128 to the BSAI FMP and proposed amendment 116 to the GOA FMP are available for public review and comment.

Sablefish (*Anoplopoma fimbria*) is managed as a groundfish species under the BSAI FMP and GOA FMP. The Council prepared, and the Secretary of Commerce (Secretary) approved, the BSAI FMP and GOA FMP under the authority of the Magnuson-Stevens Act, 16 U.S.C. 1801 *et seq.* Regulations governing U.S. fisheries and implementing the BSAI FMP and GOA FMP appear at 50 CFR parts 600 and 679.

The directed sablefish fishery in Alaska is managed under the IFQ Program established in 1995 (58 FR 59375, November 9, 1993). The IFQ Program allocates a specific portion of the non-trawl total allowable catch (TAC) to individual fishermen or groups, known as quota share owners. Fishermen are then issued individual quotas, dictating the amount of sablefish they are allowed to catch over the fishing season. Issuance of quota shares under the IFQ Program was originally based on participation in the fisheries during historical qualifying periods. However, quota share is transferable and new fishery participants can purchase quota share or lease IFQ. Quota shares and the resulting IFQ are designated for specific geographic IFQ regulatory areas and vessel categories, which authorize harvest by vessels of different size categories or harvesting and processing activity as specified in regulations at § 679.40(a)(5). This system aims to prevent overfishing, reduce bycatch, and provide economic stability for fishermen.

The CDQ Program is an economic development program associated with federally managed fisheries in the BSAI management area (57 FR 54936, November 23, 1992). The purposes of the CDQ Program are (1) to provide eligible western Alaska villages with the opportunity to participate and invest in fisheries in the BSAI management area; (2) to support economic development in western Alaska; (3) to alleviate poverty and provide economic and social benefits for residents of western Alaska; and (4) to achieve sustainable and diversified local economies in western Alaska (16 U.S.C. 1855(i)(1)(A)). The CDQ Program consists of six different non-profit managing organizations (CDQ groups) representing different geographical regions in Alaska. The CDQ Program receives annual allocations of TAC for a variety of commercially valuable species in the BSAI groundfish, crab, and halibut fisheries, which are in turn allocated among the CDQ groups. Each year, prior to establishing the IFQ allocations, NMFS allocates a percentage of the fixed gear TAC in the BSAI to the CDQ Program for use in each subarea.

Beginning in 2014, there have been several years with record-breaking year classes of Alaska sablefish. By 2017, these fish had grown large enough to be caught by the commercial fleet as an overwhelming number of small fish. Juvenile sablefish tend to be smaller in size and yield a lower commercial value by weight than large fish, particularly under current market conditions. Because of the lower prices resulting from large catches of small sablefish, stakeholders appealed for management action to provide relief from the prohibition on discarding sablefish in the fixed gear sablefish IFQ fleet. Sections 3.7.1.7 of the BSAI and GOA FMPs prohibit discarding of sablefish by persons holding sablefish IFQs and those fishing under the CDQ Program.

The Council recommended amendment 128 to the BSAI FMP and amendment 116 to the GOA FMP in April 2025. These amendments would (1) revise retention requirements to allow discards of small sablefish by catcher vessels (CVs) in the IFQ and CDQ programs as authorized in regulations, (2) revise retention requirements to allow discards of sablefish by catcher/processors (C/Ps) in the CDQ Program, (3) require all sablefish discarded by vessels in the IFQ and CDQ Programs to be carefully released as specified in regulation, (4) revise the methods for determining annual IFQs to account for a sablefish discard allowance (SDA) for the BSAI and an SDA for the GOA, and (5) make non-substantive technical edits to revise the use of ''freezer longliner'' language to refer to category A quota shares and C/Ps to increase alignment with Federal regulations. As a housekeeping measure, Amendment 116 would additionally remove unnecessary language referring to the CDQ Program in the GOA FMP.

These amendments would modify the sablefish discard prohibition to allow discards of small sablefish by CVs using fixed gear. These amendments would allow C/Ps participating in the fixed gear sablefish CDQ fishery to discard sablefish by excluding them from the revised prohibition on discarding, while retaining the status quo for C/Ps participating in the fixed gear sablefish IFQ fishery to continue to discard sablefish. These amendments would establish an SDA for the BSAI and an SDA for the GOA to account for projected discard mortality of sablefish by fixed gear vessels engaged in fishing for sablefish in the IFQ and CDQ programs. Annually, the SDA would be deducted from the fixed gear TAC after any CDQ adjustments, as described in regulations, and prior to deriving sablefish IFQ. A discard mortality rate (DMR) would be recommended by the Council's Scientific and Statistical Committee and would be used to account for discard mortality towards the SDA throughout the fishery season. DMRs are estimates of the proportion of sablefish bycatch that do not survive after being returned to the sea. The cumulative sablefish mortality that accrues to the SDA is the product of a DMR multiplied by the estimated number of discarded sablefish.

These amendments are expected to have a positive impact on private sector harvesters participating in the fixed gear IFQ or CDQ sablefish fisheries due to the increased flexibility in retaining higher value fish. Because the fixed gear sablefish TAC has historically been fully allocated to the IFQ and CDQ sablefish fisheries due to the full retention requirements, the proportional SDA deductions from the regulatory area TACs would be necessary to provide a buffer mechanism to avoid exceeding the TACs. It is necessary to establish a separate SDA to account for vessel level discard estimates because accounting

for discards against IFQ permits issued is not possible.

These amendments would make housekeeping changes to revise the use of ''Freezer Longliner'' language to refer instead to category A quota shares and C/Ps, and update initial issuance language from the 1990s. These non-substantive technical changes would update language used in the FMP to increase alignment with Federal regulations. Currently, the BSAI and GOA FMPs define ''Freezer Longliner'' as, ''any vessel engaged in fishing in the fixed gear fishery which, during a given trip, utilizes freezer capacity and delivers some or all of its groundfish catch in a frozen state,'' and designates vessel categories, transfer provisions, and use and ownership provisions based on that term. To align with Federal regulations and common usage, the term ''Freezer Longliner'' would be expanded to include the term ''Catcher/processor,'' which is defined in regulations as a vessel that is used for catching fish and processing that fish (50 CFR 679.2). Additionally, for these vessels, the designation of vessel categories, transfer provisions, and use and ownership provisions will be specified as ''category A quota shares,'' which authorize an IFQ permit holder to harvest and process IFQ species on a vessel of any length (50 CFR 679.40(a)(5)(ii)(A)).

NMFS is soliciting public comments on the proposed amendment 128 to the BSAI FMP and proposed amendment 116 to the GOA FMP through the end of the comment period (see **DATES**). NMFS intends to publish in the **Federal Register** and seek public comment on a proposed rule that would implement amendments 128 and 116, following NMFS's evaluation of the proposed rule under the Magnuson-Stevens Act.

Respondents do not need to submit the same comments on amendment 128 to the BSAI FMP and amendment 116 to the GOA FMP and the proposed rule. All relevant written comments received by the end of the comment period for this notice will be considered by NMFS in the approval/disapproval decision for amendment 128 to the BSAI FMP and amendment 116 to the GOA FMP and also considered in the decision on the proposed rule and addressed in the response to comments in the final decision on the proposed rule. Comments received after the end of the comment period for this rule will not be considered in the approval/disapproval decision on amendment 128 to the BSAI FMP and amendment 116 to the GOA FMP. To be considered, comments must be received, not just postmarked or otherwise transmitted, by the last day of the comment period (see **DATES**).

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

Dated: November 4, 2026.

Shannon Bettridge,

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

[FR Doc. 2026–22695 Filed 11–5–26; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 91, No. 214
Friday, November 6, 2026

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; 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; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and 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 December 7, 2026 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.

Food and Nutrition Administration

Title: USDA Professional Standards Training Tracker Tool (PSTTT).

OMB Control Number: 0584–0626.

Summary of Collection: This is a reinstatement of an expired information collection request. Section 306 of the Healthy Hunger-Free Kids Act of 2010 (HHFKA) requires Professional Standards for state and local school district nutrition professionals. In addition to hiring standards, mandatory annual training is required for all individuals involved in preparing school meals. To meet the training requirements and assist in locating and keeping track of training, the USDA FNA's web-based application tool with a SQL-server database is available to local educational agencies and school food authorities through the FNA public website. While training requirements are mandatory, using the USDA PSTTT to track the training is voluntary. State and local school district nutrition professionals can use any method to track and manage their training. These resources facilitate compliance with HHFKA requirements and are provided at no cost to the state, district, or school nutrition professionals.

Need and Use of the Information: State and school nutrition professionals can use the PSTTT to keep track of their training courses, learning objectives, and training hours, in accordance with HHFKA requirements. State reviewers can run reports from the PSTTT that they can use in preparation for Administrative Reviews that are conducted onsite at the school food authorities.

Description of Respondents: State, Local, or Tribal Government.

Number of Respondents: 10,006.

Frequency of Responses: Reporting: On occasion; Quarterly; Annually; Weekly; Monthly.

Total Burden Hours: 17,090.

Food and Nutrition Administration

Title: Federal Collection Methods for Supplemental Nutrition Assistance Program Recipient Claims.

OMB Control Number: 0584–0446.

Summary of Collection: This is a reinstatement of an expired information collection request. FNA is still legally required to collect this data and thereby continuing to collect it in violation of the Paperwork Reduction Act. Section 13(b) of the Food and Nutrition Act of 2008 (the Act), as amended (7 U.S.C. 2022(b)), and SNAP regulations at 7 CFR 273.18 require State agencies to refer all delinquent SNAP debts to another Federal government entity as third-party disclosure reporting to U.S. Department of the Treasury (Treasury) for collection. The Debt Collection Improvement Act of 1996 (DCIA) (Pub. L. 104–134), as amended by the Digital Accountability and Transparency Act of 2014 (Pub. L. 113–101), requires that these debts be referred to Treasury for collection when they are 120 days or more delinquent. The Treasury Offset Program (TOP), 31 CFR part 285, intercepts and offsets payments such as Federal income tax refunds and Federal salaries and applies the offset to the delinquent debt. The amount or percentage that can be offset from any payment type is set by.

Need and Use of the Information: The information is used to satisfy the requirements at Section 13(b) of the Act, as amended (7 U.S.C. 2022(b)), and SNAP regulations at 7 CFR 273.18, which requires State agencies to refer delinquent SNAP debts to Treasury for collection and notify debtors.

SNAP regulations at 7 CFR 273.18 require that State agencies establish, collect, and efficiently manage SNAP recipient claims within 120 days. Text at 7 CFR 273.18(n)(1) states that State agencies must submit debts to TOP when they are 180 days delinquent or more. However, DCIA updated this timeframe to require that eligible delinquent debts be referred to TOP within 120 days. While SNAP regulations have not yet been updated to reflect this change, States must comply with the 120-day timeframe. State agencies must submit files containing these delinquent debts to FNA weekly, which FNA then consolidates into one file and sends to Treasury each week.

The information collected under this request is used to assist:

(1) State agencies to identify eligible debts to send to TOP, request addresses for TOP notices, send TOP notices to debtors, and give due process,

(2) FNS forward files to Treasury for action and to provide Federal-level due process, and to ensure that collections are received and applied to the appropriate debt,

(3) Treasury to intercept Federal payments and offset debts, and

(4) Debtors receive, read, and respond to TOP notices.

Description of Respondents: State, Local, or Tribal Government.

Number of Respondents: 272,214.

Frequency of Responses: Reporting: On occasion; Quarterly; Annually; Weekly; Monthly.

Total Burden Hours: 46,490.

Rachelle Ragland-Greene,

Departmental Information Collection Clearance Officer.

[FR Doc. 2026–22674 Filed 11–5–26; 8:45 am]

BILLING CODE 3410–30–P

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 required regarding; 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; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and 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 December 7, 2026 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.

Farm Service Agency

Title: Farm Loan Programs—Guaranteed Farm Loan.

OMB Control Number: 0560–0155.

Summary of Collection: FSA requests a revision of the currently approved information collection to include automated data collection of information through the ProsperUS Platform. FLP administers to make and service loans guaranteed to the eligible farmers and ranchers to comply with the regulations of 7 CFR part 762, Guaranteed Farm Loans and 7 CFR part 763, Land Contract Guaranteed Loans. The loans made and serviced include farm operating and farm ownership loans. FSA also provides guarantees of loans made by private sellers of a farm or ranch on a land contract sales basis; although this program is rarely used. The reporting requirements imposed on the public by the regulations at 7 CFR part 762 and 7 CFR part 763 are necessary to administer the Farm Loan Program guaranteed loan program. For the following estimated total annual burden on respondents, the formula used to calculate the total burden hours is the estimated average time per response multiplied by the estimated total annual responses.

Need and Use of the Information: FSA uses the forms and written evidence to collect needed information. The objective of the guaranteed loan program is to provide credit to applicants who are unable to obtain credit from lending institutions without a guarantee. The information collected is used to determine lender and loan applicant eligibility for farm loan guarantees, and to ensure the lender protects the Government's financial interest. The information FSA collects is needed to effectively administer the FSA guaranteed farm loan programs. The information is collected by the FSA loan official in consultation with participating lenders.

Description of Respondents: Businesses or other for-profits and Farms.

Estimated Number of Respondents: 5,072.

Frequency of Responses: Reporting: Other (when applying for loans).

Estimated Total Annual Burden on Respondents: 125,311 hours.

Rachelle Ragland-Greene,

Departmental Information Collection Clearance Officer.

[FR Doc. 2026–22709 Filed 11–5–26; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Section 232 National Security Adjustments to Imports of Specialty Pharmaceuticals and Associated Ingredients

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites 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. The purpose of this notice is to allow for 60 days of public comment on the OMB approved emergency collection for the Temporary Final Rule ''*Section 232 National Security Adjustments to Imports of Specialty Pharmaceuticals and Associated Ingredients*'' September 23, 2026, (91 FR 60360).

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before January 5, 2027.

ADDRESSES: Interested persons are invited to submit comments by email to Nancy Kook, IC Liaison, Bureau of Industry and Security, at *PRA@bis.doc.gov* or to *PRAcomments@doc.gov.* Please reference OMB Control Number 0694–0150 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Nancy Kook, IC Liaison, Bureau of Industry and Security, phone 202–482–2440 or by email at *PRA@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

On April 1, 2025, Commerce initiated an investigation to determine the effects on the national security of imports of pharmaceuticals and pharmaceutical ingredients under Section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862). Section 232 provides authority for Commerce to

conduct investigations to determine the effects of imports of an article on the national security of the United States and for the President to adjust the imports of the article and its derivatives based on such an investigation and an affirmative determination that the article is being importing into the United States in such quantities or under such circumstances as to threaten to impair the national security of the United States.

On April 2, 2026, following the completion of the above investigation, the President issued Presidential Proclamation 11020 entitled ''Adjusting Imports of Pharmaceuticals and Pharmaceutical Ingredients Into the United States'' which imposed ad valorem tariffs on imports of certain patented pharmaceuticals and associated pharmaceutical ingredients. The Proclamation also directed a tariff rate of zero percent for certain designated specialty pharmaceutical products and their associated pharmaceutical ingredients, provided that Commerce (in consultation with the Office of the U.S. Trade Representative and Health & Human Services) determines that the products are either products of a jurisdiction that has a current or forthcoming trade and security framework agreement with the United States or otherwise meet an urgent health need in the United States. The President determined that these actions were necessary to address the affirmative determination by Commerce that imports of pharmaceuticals and pharmaceutical ingredients posed a threat to the national security of the United States.

Commerce will be required to collect certain critical information from companies seeking to obtain the ad valorem tariff rate of zero percent for imports of specialty pharmaceutical products and their associated pharmaceutical ingredients that meet an urgent health need in the United States. These collection requirements include organization information, a description of the imported product (including HTSUS Classification, Country of Origin, and Importer of Record) and a detailed rationale of how the imported product meets an urgent health need in the United States (including information such as the type of disease treated and an assessment of alternative therapies or lack of alternative therapies for the type of disease the product treats, the number of domestic patients) as well as other information required to substantiate the applications under Section 232, hereby referenced as Urgent Health Need Requests. This information will be submitted via email to Commerce. The materials are reviewed by Commerce before receiving a final determination by the Secretary.

II. Method of Collection

Electronic

III. Data

OMB Control Number: 0694–0150.

Type of Information Collection: Regular submission.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 250.

Average Responses per Year: 1.

Average Number of Responses: 250.

Estimated Time per Response: 8 hours.

Estimated Total Annual Burden Hours: 2,000 hours.

Respondent's Obligation: Voluntary.

Legal Authority: Section 232 of the Trade Expansion Act of 1962 (19 U.S.C. 1862).

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

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

[FR Doc. 2026–22725 Filed 11–5–26; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Application Process To Waive the Import Qualification Criteria Measures To Restrict Stockpiling of Polysilicon and Polysilicon Derivatives

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites 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. The purpose of this notice is to allow for 60 days of public comment on the OMB approved emergency collection for the Temporary Final Rule ''*Measures To Restrict Stockpiling of Polysilicon and Polysilicon Derivatives Under Proclamation 11052*'' (September 24, 2026, 91 FR 60505).

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before January 5, 2027.

ADDRESSES: Interested persons are invited to submit comments by email to Nancy Kook, IC Liaison, Bureau of Industry and Security, at *PRA@bis.doc.gov* or to *PRAcomments@doc.gov*). Please reference OMB Control Number 0694–0149 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Nancy Kook, IC Liaison, Bureau of Industry and Security, phone 202–482–2440 or by email at *PRA@bis.doc.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

On August 6, 2026, the President issued Proclamation 11052 (91 FR 51975), ''Adjusting Imports of Polysilicon and Its Derivatives into the United States,'' finding that imports of polysilicon and polysilicon derivatives threatened to impair the national security of the United States. Based on

that finding, the President imposed minimum import prices (MIP) and tariffs on imports of Polysilicon Products pursuant to Section 232 of the Trade Expansion Act of 1962, as amended, 19 U.S.C. 1862 (Section 232).

Consistent with Proclamation 11052, Commerce established an import qualification process for all existing importers of record (IOR) of these polysilicon and polysilicon derivatives. Commerce is requiring IORs seeking to apply for waivers of the Polysilicon Product import qualification criteria to submit details on the usages of Polysilicon Products, estimates of the anticipated type and volume of imports into the United States, and other information required to substantiate the applications for relief. This information is submitted via email to Commerce and the material is reviewed by Commerce before receiving a final determination by the Secretary.

II. Method of Collection

Electronic

III. Data

OMB Control Number: 0694–0149.

Type of Information Collection: Regular submission.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 165.

Average Responses per Year: 1.

Average Number of Responses: 165.

Estimated Time per Response: 2 hours.

Estimated Total Annual Burden Hours: 330 hours.

Respondent's Obligation: Voluntary.

Legal Authority: Presidential Proclamation 11052 (91 FR 51975), Adjusting Imports of Polysilicon and Its Derivatives into the United States.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

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

[FR Doc. 2026–22726 Filed 11–5–26; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

Northwestern University and Cornell University et. al, Notice of Decision on Application for Duty-Free Entry of Scientific Instruments

This is a decision pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, as amended by Pub. L. 106–36; 80 Stat. 897; 15 CFR part 301). On September 4, 2026, the Department of Commerce published a notice in the **Federal Register** requesting public comment on whether instruments of equivalent scientific value, for the purposes for which the instruments identified in the docket(s) below are intended to be used, are being manufactured in the United States. *See Northwestern University and Cornell University et. al; Application(s) for Duty-Free Entry of Scientific Instruments* 91 FR 56858, September 4, 2026. We received no public comments.

Comments: None received. Decision: Approved. We know of no instrument of equivalent scientific value to the foreign instrument described below, for such purposes as this is intended to be used, that was being manufactured in the United States at the time of order.

Docket No.	Applicant	Instrument
26–008	Northwestern University and Cornell University	Upgrade Parts for Cryostat.
26–019	The University of Michigan, Ann Arbor	Single frequency 652 nm VECSEL laser.
26–035	The University of Texas at Austin	Dilution refrigerator system LD400.
26–041	Rice University	Model BF–LD250 Cryogen-free refrigerator system.
26–049	Cornell University	Dilution refrigerator.
26–054	Vanderbilt University	Widely Tunable OPO Laser Source based near-field illumination unit for neaSCOPE microscope.
26–059	University of California Berkeley	Dilution Refrigerator.
26–064	University of Illinois Urbana-Champaign	ProteoxMX Dilution Refrigerator.
26–075	University of California Berkeley	Custom Dilution Refrigerator with optical access and low vibrations.
26–076	New York University	Dilution Refrigerator.
26–083	University of California Berkeley	LD250He Refrigerator System.
26–087	Purdue University	Optical Cryostat—attoDRY2100.
26–091	Purdue University	Dilution Refrigerator and 12T Magnet.
26–092	University of Illinois Urbana-Champaign	TeslatronPT with 14T Magnet.
26–094	Purdue University	Optical Cryostat—attoDRY800.
26–104	University of California, Riverside	Pharos PH2–20W–SP Laser A.
26–107	California Institute of Technology	Tunable Low-Noise Laser.
26–113	Boston University	Femtosecond Laser.
26–115	University of Wisconsin-Madison	Dilution Refrigerator.
26–116	The Regents of the University of Michigan	Angle-resolved photoemission spectroscopy analyzer, chamber, and light source.

Docket No.	Applicant	Instrument
26–117	Rice University	neofleX MALDI–TOF/TOF MS System.
26–119	University at Buffalo	MyoDish.
26–120	University of California Santa Barbara	Energy and angle resolved electron analyzer.
26–128	Fermi Forward Discovery Group, LLC	8kW Solid State Amplifier.
26–131	University of Rochester	Electron Microscope
26–134	University of Delaware	Ultra-High Vacuum System for X-ray Photoelectron Spectroscopy and Angle-resolved Photoemission Spectroscopy.
26–135	Texas Tech University	SpectromagPT system low voltage with 7T Magnet.
26–138	Washington and Lee University	inVia Qontor Spectrometer System.
26–147	Regents of University of California at Berkeley	Dilution Refrigerator.

Dated: November 3, 2026.

Lana Nigro,

Acting Director, Subsidies Enforcement, Enforcement and Compliance.

[FR Doc. 2026–22698 Filed 11–5–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–802]

Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Final Results of Antidumping Duty Administrative Review; 2024–2025

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that producers/exporters subject to this administrative review made sales of certain frozen warmwater shrimp (shrimp) from the Socialist Republic of Vietnam (Vietnam) at prices below normal value (NV) during the period of review (POR), February 1, 2024, through January 31, 2025. Additionally, Commerce determines that 29 exporters are eligible for separate rates.

DATES: Applicable November 6, 2026.

FOR FURTHER INFORMATION CONTACT: Jonathan Schueler or Matthew Lipka, 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) 482–9175 or (202) 482–7976, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 13, 2026, Commerce published the *Preliminary Results* of this administrative review and invited interested parties to comment.[1] On August 18, 2026, Commerce extended the deadline to issue these final results by 53 days.[2] Accordingly, the deadline for these final results is now November 2, 2026.

For the events subsequent to the *Preliminary Results, see* 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/frnotices.*

Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [4]

The merchandise subject to the *Order* is shrimp from Vietnam. For a full description of the scope of the *Order, see* the Issues and Decision Memorandum.[5]

Analysis of Comments Received

All issues raised by interested parties in the case and rebuttal briefs are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is provided in Appendix I to this notice.

Changes Since the Preliminary Results

Based on a review of the record and our analysis of comments received from interested parties, and for the reasons explained in the Issues and Decision Memorandum, we made certain changes to the weighted-average dumping margins applied to the two mandatory respondents, Sao Ta Foods Joint Stock Company/FIMEX VN/Sao Ta Seafood Factory/Khang An Foods Joint Stock Company (collectively, Fimex Group) [6] and Soc Trang Seafood Joint Stock Company; STAPIMEX (STAPIMEX), and the weighted-average dumping margin applicable to the non-examined companies that are eligible for a separate rate.

Use of Adverse Facts Available

For these final results, we are relying on adverse facts available (AFA), pursuant to sections 776(a) and (b) of the Act, in part, to value certain of STAPIMEX's chemical factors of production (FOP).[7] This is because STAPIMEX failed to cooperate by not acting to the best of its abilities to comply with our requests to provide descriptions of these chemical FOPs.[8] As partial AFA, we used the highest reported chemical surrogate value on

[1] *See Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Preliminary Results and Rescission, in Part, of Antidumping Duty Administrative Review; 2024–2025,* 91 FR 27002 (May 13, 2026) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Extension of Deadline for Final Results of Antidumping Duty Administrative Review,'' dated August 18, 2026.

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of Antidumping Duty Administrative Review of Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam; 2024–2025,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam,* 70 FR 5152 (February 1, 2005) (*Order*).

[5] *See* Issues and Decision Memorandum; *see also Preliminary Results* PDM at 3–4.

[6] In the thirteenth administrative review, Commerce determined that that Sao Ta Foods Joint Stock Company, aka Fimex VN and Sao Ta Seafood Factory are affiliated within the meaning of section 771(33) of the Act and comprise a single entity pursuant to 19 CFR 351.401(f). *See Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Final Results of Antidumping Duty Administrative Review, 2017–2018,* 84 FR 44859, 44860 (August 27, 2019). In the *Preliminary Results,* Commerce preliminarily determined that Khanh An Foods Joint Stock Company is affiliated with Sao Ta Foods Joint Stock Company, aka Fimex VN and Sao Ta Seafood Factory within the meaning of section 771(33) of the Act and compromises a single entity pursuant to 19 CFR 351.401(f). We find no evidence to change our decision, and we therefore continue to treat these companies as a single entity pursuant to 19 CFR 351.401(f) for these final results.

[7] *See* Issues and Decision Memorandum at Comment 4.

[8] *Id.; see also Preliminary Results* PDM at 5–9.

the record of this review as the surrogate value for the five chemical FOPs with inadequate descriptions.[9]

Separate Rates

Commerce received comments from the Fimex Group on Commerce's preliminary separate rate determinations.[10] Commerce addressed these comments in the Issues and Decision Memorandum and continues to find that the 29 companies listed in Appendix II are eligible for a separate rate, including the two mandatory respondents (*i.e.,* the Fimex Group and STAPIMEX).

The Act and Commerce's regulations do not address the establishment of a separate rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for separate-rate respondents which Commerce did not examine individually in an administrative review.

For the final results of this review, Commerce has determined the weighted-average dumping margin for the Fimex Group to be 10.71 percent, and for STAPIMEX to be 6.36 percent.[11] For the reasons explained in the Issues and Decision Memorandum, we are assigning the weighted-average of the dumping margins calculated for the Fimex Group and STAPIMEX to the non-examined respondents which qualify for a separate rate in this review.[12]

Vietnam-Wide Entity

In our *Preliminary Results,* we found that 132 companies failed to establish their eligibility for a separate rate and are considered to be part of the Vietnam-wide entity.[13] Commerce received comments from the Fimex Group on the list of companies that were preliminarily considered to be part of the Vietnam-wide entity.[14] Commerce addressed these comments in the Issues and Decision Memorandum and continues to find that 131 companies listed in Appendix III, which includes all companies listed in the *Preliminary Results* except for Khang An Foods Joint Stock Company, to be part of the Vietnam-wide entity.[15]

Because no party requested a review of the Vietnam-wide entity, and Commerce no longer considers the Vietnam-wide entity as an exporter conditionally subject to administrative reviews,[16] we did not conduct a review of the Vietnam-wide entity. Thus, the weighted-average dumping margin for the Vietnam-wide entity (*i.e.,* 25.76 percent), is not subject to change as a result of this review.

Final Results of Administrative Review

Commerce determines that the following estimated weighted-average dumping margins exist for the period February 1, 2024, through January 31, 2025:

Exporter	Weighted-average dumping margin (percent)
Sao Ta Foods Joint Stock Company/FIMEX VN/Sao Ta Seafood Factory/Khang An Foods Joint Stock Company	10.71
Soc Trang Seafood Joint Stock Company; STAPIMEX	6.36
Separate Rate Companies [17]	7.59

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties for these preliminary results 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 accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(1), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

For the Fimex Group and STAPIMEX, because the weighted-average dumping margins are not zero or *de minimis* (*i.e.,* less than 0.50 percent) in these final results, Commerce calculated importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales to the total entered value of those sales. Where we do not have entered values for all U.S. sales to a particular importer, we will calculate an importer-specific, per-unit assessment rate on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales to the total quantity of those sales.[18] To determine whether an importer-specific, per-unit assessment rate is *de minimis,* in accordance with 19 CFR 351.106(c)(2), we also will calculate an importer-specific *ad valorem* ratio based on estimated entered values.

For the 27 separate rate applicants that were not selected for individual examination in this administrative review but qualified for a separate rate, which have been assigned a weighted-average dumping margin that is not zero or *de minimis* (*i.e.,* less than 0.50 percent), Commerce will instruct, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise at the liquidation rates specified in the table above.

For sales that were not reported in the U.S. sales data submitted by the mandatory respondents, we will instruct CBP to liquidate entries associated with those sales at the rate for the Vietnam-wide entity (*i.e.,* 25.76 percent). For entries of subject merchandise during the POR produced by the mandatory respondents for which they did not know their merchandise was destined for the United States, we intend to instruct CBP to liquidate such entries at

[9] *See Preliminary Results* PDM at 9; *see also* Memorandum, ''Analysis for the Preliminary Results for Soc Trang Seafood Joint Stock Company,'' dated May 7, 2026; and Memorandum, ''Surrogate Values for the Preliminary Results,'' dated May 7, 2026.

[10] *See* Fimex Group's Letter, ''Case Brief,'' dated June 12, 2026 (Fimex's Case Brief), at 25–26.

[11] *See* Memorandum, ''Final Results Analysis Memorandum for the Fimex Group,'' dated concurrently with this notice; *see also* Memorandum, ''Final Results Analysis Memorandum for STAPIMEX,'' dated concurrently with this notice.

[12] *See* Memorandum, ''Calculation of the Final Dumping Margin for Respondents Not Selected for Individual Examination,'' dated concurrently with this notice.

[13] *See Preliminary Results* at Appendix III.

[14] *See* Fimex's Case Brief at 25–26.

[15] *See* Appendix III.

[16] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65969–70 (November 4, 2013).

[17] *See* Appendix II.

[18] *See* 19 CFR 351.212(b)(1).

the Vietnam-wide rate if there is no rate for the intermediate company or companies involved in the transaction.

With regard to the 131 companies identified in Appendix III to this notice as part of the Vietnam-wide entity, we will instruct CBP to apply an *ad valorem* assessment rate of 25.76 percent to all POR entries of subject merchandise which were exported by those companies.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) for the mandatory respondents listed above, which have a separate rate, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this review and listed in the table above; (2) for previously-examined Vietnamese and non-Vietnamese exporters not listed in Appendix II that received a separate rate in a prior completed segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific cash deposit rate; (3) for all non-Vietnamese exporters of subject merchandise which have not received their own separate rate, the cash deposit rate will be the rate applicable to the Vietnamese exporter that supplied that non-Vietnamese exporter; and (4) for all Vietnamese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the Vietnam-wide entity, (*i.e.,* 25.76 percent). These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers Regarding the Reimbursement of Duties

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

Administrative Protective Order (APO)

This notice also serves as a reminder to parties subject to APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results of administrative review and notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: November 2, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Separate Rates
V. Application of Facts Available and Use of Adverse Inference
VI. Discussion of the Issues
  Comment 1: Whether to Revise the Surrogate Value for Shrimp Feed
  Comment 2: Whether to Apply the Average-to-Average Method to Calculate the Fimex Group's Dumping Margin
  Comment 3: Whether to Correct an Error in the Fimex Group's Raw Shrimp Surrogate Value Calculation
  Comment 4: Whether to Apply Partial Facts Available to Some of STAPIMEX's Chemicals
  Comment 5: Whether to Grant a By-Product Offset for STAPIMEX
  Comment 6: Whether to Revise the Export Subsidy Offset
  Comment 7: Whether Khang An Foods Joint Stock Company Is Part of the Vietnam-Wide Entity
VII. Recommendation

Appendix II

Companies Eligible for Separate Rate Status [19]

1. Bac Lieu Fisheries Joint Stock Company; Bac Lieu Fis
2. Camau Seafood Processing and Service Joint Stock Corporation; Camau Seafood Processing and Joint-Stock Corporation; CASES
3. Camimex Group Joint Stock Company; Camimex Group [20]
4. Cantho Import Export Fishery Limited Company; CAFISH
5. Cuulong Seaproducts Company; Cuulong Seapro
6. Hai Viet Corporation; HAVICO
7. Khanh Sung Company, Ltd.; Khanh Sung Co., LTD
8. Minh Hai Joint-Stock Seafoods Processing Company; Seaprodex Minh Hai; Sea Minh Hai
9. Ngoc Tri Seafood Joint Stock Company; Ngoc Tri Seafood Company
10. Q N L Company Limited
11. Sao Ta Foods Joint Stock Company; FIMEX VN; Sao Ta Seafood Factory; Khang An Foods Joint Stock Company [21]
12. Seaprimexco Vietnam; Seaprimexco
13. Seavina Joint Stock Company; Seavina
14. Soc Trang Seafood Joint Stock Company; STAPIMEX
15. Thong Thuan Company Limited; T&T Co., LTD; Thong Thuan Cam Ranh Seafood Joint Stock Company [22]
16. Tai Kim Anh Seafood Joint Stock Corporation; TAIKA Seafood Corporation
17. Thuan Phuoc Seafoods and Trading Corporation; Thuan Phuoc Corp
18. Frozen Seafoods Factory No. 32
19. Seafoods and Foodstuff Factory
20. Trang Khanh Trading Company Limited.; Trang Khanh Seafood Co., Ltd.
21. Trong Nhan Seafood Company Limited; Trong Nhan Seafood
22. UTXI Aquatic Products Processing

[19] We have included in this list certain name variations that are included in the separate rate application/certification, and, thus are included in the separate rate, but were listed separately in the *Initiation Notice,* or not at all.

[20] Interested parties requested a review of, and we listed in the *Initiation Notice,* Camau Frozen Seafood Processing Import Export Corporation, but Commerce has previously determined that Camimex Group Joint Stock Company is the successor-in-interest to Camau Frozen Seafood Processing Import Export Corporation, so has only listed Camimex Group Joint Stock Company in this notice. *See Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 86 FR 47617, (August 26, 2021).

[21] As noted above, Commerce has determined that these entities are affiliated within the meaning of section 771(33) of the Act and comprise a single entity pursuant to 19 CFR 351.401(f).

[22] Commerce has previously determined that these entities are affiliated within the meaning of section 771(33) of the Act and comprise a single entity pursuant to 19 CFR 351.401(f). *See Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Final Results of and Final Rescission of Review, in Part, of Antidumping Duty Administrative Review; 2023–2024,* 91 FR 8429 (February 23, 2026).

Corporation; UTXICO
23. Viet I-Mei Frozen Foods Co., Ltd.; Viet I-Mei
24. Viet Nam Clean Seafood Corporation; Vietnam Clean Seafood Corporation; Vina Cleanfood
25. New Generation Seafood Joint Stock Company
26. Nha Trang Seafoods—F89 Joint Stock Company; NTSF Seafoods Joint Stock Company; NT Seafoods Corporation; Nha Trang Seaproduct Company [23]
27. Quang Minh Seafood Limited Liability Company; Quang Minh Seafood Co., Ltd [24]
28. Thong Thuan Tra Vinh Seafood Joint Stock Company
29. Viet Shrimp Corporation

Appendix III

Companies Under Review Determined To Be Part of the Vietnam-Wide Entity [25]

1. AFoods
2. Amanda Seafood Co., Ltd.
3. An Nguyen Investment Production and Group
4. Anh Khoa Seafood
5. Anh Minh Quan Corp
6. APT Co.
7. Au Vung One Seafood
8. Baclieufis
9. Bentre Forestry and Aquaproduct Import-Export Joint Stock Company aka FAQUIMEX Bentre Seafood Joint Stock Company
10. Beseaco
11. Bien Dong Seafood Co., Ltd.
12. Binh Dong Fisheries Joint Stock Company
13. Binh Thuan Import-Export Joint Stock Company
14. Blue Bay Seafood Co., Ltd.
15. Ca Mau Frozen Seafood Processing Import Export Corporation
16. Ca Mau Seafood Joint Stock Company
17. Ca Mau Seafood Processing and Services Joint Stock Company
18. Cadovimex
19. Cadovimex II Seafood Import Export and Processing Joint Stock Company
20. Cadovimex Seafood Import-Export and Processing Joint Stock Company [26]
21. Camimex Foods Joint Stock Company
22. Caseamex
23. CASES Kien Giang Branch Camau Seafood Processing & Service Joint Stock Corporation
24. CJ Cau Tre Foods Joint Stock Company
25. Coastal Fisheries Development Corporation
26. COFIDEC
27. Dai Phat Tien Seafood Co., Ltd.
28. Danang Seafood Import Export
29. Danang Seaproducts Import-Export Corporation
30. Domenal Joint Stock Company
31. Dong Hai Seafood Limited Company
32. Dong Phuong Seafood Co., Ltd.
33. Duc Cuong Seafood Trading Co., Ltd.
34. Duong Hung Seafood
35. FFC/Fine Foods Company
36. Gallant Dachan Seafood Co., Ltd.
37. Gallant Ocean (Vietnam) Joint Stock Company
38. GN Foods Joint Stock Company
39. Go Dang Joint Stock Company
40. GODACO Seafood
41. Green Farms Seafood Joint Stock Company
42. Hanh An Trading Service Co., Ltd.
43. Hoang Anh Fisheries Trading Company Limited
44. Hoang Phong Seafood Co.
45. Hong Ngoc Seafood Co., Ltd.
46. Hung Bang Company Limited
47. Hung Dong Investment Service Trading Co., Ltd.
48. HungHau Agricultural Joint Stock Company
49. Investment Commerce Fisheries Corporation
50. JK Fish Co., Ltd.
51. Khang An Foods Aquatic Products Joint Stock Company
52. Khanh Hoa Seafoods Exporting Company
53. KHASPEXCO
54. Kim Phat Seafood Import Export Company
55. Long Toan Frozen Aquatic Products Joint Stock Company
56. MC Seafood
57. Minh Anh Seafood Import Export
58. Minh Bach Seafood Company Limited
59. Minh Cuong Seafood Import Export Processing Joint Stock Company
60. Minh Hai Export Frozen Seafood Processing Joint-Stock Company, aka Minh Hai Jostoco
61. Minh Phat Seafood Company Limited [27]
62. Minh Phu Hau Giang Seafood [28]
63. Minh Phu Seafood Corporation [29]
64. Minh Qui Seafood Company Limited [30]
65. My Son Seafoods Factory
66. Nam Hai Foodstuff and Export Company Ltd.
67. Nam Phuong Foods Import Export Company Limited
68. Nam Viet Seafood Import Export Joint Stock Company/NAVIMEXCO
69. Namcan Seaproducts Import Export Joint Stock Company
70. New Wind Seafood Company Limited
71. Ngoc Trinh Bac Lieu Seafood Co., Ltd.
72. Nguyen Chi Aquatic Product Trading Company Limited
73. Nhat Duc Co., Ltd.
74. Nigico Co., Ltd.
75. Phuong Nam Foodstuff Corp.
76. QAIMEXCO
77. QNL One Member Company
78. Quoc Ai Seafood Processing Import Export Co., Ltd.[31]
79. Quoc Toan PTE
80. Quoc Toan Seafood Processing Factory
81. Quy Nhon Frozen Seafoods Joint Stock Company
82. Safe And Fresh Aquatic Products Joint Stock Company
83. Saigon Aquatic Product Trading Joint Stock Company
84. Saigon Food Joint Stock Company
85. Savvy Seafood Vietnam Co., Ltd.

[23] Commerce has previously determined that these entities are affiliated within the meaning of section 771(33) of the Act and comprise a single entity pursuant to 19 CFR 351.401(f). *See Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Preliminary Results, Partial Rescission, and Request for Revocation, In Part, of the Fifth Administrative Review,* 76 FR 12054, 12056 (March 4, 2011), unchanged in *Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Final Results and Final Partial Rescission of Antidumping Duty Administrative Review,* 76 FR 56158 (September 12, 2011).

[24] We inadvertently listed this company along with Quoc Ai Seafood Processing Import Export Co., Ltd, but it is a separate company that was requested separately by interested parties. *See* the US Shrimpers Coalition's Letter, ''Request for Administrative Review,'' dated February 28, 2025 (USSC's Review Request) at 4; *see also* the American Shrimp Processors Association's Letter, ''America Shrimp Processors Association's Request for Administrative Reviews,'' dated February 25, 2025 (ASPA's Review Request) at 7; and the Ad Hoc Shrimp Trade Action Committee's Letter, ''Request for Administrative Reviews,'' dated February 28, 2025 (AHSTAC's Review Request) at 3.

[25] *See* Memorandum, ''Names Not Granted Separate Rate Status at the Preliminary Determination,'' dated May 7, 2026.

[26] We inadvertently listed this company along with Cafatex Fishery Joint Stock Corporation/ Cafatex Corporation, but it is a separate company that was requested separately by interested parties. *See* ASPA's Review Request at 2; *see also* USSC's Review Request at 3.

[27] Shrimp produced and exported by Minh Phat Seafood Company Limited were excluded from the antidumping duty order on certain frozen warmwater shrimp from Vietnam, effective July 18, 2016. *See Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Notice of Implementation of Determination Under Section 129 of the Uruguay Round Agreements Act and Partial Revocation of the Antidumping Duty Order,* 81 FR 47756, 47757–47758 (July 22, 2016). Accordingly, we initiated this administrative review for this exporter only with respect to subject merchandise produced by another entity.

[28] Shrimp produced and exported by Minh Phu Hau Giang Seafood were excluded from the antidumping duty order on certain frozen warmwater shrimp from Vietnam, effective July 18, 2016. *See Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Notice of Implementation of Determination Under Section 129 of the Uruguay Round Agreements Act and Partial Revocation of the Antidumping Duty Order,* 81 FR 47756, 47757–47758 (July 22, 2016). Accordingly, we initiated this administrative review for this exporter only with respect to subject merchandise produced by another entity.

[29] Shrimp produced and exported by Minh Phu Seafood Corporation were excluded from the antidumping duty order on certain frozen warmwater shrimp from Vietnam, effective July 18, 2016. *See Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Notice of Implementation of Determination Under Section 129 of the Uruguay Round Agreements Act and Partial Revocation of the Antidumping Duty Order,* 81 FR 47756, 47757–47758 (July 22, 2016). Accordingly, we initiated this administrative review for this exporter only with respect to subject merchandise produced by another entity.

[30] Shrimp produced and exported by Minh Qui Seafood Company Limited were excluded from the antidumping duty order on certain frozen warmwater shrimp from Vietnam, effective July 18, 2016. *See Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Notice of Implementation of Determination Under Section 129 of the Uruguay Round Agreements Act and Partial Revocation of the Antidumping Duty Order,* 81 FR 47756, 47757–47758 (July 22, 2016). Accordingly, we initiated this administrative review for this exporter only with respect to subject merchandise produced by another entity.

[31] We inadvertently listed this company along with Quang Minh Seafood Co., Ltd, but it is a separate company that was requested separately by interested parties. *See* Preliminary Decision Memorandum.

86. SEADANANG
87. Seafood Direct 2012 One Member Limited
88. Seafood Joint Stock Company No. 4
89. Seafood Travel Construction Import-Export Joint Stock Company
90. Seanamico
91. Seaprodex Min Hai
92. Seaprodex Minh Hai Factory No. 69
93. Seaprodex Minh Hai Factory No. 78
94. Seaprodex Minh Hai Workshop 1
95. Seaproducts Joint Stock Company No. 5/Vietrosco
96. Seaspimex Vietnam
97. Simmy Seafood Company Limited
98. South Ha Tinh Seaproducts Import-Export Joint Stock Company
99. South Vina Shrimp-SVS
100. Southern Shrimp Joint Stock Company
101. Special Aquatic Products Joint Stock Company
102. T & P Seafood Company Limited
103. T&T Cam Ranh
104. Tai Nguyen Seafood Co., Ltd.
105. Tan Phong Phu Seafood Co., Ltd.
106. Tan Thanh Loi Frozen Food Co., Ltd.
107. THADIMEXCO
108. Thai Hoa Foods Joint Stock Company
109. Thai Minh Long Seafood Company Limited
110. Thaimex
111. Thanh Doan Fisheries Import-Export Joint Stock Company
112. Thanh Doan Sea Products Import & Export Processing Joint-Stock Company
113. Thanh Doan Seafood Import Export Trading Joint-Stock Company
114. The Light Seafood Company Limited
115. Thien Phu Export Seafood
116. Thinh Hung Co., Ltd.
117. Thinh Phu Aquatic Products Trading Co., Ltd.
118. Thuan Thien Producing Trading Ltd. Co.
119. Tin An Seafood Factory
120. TPP Co. Ltd.
121. Trang Corporation (Vietnam)
122. Trung Son Seafood Processing Joint Stock Company
123. Van Duc Food Company Limited
124. Viet Asia Foods Company Limited (VAFCO)
125. Viet Phu Foods and Fish Corp.
126. Vietnam Rich Beauty Food Co., Ltd.
127. VIFAFOOD
128. Vinh Hoan Corp.
129. Vinh Phat Food Joint Stock Company
130. Western Foods Company Limited
131. XNK Thinh Phat Processing Company

[FR Doc. 2026–22660 Filed 11–5–26; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–888]

Certain Carbon and Alloy Steel Cut-to-Length Plate From the Republic of Korea: Notice of Court Decision Not in Harmony With the Results of Countervailing Duty Administrative Review; Notice of Amended Final Results

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

SUMMARY: On October 27, 2026, the U.S. Court of International Trade (CIT) issued its final judgment in *POSCO* v. *United States* Consol. Court No. 24–00006, Slip Op. 26–131, sustaining the U.S. Department of Commerce (Commerce)'s second remand results pertaining to the administrative review of the countervailing duty (CVD) order on of certain carbon and alloy steel cut-to-length plate (CTL Plate) from the Republic of Korea (Korea) covering the period January 1, 2021, through December 31, 2021. Commerce is notifying the public that the CIT's final judgment is not in harmony with Commerce's final results of the administrative review, and that Commerce is amending the final results with respect to countervailable subsidy rate assigned to POSCO Co., Ltd. (POSCO).

DATES: Applicable November 6, 2026.

FOR FURTHER INFORMATION CONTACT: Rachel Accorsi or Joshua Nixon, 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) 482–7472 or (202) 482–8361, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 13, 2023, Commerce published its *Final Results* in the 2021 CVD administrative review of CTL Plate from Korea.[1] In the *Final Results,* Commerce found that POSCO, the sole mandatory respondent, received countervailable subsidies from the Government of Korea (GOK) during the period of review (POR). Commerce calculated an overall net subsidy rate of 0.87 percent *ad valorem*.[2]

POSCO appealed Commerce's *Final Results.* On August 8, 2025, the CIT remanded the *Final Results* to Commerce, directing Commerce to reconsider the following: (1) Commerce's finding that the provision of electricity for less than adequate renumeration (LTAR) in Korea was *de facto* specific under section 771(5A)(D)(iii)(III) of the Tariff Act of 1930, as amended (the Act); (2) Commerce's finding that the provision of Korean Emission Trading System (K–ETS) permits provided a financial contribution in the form of revenue forgone within the meaning of 771(5)(D) of the Act; and (3) Commerce's finding that the provision of K–ETS permits is specific under section 771(5A)(D)(i) of the Act.[3]

In the *First Final Remand Redetermination,* issued on December 9, 2025, Commerce determined that: (1) there was a lack of evidence on the record to find the provision of electricity for LTAR *de facto* specific under section 771(5A)(D)(iii)(III) of the Act and therefore found the provision of electricity for LTAR not countervailable; (2) the provision of K–ETS permits by the GOK provided a financial contribution in the form of a direct transfer of funds within the meaning of section 771(5)(D)(i) of the Act; and (3) the provision of K–ETS permits is contingent upon export performance in accordance with sections 771(5A)(A) and (B) of the Act.[4]

On April 17, 2026, the CIT issued its *Second Remand Order*[5] which sustained Commerce on its findings regarding (1) provision of electricity for LTAR and (2) the financial contribution of K–ETS permits. However, the CIT found that Commerce's determination that the provision of K–ETS permits was export contingent was not in accordance with law and remanded the third issue, Commerce's specificity finding for the provision of K–ETS permits, to Commerce for further consideration.[6]

In the *Second Final Remand Redetermination,*[7] issued on July 11,

[1] *See Carbon and Alloy Steel Cut-to-Length Plate from the Republic of Korea: Final Results of Countervailing Duty Administrative Review; 2021,* 88 FR 86318 (December 13, 2023) (*Final Results*), and accompanying Issues and Decision Memorandum.

[2] *See Final Results,* 88 FR at 86319.

[3] *See POSCO* v. *United States,* 794 F.Supp.3d 1402 (CIT 2025) (*Remand Order*).

[4] *See Final Results of Redetermination Pursuant to Second Court Remand: POSCO* v. *United States,* Court No. 24 00006, Slip Op. 25–100, dated December 9, 2025 (*First Final Remand Redetermination*), available at *https://access.trade.gov/FinalRemandRedetermination.*

[5] *See POSCO* v. *United States,* 829 F.Supp.3d 1298 (CIT 2026) (*Second Remand Order*).

[6] *Id.* at 15–17.

[7] *See Final Results of Redetermination Pursuant to Second Court Remand: POSCO* v. *United States,* Court No. 24 00006, Slip Op. 26–36, dated July 22,

2026, Commerce determined that the provision of K–ETS permits is *de facto* specific, pursuant to section 771(5A)(D)(iii)(I) of the Act. Based on this analysis, Commerce calculated a revised 0.80 percent total *ad valorem* subsidy rate for POSCO. On October 27, 2026, the CIT sustained Commerce's *Second Final Remand Redetermination*.[8]

Timken Notice

In its decision in *Timken,*[9] as clarified by *Diamond Sawblades,*[10] the U.S. Court of Appeals for the Federal Circuit held that, pursuant to section 516A(c) and (e) of the Act, Commerce must publish a notice of court decision that is not ''in harmony'' with a Commerce determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's October 27, 2026, judgment constitutes a final decision of the CIT that is not in harmony with Commerce's *Final Results.* Thus, this notice is published in fulfillment of the publication requirements of *Timken.*

Amended Final Results

Because there is now a final court judgment, Commerce is amending its *Final Results* with respect to POSCO as follows:

Producer/exporter	Subsidy rate for January 1, 2021, to December 31, 2021 (percent *ad valorem*)
POSCO Co., Ltd.[11]	0.80

Cash Deposit Requirements

Because POSCO has a superseding cash deposit rate, *i.e.,* there have been final results published in a subsequent administrative review, we will not issue revised cash deposit instructions to CBP. This notice will not affect the current cash deposit rate.

Liquidation of Suspended Entries

At this time, Commerce remains enjoined by CIT order from liquidating entries that: were produced by POSCO and exported by POSCO International and were entered, or withdrawn from warehouse, for consumption during the period January 1, 2021, through December 31, 2021. These entries will remain enjoined pursuant to the terms of the injunction during the pendency of any appeals process.

In the event the CIT's ruling is not appealed, or, if appealed, upheld by a final and conclusive court decision, Commerce intends to instruct CBP to assess countervailing duties on unliquidated entries of subject merchandise produced and/or exported by POSCO in accordance with 19 CFR 351.212(b). We will instruct CBP to assess countervailing duties on all appropriate entries covered by this review when the *ad valorem* rate is not zero or *de minimis.* Where an *ad valorem* subsidy rate is zero or *de minimis,*[12] we will instruct CBP to liquidate the appropriate entries without regard to countervailing duties.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(c) and (e) and 777(i)(1) of the Act.

Dated: November 3, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2026–22706 Filed 11–5–26; 8:45 am]

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2026 (*Second Final Remand Redetermination*), available at *https://access.trade.gov/FinalRemand Redetermination.*

[8] *See POSCO* v. *United States,* Consol. Court No. 24–00006, Slip Op. 26–131 (October 27, 2026).

[9] *See Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

[10] *See Diamond Sawblades Manufacturers Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

[11] As discussed in *Certain Carbon and Alloy Steel Cut-to-Length Plate from the Republic of Korea: Preliminary Results and Partial Rescission of Countervailing Duty Administrative Review; 2021,* 88 FR 37019 (June 6, 2023), Commerce found the following companies to be cross-owned with POSCO: Pohang Scrap Recycling Distribution Center Co. Ltd.; POSCO Chemical Co., Ltd.; POSCO M-Tech Co., Ltd.; POSCO Nippon Steel RHF Joint Venture Co., Ltd.; POSCO SPS Co., Ltd.; and POSCO Terminal Co., Ltd. The subsidy rate applies to all cross-owned companies. We note that POSCO has an affiliated trading company through which it exported certain subject merchandise during the POR, POSO International (aka POSCO International Corporation). POSCO International was not selected as a mandatory respondent but was examined in the context of POSCO. Therefore, there is not an established countervailing duty rate for POSCO International; POSCO International's subsidies are accounted for in POSCO's total subsidy rate. Instead, entries of subject merchandise exported by POSCO International will receive the rate of the producer listed on the U.S. Customs and Border Protection (CBP) entry form. Thus, the subsidy rate applied to POSCO and POSCO's cross-owned companies is also applied to POSCO International for entries of subject merchandise produced by POSCO.

[12] *See* 19 CFR 351.106(c)(2).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–234]

N-Cyclohexylbenzothiazole-2-Sulfenamide From the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value and Preliminary Affirmative Determination of Critical Circumstances

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

DATE: Applicable November 6, 2026.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that N-Cyclohexylbenzothiazole-2-Sulfenamide (CBS) from the People's Republic of China (China) is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is October 1, 2025, through March 31, 2026. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable November 6, 2026.

FOR FURTHER INFORMATION CONTACT: Allison Hollander or Caroline Carroll, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2805 and (202) 482–4948, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on June 2, 2026.[1] On September 24, 2026, Commerce postponed the preliminary determination of this investigation and the revised deadline is now October 28, 2026.[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 N-Cyclohexylbenzothiazole-2-Sulfenamide from the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation,* 91 FR 32941 (June 2, 2026) (*Initiation Notice*).

[2] *See N-Cyclohexylbenzothizole-2-Sulfenamide from the People's Republic of China: Postponement of Preliminary Determination in the Less-Than-Fair-Value Investigation,* 91 FR 60600 (September 24, 2026).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of N-

Continued

included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/frnotices.*

Scope of the Investigation

The product covered by this investigation is CBS from China. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (scope).[5] No interested party commented on the scope of the investigation as it appeared in the *Initiation Notice.* Commerce is not preliminarily modifying the scope language as it appeared in the *Initiation Notice. See* the scope in Appendix I to this notice.

Methodology

Commerce is conducting this investigation in accordance with sections 731 and 733(b) of the Act. Pursuant to sections 776(a) and (b) of the Act, Commerce preliminarily has relied upon facts otherwise available, with adverse inferences, for the China-wide entity, which includes the companies that did not respond to Commerce's quantity and value questionnaire, separate rate application, or Commerce's initial questionnaire. For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

Preliminary Affirmative Determination of Critical Circumstances

In accordance with section 733(e) of the Act and 19 CFR 351.206, Commerce preliminarily determines that critical circumstances exist with respect to imports of CBS from China for the China-wide entity. For a full description of the methodology and results of Commerce's critical circumstances analysis, *see* the Preliminary Decision Memorandum.

Combination Rates

In the *Initiation Notice,*[6] Commerce stated that it would calculate producer/exporter combination rates for the respondents that are eligible for a separate rate in this investigation. Policy Bulletin 05.1 describes this practice.[7] In this case, because no respondent qualified for a separate rate, producer/exporter combination rates were not calculated.

Preliminary Determination

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

Producer/exporter	Weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset) (percent)
China-Wide Entity	* 285.94	281.69

* Rate based on facts available with adverse inferences.

Suspension of Liquidation

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

Section 733(e)(2) of the Act provides that, given an affirmative determination of critical circumstances, any suspension of liquidation shall apply to unliquidated entries of 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. Commerce preliminarily finds that critical circumstances exist for imports of subject merchandise from the China-wide entity. In accordance with section 733(e)(2)(A) of the Act, the suspension of liquidation shall apply to all unliquidated entries of merchandise from the producer/exporter combinations 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.

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

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

These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with a preliminary determination within five

Cyclohexylbenzothiazole-2-Sulfenamide from the People's Republic of China,'' 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,* 91 FR at 32942.

[6] *See Initiation Notice,* 91 FR at 32945.

[7] *See* Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, ''Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries,'' (April 5, 2005) (Policy Bulletin 05.1), available on Commerce's website at *https://www.trade.gov/enforcement-and-compliance-policy-bulletins-0.*

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 adverse facts available (AFA) to the China-wide entity in this investigation in accordance with section 776 of the Act, and the applied AFA rate is based solely on the petition, there are no calculations to disclose.

Verification

Because the mandatory respondents in this investigation did not provide information requested by Commerce, withdrew from participating in this proceeding, and Commerce preliminarily determines each of the mandatory respondents to have been uncooperative, verification will not be conducted.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 14 days after the date of publication of the preliminary determination, unless the Secretary alters the time limit. 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.[8] 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.[9]

As provided under 19 CFR 351.309(c)(2)(iii) and (d)(2)(iii), we request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[10] 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).[11]

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: (1) the party's name, address, and telephone number; (2) the number of participants and whether any participant is a foreign national; and (3) 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.

Final Determination

Section 735(a)(1) of the Act and 19 CFR 351.210(b)(1) provide that Commerce will issue the final determination within 75 days after the date of its preliminary determination. Accordingly, Commerce will make its final determination no later than 75 days after the signature date of this preliminary determination.

U.S. International Trade Commission Notification

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

Notification to Interested Parties

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

Dated: October 28, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I

Scope of the Investigation

The product subject to this investigation is N-Cyclohexylbenzothiazole-2-sulfenamide (CBS), an organic compound also known as N-cyclohexyl-2-benzothiazolesulfenamide, N-(1,3- benzothiazol-2-ylsulfanyl) cyclohexanamine and N-cyclohexylbenzothiazol-2-sulphenamide. It may additionally be termed Accelerator CZ, CBTS, Thiohexam, HIP4, Curax, DURAX, Conaca, Conach, Conacs, or Celacs. A CBS assay or sample most commonly reflects a concentration of 94 to 99 percent.

CBS is most commonly in the form of an off-white or light gray powder, oiled powder, or granule, though CBS imported in a different color or form is included in the scope. CBS typically has a melting point of 90 to 110°C and a molecular weight of 264.4 g/mol. CBS may be imported in a solution of benzene, ethanol, or acetone. CBS has the chemical formula C13H16N2S2 and is assigned the Chemical Abstract Service (CAS) registry No. 95–33–0.

The scope also includes CBS that is commingled with CBS from sources not subject to this investigation.

CBS powder, oiled powder, and granules are classified under subheading 2934.20.8000, Harmonized Tariff Schedule of the United States (HTSUS). Imports of CBS may also be classified under subheadings 3812.10.1000 and 3812.10.5000, HTSUS. Although the HTSUS and CAS numbers 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. Period of Investigation
IV. Discussion of the Methodology
V. Preliminary Affirmative Determination of Critical Circumstances
VI. Adjustments to Cash Deposit Rates for Export Subsidies in the Companion Countervailing Duty Investigation
VII. Recommendation

[FR Doc. 2026–22710 Filed 11–5–26; 8:45 am]

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[8] *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*).

[9] *See* 19 351.309(c)(2) and (d)(2).

[10] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[11] *See APO and Service Final Rule.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–918; A–552–812; C–552–813]

Steel Wire Garment Hangers From the People's Republic of China and the Socialist Republic of Vietnam: Final Affirmative Determination of Circumvention of the Antidumping Duty Order on Steel Wire Garment Hangers From the People's Republic of China and the Antidumping and Countervailing Duty Orders on Steel Wire Garment Hangers From the Socialist Republic of Vietnam

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that imports of steel wire garment hangers (hangers), completed in Cambodia using: (1) steel wire or (2) steel wire and

paper accessories, produced in the People's Republic of China (China) or the Socialist Republic of Vietnam (Vietnam), are circumventing the antidumping duty (AD) order on hangers from China, or the AD and countervailing duty (CVD) orders on hangers from Vietnam.

DATES: Applicable November 6, 2026.

FOR FURTHER INFORMATION CONTACT: Braeden Lowe, 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) 482–9124.

SUPPLEMENTARY INFORMATION:

Background

On October 6, 2008 and February 5, 2013, Commerce published in the **Federal Register** the AD order on hangers from China,[1] and the AD and CVD orders on hangers from Vietnam, respectively.[2] On August 12, 2025, Commerce initiated country-wide circumvention inquiries pursuant to section 781(b) of the Tariff Act of 1930, as amended (the Act), to determine whether imports of hangers completed in Cambodia using: (1) steel wire or (2) steel wire and paper accessories, produced in China or Vietnam, are circumventing the *China Order* or the *Vietnam Orders* and, accordingly, should be covered by the scope of the *China Order* or the scope of the *Vietnam Orders*.[3] On September 22, 2026, Commerce published the affirmative *Preliminary Determination* of these circumvention inquiries.[4] Concurrent with the *Preliminary Determination,* we also extended the deadline to issue this final determination until October 30, 2026.[5] We invited parties to comment on the *Preliminary Determination* of these inquiries. We received no comments.

Scope of the Orders

For a complete description of the scope of the *China Order* and the scope of the *Vietnam Orders, see* Appendix I and II of this notice.[6]

Merchandise Subject to the Circumvention Inquiries

These circumvention inquiries cover hangers completed in Cambodia using either: (1) steel wire; or (2) steel wire and paper accessories produced in China or Vietnam, where the hangers are subsequently exported from Cambodia to the United States.

Affirmative Final Determination of Circumvention

Because we received no comments from any interested party, this final determination of circumvention remains unchanged from the *Preliminary Determination* and no decision memorandum accompanies this notice. Consistent with the *Preliminary Determination,* Commerce continues to determine that hangers completed in Cambodia using Chinese-origin or Vietnamese origin inputs, *i.e.,* steel wire or steel wire and paper accessories, are circumventing the *China Order* or the *Vietnam Orders,* each on a country-wide basis.[7] As a result, in accordance with section 781(b) of the Act, we determine that this merchandise should be included within the scope of the *China Order* or the scope of the *Vietnam Orders.*

Continuation of Suspension of Liquidation and Cash Deposit Requirements

Based on this affirmative final country-wide determination of circumvention with respect to hangers exported from Cambodia, in accordance with 19 CFR 351.226(I)(3), we will direct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation and require a cash deposit of estimated antidumping or countervailing duties on unliquidated entries of hangers from Cambodia that were entered, or withdrawn from warehouse, for consumption, on or after August 12, 2025, the date of publication of the initiation of this circumvention inquiry in the **Federal Register**.

The suspension of liquidation and cash deposit requirements will remain in effect until further notice.[8]

For this final determination, we continue to implement the cash deposit requirements and certification process outlined in the *Preliminary Determination*.[9] Specifically, Commerce found that no exporter of hangers from Cambodia is eligible to certify the origin of the steel or steel and paper inputs used to produce hangers in Cambodia. However, we established a certification program that allows parties (excluding parties to which Commerce applied adverse facts available) to certify that entries of hangers exported from Cambodia were produced using Chinese, rather than Vietnamese, steel wire or steel wire and paper accessories. In order to certify that shipments were not subject to the *Vietnam Orders,* the importer, exporter, and producer are required to provide documentation to CBP at the time of entry supporting the claim that the steel wire or steel wire and paper accessories were sourced from China. Should we determine at a later date that a more general certification program (*e.g.,* one where parties can certify that the imported hangers are not produced with Chinese- or Vietnamese inputs) is appropriate,

[1] *See Notice of Antidumping Duty Order: Steel Wire Garment Hangers from the People's Republic of China,* 73 FR 58111 (October 6, 2008) (*China Order*).

[2] *See Steel Wire Garment Hangers from the Socialist Republic of Vietnam: Antidumping Duty Order,* 78 FR 8105 (February 5, 2013); and *Certain Steel Wire Garment Hangers from the Socialist Republic of Vietnam: Countervailing Duty Order,* 78 FR 8107 (February 5, 2013) (collectively, *Vietnam Orders*).

[3] *See Steel Wire Garment Hangers from the People's Republic of China and the Socialist Republic of Vietnam: Initiation of Circumvention Inquiries of the Antidumping and Countervailing Duty Orders,* 90 FR 38723 (August 12, 2025) (*Initiation Notice*), and accompanying Initiation Checklists, ''Steel Wire Garment Hangers from the People's Republic of China: Circumvention Initiation Checklist'' and ''Steel Wire Garment Hangers from the Socialist Republic of Vietnam: Circumvention Initiation Checklist.''

[4] *See Steel Wire Garment Hangers from the People's Republic of China and the Socialist Republic of Vietnam: Preliminary Affirmative Determination of Circumvention of the Antidumping Duty Order on Steel Wire Garment Hangers from the People's Republic of China and the Antidumping and Countervailing Duty Orders on Steel Wire Garment Hangers from the Socialist Republic of Vietnam,* 91 FR 60086 (September 22, 2026) (*Preliminary Determination*); *see also* Memoranda, ''Decision Memorandum for the Preliminary Affirmative Determination of Circumvention of the Antidumping Duty Order on Steel Wire Garment Hangers from the People's Republic of China,'' and ''Decision Memorandum for the Preliminary Affirmative Determination of Circumvention of the Antidumping and Countervailing Duty Orders on Steel Wire Garment Hangers from the Socialist Republic of Vietnam,'' dated September 18, 2026 (collectively, Preliminary Decision Memoranda).

[5] *See* Memorandum, ''Extension of Deadline for the Final Determinations in the Circumvention Inquiries Pertaining to Cambodia,'' dated September 17, 2026.

[6] *See* Appendix I (Scope of the *China Order*) and Appendix II (Scope of the *Vietnam Orders*).

[7] *See Preliminary Determination,* 91 FR at 60087; *see also* Preliminary Decision Memoranda.

[8] *See Preliminary Determination,* 91 FR at 60087.

[9] Consistent with our recent determinations, where AD/CVD orders from two countries (*i.e.,* here, China and Vietnam) potentially apply to an entry, Commerce instructed CBP to suspend the entry and collect cash deposits at the rates applicable to the *Vietnam Orders* (*i.e.,* the AD cash deposit rate established for the Vietnam-wide entity (220.68 percent) and the CVD cash deposit rate established for all other companies (31.58 percent)) under the following third-country case numbers: A–555–812 (Vietnam AD), and C–555–813 (Vietnam CVD). For entries of hangers from Cambodia for which the producer, exporter, and importer have certified in Commerce's dual circumvention certification program that the merchandise was produced using Chinese-origin steel wire or steel wire and paper accessories, Commerce directed CBP to suspend liquidation and require a cash deposit at the AD cash deposit rate established for hangers from China under the following third-country case number: A–555–918. *See Preliminary Determination,* 91 FR at 60087; *see also* certification requirements and certifications at Appendix III and IV.

Commerce will release the required certification language, and establish such a certification program, at that time.

Administrative Protective Order

This notice will serve as the only reminder to all parties subject to an administrative protective order (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 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 sanctionable violation.

Notification to Interested Parties

This determination is issued and published in accordance with sections 781(b) of the Act 19 CFR 351.226(g)(1).

Dated: October 30, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I

Scope of the China Order

The merchandise subject to the *Order* is steel wire garment hangers, fabricated from carbon steel wire, whether or not galvanized or painted, whether or not coated with latex or epoxy or similar gripping materials, and/or whether or not fashioned with paper covers or capes (with or without printing) and/or nonslip features such as saddles or tubes. These products may also be referred to by a commercial designation, such as shirt, suit, strut, caped, or latex (industrial) hangers.

On October 30, 2026, Commerce determined that steel wire garment hangers that are completed in Cambodia using Chinese-origin (1) steel wire or (2) steel wire and paper accessories and subsequently exported to the United States are subject to the *Order.*

Specifically excluded from the scope of the *Order* are wooden, plastic, and other garment hangers that are not made of steel wire. Also excluded from the scope of the *Order* are chrome-plated steel wire garment hangers with a diameter of 3.4 mm or greater.

The products subject to the *Order* are currently classified under U.S. Harmonized Tariff Schedule (HTSUS) subheadings 7326.20.0020, 7323.99.9060, and 7323.99.9080. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

Appendix II

Scope of the Vietnam Orders

The merchandise subject to the *Orders* is steel wire garment hangers, fabricated from carbon steel wire, whether or not galvanized or painted, whether or not coated with latex or epoxy or similar gripping materials, and whether or not fashioned with paper covers or capes (with or without printing) or nonslip features such as saddles or tubes. These products may also be referred to by a commercial designation, such as shirt, suit, strut, caped, or latex (industrial) hangers.

On October 30, 2026, Commerce determined that steel wire garment hangers that are completed in Cambodia using Vietnamese-origin (1) steel wire or (2) steel wire and paper accessories and subsequently exported to the United States are subject to the *Orders.*

Specifically excluded from the scope of the *Orders* are (a) wooden, plastic, and other garment hangers that are not made of steel wire; (b) steel wire garment hangers with swivel hooks; (c) steel wire garment hangers with clips permanently affixed; and (d) chrome plated steel wire garment hangers with a diameter of 3.4 millimeters (mm) or greater.

The products subject to the *Orders* are currently classified under U.S. Harmonized Tariff Schedule (HTSUS) subheadings 7326.20.0020 and 7323.99.9080. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive

Appendix III

Certification Program Requirements

The importer is required to complete and maintain the applicable importer certification, and maintain a copy of the applicable producer certification, and retain all supporting documentation for both certifications. With the exception of the entries described below, the importer certification must be completed, signed, and dated by the time the entry summary is filed for the relevant entry.

If the producing company and the exporting company are the same, the importer, or the importer's agent, must submit the importer's certification, the producer/exporter certification, and documentation demonstrating that the country-of-origin of the (1) steel wire or (2) steel wire and paper accessories used in the production of the exported steel wire garment hangers was Chinese. Such certifications and documentation must be submitted to CBP at the time that the entry summary is filed by uploading these documents into the document imaging system (DIS) in the Automated Customs Environment (ACE).

If the producing company and the exporting company are different, the importer, or the importer's agent, must submit the importer's certification, the producer's certification, and the exporter's certification, and documentation demonstrating the Chinese-origin of the (1) steel wire or (2) steel wire and paper accessories used in the production of the exported steel wire garment hangers. Such certifications and documentation must be submitted to CBP at the time that the entry summary is filed by uploading these documents into DIS in ACE.

Where the importer uses a broker to facilitate the entry process, the importer should obtain the entry summary number from the broker. Agents of the importer, such as a broker, however, are not permitted to certify on behalf of the importer. Consistent with CBP's procedures, an importer shall identify certified entries by using the importer's additional declaration (record 54), AD/CVD Certification Designation (type code 6) when filing an entry summary.

Where the producer and the exporter are the same entity, the producer/exporter is required to complete and maintain the applicable producer/exporter certification and provide the importer with a copy of that certification and all supporting documentation (*e.g.,* invoice, purchase order, production records, etc.). With the exception of the entries described below, the producer certification must be completed, signed, and dated by the time of shipment of the relevant entry. The producer/exporter certification should be completed by the party producing and exporting the steel wire garment hangers that were manufactured in Cambodia to the United States.

Where the producer and exporter are different entities, (1) the producer is required to complete and maintain the applicable producer certification and provide the importer with a copy of that certification and all supporting documentation (*e.g.,* invoice, purchase order, production records, etc.), and (2) the exporter is required to complete and maintain the applicable exporter certification and provide the importer with a copy of that certification and all supporting documentation (*e.g.,* invoice, purchase order, production records, etc.).

Additionally, the claims made in the certifications and supporting documentation are subject to verification by Commerce or CBP. Importers and producers are required to maintain the certifications and supporting documentation until the later of: (1) the date that is five years after the latest entry date of the entries covered by the certification; or (2) the date that is three years after the conclusion of any litigation in the United States courts regarding such entries.

For all steel wire garment hangers that were entered, or withdrawn from warehouse, for consumption during the period August 12, 2025 (the date of publication of the initiation of these circumvention inquiries), through 45 days from the date on which Commerce published its preliminary circumvention findings in the **Federal Register**, where the entry has not been liquidated (and entries for which liquidation has not become final), the importer and producer certifications should be completed and signed as soon as practicable, but not later than 45 days of the date on which Commerce published its preliminary circumvention findings in the **Federal Register** . The importer's certification, the producer's certification, the commercial invoice, and documentation supporting the country of origin of the steel wire or type of input if not steel wire used to produce the steel wire garment hangers should be uploaded to the DIS in ACE as soon as practicable, but not later than 45 days of the date on which Commerce published its preliminary circumvention findings in the **Federal Register**. For such unliquidated

entries made prior to the publication of these preliminary determinations which are suspended under the antidumping and countervailing duty orders, the importer or producer each have the option to complete a blanket certification covering multiple entries, individual certifications for each entry, or a combination thereof.

As discussed in the Preliminary Decision Memoranda, this dual circumvention certification program is not available for companies to which Commerce has applied facts available with adverse inferences. Accordingly, as discussed in the Preliminary Decision Memoranda, Commerce preliminarily determines that Alpha Hanger, Everbrit and Kaining are ineligible to certify that any entries of hangers are made of Chinese-origin (1) steel wire or (2) steel wire and paper accessories.

Appendix IV

Importer Certification

I hereby certify that:

A. My name is {IMPORTING COMPANY OFFICIAL'S NAME} and I am an official of {IMPORTING COMPANY}, located at {ADDRESS OF IMPORTING COMPANY}.

B. I have direct personal knowledge of the facts regarding the importation into the Customs territory of the United States of the steel wire garment hangers assembled in Cambodia that entered under entry summary number(s), identified below, and are covered by this certification. ''Direct personal knowledge'' refers to facts the certifying party is expected to have in its own records. For example, the importer should have direct personal knowledge of the importation of steel wire garment hangers, including the producer, exporter and/or foreign seller's identity and location.

C. If the importer is acting on behalf of the first U.S. customer, include the following sentence as paragraph C of this certification:

The steel wire garment hangers covered by this certification were imported by {IMPORTING COMPANY} on behalf of {U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}.

If the importer is not acting on behalf of the first U.S. customer, include the following sentence as paragraph C of this certification:

{NAME OF IMPORTING COMPANY} is not acting on behalf of the first U.S. customer.

D. The steel wire garment hangers covered by this certification were shipped to {NAME OF PARTY IN THE UNITED STATES TO WHOM THE MERCHANDISE WAS FIRST SHIPPED}, located at {U.S. ADDRESS TO WHICH MERCHANDISE WAS SHIPPED}.

E. I have personal knowledge of the facts regarding the assembly of the imported products covered by this certification. ''Personal knowledge'' includes facts obtained from another party, (*e.g.,* correspondence received by the importer (or exporter) from the producer regarding the Chinese inputs used to produce the imported products).

F. This certification applies to the following entries (repeat this block as many times as necessary):

Entry Summary #:
Entry Summary Line Item #:
Foreign Seller's Address:
Foreign Seller's Invoice #:
Foreign Seller's Invoice Line Item #:
Country of Origin of steel wire:
Country of Origin of paper accessories (if applicable):
Producer:
Producer's Address:

G. The steel wire garment hangers covered by this certification contain only steel wire or steel wire and paper accessories produced in China.

H. I understand that {IMPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, certificates of origin, product data sheets, productions records, invoices, *etc.*) until the later of (1) the date that is five years after the latest entry date of the entries covered by the certification or (2) the date that is three years after the conclusion of any litigation in the United States courts regarding such entries.

I. I understand that, if the producer and the exporter are not the same entity, {IMPORTING COMPANY} is required to maintain a copy of the producer certification (attesting to the assembly of the imported merchandise identified above, if the producing company and the exporting company are not the same), and any supporting documentation provided to the importer by the producer, until the later of (1) the date that is five years after the latest entry date of the entries covered by the certification or (2) the date that is three years after the conclusion of any litigation in the United States courts regarding such entries.

J. I understand that, if the producer and the exporter are not the same entity, {IMPORTING COMPANY} is required to maintain a copy of the exporter certification (attesting to the assembly and exportation of the imported merchandise identified above, if the producing company and the exporting company are not the same), and any supporting documentation provided to the importer by the exporter, until the later of (1) the date that is five years after the latest entry date of the entries covered by the certification or (2) the date that is three years after the conclusion of any litigation in United States courts regarding such entries.

K. I understand that, if the producer and the exporter are the same entity, {IMPORTING COMPANY} is required to maintain a copy of the producer/exporter certification (attesting to the assembly/exportation of the imported merchandise identified above, if the producing company and the exporting company are the same), and any supporting documentation provided to the importer by the exporter, until the later of (1) the date that is five years after the latest entry date of the entries covered by the certification or (2) the date that is three years after the conclusion of any litigation in United States courts regarding such entries.

L. I understand that {IMPORTING COMPANY} is required to submit a copy of the importer, exporter (as applicable), producer (as applicable), and exporter/producer certifications (as applicable) as part of the entry summary by uploading them into the document imaging system (DIS) in ACE, and to provide U.S. Customs and Border Protection (CBP) and/or the U.S. Department of Commerce (Commerce) with the importer certification, and any supporting documentation, and a copy of the exporter, producer, or exporter/producer's certification, and any supporting documentation provided to the importer by such parties, upon request of either agency. Consistent with CBP's procedures, importers shall identify certified entries by using importers' additional declaration (record 54) AD/CVD Certification Designation (type code 06) when filing entry summary.

M. I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce.

N. I understand that failure to maintain the required certification and supporting documentation, or failure to substantiate the claims made herein, or not allowing CBP and/or Commerce to verify the claims made herein, may result in a *de facto* determination that all entries to which this certification applies are within the scope of the antidumping duty (AD) and countervailing duty (CVD) orders on steel wire garment hangers from Vietnam. I understand that such finding will result in:

(i) suspension of liquidation at the AD and CVD rates applicable to the Vietnam Order of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met;

(ii) the importer being required to post the AD and CVD cash deposits determined by Commerce; and

(iii) the importer no longer being allowed to participate in the certification process.

O. I understand that agents of the importer, such as brokers, are not permitted to make this certification. When a broker or other party was used to facilitate the entry process, {NAME OF IMPORTING COMPANY} obtained the entry summary number and date of entry summary from that party.

P. This certification was completed by the time of filing the entry summary or within 45 days of the date on which Commerce published its preliminary circumvention findings in the **Federal Register**.

Q. I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government.

Signature

{NAME OF COMPANY OFFICIAL}

{TITLE OF COMPANY OFFICIAL}

{DATE}

Exporter Certification

The party that made the sale to the United States, if different from the party that produced the merchandise, should fill out the exporter certification.

I hereby certify that:

A. My name is {COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF FOREIGN COMPANY THAT MADE THE SALE TO THE UNITED STATES}, located at

{ADDRESS OF FOREIGN COMPANY THAT MADE THE SALE TO THE UNITED STATES}.

B. I have direct personal knowledge of the facts regarding the assembly and exportation of the steel wire garment hangers for which sales are identified below. ''Direct personal knowledge'' refers to facts the certifying party is expected to have in its own records. For example, an exporter should have direct personal knowledge of the use of Chinese inputs in the assembly of hangers imported into the United States, the exportation of steel wire garment hangers, as well as the producer's identity and location.

C. The steel wire garment hangers covered by this certification were shipped to {NAME OF PARTY IN THE UNITED STATES TO WHOM MERCHANDISE WAS FIRST SHIPPED}, located at {U.S. ADDRESS TO WHICH MERCHANDISE WAS SHIPPED}.

D. The steel wire garment hangers covered by this certification contain only steel wire or steel wire and paper accessories produced in China.

E. This certification applies to the following sales to {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER} (repeat this block as many times as necessary):

Foreign Seller's Invoice # to U.S. Customer:
Foreign Seller's Invoice to U.S. Customer Line item #:
Producer Name:
Producer's Address:
Producer's Invoice # to Foreign Seller:

F. I understand that {NAME OF FOREIGN COMPANY THAT MADE THE SALE TO THE UNITED STATES} is required to maintain a copy of this certification and the producer certification (attesting to the assembly of the imported merchandise identified above, if the producing company and the exporting company are not the same), and sufficient documentation supporting these certifications (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, product data sheets, productions records, invoices, *etc.*) until the later of: (1) the date that is five years after the latest date of the entries covered by the certification; or (2) the date that is three years after the conclusion of any litigation in the United States courts regarding such entries.

G. I understand that {NAME OF FOREIGN COMPANY THAT MADE THE SALE TO THE UNITED STATES} is required to provide the U.S. importer with a copy of both this certification and the producer certification, and is required to provide U.S. Customs and Border Protection (CBP) and/or the U.S. Department of Commerce (Commerce) with this certification and the producer certification, and any supporting documents, upon request of either agency.

H. I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce.

I. I understand that failure to maintain the required certification and supporting documentation, or failure to substantiate the claims made herein, or not allowing CBP and/or Commerce to verify the claims made herein, may result in a *de facto* determination that all sales to which this certification applies are within the scope of the antidumping duty and countervailing duty orders on steel wire garment hangers from Vietnam. I understand that such a finding will result in:

(i) suspension of all unliquidated entries at the AD and CVD rates applicable to the Vietnam Order (and entries for which liquidation has not become final) for which these requirements were not met;

(ii) the importer being required to post the antidumping duty and countervailing duty cash deposits determined by Commerce; and

(iii) the seller/exporter no longer being allowed to participate in the certification process.

J. I understand that agents of the seller/exporter, such as freight forwarding companies or brokers, are not permitted to make this certification.

K. This certification was completed at time of shipment or within 45 days of the date on which Commerce published its preliminary circumvention findings in the **Federal Register**.

L. I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government.

Signature

{NAME OF COMPANY OFFICIAL}

{TITLE OF COMPANY OFFICIAL}

{DATE}

Producer Certification

The party that assembled the steel wire garment hangers exported to the United States, if different from the party that exported the merchandise, should fill out the producer certification.

I hereby certify that:

A. My name is {COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF FOREIGN COMPANY THAT ASSEMBLED THE STEEL WIRE GARMENT HANGERS SOLD TO THE UNITED STATES}, located at {ADDRESS OF FOREIGN COMPANY THAT ASSEMBLED THE STEEL WIRE GARMENT HANGERS SOLD TO THE UNITED STATES}.

B. I have direct personal knowledge of the facts regarding the assembly and exportation of the steel wire garment hangers for which sales are identified below. ''Direct personal knowledge'' refers to facts the certifying party is expected to have in its own records. For example, a producer should have direct personal knowledge of the use of Chinese inputs in the assembly of hangers imported into the United States, and the exporter's name and address.

C. The steel wire garment hangers covered by this certification were sold to {NAME OF FOREIGN COMPANY THAT EXPORTED THE MERCHANDISE TO THE UNITED STATES}, located at {ADDRESS OF FOREIGN COMPANY THAT EXPORTED THE MERCHANDISE TO THE UNITED STATES}.

D. The steel wire garment hangers covered by this certification were shipped by the {FOREIGN COMPANY THAT EXPORTED THE MERCHANDISE TO THE UNITED STATES} to {NAME OF PARTY IN THE UNITED STATES TO WHOM MERCHANDISE WAS FIRST SHIPPED}, located at {U.S. ADDRESS TO WHICH MERCHANDISE WAS SHIPPED}.

E. The steel wire garment hangers covered by this certification contain only steel wire or steel wire and paper accessories produced in China.

F. This certification applies to the following sales to {NAME OF FOREIGN EXPORTER}, located at {ADDRESS OF FOREIGN EXPORTER} (repeat this block as many times as necessary):

Producer Name:
Producer's Address:
Producer's Invoice # to Foreign Seller:
Name of Producer of Steel Wire Input:
Address of Supplier of Steel Wire Input:
Name of Producer of Paper Accessory Input:
Address of Supplier of Paper Accessory Input:

G. I understand that {NAME OF FOREIGN COMPANY THAT ASSEMBLED THE STEEL WIRE GARMENT HANGERS SOLD TO THE UNITED STATES} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, product data sheets, productions records, invoices, *etc.*) until the later of: (1) the date that is five years after the latest date of the entries covered by the certification; or (2) the date that is three years after the conclusion of any litigation in the United States courts regarding such entries.

H. I understand that {NAME OF FOREIGN COMPANY THAT ASSEMBLED THE STEEL WIRE GARMENT HANGERS SOLD TO THE UNITED STATES} is required to provide the {NAME OF FOREIGN EXPORTER} with a copy of this certification and is required to provide U.S. Customs and Border Protection (CBP) and/or the U.S. Department of Commerce (Commerce) with this certification, and any supporting documents, upon request of either agency.

I. I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce.

J. I understand that failure to maintain the required certification and supporting documentation, or failure to substantiate the claims made herein, or not allowing CBP and/or Commerce to verify the claims made herein, may result in a *de facto* determination that all sales to which this certification applies are within the scope of the antidumping duty and countervailing duty orders on steel wire garment hangers from Vietnam. I understand that such a finding will result in:

(i) suspension of all unliquidated entries at the AD and CVD rates applicable to the Vietnam Order (and entries for which liquidation has not become final) for which these requirements were not met;

(ii) the importer being required to post the antidumping duty and countervailing duty cash deposits determined by Commerce; and

(iii) the seller/exporter no longer being allowed to participate in the certification process.

K. I understand that agents of the seller/exporter, such as freight forwarding companies or brokers, are not permitted to make this certification.

L. This certification was completed at time of shipment or within 45 days of the date on which Commerce issued its preliminary circumvention findings in the **Federal Register**.

M. I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government.

Signature

{NAME OF COMPANY OFFICIAL}

{TITLE OF COMPANY OFFICIAL}

{DATE}

Producer/Exporter Certification

The party that produced and made the sale to the United States should fill out the producer/exporter certification.

I hereby certify that:

A. My name is {COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF FOREIGN COMPANY THAT ASSEMBLED AND MADE THE SALE TO THE UNITED STATES}, located at {ADDRESS OF FOREIGN COMPANY THAT ASSEMBLED AND MADE THE SALE TO THE UNITED STATES}.

B. I have direct personal knowledge of the facts regarding the assembly and exportation of the steel wire garment hangers for which sales are identified below. ''Direct personal knowledge'' refers to facts the certifying party is expected to have in its own records. For example, an exporter/producer should have direct personal knowledge of the use of Chinese inputs in the assembly of steel wire garment hangers imported into the United States.

C. The steel wire garment hangers covered by this certification were shipped to {NAME OF PARTY IN THE UNITED STATES TO WHOM MERCHANDISE WAS FIRST SHIPPED}, located at {U.S. ADDRESS TO WHICH MERCHANDISE WAS SHIPPED}.

D. The steel wire garment hangers covered by this certification contain only steel wire or steel wire and paper accessories produced in China.

E. This certification applies to the following sales to {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER} (repeat this block as many times as necessary):

Foreign Producer/Seller's Invoice # to U.S. Customer:

Foreign Producer/Seller's Invoice to U.S. Customer Line item #:

Producer/Seller's Name:

Producer/Seller's Address:

Name of Producer of Steel Wire Input:

Address of Supplier of Steel Wire Input:

Name of Producer of Paper Accessory Input:

Address of Supplier of Paper Accessory Input:

F. I understand that {NAME OF FOREIGN COMPANY THAT ASSEMBLED AND MADE THE SALE TO THE UNITED STATES} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, product data sheets, productions records, invoices, *etc.*) until the later of: (1) the date that is five years after the latest date of the entries covered by the certification; or (2) the date that is three years after the conclusion of any litigation in the United States courts regarding such entries.

G. I understand that {NAME OF FOREIGN COMPANY THAT PRODUCED AND MADE THE SALE TO THE UNITED STATES} is required to provide the U.S. importer with a copy of this certification and is required to provide U.S. Customs and Border Protection (CBP) and/or the U.S. Department of Commerce (Commerce) with this certification, and any supporting documents, upon request of either agency.

H. I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce.

I. I understand that failure to maintain the required certification and supporting documentation, or failure to substantiate the claims made herein, or not allowing CBP and/or Commerce to verify the claims made herein, may result in a *de facto* determination that all sales to which this certification applies are within the scope of the antidumping duty and countervailing duty orders on steel wire garment hangers from Vietnam. I understand that such a finding will result in:

(i) suspension of all unliquidated entries at the AD and CVD rates applicable to the Vietnam Order (and entries for which liquidation has not become final) for which these requirements were not met;

(ii) the importer being required to post the antidumping duty and countervailing duty cash deposits determined by Commerce; and

(iii) the seller/exporter no longer being allowed to participate in the certification process.

J. I understand that agents of the seller/exporter, such as freight forwarding companies or brokers, are not permitted to make this certification.

K. This certification was completed at time of shipment or within 45 days of the date on which Commerce published its preliminary circumvention findings in the **Federal Register**.

L. I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government.

Signature

{NAME OF COMPANY OFFICIAL}

{TITLE OF COMPANY OFFICIAL}

{DATE}

[FR Doc. 2026–22658 Filed 11–5–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Oakland University, et.al; Application(s) for Duty-Free Entry of Scientific Instruments

Pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, asamended by Pub. L. 106–36; 80 Stat. 897; 15 CFR part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.Further information on the application can be found here: *https://www.trade.gov/sips-florence-frs.*

Comments must comply with 15 CFR 301.5(a)(3) and (4) of the regulations and be postmarked on or before November 27, 2026. Address written comments to Statutory Import Programs Staff, Room 40005, U.S. Department of Commerce, Washington, DC 20230. Please also email a copy of those comments to *SIPS-Florence@trade.gov.*

Docket No.	Applicant	Instrument
26–125	Oakland University	JSM–1T710HKLV Low Vacuum Scanning Electron Microscope.
26–127	University of Virginia	Radio Telescope.
26–129	University of Iowa	Leica Confocal Microscope.
26–130	University of Miami	FluoTime 300.
26–136	UChicago Argonne LLC	RF Power Amplifier.
26–137	Iowa State University (dba Ames National Laboratory)	Gyrotron and DNP Probe.
26–139	UChicago Argonne LLC	Electron Beam Evaporator.
26–141	Massachusetts Institute of Technology	1.3mm probe for a 600MHz NMR Spectrometer.
26–143	New York University	Dilution Refrigerator.
26–144	UChicago Argonne LLC	Solid State RF Amplifier Parts.
26–146	UChicago Argonne LLC	RF Beam Position Monitor Electronics.

Docket No.	Applicant	Instrument
26–148	University of Massachusetts-Amherst	Heliosmart He Recovery System for 800MHz NMR Spectrometer.
26–149	Rice University	Voltage Preamplifiers and Power Supplies.
26–150	Battelle Memorial Institute	ZSX Primus IV Sequential Wavelength-Dispersive X-Ray Fluorescence Spectrometer.
26–151	Stanford University	Scanning tunneling microscope with helium3 insert.
26–152	University of California, Riverside	Cryocooling LD400 System w PT310 and Wiring Options and Upgrade to PT310–RM Cryocooler.
26–153	Clemson University	Nuclear Magnetic Resonance.
26–154	University of Maryland	Proteox 450 System Cryostat.
26–155	University of North Carolina at Chapel Hill	Krios G4 CryoElectron Microscope.
26–156	Battelle Memorial Institute	Nanotag Freshwater DSP.
26–157	University of Michigan	XYZ Stage and Rotator.
26–159	University of Pittsburgh	Mass Spectrometer.
26–160	University of Kentucky	Tekna Tek15 Plasmasonic ICPT15 15kW Induction Plasma High Enthalpy Wind Tunnel.
26–161	University of South Carolina	DEBEN–907–00047: DEBEN CENTAURUS–PMT CL Detector, DEBEN WDS PORT.
26–162	Mass General Brighan Inc.	Biospec 15T/11cm Magnetic Resonance Imaging.
26–163	Michigan State University	Ultrafast Spinning Probe for Solid-State Nuclear Magnetic Resonance Spectrometer.
26–164	University of Arizona	Modulator for an X-band Magnetron, standard Model M060, combined with a microwave isolator and waveguide parts.
26–168	University of Alabama at Birmingham	JSM–IT810(HL) Scanning Electron Microscope System.
26–169	University of Illinois Chicago	timsTOE flex LC–MS System.
26–170	Brookhaven National Laboratory	Multi-Purpose Electron Microscope Model: JEM–F200 (CF–HR) and accessories and attachments.
26–171	UChicago Argonne LLC	LD400 GHS2 with Custom MXC Plate.
26–172	Mayo Clinic	MRI BioSpec 70/20 USR System.
26–173	Columbia University	Tunable Laser Source (Model TSL–570A).
26–174	University of Texas and Austin	ID281–SO–8 channel Superconducting Nanowire Single-Photon Detectors.
26–175	University of Illinois	Chameleon Discovery NX with TPR: Dual (Laser).
26–176	Battelle Memorial Institute	Apreo 2S LoVac Field Emissions Scanning Electron Microscope and ancillary equipment.
26–177	University of Illinois Urbana-Champaign	OptoRes Laser.
26–186	Lawrence Berkeley National Laboratory	Superconducting Nanowire Single-Photon Detector.
26–187	University of California	Dilution Refrigerator.
26–190	University of Wisconsin Madison	Motif video recording system (Custom Kastl HighRes System V2).

Dated: November 3, 2026.

Lana Nigro,

Acting Director, Subsidies Enforcement, Enforcement and Compliance.

[FR Doc. 2026–22700 Filed 11–5–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XG147]

Atlantic Highly Migratory Species; Advisory Panel

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

ACTION: Notice; solicitation of nominations.

SUMMARY: NMFS solicits nominations for the Atlantic Highly Migratory Species (HMS) Advisory Panel (AP). NMFS consults with and considers the comments and views of the HMS AP when preparing and implementing fishery management plans (FMPs) or FMP amendments for Atlantic swordfish, sharks, tunas, and billfish. Nominations are being sought to fill approximately one third (10) of the seats on the HMS AP, each with a 3-year appointment. NMFS will consider individuals with definable interests in recreational and commercial fishing and related industries, including those from the environmental community and non-governmental organizations, for membership on the HMS AP.

DATES: Submit nominations on or before December 7, 2026.

ADDRESSES: You may submit nominations and requests for the AP Statement of Organization, Practices, and Procedures by email to *HMSAP.Nominations@noaa.gov*. Include in the subject line the following identifier: ''HMS AP Nominations.''

FOR FURTHER INFORMATION CONTACT: Anna Quintrell at 301–427–8503 or via email at *HMSAP.Nominations@noaa.gov*.

SUPPLEMENTARY INFORMATION: HMS fisheries (swordfish, sharks, tunas, and billfish) are managed under the 2006 Consolidated HMS FMP and its amendments pursuant to the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) and consistent with the Atlantic Tunas Convention Act (16 U.S.C. 971 *et seq.*). HMS implementing regulations are at 50 CFR part 635.

The Magnuson-Stevens Act requires NMFS to establish an AP for each HMS FMP (16 U.S.C. 1854(g)(1)(A)–(B)). Since the inception of the AP in 1998, NMFS has consulted with and considered the comments and views of AP members when preparing and implementing HMS FMPs or FMP amendments. In this notice, NMFS solicits nominations for the HMS AP.

Nominations are being sought to fill approximately one third (10) of the seats on the HMS AP for 3-year appointments. NMFS will consider individuals with definable interests in recreational and commercial fishing and related industries, including those from the environmental community and non-governmental organizations for membership on the HMS AP as described below.

Procedures and Guidelines

Nomination Procedures for Appointments to the AP

Nomination packages should include:

1. The name and contact information, including mailing address, email address, and phone number of the nominee;

2. A description of the nominee's interest in HMS or HMS fisheries, or in particular species of swordfish, sharks, tunas, or billfish;

3. A statement of the nominee's background and/or qualifications;

4. A list of outreach resources that the nominee has at their disposal; and

5. A written commitment that the nominee shall actively participate in good faith in the meetings and tasks of the HMS AP.

Advisory Panel members will be required to comply with applicable rules of conduct, including all ethics requirements. Qualification for membership includes experience in one or more of the following:

1. HMS recreational fisheries;

2. HMS commercial fisheries;

3. Fishery-related industries (*e.g.,* marinas, bait and tackle shops);

4. The scientific community working with HMS; and/or

5. Representation of a private, non-governmental, regional, national, or international organization that represents marine fisheries, or environmental, governmental, or academic interests regarding HMS.

HMS AP Tenure

Members are appointed for 3-year terms. Approximately one third of the members' terms expire on December 31 of each year. NMFS is seeking nominations for terms beginning January 2027 and expiring December 2029.

Members can serve a maximum of three consecutive terms (a total of 9 consecutive years). Afterwards, a member must then sit off the HMS AP for a single year before becoming eligible to apply for a new term.

Participants

NMFS will accept nominations for the HMS AP that allow for representation from commercial and recreational fishing interests, scientific interests, and the environmental/non-governmental organization community, for individuals who are knowledgeable about HMS and/or HMS fisheries. Current representation on the HMS AP, as shown in table 1, consists of 12 members representing commercial interests, 12 members representing recreational interests, 4 members representing environmental interests, 4 academic representatives, and the International Commission for the Conservation of Atlantic Tunas Advisory Committee Chair. NMFS seeks to fill five commercial, three recreational, one academic, and one environmental sector vacancies for terms starting in 2027.

In filling vacancies, NMFS will seek to maintain the current representation from each of the sectors. NMFS also considers species expertise and representation from the fishing regions (Northeast, Mid-Atlantic, Southeast, Gulf of America, and Caribbean) to ensure the balance of the HMS AP. Table 1 includes the current representation on the HMS AP by sector, region, and species with terms that are expiring identified in the ''Member Status'' column. It is not meant to indicate that NMFS will only consider persons who have expertise in the species or fishing regions that are listed. Rather, NMFS will aim toward having as balanced an AP as possible. The intent is to have a group that, as a whole, reflects an appropriate and equitable balance and mix of interests given the responsibilities of the HMS AP.

TABLE 1—CURRENT REPRESENTATION ON THE HMS AP BY SECTOR, REGION, AND SPECIES

Sector	Fishing region	Species	Date appointed	Date term expires	Member status
Academic	All	Billfish/HMS	1/1/2024	12/31/2026	Expiring.
Academic	NE/Mid-Atlantic	Tuna/Shark	1/1/2025	12/31/2027	Active.
Academic	SE/Gulf	Sharks	1/1/2025	12/31/2027	Active.
Academic	Northeast	HMS	1/1/2025	12/31/2027	Active.
Commercial	Gulf	Tuna	1/1/2026	12/31/2028	Active.
Commercial	Southeast	Swordfish	1/1/2026	12/31/2028	Active.
Commercial	Mid-Atlantic/SE	Tuna	1/1/2026	12/31/2028	Active.
Commercial	Northeast	HMS	1/1/2024	12/31/2026	Expiring.
Commercial	Northeast	Tuna	1/1/2024	12/31/2026	Expiring.
Commercial	Northeast	Tuna	1/1/2024	12/31/2026	Expiring.
Commercial	Gulf of America	HMS	1/1/2024	12/31/2026	Expiring.
Commercial	Southeast/Gulf	HMS	1/1/2025	12/31/2027	Active.
Commercial	Northeast	Tuna	1/1/2024	12/31/2026	Expiring.
Commercial	All	HMS/Tuna	1/1/2025	12/31/2027	Active.
Commercial	Southeast	Sharks	1/1/2025	12/31/2027	Active.
Commercial	Northeast	Swordfish/Tuna	1/1/2025	12/31/2027	Active.
Environmental	All	Shark	1/1/2026	12/31/2028	Active.
Environmental	Gulf	HMS	1/1/2026	12/31/2028	Active.
Environmental	All	HMS	1/1/2024	12/31/2026	Expiring.
Environmental	Caribbean	HMS	1/1/2025	12/31/2027	Active.
Recreational	Mid-Atlantic	Tuna/Billfish	1/1/2024	12/31/2026	Expiring.
Recreational	Mid-Atlantic	Shark	1/1/2024	12/31/2026	Expiring.
Recreational	Northeast	Tuna/Sharks	1/1/2026	12/31/2028	Active.
Recreational	All	HMS	1/1/2026	12/31/2028	Active.
Recreational	Gulf	HMS	1/1/2026	12/31/2028	Active.
Recreational	All	HMS	1/1/2026	12/31/2028	Active.
Recreational	Southeast	HMS/Billfish	1/1/2026	12/31/2028	Active.
Recreational	Southeast	HMS/Billfish	1/1/2026	12/31/2028	Active.
Recreational	All	Billfish	1/1/2024	12/31/2026	Expiring.

TABLE 1—CURRENT REPRESENTATION ON THE HMS AP BY SECTOR, REGION, AND SPECIES—Continued

Sector	Fishing region	Species	Date appointed	Date term expires	Member status
Recreational	NE/Mid-Atlantic	HMS	1/1/2025	12/31/2027	Active.
Recreational	NE/Mid-Atlantic	Tuna/Shark	1/1/2025	12/31/2027	Active.
Recreational	Northeast	Tuna/Shark	1/1/2025	12/31/2027	Active.

Note: Terms that are expiring or associated with current members stepping down are marked as ''Expiring.''

Five additional members on the HMS AP include one member representing each of the following Fishery Management Councils: the New England Fishery Management Council, the Mid-Atlantic Fishery Management Council, the South Atlantic Fishery Management Council, the Gulf Fishery Management Council, and the Caribbean Fishery Management Council. The HMS AP also includes 22 ex-officio participants: 20 representatives of the coastal states and 2 representatives of the interstate commissions (the Atlantic States Marine Fisheries Commission and the Gulf States Marine Fisheries Commission).

NMFS will provide the necessary administrative support, including technical assistance, for the HMS AP. However, NMFS will not compensate participants with monetary support of any kind. Depending on availability of funds, members may be reimbursed for travel costs related to the HMS AP meetings.

Meeting Schedule

NMFS will hold meetings of the HMS AP as frequently as necessary and, at a minimum, twice each year. In recent years, NMFS held meetings once in the spring and once in the fall. The meetings may be held in conjunction with public hearings.

Dated: November 3, 2026.

Shannon Bettridge,

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

[FR Doc. 2026–22669 Filed 11–5–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XG156]

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review; Public Meeting

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

ACTION: Notice of webinar.

SUMMARY: The Southeast Data Assessment and Review (SEDAR) 90 assessment process of South Atlantic Red Snapper will consist of a Data Workshop, a series of Assessment Webinars, and a Review Workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 90 Assessment Webinar 13 will be held from 1 p.m. until 4 p.m. EDT on December 4, 2026.

ADDRESSES:

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

Meeting address: The SEDAR 90 Assessment Webinar 13 will be held via webinar. The webinar is open to members of the public. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice. *https://www.sedarweb.org.*

FOR FURTHER INFORMATION CONTACT: Emily Ott, SEDAR Coordinator; (843) 302–8434. Email: *Emily.Ott@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with the NMFS and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the SEDAR process. SEDAR is a participatory process for developing, evaluating and reviewing information used for fisheries management advice. This multi-step process for determining the status of fish stocks in the Southeast Region may include (1) a data stage, (2) an assessment stage, and (3) a review stage. Each stage produces a report summarizing decisions made during that stage. A final stock assessment report is produced at the end of a SEDAR process documenting data sets used, model configurations, and the opinions from the independent peer review. Participants for SEDAR projects are appointed by the Gulf, South Atlantic, and Caribbean Fishery Management Councils and National Marine Fisheries Service Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants may include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations; International experts; and staff of Councils, Commissions, and State and Federal agencies.

The items of discussion in the SEDAR 90 Assessment Webinar 13 are as follows:

Participants will review recommendations made on Assessment Webinar 11 and continue discussion of new modeling topics. Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

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

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

Dated: November 4, 2026.

Rey Israel Marquez,

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

[FR Doc. 2026–22689 Filed 11–5–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

U.S. Integrated Ocean Observing System (IOOS®) Advisory Committee

AGENCY: U.S. Integrated Ocean Observing System (IOOS®), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice of new member solicitation for the United States Integrated Ocean Observing System (U.S. IOOS) Advisory Committee.

SUMMARY: NOAA is soliciting applications for membership on the United States Integrated Ocean Observing System Advisory Committee (the Committee), which is a Federal Advisory Committee. The Committee is mandated by the Integrated Coastal and Ocean Observation System Act of 2009 (the Act), part of the Omnibus Public Land Management Act of 2009 (Pub. L. 111–11), and the Coordinated Ocean Observations and Research Act of 2020 (Pub. L. 116–271) to provide advice to the NOAA Administrator and to the Interagency Ocean Observation Committee on the planning, integrated design, operation, maintenance, enhancement, and expansion of the United States Integrated Ocean Observing System (U.S. IOOS). NOAA is accepting applications for membership on the Committee to fill vacancies that will occur on September 14, 2027. NOAA encourages applications from individuals with expertise and/or experience in the following areas: coastal and ocean observing; data management and architecture; coastal and ocean modeling; Great Lakes; philanthropy; Non-Governmental Organization; scientific institutions (Academic); IOOS regional interests; State, local and tribal interests; blue economy; social science; public-private partnerships; marine technologies industries; ocean and coastal leadership; and other science-related fields.

DATES: Applications should be submitted no later than January 5, 2027. Applications received after January 5, 2027 may not be considered during this membership application cycle, but may be considered for future membership cycles.

ADDRESSES: Applications and questions about applications should be submitted via email *ioos.ac.staff@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Krisa Arzayus, Designated Federal Official, U.S. IOOS Advisory Committee, U.S. IOOS Office, *krisa.arzayus@noaa.gov* or visit the U.S. IOOS Advisory Committee website at *https://ioos.noaa.gov/community/u-s-ioos-advisory-committee/.*

SUPPLEMENTARY INFORMATION:

I. Background

U.S. IOOS (*https://ioos.noaa.gov*) is an integrated network of people and technology gathering coastal data and developing tracking and predictive tools to benefit the economy, the environment, and public safety at home, across the nation, and around the globe. U.S. IOOS promotes research to develop, test, and deploy innovations and improvements in coastal and ocean observation technologies and modeling systems, addresses regional and national needs for ocean information, gathers data on key coastal, ocean, and Great Lakes variables and ensures timely and sustained dissemination and availability of these data for societal benefits. U.S. IOOS benefits national safety, the economy, and the environment through support for national defense, marine commerce and forecasting, navigation safety, weather, economic development, ecosystem-based management of marine and coastal areas, conservation of ocean and coastal resources and public safety. This notice responds to the Act (Pub. L. 111–11, section 12304), which requires the Under Secretary of Commerce for Oceans and Atmosphere to solicit nominations for Committee membership. The Committee advises the NOAA Administrator and Interagency Ocean Observation Committee on matters related to the responsibilities and authorities set forth in section 12302 of the Act and other appropriate matters as the Under Secretary refers to the Committee for review and advice. The Committee has approximately fifteen voting members. For additional information about the Committee responsibilities, see *https://ioos.noaa.gov/community/u-s-ioos-advisory-committee/.*

II. Eligibility and Criteria

Membership is open to individuals from academia; local, state or tribal government; industry; non-governmental not-for-profit, and other ocean-related institutions. Full-time officers or employees of the United States are not eligible. Race or sex shall not be considered in selection of Committee members. Members shall be qualified by education, training, and experience to evaluate scientific, technical, and programmatic information related to the design, operation, maintenance, or use of the U.S. IOOS, or use of data products provided through the U.S. IOOS.

III. Terms of Service

The NOAA Administrator shall appoint new Committee members for three-year terms, renewable once for an additional three-year term. The next term will begin on September 14, 2027.

IV. Expectations

The Committee will meet at least once each year in-person, with additional virtual meetings throughout the year. In a typical year, a committee member is expected to attend at least one in-person meeting (2–4 days including travel) and commit approximately 20–25 additional hours to attend virtual meetings and draft recommendation reports. Members of the Committee will not be compensated for service on the Committee, but they may be allowed travel expenses, including per diem in lieu of subsistence, in accordance with subchapter I of chapter 57 of title 5, United States Code.

V. Application

To apply for membership, applicants must submit the following items. The entire package should not exceed eight pages.

(1) A cover letter that serves as a statement of interest to serve on the Committee and provides the requested information listed below.

(a) Applicant's area(s) of expertise, as aligned with the expertise requested in the **SUMMARY** section above.

(b) The geographic region(s) of the country most closely associated with the applicant's area of expertise. This does not need to be the region the applicant currently resides in.

(c) Previous/current leadership or professional experience that may contribute to the effectiveness of the Committee.

(d) Familiarity and experience with U.S. IOOS data, products, and services.

(e) Breadth and scope of knowledge of stakeholders, users, or other groups who interact with NOAA or other U.S. IOOS agencies and whose views and input applicant believes they can share with the panel.

(2) A short biography of 300 to 400 words.

(3) A current resume.

(4) The nominee's full name, title, institutional affiliation, mailing address, email, and phone.

VI. Selection

Nominations will be reviewed and evaluated based on expertise, Committee needs, and balance considerations. Final appointments are made by the NOAA Administrator. Individuals selected for membership become a Special Government

Employee (SGE) of the United States Government. An SGE is an officer or employee of an agency who is retained, designated, appointed, or employed to perform temporary duties, with or without compensation, for not to exceed 130 days during any period of 365 consecutive days, either on a full- time or intermittent basis. Applicants who are selected to serve on the Committee must complete the following actions before they can serve as a committee member:

(1) Security Clearance (on-line Background Check and fingerprinting).

(2) Confidential Financial Disclosure Report—SGEs are required to file annually a Confidential Financial Disclosure Report to avoid involvement in a real or apparent conflict of interest.

(3) Attend annual ethics briefings to comply with government ethics standards.

Authority: Integrated Coastal and Ocean Observation System Act, part of the Omnibus Public Land Management Act of 2009 (Public Law 111–11), and the Coordinated Ocean Observations and Research Act of 2020 (Public Law 116–271).

Krisa M. Arzayus,

Acting Director, U.S. IOOS Office, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2026–22681 Filed 11–5–26; 8:45 am]

BILLING CODE 3510–NE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Notice of Public Hearings and Availability of the Draft Environmental Impact Statement and Draft Management Plan for the Proposed Designation of the Green Bay National Estuarine Research Reserve

AGENCY: Office for Coastal Management (OCM), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce.

ACTION: Notice of availability; public hearings.

SUMMARY: Notice is hereby given that, pursuant to the Coastal Zone Management Act, as amended (CZMA), the National Oceanic and Atmospheric Administration (NOAA) Office for Coastal Management is announcing a 45-day public comment period and public hearings to solicit comments on the draft management plan (DMP) and draft environmental impact statement (DEIS) for the proposed designation of the Green Bay National Estuarine Research Reserve (Green Bay Reserve). The DMP addresses research, monitoring, education, and stewardship needs for the proposed Green Bay Reserve, and the DEIS evaluates alternatives to the proposed action, along with the potential environmental impacts of these alternatives.

DATES: NOAA is accepting written public comments on the adequacy of the DMP and DEIS for the proposed designation of the Green Bay Reserve through 11:59 p.m. Central Time (CT) on December 21, 2026. In addition, NOAA will accept oral public comments on the adequacy of the DMP and DEIS for the proposed designation of the Green Bay Reserve during a virtual public hearing held from 10 a.m. to 11:30 a.m. CT via Zoom and an in-person public hearing held from 2:30 p.m. to 4 p.m. CT on Thursday, December 10, 2026. All comments received at the December 10 public hearings and during the 45-day public comment period will be considered in preparing the final management plan and final environmental impact statement for the proposed designation of the Green Bay Reserve.

ADDRESSES: Hearing documents are available on the federal eRulemaking portal at *www.regulations.gov* (enter NOAA–NOS–2024–0006 in the *Search* box). Written comments may be submitted using the following methods:

- *Electronic Submission:* Submit all electronic public comments via the federal eRulemaking portal. Go to *www.regulations.gov* and enter NOAA–NOS–2024–0006 in the *Search* box. Click the *Comment* icon, complete the required fields, and enter or attach your comment. Written comments provided electronically must be submitted no later than 11:59 p.m. CT on December 21, 2026.
- *Mail:* Submit written comments to Erica Seiden, NOAA Office for Coastal Management, 1305 East-West Highway, 10th Floor, Silver Spring, Maryland 20910; ATTN: Green Bay NERR. Written comments provided by mail must be postmarked no later than December 21, 2026.

Instructions: All comments received are part of the public record and will be posted for public viewing on *https://regulations.gov/docket?D=NOAA-NOS-2024-0006* with no changes. All personally identifiable information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the commenter will be publicly accessible and maintained by NOAA as part of the public record. NOAA will accept anonymous comments. To do so, on the *eRulemaking Portal,* enter ''N/A'' in the required fields if you wish to remain anonymous. If you would like to submit an anonymous comment during the in-person meeting, a comment box, along with paper and writing implements, will be provided. If you would like to provide an anonymous comment during the virtual public scoping meeting, type your comment into the question box, and state that you would like to remain anonymous when your comment is read. Multimedia submissions (*i.e.,* audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. NOAA will generally not consider comments, or comment contents, located outside of the primary submission sites or addresses (*i.e.,* those posted on the web, cloud, or other file-sharing system).

Public Hearings

- The virtual public hearing will be held via Zoom at the following link: *https://wisconsin-edu.zoom.us/j/96577868965* on December 10, 2026, at 10 a.m. CT. If requested upon joining the virtual hearing, the meeting ID is 965 7786 8965. This virtual public hearing may also be joined via telephone. The telephone number is (301) 715–8592, and the access code is 96577868965#.
- The in-person public hearing will be conducted on December 10, 2026, at 2:30 p.m. CT in Room 136 of the S.T.E.M. Innovation Center at the University of Wisconsin–Green Bay campus, located at 2019 Technology Way, Green Bay, Wisconsin 54311. This hearing will be in-person only and not broadcast.

Participants can provide comments during both the virtual and in-person hearings. Both public hearings will present the same information. To ensure full consideration by NOAA, oral comments must be in English. The public hearings will be transcribed.

FOR FURTHER INFORMATION CONTACT: Erica Seiden, NOAA Office for Coastal Management, 1305 East-West Highway, 10th Floor, Silver Spring, Maryland 20910; ATTN: Green Bay NERR; (240) 429–5166; *erica.seiden@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The National Estuarine Research Reserve System (Reserve System) is a federal-state partnership program authorized under the Coastal Zone Management Act, as amended (16 U.S.C.

1461). The Reserve System protects a representative system of estuaries across the nation and is dedicated to improving estuarine science, education, and stewardship. Reserve activities directly inform the local and national management of the nation's coasts and increase the resilience of coastal communities. There are currently 30 reserves across 25 different U.S. states and territories. Together, the national reserves protect more than 1.4 million acres of estuarine habitat for long-term research, monitoring, education, and stewardship.

Each reserve is managed by a lead state agency or university and brings together local stakeholders, scientists, land management professionals, and educators to understand coastal management issues and generate local, integrated solutions. NOAA administers the Reserve System but does not own or manage the land within a reserve. Instead, NOAA provides strategic direction, national coordination, technical assistance, and funding to states to implement reserves at the local level. The designation of a reserve does not add new state or federal regulations. Memoranda of Agreement are used to articulate roles and responsibilities among relevant partners and landowners in the state and NOAA.

The Green Bay Reserve nomination process formally began on March 25, 2019, when the governor of Wisconsin submitted a letter of interest to NOAA. NOAA responded affirmatively on July 19, 2019. Between September 2020 and September 2022, the University of Wisconsin–Green Bay, with guidance from NOAA, undertook a comprehensive site selection process for the proposed Green Bay Reserve. This process was informed by input from the public, affected landowners, state and federal agency representatives, Tribal nations, academia, nongovernmental organizations, and local government units. Through this collaborative process, the state selected a site for the proposed reserve comprising three components (Peshtigo River, Lower Bay, and Sturgeon Bay) and consisting entirely of publicly owned or land trust-held areas. NOAA received the state's nomination of the proposed multicomponent site for the Green Bay Reserve on December 29, 2022. NOAA evaluated the nomination package and found that the proposed site met the Reserve System's requirements. (See 16 U.S.C. 1461(b).)

On January 25, 2024, NOAA informed the State of Wisconsin of its accepted nomination and started the formal designation process by publishing a notice of intent to prepare a draft environmental impact statement and hold scoping meetings on the proposed designation. Public hearings were held on March 19, 2024, and written comments were accepted until April 19, 2024.

The National Estuarine Research Reserve System's implementing regulations require the preparation of both a draft management plan and environmental impact statement as part of the designation process. (15 CFR 921.13.)

II. Draft Environmental Impact Statement

The purpose of the Green Bay Reserve DEIS is to inform decision-makers and the public about the potential environmental impacts of designating the proposed Green Bay Reserve as the 31st reserve in the nation. NOAA prepared this document pursuant to the National Environmental Policy Act. (NEPA; 42 U.S.C. 4321 *et seq.*) Three alternatives were evaluated as part of this DEIS:

- *No Action Alternative:* As required by the National Environmental Policy Act, a ''no action alternative'' must be considered. The no action alternative represents the scenario in which NOAA does not proceed with the proposed action. In this case, the no action alternative is the result of declining to designate the Green Bay Reserve and implement its draft management plan.
- *Alternative A:* Under this alternative, NOAA would designate the originally nominated site as a reserve. Alternative A, including upland, wetland, and open waters, is approximately 37,714 acres in size. The proposed land and waters are organized into three component areas by geography: the Peshtigo Component, the Lower Bay Component, and the Sturgeon Bay Component.
- *Alternative B:* Under this alternative, NOAA would designate a revised nominated site as a reserve. Alternative B is similar to Alternative A, though with minor modifications. Specifically, additional lands adjacent to the originally nominated site acquired by landholding partners are integrated into the proposed reserve boundary; meanwhile, small parcels that are not closely aligned with the mission of the Reserve System are removed, and the delineation of core and buffer areas are revised. Alternative B is approximately 36,502 acres in size.

These alternatives allow NOAA to evaluate environmental impacts while addressing the proposed action's purpose and need.

Designating and implementing the proposed Green Bay Reserve, under any of the analyzed alternatives, is not expected to result in significant adverse impacts to the natural or human environment. Designating the proposed Green Bay Reserve and implementing its draft management plan provides multiple benefits. First, the reserve would support existing efforts and establish new research, monitoring, education, and stewardship programs to address priority coastal management issues in the Green Bay estuary. Additionally, the reserve would leverage existing authorities to ensure a stable environment for long-term research and provide a framework for coordination and oversight to achieve its goals. Finally, the designation would bring additional financial and staff resources to support estuary management.

Once designated, the Green Bay Reserve would commence operations, with associated education, research, training, stewardship, and monitoring opportunities and activities. The draft management plan highlights activities that, independently or when aggregated with other factors, may contribute to reasonably foreseeable impacts on the affected environment. If a reserve is designated, future federal actions (including actions funded through NOAA cooperative agreements) will be evaluated individually to comply with applicable environmental laws and policies.

III. Draft Management Plan

The purpose of the draft management plan is to set a course for operating the proposed Green Bay Reserve upon designation. The plan provides for administration, research, education, training, stewardship, facilities, and management of the proposed site. (15 CFR 921.13.) The draft management plan for the proposed Green Bay Reserve supports the goals of the Reserve System (15 CFR 921.1(b)) and addresses issues relevant to northeastern Wisconsin. Specifically, the plan defines four key issues relevant to Northeast Wisconsin and the Green Bay estuary to focus on over the next five years, should the reserve be designated:

- Preparing Great Lakes communities for long-term ecosystem change and variability
- Restoring sustainable and holistic land-water connections
- Preserving biodiversity through improved ecological integrity and ecosystem resilience
- Enhancing the Bay of Green Bay's sense of place and connection to quality of life

The draft plan also defines goals that reflect the priorities of the proposed reserve during the first five years after designation:

- *Goal 1:* Strengthen community adaptation and preparation for projected impacts of climate-driven hydrologic shifts and changing lake levels
- *Goal 2:* Reduce excessive sediment, nutrient, and contaminant loadings into the Bay from watershed inputs
- *Goal 3:* Strengthen the ability of native and noninvasive species to access terrestrial, wetland, and aquatic habitats and improve interconnectedness of ecosystem components
- *Goal 4:* Restore healthy wetland, submerged aquatic, and benthic habitats and promote diverse species assemblages
- *Goal 5:* Foster historical awareness and contemporary connections between people and the Green Bay estuary
- *Goal 6:* Promote sustainable, beneficial uses of the Bay for regional communities

If designated, the Green Bay Reserve—like all reserves in the system—would be responsible for the implementation of programs related to education, research, training, stewardship, and monitoring in service to communities surrounding the Green Bay estuary. The draft management plan for the Green Bay Reserve includes information on its core programs as well as program-specific focal areas, potential for partnerships, needs, and opportunities. If designated, the development and implementation of these reserve programs would be led by the University of Wisconsin–Green Bay, the lead state agency for the proposed Green Bay Reserve.

As previously noted, the Coastal Zone Management Act's implementing regulations for the Reserve System require NOAA to provide notice in the **Federal Register** of the availability of the DEIS (15 CFR 921.13), the draft management plan (15 CFR 921.20(h)), and associated public hearing(s).

Authority: 16 U.S.C. 1461; 15 CFR 921.13.

Keelin S. Kuipers,

Acting Director, Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2026–22673 Filed 11–5–26; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF955]

Marine Mammals; File No. 29841

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Rutgers University (Responsible Party: John Wiedenmann, Ph.D.), 14 College Farm Rd., New Brunswick, NJ 08901, has applied in due form for a permit to conduct research on cetaceans.

DATES: Written comments must be received on or before December 7, 2026.

ADDRESSES: The application and related documents are available for review upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 29841 in the subject line of the email comment.

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

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

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

The applicant proposes assessing the habitat use and behavior of baleen whales within planned offshore wind construction sites and shipping areas off New Jersey with a focus on humpback (*Megaptera novaeangliae*) and endangered fin whales (*Balaenoptera physalus*). Up to 85 whales of these species may be taken annually during vessel surveys involving observations, photo-identification or video, and tagging (dart/barb and deep-implant). Minke whales (*Balaenoptera acutorostrata*), short-beaked common dolphins (*Delphinus delphis*), and endangered North Atlantic right whales (*Eubalaena glacialis*) may be unintentionally harassed and opportunistically studied. The permit is requested for 5 years.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: November 3, 2026.

Larissa Plants,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2026–22646 Filed 11–5–26; 8:45 am]

BILLING CODE 3510–22–P

CONSUMER FINANCIAL PROTECTION BUREAU

Fair Lending Report of the Consumer Financial Protection Bureau

AGENCY: Consumer Financial Protection Bureau.

ACTION: Fair Lending Report of the Consumer Financial Protection Bureau.

SUMMARY: The Consumer Financial Protection Bureau (CFPB or Bureau) is issuing its Fair Lending Report of the Consumer Financial Protection Bureau (Fair Lending Report) to Congress. This report describes our fair lending activities in rulemaking; supervision and enforcement; interagency coordination; and stakeholder engagement for calendar year 2025.

DATES: The CFPB released the 2025 Fair Lending Report on its website on October 1, 2026.

FOR FURTHER INFORMATION CONTACT: Dave Gettler, Paralegal Specialist, Office of Regulations, at 202–435–7700 or *https://reginquiries.consumerfinance.gov/.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

1. Introduction

In 2025, the CFPB transformed its fair lending program by refocusing its regulatory, supervisory, and enforcement activities on its statutory authority and identified consumer harm. Under previous administrations, the CFPB was weaponized and had gone beyond its statutory mandate. In the area of fair lending specifically, CFPB

leadership uncovered egregious examples of companies being targeted for protected political speech and exercising their constitutional rights. Throughout the reporting period, the CFPB worked to correct its course and reverse the previous administrations' abuses and overreach of its statutory mandates.

Under President Trump, the CFPB shifted the way it regulates, supervises, and enforces the laws as required under the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act). The CFPB's fair lending efforts now focus on proven, intentional racial discrimination with actual identifiable victims. The CFPB does not engage in or facilitate unconstitutional racial classification or discrimination in its enforcement of fair lending laws. The Bureau employs its resources [1] on pressing threats to consumers and in the areas that are clearly within the CFPB's statutory authority, without duplicating work of other regulators. Enforcement also is being guided by a new set of principles so that the CFPB focuses on addressing actual harm to consumers, ensuring due process, seeking collaboration when appropriate, and promoting efficiency.

To guide its fair lending efforts, CFPB leadership prioritized implementation of several executive orders, including directives prohibiting unlawful debanking,[2] terminating all discriminatory and illegal preferences,[3] and ending use of disparate impact liability in the enforcement of civil rights laws.[4] Accordingly, during the reporting period, the CFPB stopped using disparate impact in its supervision and enforcement of fair lending laws and undid previous actions relying on disparate impact. The CFPB also stopped consulting with institutions regarding special purpose credit programs (SPCPs) based on race, color, national origin, or sex and prioritized addressing unlawful debanking.

In support of the President's deregulatory agenda, the CFPB worked diligently to reverse regulatory overreach, reduce unjustified regulatory burdens, and streamline and clarify existing regulations. In 2025, the CFPB prioritized two rulemakings related to fair lending. Both rules were finalized in 2026. The first rulemaking amended Regulation B, subpart A, implementing the Equal Credit Opportunity Act (ECOA) to affirm that ECOA does not authorize disparate impact liability. The rule also prohibits use of race, color, national origin, or sex as eligibility criteria for SPCPs and clarifies the discouragement provisions, protecting targeted advertising from discouragement claims under ECOA. We made these important regulatory changes to align with the best reading of the law and to minimize risks of impermissible and unconstitutional discrimination. Importantly, the changes help ensure that credit is made available to all without regard to protected class status.

The second rulemaking amended Regulation B, subpart B, implementing section 1071 of the Dodd-Frank Act. It amended the scope of what constitutes a covered financial institution and covered credit transaction, modified the gross annual revenue threshold in the rule's definition of small business from $5 million or less to $1 million or less, removed certain data points not required by the statute, and altered certain requirements related to how data is collected. The 2023 rule had imposed a significant number of requirements that are unnecessary to advance the purposes of section 1071, and the CFPB now asks for only what the statute requires. These updates both reduce unnecessary compliance burdens and result in a substantial cost savings for impacted institutions, including a one-time savings of nearly $100M and an annual ongoing savings between $166M and $181M per year.

As this report reflects, we have made great progress implementing the President's agenda in 2025, and we are very proud of our fair lending accomplishments. These are only a few examples of the CFPB's fair lending work in 2025, as described in this report. Although the reporting period for this report is calendar year 2025, we have also included some activity that took place outside of the reporting period due to its importance and relevance to the covered topics.

2. Shifts in Fair Lending Priorities

During the reporting period, the CFPB made significant shifts in its fair lending work consistent with the current administration and CFPB leadership's fair lending policies and priorities. As explained in further detail in the subsections that follow, these changes were also guided by several executive orders, including Executive Order (E.O.) 14281, ''Restoring Equality of Opportunity and Meritocracy''; [5] E.O. 14173, ''Ending Illegal Discrimination and Restoring Merit-Based Opportunity''; [6] and E.O. 14331, ''Guaranteeing Fair Banking for all Americans.'' [7]

2.1 Terminating Disparate Impact

On April 23, 2025, President Trump issued E.O. 14281, ''Restoring Equality of Opportunity and Meritocracy,'' which directs Federal agencies to stop using disparate impact liability in the enforcement of civil rights laws.

Consistent with E.O. 14281, the CFPB no longer uses disparate impact in its supervision or enforcement of fair lending laws. Also, as described in section 5 of this report, the CFPB engaged in rulemaking consistent with these priorities.[8] In addition, the CFPB has closed all elements of open supervision exams and enforcement investigations that relied on disparate impact liability and terminated CFPB orders that relied on disparate impact liability.

Additional activity related to disparate impact occurred since the end of the reporting period. As discussed in more detail in section 5.1.2 of this report, on April 22, 2026, the CFPB issued a final rule amending Regulation B. Among other things, the final rule removed the longstanding ''effects test'' language from Regulation B and its commentary and replaced it with statements affirming that ECOA does not authorize disparate impact liability.

2.2 Terminating Consultations on Special Purpose Credit Programs

On January 21, 2025, President Trump issued E.O. 14173, ''Ending Illegal Discrimination and Restoring Merit-Based Opportunity,'' which obligates executive departments and agencies ''to terminate all discriminatory and illegal preferences'' and ''to combat illegal

[1] CFPB, *Supervision and Enforcement Priorities* (Apr. 2025), *https://www.consumerfinance.gov/enforcement/supervision-and-enforcement-priorities/.*

[2] Exec. Order (E.O.) 14281, Restoring Equality of Opportunity and Meritocracy, 90 FR 17537 (Apr. 28, 2025), *https://www.federalregister.gov/documents/2025/04/28/2025-07378/restoring-equality-of-opportunity-and-meritocracy.*

[3] E.O. 14173, Ending Illegal Discrimination and Restoring Merit-Based Opportunity, 90 FR 8633 (Jan. 31, 2025), *https://www.federalregister.gov/documents/2025/01/31/2025-02097/ending-illegal-discrimination-and-restoring-merit-based-opportunity.*

[4] E.O. 14331, Guaranteeing Fair Banking for All Americans, 90 FR 38925 (Aug. 12, 2025), *https://www.federalregister.gov/documents/2025/08/12/2025-15341/guaranteeing-fair-banking-for-all-americans.*

[5] E.O. 14281.

[6] E.O. 14173, Ending Illegal Discrimination and Restoring Merit-Based Opportunity, 90 FR 8633 (Jan. 31, 2025), *https://www.federalregister.gov/documents/2025/01/31/2025-02097/ending-illegal-discrimination-and-restoring-merit-based-opportunity.*

[7] E.O. 14331.

[8] *See* 91 FR 21620 (Apr. 22, 2026).

private sector'' race- and sex-conscious programs.

Accordingly, the CFPB no longer consults with institutions regarding any SPCPs that rely on race, color, national origin, or sex. Consistent with E.O. 14173 and recognizing the broader statutory and constitutional concerns raised by such programs, the CFPB amended subpart A of Regulation B, the regulation implementing the ECOA, to prohibit creditors from offering programs that rely on the race, color, national origin, or sex of the applicant in making eligibility determinations.[9]

2.3 Debanking

On August 7, 2025, President Trump signed E.O. 14331, ''Guaranteeing Fair Banking for All Americans,'' stating that no American should be denied access to financial services because of their political or religious beliefs.

Combating unlawful debanking is a priority, and the CFPB has dedicated resources across the Bureau to implement E.O. 14331 to ensure banking decisions are made consistent with the law and do not substitute unlawful practices for ''individualized, objective, and risk-based analyses.'' [10]

Consistent with the E.O., in 2025, the CFPB reviewed its Examination Manual and confirmed that it does not reference reputation risk. The CFPB also reviewed its guidance, regulations, and other materials used to regulate or examine financial institutions under its authority for reputation risk concepts that could result in unlawful debanking. Additionally, the CFPB reviewed consumer complaints, as well as supervisory and enforcement data, for evidence of potential unlawful debanking.

In the debanking context, the CFPB evaluates financial institutions for compliance with ECOA and the Fair Credit Reporting Act (FCRA), particularly the adverse action notice requirements under those laws. The CFPB's debanking efforts also focus on religious discrimination. In addition, the CFPB is working with other regulatory partners, including the Department of Justice (DOJ), as part of the DOJ's Equal Access to Banking Task Force, to address debanking issues more broadly.

3. Correcting Previous Administrations' Regulatory Overreach

The previous administrations' regulatory overreach affected many businesses and necessitated a course correction by the Trump administration. In the area of fair lending, CFPB leadership uncovered egregious examples of companies being targeted for protected political speech and exercising their constitutional rights. In line with new fair lending priorities, and implementing the administration's agenda, including executive orders, the CFPB's focus in 2025 was to undo the regulatory overreach of the previous administrations, including actions relying on disparate impact and other fair lending matters. The actions are listed below.

- *Bureau of Consumer Financial Protection* v. *Townstone Financial, Inc. and Barry Sturner* (N.D. Ill. 1:20–cv–04176) (not a credit union or depository institution). On July 15, 2020, the CFPB filed a lawsuit against Townstone Financial, Inc., a small Midwest firm with about ten employees and a radio program called Townstone Financial. The CFPB alleged that Townstone violated ECOA, Regulation B, and the Consumer Financial Protection Act (CFPA). The CFPB targeted Townstone based solely on perceived racial disparities in mortgage application and origination statistics. Townstone was targeted for protected free speech. CFPB used an audio mining software to search Townstone's radio show and podcasts finding that they engaged in political speech with which the CFPB's enforcement disagreed. The CFPB identified only 16 minutes out of nearly 79 hours of radio content (.33 percent) that it deemed ''disconcerting'' and that ''could be interpreted as inappropriate, incorrect, or insensitive.'' The ''disconcerting'' conduct was talking about local crime, political issues around freedom of speech, supporting local law enforcement, and telling people to check out a neighborhood before buying a home. There was no evidence of any potential customers reporting Townstone to the CFPB or finding their content offensive. The action was resolved by stipulated final judgment and order on November 7, 2024.

On March 26, 2025, shortly after the new leadership came in, the CFPB filed a motion to vacate a consent order and to return a $100K fine to Townstone, on the grounds that the CFPB discovered within its internal case files indications that the CFPB commenced and continued its investigation and litigation without a substantial predicate of actionable facts and targeted co-defendants Townstone and Townstone President and CEO, Barry Sturner, based on constitutionally protected speech. Although the court denied the CFPB's motion to vacate on June 12, 2025, the CFPB's leadership believes this fair lending case is prime example of the prior administration's weaponization of the Bureau.

- *Consumer Financial Protection Bureau Investigation of Credova Financial, LLC.* The CFPB terminated its investigation into Credova because the CFPB had determined that the investigation was a weaponization against disfavored industries and individuals. Credova's use of innovative financial technology solutions to provide consumer financing to facilitate Americans exercising their Second Amendment rights made it a target for the CFPB. The CFPB's demands were also inconsistent with the realities of how such businesses are run. The investigation is one of numerous regulation-by-enforcement actions for which the CFPB became infamous under former Director Chopra. The investigation was aimed at suppressing activities protected by the First and Second Amendment. It also represents precisely the kind of unconstitutional targeting prohibited by E.O. 14331, ''Guaranteeing Fair Banking for All Americans.''
- *Consumer Financial Protection Bureau and United States of America* v. *Colony Ridge Development, LLC; Colony Ridge BV, LLC; Colony Ridge Land, LLC; and Loan Originator Services, LLC* (S.D. Tex. No. 4:23–cv–04729) (not a credit union or depository institution). On December 20, 2023, the CFPB, together with the DOJ, filed a complaint against land development companies Colony Ridge Development, LLC and Colony Ridge BV, LLC, affiliate mortgage company Colony Ridge Land, LLC (collectively, the Colony Ridge defendants), and loan origination company Loan Originator Services, LLC (LOS). The CFPB and the DOJ alleged that defendants violated ECOA by targeting Hispanic consumers with a predatory loan product. The CFPB separately alleged violations of the CFPA and Interstate Land Sales Full Disclosure Act. The DOJ further alleged defendants' conduct violated the Fair Housing Act (FHA). On February 10, 2026, pursuant to a joint stipulation of voluntary dismissal, the CFPB dismissed its claims with prejudice. That same day, the DOJ notified the court in a joint motion for dismissal that the DOJ, along with the State of Texas, had reached a settlement resolving the DOJ's claims and the State of Texas's claims in a related matter. Following a hearing on the motion, on April 10, 2026, the remaining parties filed a joint stipulation of dismissal, dismissing the action with prejudice and withdrawing their request for continuing jurisdiction. On April 28, 2026, the court dismissed

[9] *Id.*

[10] E.O. 14331.

the action with prejudice and denied the joint motion for dismissal as moot.

■ *In re Washington Federal Bank, N.A.* (2020–BCFP–0019). On October 27, 2020, the CFPB issued an order against Washington Federal Bank, N.A., a federally insured, for-profit national bank headquartered in Seattle, Washington, to address violations of the Home Mortgage Disclosure Act (HMDA). On September 22, 2025, pursuant to the CFPB's authority under 12 U.S.C. 5563(b)(3) and under Paragraph 75 of the order, the CFPB terminated the order. Washington Federal has fulfilled several obligations under the order, including paying a civil money penalty of $200,000, and creating and implementing a compliance plan designed to ensure that its collection, recording, and reporting of HMDA data complies with applicable Federal consumer financial laws and the terms of the order.

■ *In re Washington Federal* (2013–CFPB–0005). On October 9, 2013, the CFPB issued an order against Washington Federal, a bank headquartered in Seattle, Washington, to address violations of HMDA. On September 22, 2025, pursuant to the CFPB's authority under 12 U.S.C. 5563(b)(3) and under paragraph 3 of article XII of the order, the CFPB terminated the order. Washington Federal has fulfilled several obligations under the order, including paying a civil money penalty of $34,000.

■ *In re Citibank, N.A.* (2023–CFPB–0013). On November 8, 2023, the CFPB issued an order against Citibank, N.A., which is a national bank headquartered in New York City, New York. The CFPB found that Citibank violated ECOA and Regulation B. As CFPB was aware, there was a large-scale fraud perpetuated by a crime ring of Armenians in Southern California. At the time, several rogue underwriters in one location in Citi Retail Services looked at Armenian surnames as they evaluated credit card applications and credit line increases coming from Glendale, California. As soon as Citi learned of these isolated occurrences, Citi terminated the employees, re-trained its underwriting staff, and began monitoring employee communications to ensure their decision-making was not improperly influenced by an applicant's national origin. This issue affected a very small number of applications and there has been no recurrence of the issue since these measures were implemented in 2021. On October 16, 2025, pursuant to the CFPB's authority under 12 U.S.C. 5563(b)(3) and under paragraph 74 of the order, the CFPB terminated the order and waived any alleged non-compliance therewith. Citibank has fulfilled certain obligations under the order, including paying a civil money penalty of $24,500,000 to the CFPB as required by section X, making redress payments of nearly $1.4 million required by section IX, and taking steps to implement injunctive relief to prevent future violations required by the ''Conduct Provisions.''

■ *In re Bank of America, N.A.* (2023–CFPB–0016). On November 28, 2023, the CFPB issued an order against Bank of America, N.A., which is a national bank headquartered in Charlotte, North Carolina, with branches and ATMs located in 38 States and the District of Columbia. The CFPB found that Bank of America violated HMDA and Regulation C. On June 5, 2025, pursuant to the CFPB's authority under 12 U.S.C. 5563(b)(3) and under paragraph 72 of the order, the CFPB terminated the order. Bank of America has fulfilled the obligations under the order, including payment of a civil money penalty of $12,000,000, development of a compliance plan and an annual report, and implementation of improvements to its HMDA compliance management system.

■ *Consumer Financial Protection Bureau and United States of America* v. *Trident Mortgage Company, LP* (E.D. Pa. No. 2:22–cv–02936) (not a credit union or depository institution). On July 27, 2022, the CFPB, together with DOJ, filed a complaint and proposed consent order to resolve allegations that Trident Mortgage Company, LP, violated ECOA. The court entered the consent order on September 14, 2022. On May 23, 2025, the CFPB and the DOJ filed an unopposed motion to terminate the consent order and dismiss with prejudice. On June 2, 2025, the court terminated the consent order and dismissed the case with prejudice. Trident has demonstrated a commitment to remediation, having fully disbursed the loan subsidy fund of $18,400,000 under the terms of the consent order; paid a $4,000,000 civil money penalty; and substantially complied with the other monetary and injunctive terms of the consent order.

■ *United States of America and Consumer Financial Protection Bureau* v. *Trustmark National Bank* (W.D. Tenn. No. 2:21–cv–02664). On October 22, 2021, the CFPB, together with the DOJ, filed a complaint and proposed consent order to resolve allegations that Trustmark National Bank, which is headquartered in Jackson, Mississippi, violated ECOA. The court entered the consent order on October 27, 2021. On May 20, 2025, the CFPB and the DOJ filed an unopposed motion to terminate the consent order and dismiss with prejudice. On May 21, 2025, the court vacated the judgment and dismissed the case with prejudice. Trustmark has demonstrated a commitment to remediation, having fully disbursed the loan subsidy fund of $3,850,000 under the terms of the consent order; paid a $5,000,000 civil money penalty, of which $1,000,000 was paid to the CFPB; and substantially complied with the other monetary and injunctive terms of the consent order.

■ *Consumer Financial Protection Bureau* v. *Draper & Kramer Mortgage Corporation* (N.D. Ill. No. 1:25–cv–00605) (not a credit union or depository institution). On January 17, 2025, the CFPB filed a complaint against Draper & Kramer Mortgage Corporation, along with a proposed consent order, alleging violations of ECOA. On January 24, 2025, the court entered the consent order. On May 15, 2025, the CFPB issued a no-action letter, pursuant to which the CFPB has ceased monitoring compliance with the order, is not engaging in any supervisory activity to assess compliance with the order and will take no steps to enforce the consent order. Draper & Kramer has already paid the civil money penalty required by the order and has ceased originating residential mortgage loans, making expending resources on monitoring the order unnecessary. The CFPB took this step in the interest of focusing resources on supporting U.S. taxpayers, servicemembers, veterans, and small businesses. Also, pursuant to E.O. 14281 on ''Restoring Equality of Opportunity and Meritocracy,'' the CFPB is focusing its supervisory and enforcement resources on fair lending matters with direct evidence of intentional racial discrimination and identified victims, which were not present in this matter.

■ *In re Synchrony Bank; f/k/a GE Capital Retail Bank* (2014–CFPB–0007). On June 19, 2014, the CFPB issued an order against Synchrony Bank, to address violations of ECOA and the CFPA's prohibition on deceptive acts or practices. On May 12, 2025, pursuant to the CFPB's authority under 12 U.S.C. 5563(b)(3) and under paragraph 95 of the consent order, the CFPB terminated the order. Synchrony has fulfilled its obligations under the order, including providing at least $259,000,000 in redress to affected consumers, and paying a civil money penalty of $3,500,000. In addition, the Bank ceased engaging in the practices cited in the order dated June 19, 2014. Furthermore, E.O. 14281 mandates that the CFPB eliminate the ''use of disparate-impact liability in all contexts to the maximum degree possible'' and requires that the

CFPB ''evaluate existing consent judgments and permanent injunctions that rely on theories of disparate-impact liability and take appropriate action.'' Because this order relied in part on a disparate impact theory of liability, its termination was appropriate to align with E.O. 14281.

4. This Administration's Fair Lending Supervision and Enforcement

4.1 Supervision

Title X of the Dodd-Frank Act authorizes the CFPB to supervise certain consumer financial services companies and large depository institutions and their affiliates for consumer protection purposes.[11] The CFPB's Supervision program assesses compliance with Federal consumer financial protection laws and regulations at banks and nonbanks over which the CFPB has supervisory authority.

During the reporting year, the CFPB rescinded its prior supervisory priorities and redirected its supervision efforts. Consistent with new priorities, including its focus on debanking, the CFPB reviewed supervisory data that included complaints received by institutions, for evidence of potential unlawful debanking.

While redirecting its supervisory resources, the CFPB closed 76 percent of its supervisory actions (nearly 1,500) and a substantial majority of its outstanding open examinations. Approximately 12 percent of the supervisory actions closed related to fair lending.

The CFPB's fair lending supervisory activities focus on financial institutions' compliance with ECOA and the HMDA. ECOA examination work focuses on uncovering direct evidence of intentional discrimination on a prohibited basis, systemic failures to provide applicants with legally required notices of adverse actions, and lenders' systems for identifying risks of non-compliance with ECOA and Regulation B. HMDA examination work focuses on validating the accuracy of key data points collected and submitted by lenders.

During the reporting period, the CFPB did not initiate supervisory activities or cite any fair lending violations.

4.1.1 Supervision Related Litigation

In September 2022, the CFPB was sued in the U.S. District Court for the Eastern District of Texas by the U.S. Chamber of Commerce *et al.*, challenging an update to the Unfair, Deceptive, or Abusive Acts or Practices (UDAAP) section of the CFPB's examination manual.[12] The updated manual stated that discriminatory conduct may violate the CFPA's prohibition on unfair practices and provided guidance to examiners on how discriminatory conduct should be examined to determine whether it violates the unfairness prohibition. The manual update was an example of the type of expansion of the CFPB's authority well beyond the statutory mandate under its prior leadership that the current leadership seeks to curb. The court granted plaintiffs' motion for summary judgment, vacated the manual update, and permanently enjoined the CFPB from engaging in any examination, supervision, or enforcement action against any member of the plaintiff associations based on the CFPB's interpretation of its unfairness authority set forth in the updated manual. The CFPB filed a notice of appeal in November 2023, and the appeal was stayed by the Fifth Circuit pending the Supreme Court's resolution of *CFPB* v. *CFSA*.[13] After the Supreme Court issued its decision in *CFPB* v. *CFSA,* the matter was fully briefed before the Fifth Circuit. On April 30, 2025, the parties filed a joint stipulation to dismiss the CFPB's appeal. The Fifth Circuit granted the parties' request and issued its mandate dismissing the appeal on May 1, 2025.[14]

4.2 Fair Lending Enforcement

Through enactment of the Dodd-Frank Act, Congress authorized the CFPB to bring actions to enforce Federal consumer financial law, including ECOA and HMDA.

Under this administration, the CFPB has focused its fair lending enforcement resources on matters with direct evidence of intentional racial discrimination and identified victims and has not engaged in or facilitated unconstitutional racial classification or discrimination in its enforcement of fair lending laws.

By law, the CFPB must refer to DOJ any matter when it has reason to believe that a creditor has engaged in a pattern or practice of lending discrimination in violation of ECOA.[15] The CFPB may refer other potential ECOA violations to DOJ as well.[16] In 2025, the CFPB did not refer any matters to DOJ pursuant to 15 U.S.C. 1691e(g).

5. Regulatory Actions To Advance This Administration's Agenda

In support of President Trump's economic strategy, during the reporting period, the CFPB adopted a robust deregulatory agenda focused on reversing instances of regulatory overreach.

Regulatory actions for this administration have been guided by several executive orders. For example, E.O. 14219, titled ''Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative,''[17] seeks to end Federal overreach by rescinding unlawful regulations and regulations that undermine the national interest. Consistent with E.O. 14219, in 2025, the CFPB embarked on several rulemaking projects to streamline existing regulations and reduce unjustified burdens.

The CFPB's regulatory priorities in 2025 included two fair lending related rulemakings to amend (1) Regulation B, subpart B, implementing section 1071 of the Dodd-Frank Act, and (2) Regulation B, subpart A, implementing ECOA. The CFPB also withdrew non-binding policy guidance issued by prior administrations.

For more information about the CFPB's regulatory actions, the CFPB publishes an agenda of its planned regulatory activity as part of the Unified Agenda of Federal Regulatory and Deregulatory Actions, which is coordinated by the Office of Management and Budget (OMB).[18]

5.1 Rulemaking

5.1.1 Section 1071, Small Business Lending

In April 2025, the CFPB announced its plans to reconsider certain aspects of a final rule published in May 2023 that implemented changes to ECOA made by 15 U.S.C. 1691c–2, also known as section 1071 of the Dodd-Frank Act. In light of court orders in ongoing litigation and to help effectuate this reconsideration, the CFPB published an interim final rule[19] and then a final rule[20] that extended the compliance dates of the 1071 rule by approximately one year. In November 2025, the CFPB

[11] 12 U.S.C. 5511(c).

[12] ECF No. 1, *Chamber of Commerce et al.* v. *CFPB et al.,* 6:22–cv–00381 (E.D. Tex. 2023).

[13] ECF No. 7, *Chamber of Commerce et al.* v. *CFPB et al.,* No. 23–40650 (5th Cir.).

[14] *Id.,* ECF No. 158.

[15] 15 U.S.C. 1691e(g).

[16] *Id.*

[17] E.O. 14219, Ensuring Lawful Governance and Implementing the President's ''Department of Government Efficiency'' Deregulatory Initiative, 90 FR 10583 (Feb. 25, 2025), *https://www.federalregister.gov/documents/2025/02/25/2025-03138/ensuring-lawful-governance-and-implementing-the-presidents-department-of-government-efficiency.*

[18] *https://www.consumerfinance.gov/rules-policy/regulatory-agenda.*

[19] 90 FR 25874 (June 18, 2025).

[20] 90 FR 47514 (Oct. 2, 2025).

published a proposed rule [21] to change the scope of what constitutes a covered financial institution and covered credit transaction, to modify the gross annual revenue threshold in the rule's definition of small business, to remove certain data points not required by the statute, and to alter certain requirements related to how data is collected. The CFPB also proposed extending the rule's compliance date to January 1, 2028. The CFPB believed these proposed changes would streamline the rule, reduce complexity for lenders, and improve data quality, thereby advancing the purposes of section 1071 and complying with recent executive directives.

Additional activity has occurred since the end of the reporting period. On May 1, 2026, the CFPB issued the final rule.[22] The rule reduces the scope of ''covered credit transactions'' by limiting the types of transactions subject to reporting in order to focus data collection efforts on core lending products—loans, lines of credit, and credit cards—that are most utilized by small businesses. Accordingly, the rule sets forth certain exclusions: merchant cash advances, agricultural lending, and small-dollar business credit. The rule also narrows the definition of ''covered financial institutions'' by raising the loan origination threshold from 100 to 1,000 loans annually and excluding Farm Credit System lenders.

In addition, the rule revises the definition of ''small business'' by reducing the gross annual revenue threshold from $5 million to $1 million. This will allow the CFPB to focus on collecting data related to micro and small enterprises, which are most relevant to section 1071's goals. The rule also reduces the number of collected data points, extends and adopts a uniform compliance date of January 1, 2028, and simplifies the time and manner of data collection in order to allow institutions flexibility in how they comply with statutory requirements.

The rule updates are necessary to ensure reasonable implementation that does not restrict credit availability for America's small businesses. The 2023 rule imposed a significant number of requirements that were not needed to advance the purposes of section 1071 of the Dodd-Frank Act. This rule recognizes those concerns and takes a more reflective approach, including just what the statute requires. The updates will result in cost savings for institutions and reduce the burden of data collection without sacrificing data availability.

More information is available on our website, including a page compiling key materials related to the CFPB's small business lending rulemaking.[23]

5.1.2 Section 1071 Rulemaking Related Litigation

During the reporting period, there were four cases pending related to the previous section 1071 rule issued in March 2023. Following the revised 1071 rule issued on May 1, 2026, three of those cases have been dismissed. One remains pending.

- *Texas Bankers Assoc.* v. *CFPB.* On April 26, 2023, the Texas Bankers Association and Rio Bank sued the CFPB in the U.S. District Court for the Southern District of Texas challenging the validity of the old 1071 rule.[24] On August 26, 2024, the court granted summary judgment to the CFPB, upholding the rule in full and rejecting Plaintiffs' challenges.[25] Plaintiffs appealed. On February 7, 2025, after briefings from the parties to update the court on the agency's current priorities and position, the Fifth Circuit stayed the rule for plaintiffs and intervenors in the case pending further order from the court.[26] Since the close of this reporting period, the parties filed a joint stipulation to dismiss the appeal as moot and vacate the judgment of the district court in light of the mootness of this case.[27]
- *Monticello Banking Co.* v. *CFPB.* On August 11, 2023, the Kentucky Bankers Association and several Kentucky banks sued to challenge the old rule in the U.S. District Court for the Eastern District of Kentucky.[28] During the reporting period, the CFPB moved to stay the case while it engaged in a new rulemaking to reconsider its rule implementing section 1071.[29] Granting the motion, the court extended the stay until December 1, 2025.[30] The court subsequently extended the stay until the earlier of 21 days following the issuance of the new rulemaking on section 1071, or March 20, 2026.[31] Since the end of the reporting period, in light of the new 1071 rule, plaintiffs filed a notice of voluntary dismissal and the case was closed on July 1, 2026.[32]
- *Revenue Based Finance Coalition* v. *CFPB.* Revenue Based Finance Coalition, a trade association representing merchant cash advance providers, challenged the old 1071 rule on December 26, 2023, in the U.S. District Court for the Southern District of Florida.[33] In March 2025, the CFPB informed the court that it intended to initiate a notice of proposed rulemaking revising the challenged 1071 rule in a way that better aligns with current CFPB priorities as expeditiously as reasonably possible.[34] In May 2025, the court stayed the case and rule and tolled the rule's compliance deadlines for plaintiff and its members for the length of time that the Fifth Circuit's stay order in *Texas Bankers Association* was in effect.[35] Since the end of the reporting period, in light of the new 1071 rule the parties filed a joint stipulation of dismissal. The case was closed on July 1, 2026.[36]
- *Rise Economy* v. *Vought.* On June 23, 2025, Rise Economy, along with several small businesses and equitable investment nonprofits, filed a lawsuit against the CFPB regarding its interim final rule extending the old section 1071 rule's compliance dates and a press release regarding the CFPB's enforcement priorities.[37] Since the end of the reporting period, following issuance of the CFPB's revisions to its rule implementing section 1071, plaintiffs filed a notice of voluntary dismissal, which the court granted.[38]

5.1.3 Regulation B, ECOA

On November 13, 2025, the CFPB published a proposal to amend provisions of Regulation B, subpart A, implementing ECOA to facilitate compliance with ECOA by clarifying the obligations imposed by the statute.[39]

The proposed rule provided that ECOA does not authorize disparate impact claims. It proposed to amend the prohibition on discouraging applicants or prospective applicants to clarify that it prohibits statements of intent to discriminate in violation of ECOA and is not triggered merely by negative consumer impressions. It also proposed to clarify that encouraging statements by creditors directed at one group of

[21] 90 FR 50952 (Nov. 13, 2025).

[22] 91 FR 23530 (May 1, 2026).

[23] *See https://www.consumerfinance.gov/1071-rule/.*

[24] ECF No. 1, *Texas Bankers Assoc.* v. *CFPB,* No. 7:23–cv–00144 (S.D. Tex. 2023).

[25] *Id.,* ECF No. 115.

[26] ECF No. 134, *Texas Bankers Assoc.* v. *CFPB,* No. 24–40705 (5th Cir. 2025).

[27] *Id.,* ECF No. 179.

[28] ECF No. 1, *Monticello Banking Co.* v. *CFPB,* No. 6:23–cv–00148–KKC (E.D. Ky. 2023).

[29] *Id.,* ECF No. 49.

[30] *Id.,* ECF No. 55.

[31] *Id.,* ECF No. 61.

[32] *Id.,* ECF No. 75.

[33] ECF No. 61, *Revenue Based Finance Coalition* v. *CFPB,* No. 1:23–cv–24882–DSL (S.D. Fla. 2023).

[34] *Id.,* ECF Nos. 72, 75.

[35] *Id.,* ECF No. 81.

[36] *Id.,* ECF Nos. 102, 103.

[37] ECF No. 1, *Rise Economy* v. *Vought,* No. 1:25–cv–02374 (D.D.C. 2025).

[38] *Id.,* ECF No. 46.

[39] *See* 90 FR 50901 (Nov. 13, 2025).

consumers is not prohibited discouragement as to applicants or prospective applicants who were not the intended recipients of the statements. The proposed rule would also amend the standards for SPCPs offered or participated in by for-profit organizations to include new standards and restrictions.

Additional activity has occurred since the end of the reporting period. On April 22, 2026, the CFPB issued a final rule amending Regulation B as proposed.[40] The final rule removes the longstanding ''effects test'' language from Regulation B and its commentary and replaced it with statements affirming that ECOA does not authorize disparate impact liability. Disparate impact was first read into ECOA based solely on the law's legislative history. However, under the plain meaning of ECOA's text, disparate impact is not a cognizable theory of liability under the statute and is contrary to the principles of Equal Protection.

The rule also changes the anti-discouragement provision to limit prohibited ''statements'' to spoken or written words or visual images as opposed to broader ''acts or practices'' such as branch placement or advertisement targeting. Liability also only attaches to statements that a creditor knows or should know would cause a reasonable person to believe the creditor would deny, or offer worse terms on, a credit application because of a prohibited basis characteristic. This change was designed to protect targeted advertising from discouragement claims, specifically providing that encouraging messages directed at one audience would not be treated as discouraging to others who were not the intended recipients of such messages. Merely controversial or provocative speech is to be distinguished from statements that do convey discriminatory exclusion.

In addition, the new rule prohibits for-profit creditors from using race, color, national origin, or sex (or any combination thereof) as eligibility criteria for SPCPs. For any SPCPs that still use other protected classes as eligibility criteria (such as religion, marital status, age, or public assistance income), the creditor would face new restrictions, including stringent documentation and evidence requirements. The stringent new conditions help ensure that Congress's intent to make these SPCPs available for certain credit transactions ''when it has been clearly demonstrated on the public record that without such exemption the consumers involved would effectively be denied credit.'' [41] The regulatory changes to SPCPs now align with the law's intended purpose and minimize risks of impermissible and unconstitutional discrimination.

5.1.4 Rescission of 2020 Advisory Opinion Related to ECOA (Regulation B); Special Purpose Credit Programs

Additional special purpose credit program-related activity has occurred since the end of the reporting period. On June 17, 2026, the CFPB rescinded an advisory opinion issued in December 2020 regarding Regulation B, as it applies to certain aspects of SPCPs designed and implemented by for-profit organizations to meet special social needs. Specifically, the 2020 advisory opinion clarified the content that a for-profit organization must include in a written plan that establishes and administers an SPCP under Regulation B. The advisory opinion also clarified the type of research and data that may be appropriate to inform a for-profit organization's determination that an SPCP is needed to benefit a certain class of persons.

The CFPB rescinded the advisory opinion because it contained statements that conflicted with recent amendments to Regulation B and to avoid any confusion about the appropriate standards and related conditions for SPCPs offered or participated in by for-profit organizations. For example, the advisory opinion stated that all program participants in an SPCP offered or participated in by a for-profit organization may be required ''to share one or more common characteristics (for example, race, national origin, or sex)''; the April 2026 final rule, however, prohibits any SPCP offered or participated in by a for-profit organization from using the common characteristic of race, color, national origin, or sex, or any combination thereof, as a factor in determining eligibility for the program.

Relatedly, on August 25, 2026, the CFPB along with its interagency partners rescinded [42] the interagency statement on SPCPs that was issued in 2022.[43]

5.2 Withdrawing Non-Binding Policy Guidance

In E.O. 13891, titled ''Promoting the Rule of Law Through Improved Agency Guidance Documents,'' President Trump directed Federal agencies to not use guidance documents to attempt to create new rights or obligations binding on persons or financial institutions outside of the Federal Government.

In accordance with E.O. 13891, and a realignment of priorities, the CFPB withdrew 67 guidance documents in May 2025.[44] The CFPB has previously issued non-binding policy guidance in myriad forms over its history, including advisory opinions, other interpretive rules, and policy statements. The CFPB's current policy is to avoid issuing guidance except where necessary and where such guidance would reduce rather than increase compliance burdens.

The Fair lending-related guidance withdrawn during the reporting period includes:

- Bulletin 2012–04 re: lending discrimination (Apr. 18, 2012);
- Bulletin 2013–01 re: indirect auto lending and compliance with the Equal Credit Opportunity Act (Mar. 21, 2013);
- Bulletin 2015–02 re: section 8 housing choice voucher homeownership program (May 11, 2015);
- Equal Credit Opportunity (Regulation B); Discrimination on the Bases of Sexual Orientation and Gender Identity, 86 FR 14363 (Mar. 16, 2021);
- Equal Credit Opportunity (Regulation B); Revocations or Unfavorable Changes to the Terms of Existing Credit Arrangements, 87 FR 30097 (May 18, 2022);
- Limited Applicability of Consumer Financial Protection Act's 'Time or Space' Exception to Digital Marketers, 87 FR 50556 (Aug. 17, 2022); and
- Statement on Enforcement and Supervisory Practices Relating to the Small Business Lending Rule Under the Equal Credit Opportunity Act and Regulation B, 88 FR 34833 (May 31, 2023).

For the most current information, please visit our website.

[40] *See* 91 FR 21620; *see also https://content.consumerfinance.gov/rules-policy/final-rules/equal-credit-opportunity-act-regulation-b/.*

[41] *See* Joint Explanatory Statement of the Committee of the Conference, Cong. Rec. H5493 (daily ed. Mar. 4, 1976) (text appears in House and Senate Reports).

[42] *See* Interagency Rescission of the Interagency Statement on Special Credit Programs Under the Equal Credit Opportunity Act and Regulation B, 91 FR 54875 (Aug. 25, 2026), *https://www.federalregister.gov/documents/2026/08/25/2026-17307/interagency-rescission-of-the-interagency-statement-on-special-purpose-credit-programs-under-the.*

[43] *See* Interagency Statement on Special Purpose Credit Programs Under the Equal Credit Opportunity Act and Regulation B (Feb. 22, 2022), *https://files.consumerfinance.gov/f/documents/cfpb_spcp_interagency-statement_2022-02.pdf.*

[44] Interpretive Rules, Policy Statements, and Advisory Opinions; Withdrawal, 90 FR 20084 (May 12, 2025), *https://www.federalregister.gov/documents/2025/05/12/2025-08286/interpretive-rules-policy-statements-and-advisory-opinions-withdrawal.*

6. Stakeholder Engagement

Pursuant to the CFPA, the Office of Fair Lending works with private industry and fair lending, civil rights, consumer, and community advocates to promote fair lending compliance and education.[45]

In 2025, the CFPB engaged with external stakeholders to promote its new fair lending policy priorities through webinars, advisory board meetings, and coordination with other government agencies. During the reporting year, the CFPB also published the 2024 HMDA data and several HMDA data products and resources to serve a variety of data users.

6.1 Fair Lending Outreach

In 2025, the CFPB participated in the Federal Reserve System's 2025 Interagency Fair Lending Webinar,[46] an annual webinar dedicated to fair lending compliance issues. During the webinar, the CFPB highlighted the administration's fair lending priorities, including debanking efforts and fair lending-related rulemakings.

The CFPB also convened a public meeting of its Consumer Advisory Board (CAB)[47] focused on fair lending and unlawful debanking, as well as the previous administration's regulatory overreach and how the current administration is rectifying these issues. The meeting featured discussions on the *Townstone* and *Credova* enforcement cases, two examples of the prior weaponization of the CFPB. As discussed previously, Townstone was targeted for their protected speech, whereas Credova's use of innovative financial technology solutions to provide consumer financing to facilitate the exercise of Americans' Second Amendment rights made it a target for the CFPB. During the CAB meeting, the CFPB also highlighted the administration's shifts in fair lending policy and fair lending enforcement and supervision priorities.

For more information about the CFPB's work on debanking and its fair lending enforcement and supervision efforts, see this report's sections 2.3 and 4, respectively.

6.2 Availability of 2024 HMDA Data & Resources

On March 31, 2025, the CFPB announced the availability of the 2024 HMDA modified loan application register data on the Federal Financial Institutions Examination Council's (FFIEC)[48] HMDA Platform for approximately 4,898 HMDA filers.[49] These data contain loan-level information filed by financial institutions, modified to protect consumer privacy.

On July 7, 2025, the CFPB, on behalf of the FFIEC, announced the availability of ''Snapshot'' National Loan-Level HMDA data, a static dataset of 2024 mortgage lending transactions at 4,908 financial institutions reported under HMDA as of May 19, 2025.[50] The FFIEC also released derivative data products, including Aggregate and Disclosure Reports, the HMDA Maps tool, and the 2024 HMDA Data Browser. Lastly, the FFIEC released the 2024 HMDA Dynamic National Loan-Level Dataset, One-Year National Loan-Level Dataset for 2023, and the Three-Year National Loan-Level Dataset for 2021 on the same day.

Together with the FFIEC, the CFPB updates its HMDA resources throughout the year to ensure HMDA reporters have the most up-to-date information. For example, in October 2025, the CFPB released the 2026 Filing Instructions Guide[51] (an interactive online guide) and the 2025 Supplemental Guide for Quarterly Filers.[52] The CFPB also works with the FFIEC to publish data submission resources for HMDA filers and vendors on its Resources for HMDA Filers website, *https://ffiec.cfpb.gov*.

The CFPB maintains a comprehensive suite of resources pertaining to the reporting and use of HMDA data, in addition to the annual HMDA filing guides released annually by FFIEC. These resources include Executive Summaries of HMDA rule changes;[53] Small Entity Compliance Guide;[54] Institutional and Transactional Coverage Charts;[55] a sample data collection form;[56] FAQs;[57] a Beginner's Guide to Accessing and Using HMDA Data;[58] and downloadable webinars,[59] which provide an overview of the HMDA rule.

In addition, HMDA filers can ask questions about HMDA and Regulation C, including how to submit HMDA data, by emailing the CFPB's HMDA Help at *HMDAHelp@cfpb.gov*. The CFPB also offers financial institutions, service providers, and others informal staff guidance on specific questions about the statutes and rules the CFPB implements, including ECOA and Regulation B and HMDA and Regulation C, through its Regulatory Inquiries platform.[60]

7. Interagency Engagement

Pursuant to section 1013(c)(2)(B) of the CFPA, the Office of Fair Lending is charged with coordinating with Federal and State regulators to promote consistent, efficient, and effective enforcement of Federal fair lending laws. As part of this coordination, the CFPB shares information, coordinates activity, and promotes best practices with fellow supervisory and law enforcement agencies to ensure the most effective use of resources. Proper coordination also helps prevent regulatory overreach and minimizes regulatory burden by eliminating supervision outside of the CFPB's authority or duplicative supervision.

In 2025, the CFPB coordinated its fair lending regulatory, supervisory, and enforcement activities through interagency organizations and

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[45] 12 U.S.C. 5493(c)(2).

[46] Fed. Reserve Sys., *2025 Fair Lending Interagency Webinar* (Dec. 16, 2025), *https://www.consumercomplianceoutlook.org/events/2025-fair-lending-interagency-webinar*.

[47] CFPB, *Winter 2025 Consumer Advisory Board Meeting* (Dec. 10, 2025), *https://www.youtube.com/watch?v=BxWELNSn6Go*.

[48] Collectively, the Board of Governors of the Federal Reserve System (FRB), the Federal Deposit Insurance Corporation (FDIC), the National Credit Union Administration (NCUA), the Office of the Comptroller of the Currency (OCC), and the CFPB comprise the FFIEC. The State Liaison Committee was added to FFIEC in 2006 as a voting member. Federal Fin. Inst. Examination Council, *https://www.ffiec.gov*.

[49] CFPB, *2024 HMDA Data on Mortgage Lending Now Available* (Mar. 31, 2025), *https://www.consumerfinance.gov/about-us/newsroom/2024-hmda-data-on-mortgage-lending-now-available/*.

[50] Federal Fin. Inst. Examination Council, *FFIEC Publishes 2024 Data on Mortgage Lending* (July 7, 2025), *https://www.ffiec.gov/news/press-releases/2025/an-07-07*.

[51] CFPB, *Filing instructions guide for HMDA data collected in 2025* (Oct. 2025), *https://ffiec.cfpb.gov/documentation/fig/2026/overview*.

[52] CFPB, *Supplemental Guide for Quarterly Filers for 2026* (Oct. 2025), *https://ffiec.cfpb.gov/documentation/fig/2026/supplemental-guide-for-quarterly-filers*.

[53] Summaries for several rule changes are available at: *https://www.consumerfinance.gov/compliance/compliance-resources/mortgage-resources/hmda-reporting-requirements/*.

[54] CFPB, *Home Mortgage Disclosure (Regulation C) Small Entity Compliance Guide* (Feb. 2023), *https://files.consumerfinance.gov/f/documents/cfpb_hmda_small-entity-compliance-guide_2023-02.pdf*.

[55] CFPB, *HMDA Institutional Coverage Chart, https://files.consumerfinance.gov/f/documents/cfpb_hmda-institutional-coverage_2023.pdf*; CFPB, *HMDA Transactional Coverage Chart, https://files.consumerfinance.gov/f/documents/cfpb_hmda-transactional-coverage_2023.pdf*.

[56] CFPB, *Sample Data Collection Form, https://files.consumerfinance.gov/f/documents/201708_cfpb_hmda-sample-data-collection-form.pdf*.

[57] CFPB, *Home Mortgage Disclosure Act FAQs, https://www.consumerfinance.gov/compliance/compliance-resources/mortgage-resources/hmda-reporting-requirements/home-mortgage-disclosure-act-faqs/*.

[58] CFPB, *A Beginner's Guide to Accessing and Using Home Mortgage Disclosure Act Data* (June 13, 2022), *https://files.consumerfinance.gov/f/documents/cfpb_beginners-guide-accessing-using-hmda-data_guide_2022-06.pdf*.

[59] CFPB, *HMDA Webinars, https://www.consumerfinance.gov/compliance/compliance-resources/mortgage-resources/hmda-reporting-requirements/webinars/*.

[60] *See* https://reginquiries.consumerfinance.gov/.

taskforces. Specifically, the CFPB coordinated with the DOJ in connection with the DOJ's Equal Access to Banking Task Force.

Additionally, through the FFIEC, the CFPB has robust engagements with other partner agencies that focus on fair lending issues. For example, throughout the reporting period, the CFPB continued to chair the HMDA Subcommittee, a subcommittee of the FFIEC Task Force on Consumer Compliance (TFCC). This subcommittee oversees FFIEC projects and programs involving HMDA data collection, processing, and publication, the preparation of the annual FFIEC HMDA data processing budget, and the development and implementation of other related HMDA processing projects as directed by the TFCC. The CFPB also operates and maintains the HMDA Platform with costs shared equally among the FFIEC agencies and the Department of Housing and Urban Development (HUD).

CFPB personnel also meet with personnel from other agencies, including DOJ and the prudential regulators, to coordinate on and discuss fair lending issues.

8. Statutory Reporting on Interagency ECOA Enforcement

The CFPB is statutorily required to file a report to Congress annually describing the administration of its functions under ECOA, summarizing public enforcement actions taken by other agencies with administrative enforcement responsibilities under ECOA, and providing an assessment of the extent to which compliance with ECOA has been achieved.[61]

8.1 Reporting on ECOA Enforcement

This section covers the enforcement, compliance efforts, and assessments conducted by the eleven agencies with enforcement authority under section 704 of ECOA,[62] as reported by the agencies.

TABLE 1: FFIEC AGENCIES WITH ADMINISTRATIVE ENFORCEMENT OF ECOA

FFIEC Agencies with Administrative Enforcement of ECOA				
Consumer Financial Protection Bureau (CFPB)	Federal Deposit Insurance Corporation (FDIC)	Federal Reserve Board (FRB)	National Credit Union Administration (NCUA)	Office of the Comptroller of the Currency (OCC)

TABLE 2: NON-FFIEC AGENCIES WITH ADMINISTRATIVE ENFORCEMENT OF ECOA

Non-FFIEC Agencies with Administrative Enforcement of ECOA					
Agricultural Marketing Service (AMS) of the U.S. Department of Agriculture (USDA)	Department of Transportation (DOT)	Farm Credit Administration (FCA)	Federal Trade Commission (FTC)	Securities and Exchange Commission (SEC)	Small Business Administration (SBA)

[61] 15 U.S.C. 1691f.

[62] 15 U.S.C. 1691c.

8.1.1 Public Enforcement Actions

In 2025, none of the Federal agencies with ECOA enforcement authority brought public enforcement actions for violations of ECOA.

Some agencies undertook action consistent with applicable executive orders. The FTC reported that following E.O. 14281, in the FTC's administrative action against a large automotive dealer group, Asbury Automotive, three Texas dealerships it owns, and general manager Ali Benli, the FTC amended the complaint and removed all references to allegations of disparate impact under the ECOA and Regulation B.[63] The remaining aspects of the complaint pertain to the respondents allegedly engaging in a variety of deceptive and unfair practices to impose hidden fees for unwanted add-ons on consumers, in violation of the FTC Act.[64] Litigation in this administrative matter is currently stayed, in view of ongoing litigation in a collateral Federal court matter.[65]

In addition, in 2025, the CFPB resolved several fair lending-related public enforcement actions that are described in more detail in section 4.2 above.

8.1.2 Number of Institutions Cited for ECOA and Regulation B Violations

In 2025, the CFPB and the other agencies collectively reported citing 140 institutions with violations of ECOA or Regulation B, or both.

8.1.3 Violations Cited During ECOA Examinations

Among institutions examined for compliance with ECOA and Regulation B, the FFIEC agencies reported that the most frequently cited violations were as follows:

TABLE 3—REGULATION B VIOLATIONS CITED BY FFIEC AGENCIES ENFORCING ECOA, 2025

Regulation B violations cited in 2025	Agency
12 CFR 1002.4(a); 1002.7(a): *Discrimination*—Discrimination on a prohibited basis in a credit transaction in violation of 1002.4(a); refused to grant credit to a creditworthy applicant on a prohibited basis in violation of 1002.7(a).	NCUA.
12 CFR 1002.5(d)(1): *Rules concerning requests for information*—Failure to comply with limitations on inquiring about an applicant's marital status.	OCC.
12 CFR 1002.7(d)(1): *Rules concerning extensions of credit*—Improperly required the signature of the applicant's spouse or other person without first determining that the applicant alone did not qualify for the credit requested.	FRB.
12 CFR 1002.9(a)(1); (a)(2); (a)(2)(i); (a)(3)(i); (b)(1); (b)(2); (c)(1)(ii): *Adverse Action*—Failure to provide notice to the applicant 30 days after receiving a completed application concerning the creditor's approval of, counteroffer to, or adverse action on the application in violation of (a)(1); failure to provide a written adverse action notification containing all required elements, including a statement of the action taken, the creditor's name and address, the ECOA notice required under 701(a), the name and address of the administering Federal Agency, and specific reasons for the adverse action or disclosure of the applicants right to request them in violation of (a)(2); failure to provide a statement of the specific reasons for the adverse action taken in violation of (a)(2)(i); failure to notify the applicant of action taken within a reasonable time on an application for business credit with gross revenues of 1 million or less in violation of (a)(3)(i); failure to provide certain information about ECOA in adverse action notices, including the name and address of the Federal agency that administers compliance with ECOA concerning the creditor in violation of (b)(1); failure to provide a statement of reasons for adverse action that was specific and indicated the principal reason(s) for the adverse action in violation of (b)(2); failure to provide notice of incomplete application regarding matters that an applicant can complete in violation of (c)(1)(ii).	OCC,[66] NCUA,[67] FDIC,[68] FRB.[69]
12 CFR 1002.14 (a)(1); (a)(2): *Appraisals and Valuations*—Failure to provide appraisals and other valuations.	FRB,[70] OCC.[71]

Among institutions examined for compliance with ECOA and Regulation B, the Non-FFIEC agencies reported that the most frequently cited violations were as follows:

[63] *See Asbury Auto. Grp., Inc.,* No. D–9436 (F.T.C. filed Aug. 16, 2024), Order Granting Complaint Counsel's Motion to Partially Lift Stay of Administrative Proceedings to Amend Administrative Complaint (with attached amended complaint and notice) (July 17, 2025), *https://www.ftc.gov/legal-library/browse/cases-proceedings/222-3135-asbury-automotive-group-inc-et-al-matter.* These changes occurred in paras. 32–35, 48–52, and corresponding material in the introductory paragraph and paras. 1 and 10 of the Amended Complaint. *See also* Complaint Counsel's Motion to Partially Lift Stay of Administrative Proceedings to Amend Administrative Complaint (May 6, 2025)—with attached amended complaint and notice, *https://www.ftc.gov/legal-library/browse/cases-proceedings/222-3135-asbury-automotive-group-inc-et-al-matter.*

[64] *See Asbury Auto. Grp., Inc.,* No. D–9436 (F.T.C. filed Aug. 16, 2024) (original complaint), and *Asbury Auto. Grp., Inc.,* No. D–9436 (F.T.C. filed Oct. 8, 2024) (amended complaint) at 8, *https://www.ftc.gov/system/files/ftc_gov/pdf/d9436_asbury_p3_complaint_public_redacted.pdf* and *https://www.ftc.gov/system/files/ftc_gov/pdf/611899.2024.10.08_asbury_part_3_administrative_complaint_public.pdf,* respectively.

[65] *See Asbury Auto. Grp., Inc.* No. D–9436 (Nov. 25, 2025) (order granting the Parties' Joint Expedited Motion for Further Stay and Continuance of Administrative Proceedings), *https://www.ftc.gov/system/files/ftc_gov/pdf/d9436_2025.11.25_order_granting_the_parties_joint_expedited_motion_for_further_stay_and_continuance_of_administrative_proceedings_.pdf; see also Asbury Auto. Grp., Inc.* v. *FTC,* No. 24–cv–00950 (N.D. Tex. filed Oct. 4, 2024).

[66] 12 CFR 1002.9(a)(1);(a)(2)(i); (b)(1);(b)(2); (c)(1)(ii).

[67] 12 CFR 1002.9(a)(1); (a)(2); (b)(2).

[68] 12 CFR 1002.9(a)(1); (a)(2); (b)(2).

[69] 12 CFR 1002.9(a)(3)(i).

[70] 12 CFR 1002.14(a)(1).

[71] 12 CFR 1002.14(a)(1); (a)(2).

TABLE 4—REGULATION B VIOLATIONS CITED BY NON-FFIEC AGENCIES ENFORCING ECOA, 2025

Regulation B violations cited in 2025	Agency
12 CFR 1002.9(a)(1)(i); (b)(2): *Adverse Action*—Failure to provide notice to the applicant 30 days after receiving a completed application concerning the creditor's approval of, counteroffer to, or adverse action on the application in violation of (a)(1)(i); failure to provide sufficient information in an adverse action notification, including the specific reasons for the action taken in violation of (b)(2).	FCA.
12 CFR 1002.13: *Failure to request and collect information for monitoring purposes*; Failure to obtain information for monitoring purposes.	FCA.

The AMS, SEC, Office of Aviation Consumer Protection (OACP), and the SBA reported that they received no complaints based on ECOA or Regulation B in 2025. The FTC is an enforcement agency and does not conduct compliance examinations.

8.1.4 Referrals to the DOJ

The agencies assigned enforcement authority under section 704 of ECOA must refer a matter to DOJ when there is reason to believe that a creditor has engaged in a pattern or practice of lending discrimination in violation of ECOA.[72] They also may refer other potential ECOA violations to DOJ.[73] In 2025, NCUA made four referrals to DOJ involving violations of ECOA or Regulation B. Two referrals involved discrimination based on receipt of public assistance, one involved discrimination based on age and marital status, and one involved discrimination based on age alone. The OCC made one referral to DOJ involving violations of ECOA, Regulation B, and the FHA. The matter involved discrimination on the basis of race, color, or national origin in mortgage lending.

In 2025, the CFPB, FDIC, and FRB did not refer any ECOA matters to DOJ.

9. Statutory Reporting on HMDA

Pursuant to HMDA, the CFPB in consultation with HUD, must report annually on the utility of HMDA's requirement that covered lenders report the number and dollar amount of certain mortgage loans and applications grouped according to census tract, income level, racial characteristics, age, and gender.[74]

The CFPB is currently assessing the utility of this data and expects to publish a separate report to Congress in late 2026.

Mark Paoletta,

Acting Director, Consumer Financial Protection Bureau.

[FR Doc. 2026–22645 Filed 11–5–26; 8:45 am]

BILLING CODE 4810–AM–P

[72] 15 U.S.C. 691e(g).

[73] *Id.*

[74] 12 U.S.C. 2807.

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting

TIME AND DATE: Tuesday, November 10, 2026—12:00 p.m.

PLACE: The meeting will be held remotely.

STATUS: Closed Commission Meeting.

MATTERS TO BE CONSIDERED: Briefing matter.

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Office of the Secretary, U.S. Consumer Product Safety Commission, 441 G Street NW, Washington, DC 20548, 301–504–7479 (Office) or 240–863–8938 (Cell).

Dated: November 3, 2026.

Alberta E. Mills,

Commission Secretary.

[FR Doc. 2026–22661 Filed 11–4–26; 11:15 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Department of the Navy

Meeting of the U.S. Naval Academy Board of Visitors

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

ACTION: Notice of partially closed meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the U.S. Naval Academy Board of Visitors, hereafter ''Board,'' will take place.

DATES: Open to the public, November 30, 2026, from 09:00 a.m. to 11:00 a.m. Eastern Time Zone (ET). Closed to the public, November 30, 2026, from 11:00 a.m. to 12:00 p.m. ET.

ADDRESSES: This meeting will be held at the United States Naval Academy. The meeting will be handicap accessible.

FOR FURTHER INFORMATION CONTACT: Major Shawn C. Wehrle, USMC, Executive Secretary to the Board of Visitors, Office of the Superintendent, U.S. Naval Academy, Annapolis, MD 21402–5000, 410–293–1503, *wehrle@usna.edu.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C. 1001–1014), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and the General Services Administration's Federal Advisory Committee Management Final Rule (41 CFR part 102–3).

Purpose of Meeting: The U.S. Naval Academy Board of Visitors will meet to make such inquiry, as the Board deems necessary, into the state of morale and discipline, the curriculum, instruction, physical equipment, fiscal affairs, and academic methods of the Naval Academy.

Agenda

Proposed meeting agenda for November 30, 2026.

9:00 a.m.–Call to Order (Open to Public)
9:00–10:50 a.m.—Opening Meeting (Open to Public)
10:50–11:00 a.m.—Break
11:00–12:00 p.m.—Closed Meeting (Closed to Public)

The closed meeting from 11:00–12:00 p.m. ET will consist of discussions of new and pending administrative or minor disciplinary infractions and non-judicial punishments involving midshipmen attending the Naval Academy to include but not limited to, individual honor or conduct violations within the Brigade, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. For this reason, a portion of this meeting will be closed to the public, as the discussion of such information cannot be adequately segregated from other topics, which precludes opening the closed meeting to the public. The Principal Deputy General Counsel has determined in writing that the meeting shall be partially closed to the public because the discussions during the closed meeting from 11:00 a.m.–12:00 p.m. ET will be concerned with matters protected under sections 552b(c)(5), (6), and (7) of title 5, U.S.C.

Authority: 5 U.S.C. 552b.

Meeting Accessibility: Pursuant to FACA and 41 CFR 102–3.140, this meeting is open to the public. Please contact the Executive Secretary five business days prior to the meeting at *Admin-Routing@usna.edu* to coordinate access to the meeting.

Written Statements: Pursuant to 5 U.S.C. 1009(a)(3), interested persons may submit a written statement for consideration at any time, but it should be received by the Designated Federal Officer at least five business days prior to the meeting date so that the comments may be made available to the Board for their consideration prior to the meeting. Written statements should be submitted via mail to 121 Blake Rd., Annapolis, MD 21402. Please note that since the Board operates under the provisions of the FACA, as amended, all submitted comments and public presentations may be treated as public documents and may be made available for public inspection, including, but not limited to, being posted on the board website.

M.A. Tabach,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2026–22713 Filed 11–5–26; 8:45 am]

BILLING CODE 3810–FF–P

ELECTION ASSISTANCE COMMISSION

Agency Information Collection Activities

AGENCY: Election Assistance Commission.

ACTION: Notice; request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the U.S. Election Assistance Commission (EAC) gives notice that it is requesting from the Office of Management and Budget (OMB) an extension of the previously approved information collection OMB Control Number 3265–0026 EAC Progress Report (EAC–PR).

DATES: Comments must be received by 5 p.m. Eastern on Wednesday, December 9, 2026.

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

FOR FURTHER INFORMATION CONTACT: For further information, please contact Risa Garza, Office of Grants Management, Election Assistance Commission, by email at: *grants@eac.gov.*

SUPPLEMENTARY INFORMATION:

Title and OMB Number: EAC Progress Report (EAC–PR); OMB Control Number: 3265–0026.

Purpose: This proposed information collection was previously published in the **Federal Register** on August 3, 2026 (91 FR, pp. 48847–48848) and allowed 60 days for public comment. The purpose of this notice is to allow an additional 30 days for public comment from all interested individuals and organizations.

The EAC–PR is employed for both interim and final progress reports for grants issued under HAVA authority. This format contains no changes to the report or instructions since the approved standard request in November 2023. The PR directly benefits award recipients by making it easier for them to administer federal grant and cooperative agreement programs through standardization of the types of information required in progress reporting, thereby reducing their administrative effort and costs.

The requirement for grantees to report on performance is the OMB grants policy. Specific citations are contained inCode of Federal Regulations TITLE 2, PART 200—UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR FEDERAL AWARDS.

Public Comments

Comments are invited on (a) ways to enhance the quality, utility, and clarity of the information collected from respondents, including through the use of automated collection techniques or other forms of information technology; and (b) 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.

Annual Reporting Burden

*Respondents:*All EAC grantees and state governments.

EAC grant	Instrument	Total number of respondents	Total number of responses per year	Average burden hours per response	Annual burden hours
251	EAC–PR	29	2	1	58
101	EAC–PR	12	2	1	24
Election Security	EAC–PR	56	1	1	56
Total					138

The estimated annualized cost of this burden is $3,576.96, calculated by multiplying the annualized burden (138 hours) by an hourly rate of $25.92 (GS–8/Step 5 hourly basic rate).

Seton Parsons,

Senior Associate Counsel, U.S. Election Assistance Commission.

[FR Doc. 2026–22712 Filed 11–5–26; 8:45 am]

BILLING CODE 4810–71–P

DEPARTMENT OF ENERGY

President's Council of Advisors on Science and Technology (PCAST)

AGENCY: Department of Energy.

ACTION: Notice of rescheduled open meeting.

SUMMARY: This notice announces a rescheduled virtual/livestreamed meeting of the President's Council of Advisors on Science and Technology (PCAST), originally scheduled for Friday, November 6, 2026, and published in the **Federal Register** on Thursday, October 22, 2026. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Friday, November 13, 2026; 12:00–1:00 p.m. EST.

ADDRESSES: Registration for the livestream can be found here: *https://www.zoomgov.com/webinar/register/WN_LkiBqVceRbmUKWGtawc1_g#/registration.*

FOR FURTHER INFORMATION CONTACT: Kristen Ellis, PCAST Designated Federal Officer, U.S. Department of Energy, 1000 Independence Ave. SW, Washington, DC 20585; Phone: (202) 586–5810; or Email: *pcast@doe.gov*.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: PCAST advises the President on matters involving science, technology, education, and innovation policy. The Committee provides the President with scientific and technical information that is needed to inform public policy relating to the American economy, the American worker, national and homeland security, and other topics. PCAST responds to requests from the President or co-chairs for information, analysis, evaluation, or advice. In addition, PCAST solicits information and ideas from a broad range of stakeholders including the research community; private sector; universities; national laboratories; state, local and Tribal governments; foundations; and non-profit organizations. PCAST also provides advice in response to requests from the Super Intelligence Force.

Tentative Agenda: (agenda topics are subject to change; please contact Kristen Ellis at: *pcast@doe.gov* for the most current agenda)

- Chair Update
- Charges to the Board
- Board Business
- Public Comments
- Closing Remarks

Public Participation: The meeting is open to the public and public comment can be given orally or in writing. Fifteen minutes are allocated during the meeting for public comment and those wishing to make oral comment will be given maximum timeframe of two minutes. To register to speak, please contact *pcast@doe.gov* not later than seven days in advance of the meeting.

Written comments received at least two working days prior to the meeting will be provided to the members and included in the meeting minutes. Written comments received within two working days after the meeting will be included in the minutes. For additional information on public comment and to submit written comment, please contact *pcast@doe.gov*. The PCAST welcomes the attendance of the public at its meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact *pcast@doe.gov* at least seven days in advance of the meeting.

Meeting conduct: The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Questioning of board members or presenters by the public is not permitted.

Minutes: Minutes will be available at the following website: *https://www.whitehouse.gov/ostp/presidents-council-of-advisors-on-science-and-technology/*.

Signing Authority: This document of the Department of Energy was signed on November 3, 2026, by David Borak, Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 4, 2026.

Treena V. Garrett,

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

[FR Doc. 2026–22668 Filed 11–5–26; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. Each filing may be viewed on the Commission's website at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. 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.

Docket Nos.	File date	Presenter or requester
Prohibited:		
1. CP26–536–000	10–27–2026	FERC Staff.[1]
Exempt:		
1. FA25–4–000	10–21–2026	FERC Staff.[2]
2. FA25–4–000	10–21–2026	FERC Staff.[3]
3. EL26–67–000 EL26–68–000	10–26–2026	FERC Staff.[4]

Docket Nos.	File date	Presenter or requester
EL26–69–000 EL26–70–000 EL26–71–000 EL26–72–000		
4. P–2438–000	11–02–2026	FERC Staff.[5]

[1] Memo providing summary of the 10/14/26 call with Shannon Miller on behalf of Texas Gas Transmission.
[2] Letter communication dated 10/14/26 from U.S. Representatives Jefferson Van Drew.
[3] Letter communication dated 10/5/26 from U.S. Representatives Jefferson Van Drew.
[4] Letter communication dated 10/5/26 from the National Congress of American Indians.
[5] Letter communication dated 10/29/26 from New York State Senator Pamela A. Helming.

Dated: November 3, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–22724 Filed 11–5–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following Electric Corporate filings:

Docket Numbers: EC27–12–000.

Applicants: North Fork Solar Project, LLC, RE Desert Bloom LLC, Enel Green Power North America, Inc., Bayou Galion Solar Project, LLC, Liberty County Solar Project, LLC, RE Papago PV LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Bayou Galion Solar Project, LLC, et al.

Filed Date: 10/30/26.

Accession Number: 20261030–5443.

Comment Date: 5 p.m. ET 11/20/26.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL27–10–000.

Applicants: Sweetwater Energy Storage, *LLC* v. *Public Service Company of New Mexico*.

Description: Complaint of Sweetwater Energy Storage, *LLC* v. *Public Service Company of New Mexico*.

Filed Date: 11/2/26.

Accession Number: 20261102–5311.

Comment Date: 5 p.m. ET 11/23/26.

Take notice that the Commission received the following Electric Rate filings:

Docket Numbers: ER10–566–006; ER10–2774–008; ER11–3917–006; ER24–2897–002; ER24–2898–002.

Applicants: Mordor ES2 LLC, Mordor ES1 LLC, Mojave Solar LLC, Arizona Solar One LLC, Coso Geothermal Power Holdings, LLC.

Description: Notice of Non-Material Change in Status of Coso Geothermal Power Holdings, LLC, et al.

Filed Date: 1/31/25.

Accession Number: 20250131–5542.

Comment Date: 5 p.m. ET 2/21/25.

Docket Numbers: ER13–2322–011.

Applicants: Duke Energy Progress, Inc.

Description: Notice of Termination of Interconnection Agreement of Duke Energy Progress, LLC.

Filed Date: 10/27/26.

Accession Number: 20261027–5206.

Comment Date: 5 p.m. ET 11/17/26.

Docket Numbers: ER26–2026–001.

Applicants: Light Energy, LLC.

Description: Notice of Non-Material Change in Status of Light Energy, LLC.

Filed Date: 10/27/26.

Accession Number: 20261027–5205.

Comment Date: 5 p.m. ET 11/17/26.

Docket Numbers: ER26–3798–001.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Amendment to Ministerial Clean-Up Filing, RAA, Article 1, Definitions to be effective 4/1/2018.

Filed Date: 11/3/26.

Accession Number: 20261103–5154.

Comment Date: 5 p.m. ET 11/24/26.

Docket Numbers: ER27–276–001.

Applicants: Citizens S-Line Transmission LLC.

Description: Tariff Amendment: Correction to Annual Operating Cost True-Up Adj Informational to be effective 1/1/2027.

Filed Date: 11/3/26.

Accession Number: 20261103–5103.

Comment Date: 5 p.m. ET 11/24/26.

Docket Numbers: ER27–277–001.

Applicants: Citizens Sycamore-Penasquitos Transmission LLC.

Description: Tariff Amendment: Correction to Annual Operating Cost True-Up Adj Informational to be effective 1/1/2027.

Filed Date: 11/3/26.

Accession Number: 20261103–5100.

Comment Date: 5 p.m. ET 11/24/26.

Docket Numbers: ER27–278–001.

Applicants: Citizens Sunrise Transmission LLC.

Description: Tariff Amendment: Correction to Annual Operating Cost True-Up Adj Informational to be effective 1/1/2027.

Filed Date: 11/3/26.

Accession Number: 20261103–5101.

Comment Date: 5 p.m. ET 11/24/26.

Docket Numbers: ER27–400–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1166R49 Oklahoma Municipal Power Authority NITSA and NOA to be effective 10/1/2026.

Filed Date: 11/2/26.

Accession Number: 20261102–5282.

Comment Date: 5 p.m. ET 11/23/26.

Docket Numbers: ER27–401–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: PJM–MISO CTS Retirement to be effective 1/13/2027.

Filed Date: 11/2/26.

Accession Number: 20261102–5283.

Comment Date: 5 p.m. ET 11/23/26.

Docket Numbers: ER27–402–000.

Applicants: E South Hero Co. LLC.

Description: Compliance filing: Notice of Change in Category Seller Status and Revisions to MBR Tariff to be effective 11/3/2026.

Filed Date: 11/2/26.

Accession Number: 20261102–5296.

Comment Date: 5 p.m. ET 11/23/26.

Docket Numbers: ER27–403–000.

Applicants: ER Nava Storage, LLC.

Description: Compliance filing: Notice of Change in Category Seller Status and Revisions to MBR Tariff to be effective 11/3/2026.

Filed Date: 11/2/26.

Accession Number: 20261102–5299.

Comment Date: 5 p.m. ET 11/23/26.

Docket Numbers: ER27–404–000.

Applicants: ER South Street Storage, LLC.

Description: Compliance filing: Notice of Change in Category Seller Status and Revisions to MBR Tariff to be effective 11/3/2026.

Filed Date: 11/2/26.

Accession Number: 20261102–5306.

Comment Date: 5 p.m. ET 11/23/26.

Docket Numbers: ER27–405–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2026–11–03_SA 4277 Ameren IL 1st Rev MPFCA (J1289 J1453 J1454) (Latham) to be effective 1/3/2027.

Filed Date: 11/3/26.

Accession Number: 20261103–5047.

Comment Date: 5 p.m. ET 11/24/26.

Docket Numbers: ER27–406–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2026–11–03_SA 4899 Lake Charlotte Solar-SMMPA GIA (S1080) to be effective 10/26/2026.

Filed Date: 11/3/26.

Accession Number: 20261103–5067.

Comment Date: 5 p.m. ET 11/24/26.

Docket Numbers: ER27–407–000.

Applicants: Midcontinent Independent System Operator, Inc., Ameren Illinois Company.

Description: § 205(d) Rate Filing: Ameren Illinois Company submits tariff filing per 35.13(a)(2)(iii: 2026–11–03_SA 4908 Ameren Illinois-Two Roads Solar E&P (J2565 J2809) to be effective 11/4/2026.

Filed Date: 11/3/26.

Accession Number: 20261103–5105.

Comment Date: 5 p.m. ET 11/24/26.

Docket Numbers: ER27–408–000.

Applicants: ISO New England Inc., The Narragansett Electric Company, The Narragansett Electric Company.

Description: § 205(d) Rate Filing: The Narragansett Electric Company submits tariff filing per 35.13(a)(2)(iii: RIE; Post-Retirement Benefits Other Than Pensions Expenses Refund Report to be effective 1/4/2027.

Filed Date: 11/3/26.

Accession Number: 20261103–5153.

Comment Date: 5 p.m. ET 11/24/26.

Take notice that the Commission received the following Qualifying Facility filings:

Docket Numbers: QF27–127–000.

Applicants: PLK000.Z PROJECTCO, LLC.

Description: Form 556 of PLK000.Z PROJECTCO, LLC.

Filed Date: 10/29/26.

Accession Number: 20261029–5288.

Comment Date: 5 p.m. ET 11/19/26.

Take notice that the Commission received the following Electric Reliability filings:

Docket Numbers: RD27–1–000.

Applicants: North American Electric Reliability Corporation.

Description: Petition of the North American Electric Reliability Corporation for Approval of Proposed Reliability Standards FAC–011–5 and TOP–003–9.

Filed Date: 11/2/26.

Accession Number: 20261102–5377.

Comment Date: 5 p.m. ET 12/2/26.

Docket Numbers: RD27–2–000.

Applicants: North American Electric Reliability Corporation.

Description: Petition of North American Electric Reliability Corporation for Approval of Proposed Reliability Standard TPL–001–6.

Filed Date: 11/2/26.

Accession Number: 20261102–5378.

Comment Date: 5 p.m. ET 12/2/26.

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.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or *OPP@ferc.gov.*

Dated: November 3, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–22718 Filed 11–5–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3071–008]

Blue Earth County, Minnesota; Notice of Reasonable Period of Time for Water Quality Certification Application

On October 30, 2026, Minnesota Pollution Control Agency (Minnesota PCA) submitted to the Federal Energy Regulatory Commission (Commission) notice that it received a request for a Clean Water Act section 401(a)(1) water quality certification as defined in 40 CFR 121.5, from Blue Earth County, Minnesota, in conjunction with the above captioned project on October 9, 2026. Pursuant to the Commission's regulations,[1] we hereby notify the Minnesota PCA of the following:

Date of Receipt of the Certification Request: October 9, 2026.

Reasonable Period of Time to Act on the Certification Request: October 9, 2027.

If Minnesota PCA fails or refuses to act on the water quality certification request on or before the above date, then the certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

(Authority: 18 CFR 2.1)

Dated: November 3, 2026.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2026–22714 Filed 11–5–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM23–9–000]

Filing Process and Data Collection for the Electric Quarterly Report Notice of Technical Conference

Take notice that Commission staff will convene a technical conference in the above-referenced proceeding on Tuesday, February 9, and Wednesday, February 10, 2027, from 10:00 a.m. to 4:00 p.m. Eastern Standard Time. The conference will be held at the Commission's headquarters at 888 First Street NE, Washington, DC 20426 in the Kevin J. McIntyre Commission Meeting Room.

The conference will take place in hybrid format to allow both in-person and virtual attendance. Prior to the technical conference, a detailed agenda and registration information will be published in a supplemental notice in this proceeding and posted on the Commission's Order No. 917 web page.

Interested parties may use the Commission's eSubscription web page to receive email notifications of issuances in a subscribed docket. For assistance with any FERC Online service, please email *FERC OnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

FERC conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility

[1] 18 CFR 6.1(b).

accommodations please send an email to *accessibility@ferc.gov* or call toll free (866) 208–3372 (voice) or (202) 502–8659 (TTY), or send a fax to (202) 208–2106 with the required accommodations.

(Authority: 16 U.S.C. 825h.)

Dated: November 3, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–22723 Filed 11–5–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP27–9–000]

Columbia Gulf Transmission, LLC; Notice of Application and Establishing Intervention Deadline

Take notice that on October 20, 2026, Columbia Gulf Transmission, LLC (Columbia Gulf), 700 Louisiana Street, Suite 1300, Houston, Texas 77002, filed an application under section 7(c) of the Natural Gas Act (NGA) and Part 157 of the Commission's regulations requesting authorization for its Clark Project (Project). The Project consists of constructing: (1) approximately 8.68 miles of new 30-inch-diameter greenfield pipeline; (2) an aboveground tie-in to Columbia Gulf's existing mainline, including a new launcher/receive assembly; and (3) an aboveground meter station with launcher/receiver assembly, all located in Estill and Clark Counties, Kentucky. The Project will provide approximately 250,000 dekatherms per day of firm transportation service to East Kentucky Power Cooperative, Inc. to serve its existing J.K. Smith electric generation plant. Columbia Gulf proposes to apply the existing FTS–1 base system recourse reservation and commodity rates for the Project and requests a predetermination of rolled-in rate treatment. Columbia Gulf estimates the total cost of the Project to be $95,204,268, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

Any questions regarding the application should be directed to David A. Alonzo, Director, Certificates, Columbia Gulf Transmission, LLC, 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700, by phone at (832) 320–5477 or by email at *david_alonzo@tcenergy.com.*

Pursuant to section 157.9 of the Commission's Rules of Practice and Procedure,[1] within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Water Quality Certification

Columbia Gulf stated that a water quality certificate under section 401 of the Clean Water Act is required for the project from Kentucky Energy and Environment Cabinet, Department of Environmental Protection. When available, Columbia Gulf should submit to the Commission a copy of the request for certification for the Commission authorization, including the date the request was submitted to the certifying agency, and either (1) a copy of the certifying agency's decision or (2) evidence of waiver of water quality certification.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file comments on the project, you can protest the filing, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on November 24, 2026. How to file protests, motions to intervene, and comments is explained below.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation (OPP) at (202) 502–6595 or *OPP@ferc.gov.*

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections, to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be.

Protests

Pursuant to sections 157.10(a)(4)[2] and 385.211[3] of the Commission's regulations under the NGA, any person[4] may file a protest to the application. Protests must comply with the requirements specified in section 385.2001[5] of the Commission's regulations. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

To ensure that your comments or protests are timely and properly recorded, please submit your comments on or before 5:00 p.m. Eastern Time on November 24, 2026.

There are three methods you can use to submit your comments or protests to the Commission. In all instances, please reference the Project docket number CP27–9–000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

[1] 18 CFR 157.9.

[2] 18 CFR 157.10(a)(4).

[3] 18 CFR 385.211.

[4] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[5] 18 CFR 385.2001.

(2) You may file your comments or protests electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments or protests by mailing them to the following address below. Your written comments must reference the Project docket number (CP27–9–000).

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,[6] has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure[7] and the regulations under the NGA[8] by the intervention deadline for the project, which is 5:00 p.m. Eastern Time on November 24, 2026. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP27–9–000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Intervention.'' The eFiling feature includes a document-less intervention option; for more information, visit *https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf.;* or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP27–9–000.

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 204263.

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail at: David A. Alonzo, Director, Certificates, Columbia Gulf Transmission, LLC, 700 Louisiana Street, Suite 1300, Houston, Texas 77002–2700 or by email (with a link to the document) at *david_alonzo@tcenergy.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed[9] motions to intervene are automatically granted by operation of Rule 214(c)(1).[10] Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.[11] A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from OPP at (202) 502–6595 or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Intervention Deadline: 5:00 p.m. Eastern Time on November 24, 2026.

(Authority: 18 CFR 2.1)

Dated: November 3, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–22722 Filed 11–5–26; 8:45 am]

BILLING CODE 6717–01–P

[6] 18 CFR 385.102(d).

[7] 18 CFR 385.214.

[8] 18 CFR 157.10.

[9] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

[10] 18 CFR 385.214(c)(1).

[11] 18 CFR 385.214(b)(3) and (d).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP26–576–000]

Transcontinental Gas Pipe Line Company, LLC; Notice of Schedule for the Preparation of an Environmental Assessment for the Leidy Access Expansion Project

On September 4, 2026, Transcontinental Gas Pipe Line Company, LLC (Transco) filed an application in Docket No. CP26–576–000 requesting a Certificate of Public Convenience and Necessity pursuant to Section 7(c) of the Natural Gas Act to construct and operate certain natural gas pipeline facilities. The proposed project is known as the Leidy Access Expansion Project (Project) and would enable Transco to provide an incremental 183,100 dekatherms per day of year-round firm transportation capacity from the Marcellus Shale production area in northeastern Pennsylvania to a new transfer point east of Compressor Station 515 in Luzerne County, Pennsylvania.

On September 21, 2026, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for the Project. Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's environmental document for the Project.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) for the Project and the planned schedule for the completion of the environmental review.[1] The EA will be issued for a 30-day comment period.

Schedule for Environmental Review

Issuance of EA—March 26, 2027
90-day Federal Authorization Decision Deadline[2]—June 24, 2027

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

The Project will consist of the following components, all within Luzerne County, Pennsylvania:

- about 3.4 miles of 42-inch-diameter pipeline (Diamond Loop), all of which would be collocated with Transco's Leidy Loop Lines B and C;
- addition of pig launcher/receiver[3] and tie-in facilities at Transco's existing Compressor Station 515;
- a new mainline valve site that includes a tie-in and pig launcher/receiver at the terminus of the proposed Diamond Loop; and
- additional ancillary facilities, such as cathodic protection.

Background

On October 1, 2026, the Commission issued a *Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed Leidy Access Expansion Project* (Notice of Scoping). The Notice of Scoping was sent to affected landowners; federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. In response to the Notice of Scoping, the Commission received comments from one landowner. The primary issues raised by the commenter include temporary construction effects (such as vegetation), adequate erosion control, property access, protection of future property use, and potential future changes. All substantive comments will be addressed in the EA.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This service provides automatic notification of filings made to subscribed dockets, document summaries, and direct links to the documents. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or *OPP@ferc.gov.*

Additional information about the Project is available from the FERC website (*www.ferc.gov*). Using the ''eLibrary'' link, select ''General Search'' from the eLibrary menu, enter the selected date range and ''Docket Number'' excluding the last three digits (*i.e.,* CP26–576), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

(Authority: 18 CFR 2.1.)

Dated: November 3, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–22721 Filed 11–5–26; 8:45 am]

BILLING CODE 6717–01–P

[1] For tracking purposes under the National Environmental Policy Act, the unique identification number for documents relating to this environmental review is EAXX–019–20–000–1790772793.

[2] The Commission's deadline applies to the decisions of other federal agencies, and state agencies acting under federally delegated authority, that are responsible for federal authorizations, permits, and other approvals necessary for proposed projects under the Natural Gas Act. Per 18 CFR 157.22(a), the Commission's deadline for other agency's decisions applies unless a schedule is otherwise established by federal law.

[3] A ''pig'' is a tool that the pipeline company inserts into and pushes through the pipeline for cleaning, conducting internal inspections, or other purposes. A pig launcher/receiver is where pigs are inserted/retrieved from the pipeline.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP26–560–000]

Dauphin Island Gathering Partners; Notice of Schedule for the Preparation of an Environmental Assessment for the Dauphin Island Gathering Partners Abandonment Project

On July 31, 2026, Dauphin Island Gathering Partners (DIGP) filed an application in Docket No. CP26–560–000 requesting Authorization pursuant to Section 7(b) of the Natural Gas Act to abandon certain natural gas pipeline facilities. The proposed project is known as the Dauphin Island Gathering Partners Abandonment Project (Project) and would involve DIGP to abandon a total of about 119.3 miles of existing interstate natural gas pipeline and related appurtenances in Mobile County, Alabama, Alabama state waters, and federal offshore waters.

On August 7, 2026, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for the Project. Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's environmental document for the Project.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) for the Project and the planned schedule for the

completion of the environmental review.[1]

Schedule for Environmental Review

Issuance of EA—February 5, 2027

90-day Federal Authorization Decision Deadline[2]—May 6, 2027

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

DIGP seeks authorization to abandon its entire offshore natural gas pipeline gathering and transportation system, consisting of about 119.3 miles of 20-inch-diameter and 24-inch-diameter pipeline and all associated appurtenances in Mobile County, Alabama, Alabama state waters, and federal offshore waters. According to DIGP its system is no longer economically feasible due to the depletion of attached reserves and the lack of new lease activity in the vicinity. DIGP also states that abandonment is needed to eliminate environmental and safety risks due to aging energy infrastructure and harsh offshore environment conditions.

Background

On September 15, 2026, the Commission issued a *Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed Dauphin Island Gathering Partners Abandonment Project* (Notice of Scoping). The Notice of Scoping was sent to affected landowners; federal, state, and local government agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. The U.S. Fish and Wildlife Service filed a letter concurring with the applicant's determinations on federally listed species in the project area. The U.S. Environmental Protection Agency filed a comment letter stating it has no comments.

[1] For tracking purposes under the National Environmental Policy Act, the unique identification number for documents relating to this environmental review is EAXX–019–20–000–1787659366.

[2] The Commission's deadline applies to the decisions of other federal agencies, and state agencies acting under federally delegated authority, that are responsible for federal authorizations, permits, and other approvals necessary for proposed projects under the Natural Gas Act. Per 18 CFR 157.22(a), the Commission's deadline for other agency's decisions applies unless a schedule is otherwise established by federal law.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This service provides automatic notification of filings made to subscribed dockets, document summaries, and direct links to the documents. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202)502–6595 or *OPP@ferc.gov*.

Additional information about the Project is available from the FERC website (*www.ferc.gov*). Using the ''eLibrary'' link, select ''General Search'' from the eLibrary menu, enter the selected date range and ''Docket Number'' excluding the last three digits (*i.e.,* CP26–560), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov.* The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

(Authority: 18 CFR 2.1.)

Dated: November 3, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–22720 Filed 11–5–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

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

Filings Instituting Proceedings

Docket Numbers: PR27–9–000.
Applicants: UGI Utilities, Inc.
Description: § 284.123 Rate Filing: Rate Election Effective November 2026 to be effective 11/2/2026.
Filed Date: 10/30/26.
Accession Number: 20261030–5288.
Comment Date: 5 p.m. ET 11/20/26.

Docket Numbers: RP27–142–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases eff 11–1–2026 to be effective 11/1/2026.
Filed Date: 11/2/26.
Accession Number: 20261102–5163.
Comment Date: 5 p.m. ET 11/16/26.

Docket Numbers: RP27–143–000.
Applicants: BBT Trans-Union Interstate Pipeline, L.P.
Description: § 4(d) Rate Filing: Negotiated Rate Tariff Filing 2026 to be effective 11/1/2026.
Filed Date: 11/2/26.
Accession Number: 20261102–5195.
Comment Date: 5 p.m. ET 11/16/26.

Docket Numbers: RP27–144–000.
Applicants: Destin Pipeline Company, L.L.C.
Description: Compliance filing: Annual Fuel Retention Adjustment to be effective 12/1/2026.
Filed Date: 11/2/26.
Accession Number: 20261102–5218.
Comment Date: 5 p.m. ET 11/16/26.

Docket Numbers: RP27–145–000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Negotiated Rate Capacity Release Agreements—11/01/2026 to be effective 11/1/2026.
Filed Date: 11/2/26.
Accession Number: 20261102–5223.
Comment Date: 5 p.m. ET 11/16/26.

Docket Numbers: RP27–146–000.
Applicants: Mountain Valley Pipeline, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Capacity Release Agreements—11/01/2026 to be effective 11/1/2026.
Filed Date: 11/2/26.
Accession Number: 20261102–5224.
Comment Date: 5 p.m. ET 11/16/26.

Docket Numbers: RP27–147–000.
Applicants: Midwestern Gas Transmission Company.
Description: Compliance filing: 2025–2026 Cashout Report to be effective N/A.
Filed Date: 11/2/26.
Accession Number: 20261102–5270.
Comment Date: 5 p.m. ET 11/16/26.

Docket Numbers: RP27–148–000.
Applicants: Viking Gas Transmission Company.
Description: Compliance filing: 2025–2026 Gas Sales and Purchases Report to be effective N/A.
Filed Date: 11/2/26.
Accession Number: 20261102–5281.
Comment Date: 5 p.m. ET 11/16/26.

Docket Numbers: RP27–149–000.
Applicants: Midwestern Gas Transmission Company.
Description: Compliance filing: 2025–2026 Gas Sales and Purchases Report to be effective N/A.
Filed Date: 11/2/26.
Accession Number: 20261102–5284.
Comment Date: 5 p.m. ET 11/16/26.

Docket Numbers: RP27–150–000.
Applicants: Guardian Pipeline, L.L.C.
Description: Compliance filing: 2025–2026 Gas Sales and Purchases Report to be effective N/A.
Filed Date: 11/2/26.
Accession Number: 20261102–5287.
Comment Date: 5 p.m. ET 11/16/26.
Docket Numbers: RP27–151–000.
Applicants: Rockies Express Pipeline LLC.
Description: § 4(d) Rate Filing: REX 2026–11–02 Negotiated Rate Agreement Amendment to be effective 1/1/2027.
Filed Date: 11/2/26.
Accession Number: 20261102–5294.
Comment Date: 5 p.m. ET 11/16/26.
Docket Numbers: RP27–152–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Neg Rate Agmts eff. November 1, 2026 to be effective 11/1/2026.
Filed Date: 11/2/26.
Accession Number: 20261102–5316.
Comment Date: 5 p.m. ET 11/16/26.
Docket Numbers: RP27–153–000.
Applicants: Texas Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Neg Rate Agmts eff. November 1, 2026 to be effective 11/1/2026.
Filed Date: 11/2/26.
Accession Number: 20261102–5319.
Comment Date: 5 p.m. ET 11/16/26.
Docket Numbers: RP27–156–000.
Applicants: Rover Pipeline LLC.
Description: § 4(d) Rate Filing: Summary of Negotiated Rate Capacity Release Agreements 11–3–2026 to be effective 11/1/2026.
Filed Date: 11/3/26.
Accession Number: 20261103–5052.
Comment Date: 5 p.m. ET 11/16/26.

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*) by querying the docket number.

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

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or *OPP@ferc.gov.*

Dated: November 3, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–22719 Filed 11–5–26; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL OPRM–FAD–247]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Federal Activities Division, General Information 202–993–3272 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed October 26, 2026 10 a.m. EST Through November 2, 2026 10 a.m. EST

Pursuant to CEQ Guidance on 42 U.S.C. 4332.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search.*

EIS No. 20260138, Final, NRCS, ID, Final Watershed Plan and Environmental Impact Statement for Agricultural Water Management & Public Recreation in North Cache Valley, Contact: Daniel Murdock 208–513–3853.

EIS No. 20260139, Final, FHWA, MD, Chesapeake Bay Crossing Study Tier 2, Contact: Alexander Bienko 410–779–7148.

EIS No. 20260140, Draft, NOAA, WI, Proposed Green Bay National Estuarine Research Reserve, Comment Period Ends: 12/21/2026, Contact: Erica Seiden 240–429–5166.

Dated: November 2, 2026.

Nancy Abrams,

Deputy Director, Federal Activities Division.

[FR Doc. 2026–22684 Filed 11–5–26; 8:45 am]

BILLING CODE 6560–50–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, Benjamin W. McDonough, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than November 23, 2026.

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. *Richard Albers, Battle Creek, Nebraska; and Starlee Johnson, Gilbert, Arizona;* to join the Rossiter/Schrempp Family Control Group, a group acting in concert, to acquire voting shares of Cedar Bancorp, Hartington, Nebraska, and thereby indirectly acquire voting shares of Bank of Hartington, both of Hartington, Nebraska.

B. Federal Reserve Bank of Dallas (Lindsey Wieck, Director, Mergers & Acquisitions) 2200 North Pearl Street,

Dallas, Texas 75201–2272. Comments can also be sent electronically to *Comments.applications@dal.frb.org:*

1. *Elizabeth Ricks, San Antonio, Texas, individually, and as a co-trustee, of the First Commercial Financial Corporation Employee Stock Ownership Trust (ESOP), Seguin, Texas; and James Long, as co-trustee of the ESOP, New Braunfels, Texas;* as a group acting in conert, to acquire voting shares of First Commercial Financial Corporation, and thereby indirectly acquire voting shares of First Commercial Bank, N.A., both of Seguin, Texas.

Board of Governors of the Federal Reserve System.

Benjamin W. McDonough,

Secretary of the Board.

[FR Doc. 2026–22716 Filed 11–5–26; 8:45 am]

BILLING CODE P

OFFICE OF GOVERNMENT ETHICS

Potential Improvements to the OGE Form 278e (Executive Branch Personnel Public Financial Disclosure Report) and the OGE Form 450 (Executive Branch Confidential Financial Disclosure Report)

AGENCY: Office of Government Ethics (OGE).

ACTION: Notice of public meeting.

SUMMARY: The U.S. Office of Government Ethics (OGE) is hosting a public meeting to obtain input from interested parties regarding potential improvements to the OGE Form 278e and the OGE Form 450 as part of a form revision planning process that will precede the next requested renewal of these forms under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The next scheduled renewal is in 2027.

DATE:

Public Meeting Date: The public meeting will be held virtually via Microsoft Teams on December 10, 2026, from 1:00 p.m. to 2:30 p.m., Eastern time.

Registration: By close of business on December 3, 2026.

Written Comment Period Dates: For written comments to be discussed at the meeting, they must be received by December 3, 2026.

Information on how to register for this meeting and to submit a written comment may be found in the **SUPPLEMENTARY INFORMATION** section of this notice.

ADDRESSES: The public meeting will be held via TEAMS Meetings.

FOR FURTHER INFORMATION CONTACT: Jody Keegan or Jack MacDonald; Program Analyst, Ethics Law and Disclosure Division, Office of Government Ethics, 250 E Street SW, Suite 750, Washington, DC 20024–3249; Telephone: (202) 482–9300; TTY: (800) 877–8339.

SUPPLEMENTARY INFORMATION: On September 10, 2026, OGE held a listening session to seek agency input on issues specifically related to potential language and formatting changes to the OGE Form 278e and the OGE Form 450. OGE is now inviting all interested members of the public to share ideas, provide information, and express concerns about potential changes to the forms. This meeting will allow stakeholders and members of the public to both hear and respond to the concerns of other participants and for OGE to further develop its understanding of the views of various stakeholders. The goal of this meeting is for OGE to receive input regarding possible changes to the forms rather than come to a consensus about what changes to make.

Commenters may make any suggestions that they believe will improve the OGE Form 278e or the OGE Form 450. However, the public financial disclosure requirements are dictated by the Ethics in Government Act (EIGA), 5 U.S.C. 13101 *et seq.,* and 5 CFR part 2634 of the OGE regulations. OGE will be unable to consider any suggested change that would require a statutory or regulatory change as part of this form revision cycle. Additionally, when considering suggested changes, OGE will consider any potential cost burden, particularly if the change will require reprogramming of agency or Government-wide electronic filing systems. Generally, text changes within the instructions impose substantially fewer costs than changes to the look or order of the data entry grids. Commenters should consider and explain how the changes they are proposing provide concrete benefits, such as easier identification of potential conflicts of interest or ease of use of the forms.

To facilitate discussion at the public meeting, OGE welcomes input on issues related to suggested changes to the OGE Form 278e and the OGE Form 450 including, but not limited to, the following topics on which OGE has previously received comments:

Potential Areas for Comment on the OGE Form 278e

1. General Information Fields

The OGE Form 278e includes certain general information fields on the first page, such as the filer's name and position. These fields are not specifically authorized in the controlling statutory and regulatory authorities but are deemed permissible because they are necessary to provide an adequate understanding and processing of the form and do not impose any undue privacy or data entry burdens on filers.

(a) Filing Extensions, Late Fee Waivers and Payments

OGE received a suggestion for providing multiple spaces on the cover of the form in which the agency can document filing extensions, late filing fee waivers, and late filing fee payments. OGE is interested in views on whether such additions would be useful. Feedback that OGE has received indicates that adding such fields for agencies to complete can benefit the agencies themselves and does not contribute to the public burden from completing the forms.

2. Excepted Investment Fund (EIF) Field

OGE is considering changing the EIF field. The EIF field currently contains three choices: Yes (the item is an asset with underlying portfolio holdings but the item qualifies as an excepted investment fund); No (the item is an asset with underlying portfolio holdings and the asset does not qualify as an excepted investment fund); and N/A (the item is a source of non-investment income or the item is an asset without underlying portfolio assets). OGE is considering providing a two-step process that first inquires whether the asset has underlying holdings and second, if it does, whether it qualifies as an EIF. OGE is interested in ideas and views on how the EIF two-step process should appear on the form such that it will provide clarity to filers, agency reviewers, and the general public. Alternatively, OGE is considering changing to a simple Yes or No field. OGE is interested in whether this would reduce the accuracy of the reporting and reduce the information available to the public.

3. Definitions

OGE has received comments requesting clarification to the instructions and expansion of the list of terms to include, but are not limited to, honorarium, personal residence, relative, asset valuation, purchase, sale, exchange, and security. OGE is interested in views on specific text suggestions outside of those provided and as currently stated in the Public Financial Disclosure Guide. OGE seeks comments on whether the instructions to any part of the form should include additional definitions of key terms and

whether there are specific terms that need further definition.

4. Instructions

OGE has received comments requesting that OGE clarify the instructions and make them consistent with the statutory and regulatory reporting exclusions, and exceptions in the Public Financial Disclosure Guide (the ''guide''), specifically as it relates to the use of ''description'' in each part, permitted asset valuation, retention or disposition of employer-awarded equity, sharing in profits, and carried interests (*e.g.,* vested or unvested stock options, restricted stock, future sale of a company's profits). OGE is interested in views on specific text suggestions in the forms and seeks comments on whether the instructions to any part of the form should include additional reporting concepts and/or key terms. OGE is considering expanding the current instructions for each part of the report and providing helpful hyperlinks to the guide.

5. Examples

OGE is considering adding a list of examples to the OGE Form 278e applicable to each section, similar to the OGE Form 450 examples. OGE is interested in views on whether there are specific topic areas for which an example would be particularly useful.

Potential Areas for Comment on the OGE Form 450

1. Definitions and Examples

The last page of the OGE Form 450 includes examples for each Part. OGE seeks comments on whether any of these examples should be revised or removed, what new examples would be of value for the typical filer, and whether any new definitions should be added to the instructions.

2. Asset Ownership Identification

OGE has received comments requesting the addition of a column reflecting asset ownership. OGE is considering adding this column to the report and seeks comment on whether inclusion of this optional information in the form would provide any added benefit or clarity.

3. Asset Valuation Threshold Identification

OGE has received comments requesting the addition of a column reflecting asset valuation threshold identification. OGE is considering adding a question with a ''Yes'' or ''No'' response to whether an asset is above the relevant regulatory *de minimis* level to ease time spent by agency reviewers reaching back to filers. OGE seeks comments on whether inclusion of this optional information in the form would provide any added benefit or clarity.

4. Redesign of the Form

OGE has received comments and suggestions requesting that OGE include more and/or clarify certain definitions and examples that appear on the hard-copy PDF and Excel versions. OGE is considering re-designing the form by removing the instructions, examples, and definitions from the top of each Part, and instead creating new instructions, definitions, and examples pages at the beginning of the form, similar to how the current OGE Form 278e is structured. OGE is also considering providing hyper-links to a new user-friendly HTML version of the OGE Form 450 Reviewers Guide to make preparation and review of the form easier for the filers and agency reviewers.

(a) Addition of an EIF Column

OGE has received comments and requests to provide EIF information on the form, which would clarify whether an asset itself is an EIF or holds underlying assets that are EIFs. OGE seeks comments on whether inclusion of an optional EIF column/field would provide any added benefit or clarity.

Registration: Individuals wishing to attend the public meeting must register at *https://events.gcc.teams.microsoft.com/event/6e6ab2cf-348e-4d4d-bc92-316cb46fdbad@c0abca44-0182-40a9-8010-01ec94254f77?source=copyLinkLegacyShareLinkDialog.*

Meeting information will be provided at the time of registration.

Written Comments: You may submit comments in writing to OGE by use of the following methods:

Email: Forms@OGE.gov. Include ''OGE PRA Form 278e and OGE Form 450 Review'' in the subject line. *Mail:* Office of Government Ethics, 250 E Street SW, Suite 750, Washington, DC 20024–3249, Attention: ''OGE PRA Form 278e and OGE Form 450 Review.''

Instructions: Comments may be posted on OGE's website, *https://www.oge.gov*. Sensitive personal information, such as account numbers or Social Security numbers, should not be included. Comments generally will not be edited to remove any identifying or contact information.

Authority: Ethics in Government Act (EIGA), 5 U.S.C. 13122.

Approved: November 3, 2026.

Keith Sonderling,

Acting Director, U.S. Office of Government Ethics.

[FR Doc. 2026–22659 Filed 11–5–26; 8:45 am]

BILLING CODE 6345–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Assistance Listing Number: 93.576]

Announcement of the Intent To Award a Single-Source Cooperative Agreement to the Welcoming Initiative for Newcomers in San Diego, California

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

ACTION: Notice of issuance of a single-source cooperative agreement.

SUMMARY: The ACF, ORR announces the intent to award a single-source cooperative agreement in the amount of up to $3,500,000 to the Welcoming Initiative for Newcomers (WIN) in San Diego, California, for the next phase of the State Capacity and Readiness Initiative. Building on the nationwide baseline assessment and related readiness products completed under WIN's prior cooperative agreement, the proposed project will support an updated assessment of state capacity, support development of training and technical assistance resources, support for pilot implementation and learning, and engagement with states not participating in the pilots. The project will also identify service and capacity gaps and provide recommendations concerning additional grants, contracts, technical assistance, or other resources ORR may need to support a state-centered refugee resettlement model.

DATES: The proposed period of performance is November 1, 2026, through October 31, 2027.

FOR FURTHER INFORMATION CONTACT: Miro Marinovich, Office of Refugee Resettlement, Administration for Children and Families, 330 C Street SW, Washington, DC 20201. Telephone: (202) 729–3638; Email: *RBfrontoffice@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: ORR intends to undertake the next phase of the State Capacity and Readiness Initiative to support implementation of a state-centered refugee resettlement

model. Under a prior cooperative agreement, WIN conducted a nationwide baseline assessment of state readiness and capacity and developed related assessment and planning products. The proposed award will build on that foundational work by moving the initiative from baseline assessment to implementation support, pilot learning, and state and local capacity building.

Under the proposed cooperative agreement, WIN will conduct a nationwide assessment of local resettlement partners and identify the support they will need from states, ORR, training and technical assistance providers, and other entities to deliver services effectively. WIN will also update the assessment of state capacity and readiness to reflect current infrastructure, staffing, partnerships, service-delivery capabilities, and implementation needs.

WIN will collaborate with Switchboard, or another ORR-designated training and technical assistance provider, to inform the development and delivery of training, tools, templates, and other resources that strengthen state readiness and implementation capacity. WIN will support ORR's pilot activities by recommending approaches for information collection and pilot assessment, coordinating regular engagement with participating states and partners, documenting implementation experience, and synthesizing findings and lessons learned. WIN will develop a national data dashboard to support capacity planning.

For states not participating in the pilots, WIN will support ORR and ORR regional staff with meeting coordination, agenda development, briefing materials, and other state-engagement activities. WIN will also identify service gaps, capacity limitations, and unmet implementation needs and provide recommendations concerning additional federal assistance that may be needed to support broader implementation of the state-centered model.

Expected project products will include updated state and local capacity findings, analyses of service and support gaps, pilot-learning summaries, recommendations for training and technical assistance resources, state-engagement materials, and recommendations to inform future ORR program and funding decisions.

ORR will be substantially involved in the project by refining the work plan, identifying priority questions, coordinating engagement with pilot and non-pilot states, reviewing assessment tools and project products, and determining how findings will inform implementation and future federal assistance. This level of federal participation supports use of a cooperative agreement.

ORR proposes to issue the single-source cooperative agreement to WIN because WIN was the recipient of the prior cooperative agreement and developed the baseline assessment, readiness products, analytical approaches, and stakeholder relationships upon which the proposed work will directly build. Through that work, WIN acquired detailed knowledge of the initiative's methodology, findings, implementation context, and state and local capacity needs.

WIN's institutional knowledge and established relationships with state and local refugee-resettlement stakeholders will allow the next phase to begin without requiring ORR and its partners to reconstruct project history, reestablish working relationships, or repeat previously completed engagement and data-gathering activities. Selecting WIN will preserve continuity between the assessment and implementation phases, reduce duplicative start-up activities and information requests, and support timely use of Fiscal Year (FY) 2027 pilot findings in FY 2028 program and resource planning.

The proposed project will strengthen federal, state, and local coordination; provide practical implementation support to states and local resettlement partners; and help ORR target future grants, contracts, and technical assistance toward demonstrated service and capacity needs.

Statutory Authority: Under section 8 U.S.C. 1522(b)(1) of the Refugee Act, ORR is authorized to make grants to and contracts with public or private nonprofit agencies for the initial resettlement of refugees in the United States. This action further advances the intent of 8 U.S.C. 1522(a)(2) by creating mechanisms through which ORR can, to the maximum extent possible, incorporate state recommendations into refugee placement and capacity planning decisions.

Elizabeth A. Leo,

Grants Policy Branch Chief, Office of Grants Policy, Office of Administration.

[FR Doc. 2026–22676 Filed 11–5–26; 8:45 am]

BILLING CODE 4184–89–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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; PAR Panel: Innovation Grants to Nurture Initial Translational Efforts (IGNITE).

Date: December 2, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Baskaran Thyagarajan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 800B, Bethesda, MD 20892, (301) 594–0331, *thyagarajanb2@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: HeartShare 2.0.

Date: December 2, 2026.

Time: 9:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Vivian Tang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–6208, *tangvw@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Limited Competition U01 and U24 Applications for the Adolescent Brain Cognitive Development—Extended (ABCD–E) Study Renewal.

Date: December 2, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: DeAnna L. Adkins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–6022, *deanna.adkins@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Clinical Oncology and Radiation Therapies.

Date: December 2–3, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Amr M. Ghaleb, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 812, Bethesda, MD 20892, (301) 443–5851, *amr.ghaleb@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Therapeutic Development for Developmental, Psychiatric, and Substance Use Disorders.

Date: December 2, 2026.

Time: 9:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Sudhirkumar U. Yanpallewar, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892, (301) 594–7593, *yanpalls@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Cancer Research.

Date: December 2–3, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Michael M. Opata, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–3074, *michael.opata@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics on Gene Regulation and Signaling Pathways in Cancer.

Date: December 2–3, 2026.

Time: 9:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Leila Bahadori Toulabi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–8951, *leila.toulabi@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer Management and Treatment.

Date: December 2, 2026.

Time: 9:30 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Erica C. Spears, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–3211, *spearsec@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: BRAIN Initiative—Next Generation Sensor Technology and Neurotechnology Partnerships.

Date: December 2, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Joshua D. Powell, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–5370, *josh.powell@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–26–121 Maximizing Investigators' Research Award (R35).

Date: December 2–3, 2026.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: James J. Li, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7849, Bethesda, MD 20892, 301–806–8065, *lijames@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: November 3, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–22662 Filed 11–5–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs & Border Protection

Document Image System (DIS) Pilot for Used Self-Propelled Vehicles Export Document Submission: Renewal of Test

AGENCY: U.S. Customs and Border Protection, DHS.

ACTION: General notice.

SUMMARY: This notice announces that U.S. Customs and Border Protection (CBP) is renewing the Document Image System (DIS) Pilot for Used Self-Propelled

Vehicles (USPV) Export Document Submission (DIS USPV Test) for an additional two years. This voluntary pilot evaluates the feasibility of using the DIS to allow participants to submit the required vehicle ownership documentation for USPVs to CBP. This notice includes a description of the pilot, the eligibility requirements for participation, and invites public comment on any aspect of the pilot.

DATES: The voluntary pilot initially began on January 9, 2023. This renewal is effective November 6, 2026. The renewed test will run for an additional two years from the date of publication of this notice in the **Federal Register**.

ADDRESSES: Interested parties should contact their local CBP vehicle export processing office and express their interest and intent to participate in the DIS pilot. Written comments concerning the program, policy, and technical issues may be submitted at *UsedVehicleDISTEST@cbp.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Peter Russell, Outbound Enforcement and Policy (OEP), Cargo and Conveyance Security (CCS), Office of Field Operations (OFO), CBP, at *Peter.M.Russell@cbp.dhs.gov,* and David Garcia, CCS, OFO, CBP at *David.USCS.Garcia@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Current Requirements for Export of Used Self-Propelled Vehicles

The current regulations are set forth in part 192 of title 19 of the Code of Federal Regulations (19 CFR part 192). Among other things, part 192 includes regulations pertaining to procedures for the lawful exportation of Used Self-Propelled Vehicles (USPVs). Currently, 19 CFR 192.2 requires that in the case of a vehicle being exported by vessel or aircraft, both the required documentation describing the vehicle

and the vehicle must be presented to CBP at least 72 hours prior to export, and in the case of a vehicle being exported at a land border crossing (by rail, highway, or under its own power), the required documentation must be submitted at least 72 hours prior to export, and the vehicle must be presented at the time of export. The required documentation includes the vehicle identification number (VIN) or, if the vehicle does not have a VIN, the product information number (PIN). Section 192.2(b) specifies the types of documents that must be submitted in different circumstances. Exportation of a vehicle is permitted only upon compliance with these requirements unless, as per section 192.2(a), the vehicle was entered into the United States under an in-bond procedure, or under a carnet or Temporary Importation Bond (TIB). Such vehicles are exempt from these requirements. As a matter of policy, CBP also recognizes as exempt a vehicle entered under a personal exemption for non-residents who entered the vehicle for a one-year period. *See www.cbp.gov/trade/basic-import-export/export-docs/motor-vehicle#.*

B. Description and Purpose of Pilot

CBP announced the DIS USPV Test by a **Federal Register** notice published on May 10, 2022 (87 FR 28022) (the 2022 Test Notice) and began the test on January 9, 2023. The DIS USPV test is intended to evaluate the process and whether this process will expedite and modernize the document submission and review process for the export of USPVs. CBP is renewing this DIS USPV Test to continue its evaluation. All procedures and criteria announced in the 2022 Test Notice remain applicable to this renewal.

In this voluntary pilot, participants submit the required ownership documentation as set forth in 19 CFR part 192 through the DIS in CBP's Automated Commercial Environment (ACE), using either the Electronic Data Interchange (EDI) via an Automated Broker Interface (ABI), or via email at *docs@cbp.dhs.gov.* Participants are required to submit the documentation in accordance with existing regulatory timeframes which vary by type of vehicle,[1] and the timeframes for presenting the documents and vehicle vary by manner of export.[2] The DIS USPV Test changes only the *manner* in which the required documents are submitted to CBP. For pilot participants, CBP will waive the requirement in 19 CFR 192.2 to present original physical copies of the documents and require the documents to be submitted electronically using the DIS (EDI or email) instead. However, CBP will retain the right to request original documents on an as-needed basis. All other requirements of 19 CFR part 192, including the requirement to present the vehicle, will remain unchanged.[3]

Under the pilot, the electronically submitted documents are linked to the Electronic Export Information (EEI)[4] filing in the Automated Export System (AES) via the Internal Transaction Number (ITN) generated at the time of the EEI submission. Participants are required to transmit a valid ITN number to CBP with the DIS submission. Participants must submit EEI prior to submitting the vehicle documents to DIS. CBP will request original documentation and conduct a physical examination of the vehicle when necessitated by the results of targeting and risk assessment.

Participants will receive an automated response in the format in which the required documents were submitted, EDI or email, confirming that the document submission was received.[5] The participants will be able to use the automated response together with the AES-generated ITN to show that they complied with CBP's reporting requirements. The documentation submitted via the DIS will be used by CBP to review and process vehicles pending export to ensure compliance with U.S. laws and regulations. CBP reserves the right to request original (paper) documentation at any time. Consequently, pilot participants must continue to have access to the documentation in its original form for the entire time from submission to clearance by CBP, in the same manner as required by 19 CFR part 192.

Participation in the pilot does not alter participants' obligations to comply with any other applicable statutory or regulatory requirements. Participants will continue to be subject to applicable penalties for non-compliance with CBP or other U.S. Government agency program requirements or any statutory sanctions if a violation of U.S. export control laws occurs or prohibited articles are discovered with a vehicle presented for export from the United States.

C. Renewal of Pilot

As noted, CBP has been conducting this pilot since 2023. Renewing the pilot will allow CBP to continue to conduct targeting electronically, facilitate legitimate exportation of USPVs, and allow for greater participation in the pilot.

Continuing the pilot will allow CBP to test the mechanisms through which the required documentation may be submitted electronically, as a preliminary step towards moving to a more automated and efficient export reporting system for export of used self-propelled vehicles. Having the required documentation available electronically will enable CBP to institute better risk-based targeting of exports. This will be accomplished by making electronic document and information submission the primary means for meeting export reporting requirements and reserving field inspection of vehicles and examination of original ownership documentation only for cases where targeting and risk assessment have identified a need for additional scrutiny. The receipt of the electronic ownership documentation will also improve CBP's ability to target and identify high-risk vehicle exports pre-departure while facilitating the process for legitimate exportation through a more streamlined and efficient port procedure. Considering the high volume of vehicle exports, it is expected that the electronic submission of the required documentation will have a significant impact on the speed and efficiency of vehicle export processing.

From 2023–2025, there was an annual average of 1.3 million USPVs exported from the United States.[6] During that timeframe, approximately one third of all document submissions were

[1] For example, U.S.-titled vehicles, vehicles with title that evidences third-party ownership/claims, foreign-titled vehicles, etc. *See* 19 CFR 192.2(b).

[2] *See* 19 CFR 192.2(c).

[3] The pilot does not change the specific documents required for any particular type of vehicle, nor does it change the timeframes by which the documentation must be submitted. The pilot also does not change the requirement to present the vehicle to CBP, as set forth in 19 CFR.192.2(c) and (d). 19 CFR part 192 exempts certain categories of vehicles from the EEI filing requirement of the Census Foreign Trade Regulations (15 CFR part 30, subpart E). The EEI filing requirements remain unchanged under this pilot.

[4] The EEI is required pursuant to the Census Foreign Trade Regulations (FTR). 15 CFR part 30, subpart E. 19 CFR part 192 also sets forth CBP's requirements pertaining to the AES, implemented by FTR. The AES is the electronic system of record for collecting EEI from persons exporting goods from the United States to foreign countries. The EEI for all used self-propelled vehicles must be filed via AES regardless of value or country of destination 72 hours prior to export. 15 CFR 30.2(a)(1)(iv)(H), (b)(5).

[5] This is different from the current process whereby CBP ports of export stamp the original documentation provided by the exporter and the exporter then uses the stamped documentation as evidence that CBP cleared the vehicle prior to departure from the United States.

[6] Information provided by CBP Cargo and Conveyance Security Directorate, Office of Field Operations subject matter expert on May 26, 2026.

tendered via DIS as part of this DIS USPV Test.[7] Under the current regulatory export procedures, the person who is attempting to export a USPV must present to CBP both the vehicle and specified paper documents. This paper process is a drain on limited CBP staffing resources at ports with significant traffic because it requires CBP to devote numerous hours to review vehicle export paperwork. The pilot will allow CBP to assess the effectiveness of these electronic procedures and will allow the agency to test the functionality of the systems required for electronic submission. The results of the pilot will help CBP determine whether to eventually require, through rulemaking, the electronic submission of vehicle ownership documentation using the DIS.

The pilot will continue to run for approximately two years from the date of publication of this notice in the **Federal Register**.

D. Eligibility Requirements

Eligibility is limited to parties who are responsible for submitting the documentation required by 19 CFR 192.2 as part of the export transaction and who have access to the ITN for the AES commodity filing. In addition, participants must agree to submit the required documentation via the DIS, as described above.

E. Application Process and Acceptance

Parties interested in participating in this pilot should, as a preliminary matter, submit a request to receive export updates via the Cargo Systems Messaging Service (CSMS). Requests may be made at *https://www.cbp.gov/trade/automated/cargo-systems-messaging-service.* The CSMS is used to provide pilot participants with technical and operational updates and guidance throughout the pilot, and may be used to announce technical, non-substantive changes to the pilot.

Detailed instructions for participation in the pilot can be found in the DIS Instructional Guide for the Exportation of Used Self-Propelled Vehicles located on the CBP website, at *https://www.cbp.gov/trade/basic-import-export/export-docs/motor-vehicle.* There is no specific application for participation in the pilot. However, interested participants must communicate their interest and intent to the relevant port before taking any other action. The port will further direct potential pilot participants regarding next steps. Prospective participants will be asked to submit the first submission of ownership documents and contact their local CBP vehicle processing office to verify that their first transmission of ownership documents is successful, prior to being granted participation in the pilot. Once this review and verification are complete, participants will be permitted to participate fully in the pilot.

Participation in the pilot is open to all eligible parties that have been approved to participate, subject to the discretion of the Port Director at the port from which parties intend to export the USPVs.

F. Technical Specifications

Ownership documents must be submitted via the DIS, either using the EDI via an approved ABI or via email at *docs@cbp.dhs.gov* in a PDF format up to 10MB. Detailed instructions for participation in the pilot can be found in a document named DIS Instructional Guide for the Exportation of Used Self-Propelled Vehicles located on the CBP website, at *https://www.cbp.gov/trade/basic-import-export/export-docs/motor-vehicle.*

G. Evaluation of the Pilot

While the pilot is ongoing, CBP will evaluate the effectiveness of using the DIS and will determine if any extensions or modifications are needed. Technical modifications will be announced using the CSMS. Any substantive changes to the pilot, including extensions, will be announced in the **Federal Register**.

The results of the pilot will help CBP analyze and evaluate the effectiveness of using the DIS or some other method to collect export documentation for USPVs. When sufficient analysis and evaluation have been conducted, CBP will decide whether to require electronic submission of ownership documentation using the DIS or some other method. Any changes to the regulations will be made through rulemaking.

H. Confidentiality

All data submitted into ACE is subject to the Trade Secrets Act (18 U.S.C. 1905) and is considered confidential, except to the extent otherwise provided by law. However, participation in this or any ACE pilot is not confidential and upon a written Freedom of Information Act (FOIA) request, the name(s) of an approved participant(s) will be disclosed by CBP in accordance with 5 U.S.C. 552.

[7] Information provided by CBP Cargo and Conveyance Security Directorate, Office of Field Operations subject matter expert on May 26, 2026.

II. Applicability of Initial Test Notice

All provisions in the 2022 Test Notice remain applicable, subject to the extension of the time provided in this renewal.

III. Privacy

CBP will ensure that all Privacy Act requirements and applicable policies are adhered to during the implementation of this pilot.

IV. Paperwork Reduction Act

The Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3507(a)) requires that CBP consider the impact of paperwork and other information collection burdens imposed on the public. An agency may not conduct, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by the Office of Management and Budget (OMB). The collection of information regarding Exportation of Self-Propelled Vehicles was previously reviewed and approved by OMB in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) under OMB Control Number 1651–0054. No new information is collected under this pilot. Therefore, no new information collection or update to the existing information collection is required.

Diane J. Sabatino,

Executive Assistant Commissioner, Office of Field Operations, U.S. Customs and Border Protection.

[FR Doc. 2026–22728 Filed 11–5–26; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2026–0001]

Notice of Adjustment of Statewide Per Capita Impact Indicator

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: FEMA gives notice that the statewide per capita impact indicator under the Public Assistance program for disasters with an incident start date on or after October 1, 2026, will be increased.

DATES: This adjustment applies to major disasters with an incident start date on or after October 1, 2026.

FOR FURTHER INFORMATION CONTACT: Robert M. Pesapane, Recovery Directorate, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–3834.

SUPPLEMENTARY INFORMATION: FEMA regulations at 44 CFR 206.48 provides that FEMA will adjust the statewide per capita impact indicator under the Public Assistance program to reflect changes in the Consumer Price Index for All Urban Consumers published by the Department of Labor.

FEMA gives notice that the statewide per capita impact indicator will be increased to $2.01 for all disasters with an incident start date on or after October 1, 2026.

FEMA bases the adjustment on an increase in the Consumer Price Index for All Urban Consumers of 3.4 percent for the 12-month period that ended in August 2026. The Bureau of Labor Statistics of the U.S. Department of Labor released the information on September 11, 2026.

(Catalog of Federal Domestic Assistance No. 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters).

Cameron Hamilton,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2026–22694 Filed 11–5–26; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2026–0001]

Notice of Adjustment of Minimum Project Worksheet Amount

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: FEMA gives notice that the minimum Project Worksheet Amount under the Public Assistance program for disasters and emergencies declared on or after October 1, 2026, will be increased.

DATES: This adjustment applies to major disasters and emergencies declared on or after October 1, 2026.

FOR FURTHER INFORMATION CONTACT: Robert M. Pesapane, Recovery Directorate, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–3834.

SUPPLEMENTARY INFORMATION: FEMA regulations at 44 CFR 206.202(d)(2) provides that FEMA will annually adjust the minimum Project Worksheet amount under the Public Assistance program to reflect changes in the Consumer Price Index for All Urban Consumers published by the Department of Labor.

FEMA gives notice of an increase to $4,300 for the minimum amount that will be approved for any Project Worksheet under the Public Assistance program for all major disasters and emergencies declared on or after October 1, 2026.

FEMA bases the adjustment on an increase in the Consumer Price Index for All Urban Consumers of 3.4 percent for the 12-month period that ended in August 2026. This is based on information released by the Bureau of Labor Statistics at the U.S. Department of Labor on September 11, 2026.

(Catalog of Federal Domestic Assistance No. 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters).

Cameron Hamilton,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2026–22697 Filed 11–5–26; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2026–0001]

Notice of Award Amount Adjustment for Serious Needs Assistance

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: FEMA gives notice of the award amount for Serious Needs Assistance provided under the Individuals and Households Program for emergencies and major disasters declared on or after October 1, 2026.

DATES: This adjustment applies to emergencies and major disasters declared on or after October 1, 2026.

FOR FURTHER INFORMATION CONTACT: Zachary Usher, Recovery Directorate, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 212–1000.

SUPPLEMENTARY INFORMATION: FEMA regulations at 44 CFR 206.119(b)(1) prescribe that FEMA will annually adjust the award amount for Serious Needs Assistance (SNA) provided under the Individuals and Households Program. FEMA gives notice that the award amount for SNA provided to an individual or household under section 408 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act with respect to any single emergency or major disaster is $820. The increase in award amount is for any single emergency or major disaster declared on or after October 1, 2026.

FEMA bases the adjustment on an increase in the Consumer Price Index for all Urban Consumers of 3.4 percent for the 12-month period, which ended in August 2026. The Bureau of Labor Statistics of the U.S. Department of Labor released the information on September 11, 2026.

(Catalog of Federal Domestic Assistance No. 97.048, Federal Disaster Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance — Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs)

Cameron Hamilton,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2026–22692 Filed 11–5–26; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2026–0001]

Notice of Adjustment of Countywide Per Capita Impact Indicator

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: FEMA gives notice that the countywide per capita impact indicator under the Public Assistance program for disasters with an incident start date on or after October 1, 2026, will be increased.

DATES: This adjustment applies to major disasters with an incident start date on or after October 1, 2026.

FOR FURTHER INFORMATION CONTACT: Robert M. Pesapane, Recovery Directorate, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–3834.

SUPPLEMENTARY INFORMATION: In assessing damages for area designations under 44 CFR 206.40(b), FEMA uses a countywide per capita indicator to evaluate the impact of the disaster at the county level. FEMA will adjust the countywide per capita impact indicator under the Public Assistance program to reflect annual changes in the Consumer

Price Index for All Urban Consumers published by the Department of Labor.

FEMA gives notice of an increase in the countywide per capita impact indicator to $5.03 for all disasters with an incident start date on or after October 1, 2026.

FEMA bases the adjustment on an increase in the Consumer Price Index for All Urban Consumers of 3.4 percent for the 12-month period that ended in August 2026. The Bureau of Labor Statistics of the U.S. Department of Labor released the information on September 11, 2026.

(Catalog of Federal Domestic Assistance No. 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters).

Cameron Hamilton,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2026–22691 Filed 11–5–26; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2026–0001]

Notice of Maximum Amount of Assistance Under the Individuals and Households Program

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: FEMA gives notice of the maximum amount for assistance under the Individuals and Households Program for emergencies and major disasters declared on or after October 1, 2026.

DATES: This adjustment applies to emergencies and major disasters declared on or after October 1, 2026.

FOR FURTHER INFORMATION CONTACT: Zachary Usher, Recovery Directorate, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 212–1000.

SUPPLEMENTARY INFORMATION: Section 408 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act), 42 U.S.C. 5174, prescribes that FEMA must annually adjust the maximum amount for assistance provided under the Individuals and Households Program (IHP). FEMA gives notice that the maximum amount of IHP financial assistance provided to an individual or household under section 408 of the Stafford Act with respect to any single emergency or major disaster is $46,400 for housing assistance and $46,400 for other needs assistance. The increase in award amount is for any single emergency or major disaster declared on or after October 1, 2026. In addition, in accordance with 44 CFR 61.17(c), this increases the maximum amount of available coverage under any Group Flood Insurance Policy (GFIP) issued.

FEMA bases the adjustment on an increase in the Consumer Price Index for All Urban Consumers of 3.4 percent for the 12-month period, which ended in August 2026. The Bureau of Labor Statistics of the U.S. Department of Labor released the information on September 11, 2026.

(Catalog of Federal Domestic Assistance No. 97.048, Federal Disaster Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs).

Cameron Hamilton,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2026–22693 Filed 11–5–26; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2026–0001]

Notice of Adjustment of Disaster Grant Amounts

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: FEMA gives notice of an adjustment to the threshold for Small Project subgrants made to state, tribal, and local governments and private nonprofit facilities for disasters declared on or after October 1, 2026.

DATES: This adjustment applies to major disasters and emergencies declared on or after October 1, 2026.

FOR FURTHER INFORMATION CONTACT: Robert M. Pesapane, Recovery Directorate, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–3834.

SUPPLEMENTARY INFORMATION: The Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207, as amended by the Sandy Recovery Improvement Act, Public Law 113–2, provides that FEMA will annually adjust the threshold for assistance provided under section 422, Simplified Procedures, relating to the Public Assistance program, to reflect changes in the Consumer Price Index for All Urban Consumers published by the Department of Labor.

FEMA gives notice that $1,130,900 is the threshold for any Small Project subgrant made to state, tribal, and local governments or to the owner or operator of an eligible private nonprofit facility under section 422 of the Stafford Act for all major disasters or emergencies declared on or after October 1, 2026.

FEMA bases the adjustment on an increase in the Consumer Price Index for All Urban Consumers of 3.4 percent for the 12-month period that ended in August 2026. This is based on information released by the Bureau of Labor Statistics at the U.S. Department of Labor on September 11, 2026.

(Catalog of Federal Domestic Assistance No. 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters)

Cameron Hamilton,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2026–22696 Filed 11–5–26; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA–2026–0166]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; The Department of Homeland Security, Emergency Communications Division, Communications Assets Survey and Mapping (CASM) Tool Registration Tool

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: 30-Day notice of information collection; request for comment; OMB Control Number: 1670–0043.

SUMMARY: The Emergency Communications Division (ECD) within the Cybersecurity and Infrastructure Security Agency (CISA) submits the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance. CISA previously published this information collection request (ICR) in the **Federal Register** on 08/19/2026 for a 60-day public comment period. The control number for this collection is 1670–0043. No comments were received by CISA. The purpose of this notice is

to allow additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until December 7, 2026. Submissions received after the deadline for receiving comments may not be considered.

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.

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

FOR FURTHER INFORMATION CONTACT: If additional information is required contact: Anais Azoulay, 202–704–5829, *anais.azoulay@cisa.dhs.gov*.

SUPPLEMENTARY INFORMATION: The Department of Homeland Security (DHS) Cybersecurity and Infrastructure Security Agency (CISA) Emergency Communications Division (ECD), formed under Title XVIII of the Homeland Security Act of 2002, 6 U.S.C. 571 *et seq.,* as amended, is required, pursuant to 6 U.S.C. 571(c)(5) to conduct extensive, nationwide outreach and foster the development of interoperable emergency communications capabilities by state, regional, local, and tribal governments and public safety agencies, and by regional consortia thereof. To achieve this, ECD provides the communications assets and survey mapping (CASM) tool. The CASM tool is the primary resource nationwide for the emergency communications community to inventory and share asset and training information for the purpose of planning public safety communications operability and interoperability.

ECD provides the communications assets survey and mapping (CASM) tool as a secure and free nationwide database to contain communications capabilities for use by federal, state, local, territorial, and tribal (SLTT) emergency personnel. CASM allows federal employees and SLTT statewide interoperability coordinators (SWIC) to inventory emergency communication equipment and resources. The information entered is voluntary and used by SWIC to support tactical planning and coordination during emergencies. ECD does not utilize the information entered into CASM. ECD only provides, maintains, and stores the information entered in the CASM database and only has administrative access to the information entered.

CASM Registration

To get access to the CASM tool, users click on the ''request new access'' link on the CASM login page (*https://login.CASM.cisa.dhs.gov/*). The registration requires that users enter their name, contact information, reason for their access request, type of data to access, and access level. Once entered, the access request is routed to their organization's approving authority. Once the organization's approving authority vets and authorizes the access request, the user account is automatically created, and users are notified via an auto-generated email.

CASM Modules

The CASM consists of voluntary modules related to the different types of capabilities. There is a module for assets, which contains information about emergency equipment, the equipment capabilities and location. There is a personnel module, which contains personnel name, contact information and information about their communications unit (COMU) training. The personnel module allows SWICs to track their personnel's COMU training.

All information is collected via electronic means. The CASM registration and database tool is available online via *https://login.CASM.cisa.dhs.gov/*. Users can also access and enter information via the CASM resource finder mobile app.

This information collection does not impact small businesses or other small entities.

This database allows ECD to execute its statutory authority under 6 U.S.C. 571 to conduct extensive, nationwide outreach to support and promote the ability of emergency response providers and relevant government officials to continue to communicate in the event of natural disasters, acts of terrorism, and other man-made disasters. Without CASM and the federal government's ability to empower the states, ECD would not have an organic way for states to create a centralized and secure emergency assets and equipment database. Information is protected by the Privacy Act of 1974 and is kept private or anonymous to the extent allowable by law.

The DHS Privacy Office review finds that this is a privacy sensitive collection requiring a privacy impact assessment (PIA) and system of records notice (SORN). The collection is covered by PIA—DHS/ALL/PIA–006 DHS general contacts list and SORN—DHS/ALL–002 DHS mailing and other lists system, 73 FR 71659 (NOV 25, 2008) and SORN—DHS/ALL–004 general information technology access account records system (GITAARS), 77 FR 70792 (NOV. 27, 2012).

This is an extension of a currently approved collection without change.

Analysis

Agency: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

Title: Communications Assets Survey and Mapping (CASM) Tool Registration Form.

OMB Number: 1670–0043.

Frequency: Annually.

Affected Public: Emergency Communication Personnel.

Number of Respondents: 56 Annually.

Estimated Time per Respondent: 0.08 hours (5 minutes) per Registration, 0.5 Hours (30 Minutes) per Module.

Total Burden Hours: 341 Hours Annually.

Total Annual Burden Cost: $19,981.

Total Annual Government Burden Cost: $3,000,000.

Winfield P. Werntz,

Acting Chief Information Officer, Department of Homeland Security, Cybersecurity and Infrastructure Security Agency.

[FR Doc. 2026–22707 Filed 11–5–26; 8:45 am]

BILLING CODE 9111–LF–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA–2026–0265]

Agency Information Collection Activities: Incident Communications Activity Report

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA),

Department of Homeland Security (DHS).

ACTION: 60-Day notice and request for comments; extension of a previously approved collection.

SUMMARY: The Emergency Communications Division (ECD) within Cybersecurity and Infrastructure Security Agency (CISA) submits the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance.

DATES: Comments are encouraged and will be accepted until January 5, 2027. Submissions received after the deadline for receiving comments may not be considered.

ADDRESSES: You may submit comments, identified by docket number Docket # CISA–2026–0265, by following the instructions below for submitting comment via the Federal eRulemaking Portal at *http://www.regulations.gov.*

Instructions: All comments received must include the agency name and docket number Docket #CISA–2026–0265. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Kylie-Anne Noreiga at 202–329–5161 or at *kylie-anne.noreiga@cisa.dhs.gov*.

SUPPLEMENTARY INFORMATION: The Cybersecurity and Infrastructure Security Agency (CISA) Emergency Communications Division (ECD) is mandated by The Cybersecurity and Infrastructure Security Act of 2018, 6 U.S.C. 652(f) under Sections (9) carry out emergency communications responsibilities, in accordance with subchapter XIII; (10) carry out cybersecurity, infrastructure security, and emergency communications stakeholder outreach and engagement and coordinate that outreach and engagement with critical infrastructure Sector Risk Management Agencies, as appropriate; and (11) provide education, training, and capacity development to Federal and non-Federal entities to enhance the security and resiliency of domestic and global cybersecurity and infrastructure security.

This information collection is requested to be completed by ECD stakeholders, including state and local emergency communications professionals—through The Incident Communications Activity Report (ICAR) form. The ICAR was developed with the intention of capturing and documenting the emergency communications activity and utilization of public safety communications technologies controlled by state or local emergency response officials organized to provide command and coordination for an incident, planned event, or exercise. As a result, CISA/ECD seeks to renew a standard request from the Paper Reduction Act (PRA) to review, analyze, and revise current Incident Communication Activity.

The Emergency Communications Division (ECD) is a division within the Cybersecurity and Infrastructure Security Agency (CISA) which serves under the direction of the Department of Homeland Security (DHS). ECD coordinates with National Security and Emergency Preparedness (NS/EP) communications stakeholders to enable use of technical assistance and information sharing to reduce communications system impacts or vulnerabilities. CISA has authority to perform assessments and evaluations for federal and non-federal entities, with consent and upon request. CISA responds to 6 U.S.C. 571(c) to enhance interoperable communications capabilities, training, planning, and implementation across federal, state, local, tribal, and territorial (FSLTT) entities and critical infrastructure key resources. The information collected will provide on-the-ground data on emergency communications activity and utilization of public safety communications technologies controlled by state or local emergency response officials organized to provide command and coordination for an incident, planned event, or exercise. The information captured focuses on several key areas: incident complexity, command and coordination systems, and all-hazards information and communications technology positions, resources (*e.g.,* voice and data systems, interoperability techniques, and planning references), challenges and general conditions encountered during the incident.

ICAR will be submitted electronically by the emergency responder with overall information and communications technology responsibilities within the identified command and coordination organization, for a reporting period.

This information will inform other jurisdictions on best practices while permitting data-driven decisions on future policy improvements. CISA, in support of the National Council of Statewide Interoperability Coordinators (NCSWIC) and the CISA interoperable-communications program known as SAFECOM, will collect data through a two-page report to capture the emergency communications activity and utilization of public safety communications technologies controlled by state or local emergency response officials organized to provide command and coordination for an incident, planned event, or exercise. CISA's goal is to identify lessons learned to drive strategy and improve existing or offer new technical assistance within the scope of emergency communications activity for Incidents, Planned Events, or Exercises. The ICAR is completed by the person with overall information and communications technology responsibilities with the identified command and coordination organization, for the indicated reporting period. The reporting period is flexible to meet agency or jurisdictional program needs. The report is designed to accommodate a single report for the incident or event duration, or multiple reports for smaller time periods within the same incident or event. State, local, territorial, or tribal incident communications, organizational and technical challenges and best practices will be captured. Collecting and summarizing this data will drive our nationwide response, drive strategy, and goal development subsequently improving existing and/or offer new Technical Assistance options to stakeholders.

The ICAR is an electronically submitted form to populate the data sets which will be loaded, stored, and analyzed in the division's data analytics system. Electronic data collection enables an efficient and straightforward submission process to submit, reducing the time and effort for the submitter while also reducing errors.

ICAR form is voluntarily submitted using a Microsoft Teams Form link. The ICAR form will require a total effort of approximately five minutes for completion. The ICAR form will be completed per incident. Leveraging the MS Forms and a fillable PDF there will be no printing of forms needed, no preparing and sending emails or memos per incident. Participants will be able to input free form information in addition to drop down type questions.

The current existing collection approved by OMB is set to expire on December 31, 2026.

There are no changes to the burden or information being collected.

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary

for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Analysis

Agency: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

Title: Incident Communications Activity Report (ICAR).

OMB Number: 1670–0050.

Frequency: Annually.

Affected Public: State, Local, Territorial and Tribal; Public Safety Communications Personnel.

Number of Respondents: 450.

Estimated Time per Respondent: 0.083 hours (5 minutes).

Total Burden Hours: 37.5 hours.

Total Annual Burden Cost: $2,474.61.

Total Annual Government Burden Cost: $27,887.79.

Winfield P. Werntz,

Acting Chief Information Officer, Department of Homeland Security, Cybersecurity and Infrastructure Security Agency.

[FR Doc. 2026–22705 Filed 11–5–26; 8:45 am]

BILLING CODE 9111–LF–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–44163; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before October 24, 2026, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted by November 23, 2026.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State>.'' If you have no access to email, you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 2013, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 2013, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before October 24, 2026. Pursuant to 36 CFR 60.13, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State or Tribal Historic Preservation Officers.

Key: State, County, Property Name, Multiple Name(if applicable), Address/Boundary, City, Vicinity, Reference Number.

CONNECTICUT

Windham County

Old Plainfield Cemetery, Cemetery Road (Map 8, Block 0048, Lot 012A), Plainfield, SG100013674

IDAHO

Clearwater County

Evergreen Grange Hall, (The Grange in Idaho MPS), 3149 Middle Road, Lenore vicinity, MP100013662

Latah County

Bovill Historic Commercial District, 100–207 Main Street, Bovill, SG100013663

MICHIGAN

Jackson County

Grass Lake Commercial Historic District. Generally includes Michigan Avenue from Maple Street on the east to Clark Street on the west. Grass Lake, SG100013676

Mecosta County

Mecosta County Jail, 220 South Stewart Avenue, Big Rapids, SG100013677

MONTANA

Wheatland County

Judith Gap Jail, 125 ft. south of the SW corner of 4th Ave. and Meagher St. on Meagher St., Judith Gap, SG100013671

NEW YORK

Erie County

Shoreline Apartment Complex, Carolina St., Seventh St., and Busti Ave., Buffalo, SG100013668

New York County

Headquarters of the National Society of Colonial Dames in the State of NY, 215 East 71st Street, New York, SG100013669

Ulster County

First Presbyterian Church of Marlborough, 51–55 Grand Street, Marlborough, SG100013670

OHIO

Franklin County

Union Grove Baptist Church, (Twentieth-Century African American Civil Rights Movement in Ohio MPS), 266 North Champion Avenue, Columbus, MP100013661

OKLAHOMA

Kiowa County

Mountain Park Jail, (Calabooses (Early Jails) in Oklahoma MPS), Between Main St. Parker Ave. Broadway Ave. and Spruce St., Mountain Park, MP100013667

PENNSYLVANIA

Westmoreland County

Miller-Markle Farm, (Agricultural Resources of Pennsylvania c1700–1960 MPS), 600 Mt. Pleasant Rd., South Huntingdon Township, MP100013659

TEXAS

Travis County

Evergreen Cemetery, 3304 E 12th Street, Austin, SG100013660

UTAH

Salt Lake County

Gilgal Sculpture Garden, 749 East 500 South, Salt Lake City, SG100013664

VERMONT

Orange County

West Fairlee Village Historic District. District centered on the intersection of Vermont Route 113, Beanville Road, and Mill Street, also including portions of Back Street. West Fairlee, SG100013675

WASHINGTON

Skagit County

Skagit Salmon Hatchery Building, (Historic Washington State Fish Hatcheries (1889–1974) MPS), 8319 Fish Hatchery Road, Marblemount, MP100013665

Walla Walla County

Walla Walla County Courthouse, 315 W Main Street, Walla Walla, SG100013666

Additional documentation has been received for the following resource(s):

PENNSYLVANIA

Delaware County

Chester Courthouse (Additional Documentation), 412 Avenue of the States, Chester, AD71000702

Authority: 36 CFR 60.13

James Gabbert,

Program Manager, Acting Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2026–22670 Filed 11–5–26; 8:45 am]

BILLING CODE 4312–52–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2027–008]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: We are proposing renewal from the Office of Management and Budget (OMB) of an approved information collection, Facility Access Media (FAM) Request, NA Form 6006, used by all individuals requesting recurring access to non-public areas of NARA's facilities and IT network. We invite you to comment on the proposed information collections.

DATES: OMB must receive written comments on or before December 7, 2026.

ADDRESSES: Send any comments and recommendations on the proposed information collection in writing to *www.reginfo.gov/public/do/PRAMain.* You can 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: Kristin Phillips, Paperwork Reduction Act Officer, by email at *kristin.phillips@nara.gov* or by telephone at 616–254–0405 with requests for additional information or copies of the proposed information collection and supporting statement.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), we invite the public and other Federal agencies to comment on proposed information collections. We published a notice of proposed collection for these information collections on August 12, 2026 (91 FR 52085) and we received no comments. In the 60-day notice the respondents and burden hours were represented for three years. We've corrected those figures in this notice with the actual annual respondents and burden hours. We are therefore submitting the described information collections to OMB for approval.

If you have comments or suggestions, they should address one or more of the following points: (a) whether the proposed information collections are necessary for NARA to properly perform its functions; (b) our estimate of the burden of the proposed information collections and its accuracy; (c) ways we could enhance the quality, utility, and clarity of the information we collect; (d) ways we could minimize the burden on respondents of collecting the information, including through information technology; and (e) whether these collections affect small businesses.

In this notice, we solicit comments concerning the following information collection:

Title: Facility Access Media (FAM) Request.

OMB number: 3095–0057.

Agency form number: NA Form 6006.

Type of review: Regular.

Affected public: Individuals or households.

Estimated number of respondents: 1,500.

Estimated time per response: 3 minutes.

Frequency of response: On occasion.

Estimated total annual burden hours: 75 hours.

Abstract: The Facility Access Media (FAM) Request, NA Form 6006, is completed by all individuals requiring recurring access to non-public areas of NARA's facilities and IT network (such as NARA employees, contractors, volunteers, NARA-related foundation employees, volunteers, interns, and other non-NARA federal employees, such as federal agency reviewers) herein referred to as ''applicants,'' in order to obtain NARA Facility Access Media (FAM). After approval of the request, the applicant is given a FAM, if approved, and is then able to access non-public areas of NARA facilities and IT network. The collection of information is necessary to comply with Homeland Security Presidential Directive (HSPD) 12 requirements for secure and reliable forms of personal identification issued by federal agencies to their employees, contractors, and other individuals requiring recurring access to non-public areas of government facilities and information services. This form was developed to comply with this requirement.

Gulam Shakir,

Executive for Information Services/CIO.

[FR Doc. 2026–22672 Filed 11–5–26; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

Proposal Review; Notice of Meetings

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces its intent to hold proposal review meetings throughout the year. The purpose of these meetings is to provide advice and recommendations concerning proposals submitted to the NSF for financial support. The agenda for each of these meetings is to review and evaluate proposals as part of the selection process for awards. The review and evaluation may also include an assessment of the progress of awarded proposals. These meetings will primarily take place at NSF's headquarters, 401 Dulany Street, Alexandria, VA 22314.

These meetings will be closed to the public. The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act. NSF will continue to review the agenda and merits of each meeting for overall compliance of the Federal Advisory Committee Act.

These closed proposal review meetings will not be announced on an individual basis in the **Federal Register**. NSF intends to publish a notice similar to this on a quarterly basis. For an advance listing of the closed proposal review meetings that include the names of the proposal review panel and the time, date, place, and any information on changes, corrections, or cancellations, please visit the NSF website: *https://nsf.gov/events/proposal-review-panels.* This

information may also be requested by telephone, 703/292–8687.

Dated: November 4, 2026.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2026–22690 Filed 11–5–26; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–368; NRC–2026–5215]

Entergy Operations Inc.; Arkansas Nuclear One, Unit 2; License Amendment Application

AGENCY: Nuclear Regulatory Commission.

ACTION: Opportunity to comment, request a hearing, and petition for leave to intervene.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC, the Commission) is considering issuance of an amendment to Renewed Facility Operating License No. NPF–6, issued to Entergy Operations, Inc. (Entergy, the licensee), for operation of Arkansas Nuclear One, Unit 2 (ANO–2). The proposed amendment would revise the technical specifications (TSs) for ANO–2, by modifying the note associated with Surveillance Requirement (SR) 4.1.3.1.2 to permit Control Element Assembly (CEA) 29 to be excluded from exercising for the remainder of Cycle 32. This change would allow CEA 29 to remain out of the exercising surveillance until the planned refueling outage 2R32, currently scheduled for September 2027.

DATES: Submit comments by November 20, 2026. Request for a hearing or petitions for leave to intervene must be filed by January 5, 2027.

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–2026–5215. Address questions about Docket IDs in *Regulations.gov* to Bridget Curran; telephone: 301–415–1003; email: *Bridget.Curran@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Nuclear Material Safety and Safeguards, Mail Stop: TWFN–5–A85, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Guidance and Publications Branch.

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: M. Elena Herrera, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–8208; email: *Maria.Herrera@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2026–5215 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–2026–5215.
- *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 ADAMS Public Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The license amendment request to exclude exercising CEA 29 from SR 4.1.3.1.2 is available in ADAMS under Accession No. ML26260A338, and a supplement to the license amendment request is available in ADAMS under Accession No. ML26281A182.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2026–5215 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Introduction

The NRC is considering issuance of an amendment to Renewed Facility Operating License No. NPF–6, issued to Entergy, for operation of ANO–2, located in Pope County, Arkansas.

The proposed amendment would revise the technical specifications for ANO–2 by modifying the note associated with SR 4.1.3.1.2 to permit CEA 29 to be excluded from exercising for the remainder of Cycle 32. This change would allow CEA 29 to remain out of the exercising surveillance until the planned refueling outage 2R32, currently scheduled for September 2027.

Pursuant to the requirements of sections 50.91 and 50.92 of title 10 of the *Code of Federal Regulations* (10 CFR), the licensee requested approval of the amendment under exigent circumstances. In its application, the licensee explained that it submitted this application under exigent circumstances due to the need for NRC review and, if pertinent requirements are met, approval of the amendment before the next required surveillance date, scheduled for December 16, 2026, to avoid a required plant shutdown and to prevent an unnecessary transient or reactivity excursion while deferring CEA 29 repair until the planned refueling outage 2R32.

Before any issuance of the proposed license amendment, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended (the Act), and NRC's regulations.

Pursuant to 10 CFR 50.91(a)(6), for amendments to be granted under exigent circumstances, the NRC has made a proposed determination that the license amendment request involves no significant hazards consideration (NSHC). Under the NRC's regulations in 10 CFR 50.92, this means that operation

of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of NSHC, which is presented below:

(1) Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

One function of the CEAs is to provide a means of rapid negative reactivity addition into the core. This occurs upon receipt of a signal from the Reactor Protection System (RPS). This function will continue to be accomplished with the approval of the proposed change. Typically, once per 184 days, each CEA is moved at least five inches to ensure the CEA is free to move. CEA 29 remains trippable (free to move) as illustrated by startup during spring of 2026 and during power restoration following installation of the temporary modification in June 2026. However, due to failure of the pull-down coil, future exercising of the CEA could result in the CEA inadvertently inserting into the core during CEA movement. Undesired operation of a CEA, which includes a CEA drop event, is an abnormal occurrence and has been previously evaluated as part of the ANO–2 accident analysis. Inadvertent CEA insertion will result in a reactivity transient and power reduction and could lead to a reactor shutdown if the CEA is deemed to be unrecoverable. The proposed change would minimize the potential for inadvertent insertion of CEA 29 into the core by maintaining the CEA in place. The proposed change will not affect the CEAs ability to insert fully into the core upon receipt of a reactor trip signal.

No additional modifications are proposed to the RPS or associated Control Element Drive Mechanism Control System (CEDMCS) logic regarding the ability of CEA 29 to remain available for immediate insertion due to a trip signal. The accident mitigation features of the plant are not affected by the proposed amendment. Because CEA 29 remains trippable, no additional reactivity considerations need to be taken into consideration. Nevertheless, Entergy has evaluated the reactivity consequences associated with failure of CEA 29 to insert upon a reactor trip in accordance with TS requirements for Shutdown Margin (SDM) and has determined that SDM requirements would be met should such an event occur at any time during the remainder of Cycle 32 operation.

Therefore, this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

CEA 29 remains trippable. The proposed change will not introduce any new design changes or systems that can prevent the CEA from performing its specified safety function. As discussed previously, CEA mis-operation has been previously evaluated in the ANO–2 accident analysis. Furthermore, SDM has been shown to remain within limits should an event occur at any time during the remainder of operating Cycle 32 such that CEA 29 fails to insert into the core upon receipt of a reactor trip signal. Therefore, this change does not create the possibility of a new or different kind of accident from an accident previously evaluated.

(3) Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

SR 4.1.3.1.2 is intended to verify CEAs are free to move (*i.e.,* not mechanically bound). The physical and electrical design of the CEAs, and past operating experience provides high confidence that CEAs remain trippable whether or not exercised during each SR interval. Excluding further exercising of CEA 29 for the remainder of Cycle 32 operation does not directly relate to the potential for CEA binding to occur. No mechanical binding has been previously experienced at ANO–2. In addition, Entergy has concluded that required SDM will be maintained should CEA 29 fail to insert following a reactor trip at any point during the remainder of Cycle 32 operation.

Therefore, this change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the license amendment request involves a NSHC.

In accordance with 10 CFR 50.91(a)(6), where the Commission finds that exigent circumstances exist, in that a licensee and the Commission must act quickly and that time does not permit the Commission to publish a **Federal Register** notice allowing 30 days for prior public comment, and it also determines that the amendment involves NSHCs, it can issue a **Federal Register** notice providing notice of an opportunity for hearing and allowing at least two weeks from the date of the notice for prior public comment. Therefore, in accordance with 10 CFR 50.91(a)(6)(i)(A), the NRC staff is providing a 14-day notice period for public comment.

The NRC is seeking public comments on this proposed determination that the license amendment request involves NSHC. Any comments received within 14 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 14-day notice period. However, if circumstances change during the notice period, such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the notice period, provided that its final determination is that the amendment involves NSHC. The final determination will consider all public and State comments received. The Commission expects that the need to take this action will occur very infrequently.

III. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult 10 CFR 2.309. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

Petitions must be filed no later than 60 days from the date of publication of this notice in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii).

If a hearing is requested, and the Commission has not made a final

determination on the issue of NSHC, the Commission will make a final determination on the issue of NSHC, which will serve to establish when the hearing is held. If the final determination is that the license amendment request involves NSHC, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the license amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h) no later than 60 days from the date of publication of this notice. Alternatively, a State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof, may participate as a non-party under 10 CFR 2.315(c).

For information about filing a petition and about participation by a person not a party under 10 CFR 2.315, see ADAMS Accession No. ML20340A053 (*https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML20340A053*) and the NRC's public website (*https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing.html#participate*).

IV. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including documents filed by an interested State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on electronic submissions is located in the ''Guidance for Electronic Submissions to the NRC'' (ADAMS Accession No. ML13031A056), and on the NRC's public website (*https://www.nrc.gov/site-help/e-submittals.html*).

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *Hearing.Docket@nrc.gov,* or by telephone at 301–415–1677, to: (1) request a digital identification (ID) certificate, which allows the participant (or their counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or their counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website (*https://www.nrc.gov/site-help/e-submittals/getting-started.html*). After a digital ID certificate is obtained and a docket is created, the participant must submit adjudicatory documents in the Portable Document Format. Guidance on submissions is available on the NRC's public website (*https://www.nrc.gov/site-help/electronic-sub-ref-mat.html*). A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. ET on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed in order to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website (*https://www.nrc.gov/site-help/e-submittals.html*), by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., ET, Monday through Friday, except Federal holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)–(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available on the NRC's public website (*https://ehd.nrc.gov*), unless otherwise excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as previously described, click ''cancel'' when the link requests certificates and you will be automatically directed to the NRC's electronic hearing docket where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

For further details with respect to this action, see the application for license amendment dated September 17, 2026, as supplemented by letter dated October 8, 2026 (ADAMS Accession Nos. ML26260A338 and ML26281A182, respectively).

Attorney for licensee: Susan Raimo, Associate General Counsel, Nuclear, 101 Constitution Avenue NW, Washington, DC 20001.

NRC Branch Chief: Hipólito González.

Authority: 42 U.S.C. 2011 *et seq.*

Dated: November 4, 2026.

For the Nuclear Regulatory Commission.

Maria Herrera Torres,

Project Manager, Operating Reactor Licensing Branch 4, Division of Licensing 1, Office of Nuclear Reactor Regulation.

[FR Doc. 2026–22711 Filed 11–5–26; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. K2026–328; MC2027–25 and K2027–26; MC2027–26 and K2027–27]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 12, 2026.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *https://www.prc.gov*. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Public Proceeding(s)
III. Summary Proceeding(s)

I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). The Public Representative does not represent any individual person, entity or particular point of view, and, when Commission attorneys are appointed, no attorney-client relationship is established. Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. *See* 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)–(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

II. Public Proceeding(s)

1. *Docket No(s).:* K2026–328; *Filing Title:* USPS Request Concerning Amendment One to Priority Mail & USPS Ground Advantage Contract 1059 and Materials Under Seal; *Filing Acceptance Date:* November 3, 2026; *Filing Authority:* 39 CFR. 3035.105 and 39 CFR 3041.505; *Public Representative:* Kenneth Moeller; *Comments Due:* November 12, 2026.

2. *Docket No(s).:* MC2027–25 and K2027–26; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 1123 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 3, 2026; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jennaca Upperman; *Comments Due:* November 12, 2026.

III. Summary Proceeding(s)

1. *Docket No(s).:* MC2027–26 and K2027–27; *Filing Title:* USPS Request to Add New Fulfillment Standardized Distinct Product, PM–GA Contract 1124, and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 3, 2026; *Filing Authority:* 39 U.S.C. 3642 and 3633, 39 CFR 3035.105, and 39 CFR 3041.325.

This Notice will be published in the **Federal Register**.

Danielle LeFlore,

Legal Assistant.

[FR Doc. 2026–22708 Filed 11–5–26; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106803; File No. SR–CboeEDGX–2026–074]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Introduce a Trade by Trade Report for EDGX Options and To Amend Its Fee Schedule To Adopt Fees for the Trade by Trade Report

November 3, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 21, 2026, Cboe EDGX Exchange, Inc. (''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (''EDGX'' or the ''Exchange'') proposes to introduce a Trade by Trade report for EDGX Options and to amend its fee schedule to adopt fees for the Trade by Trade report. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission's website (*https://www.sec.gov/rules/sro.shtml*), the Exchange's website (*https://www.cboe.com/us/equities/regulation/rule_filings/edgx/*), and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to introduce a Trade by Trade report (''TBT Report'') for its equity options platform (''EDGX Options''), which will be available for purchase by Options Members and non-Options Members, and to amend the EDGX Options fee schedule to adopt fees for the TBT Report, including a free sample. The proposed TBT Report is based on the TBT Report recently adopted by the Exchange's affiliated options exchange, Cboe Exchange, Inc. (''Cboe Options'').[5]

Trade by Trade Report

The TBT Report will provide subscribers with comprehensive trade-by-trade level detail for each options transaction executed on EDGX Options. The TBT Report will be produced and updated at the end of each trading day and be made available to subscribers overnight after midnight Eastern Time (*i.e.,* T+1), ensuring that the data is strictly historical and cannot be used to influence intraday trading decisions.

Specifically, each row in the TBT Report will represent a single trade event and will include transaction time, underlying symbol, Options Symbology Initiative (''OSI'') details (*e.g.,* root, expiry, strike, call/put), trade size, trade price, market context indicators (*e.g.,* National Best Bid/National Best Offer, EDGX Options best bid/best offer), side of the market (*i.e.,* buy or sell), transaction type (opening or closing), and origin (*i.e.,* the Capacity of the order, such as Priority Customer, Professional, broker-dealer, and Market Maker),[6] as well as, for a subscriber that is an Options Member, that Options Member's execution IDs for both Simple Book[7] and Complex Order Book[8] trades, which will better allow for accurate linkage and reconstruction of trading activity.

The Exchange anticipates a wide variety of market participants would purchase the TBT Report, including, but not limited to, individual customers, buy-side investors, and investment banks. The Exchange believes the proposed TBT Report will aid subscribers in performing detailed transaction-level analysis, compliance checks, and historical market reconstruction. The TBT Report may also serve as a foundation for analytics on liquidity, price formation, and trade behavior at a trade-by-trade level. The proposed TBT Report is a completely voluntary product, in that the Exchange is not required by any rule or regulation to make this data available, and potential subscribers are not required to purchase the TBT Report and may do so only if they voluntarily choose to.

Proposed Fees

The Exchange proposes to provide in the EDGX Options fee schedule that firms may purchase the TBT Report on a subscription basis or by ad hoc request for a specified month.[9] The Exchange proposes to assess a monthly fee of $6,000 for subscribing to the TBT Report. The Exchange also proposes to adopt a fee of $4,000 per month for ad hoc requests of the TBT Report. An ad hoc request can be for any number of months for which the data is available, beginning with March 1, 2019.

The Exchange also proposes to offer a free sample consisting of End-of-Day Trade by Trade Historical Data for the period July 1, 2022 through July 31, 2022. The free sample will be available to both Options Members and non-Options Members who have not previously purchased the TBT Report or previously received a free sample. The Exchange believes the proposed free sample will serve as an incentive for new subscribers to start purchasing such data. Particularly, the Exchange believes it will give potential subscribers the ability to evaluate historical options trading data before purchasing the TBT Report. The Exchange notes that Cboe Options is concurrently filing a proposed rule change to adopt the same free sample for its TBT Report. The Exchange also notes that another exchange offers a free trial for new subscribers of a similar data product.[10]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed fees are consistent with Section 6(b)(4) of the Act,[14] which

[5] *See* Securities Exchange Act Release No. 104415 (December 16, 2025), 90 FR 59603 (December 19, 2025) (SR–CBOE–2025–088); Securities Exchange Act Release No. 104795 (February 10, 2026), 91 FR 6940 (February 13, 2026) (SR–CBOE–2026–010).

[6] The term ''Capacity'' means the capacity in which a User submits an order, which the User specifies by applying the corresponding code to the order. *See* EDGX Rule 16.1.

[7] The term ''Simple Book'' means the Exchange's regular electronic book of orders. *See* Rule 21.20(a).

[8] *See* Rule 21.20(a) (defining the Complex Order Book).

[9] The Exchange proposes to make clear in the fee schedule that a mid-month subscription or an ad hoc historical request for specific dates (*e.g.,* March 17, 2023–March 31, 2023) will be prorated.

[10] *See* Nasdaq ISE, Options 7 Pricing Schedule, Section 10A, Market Data.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

[14] 15 U.S.C. 78f(b)(4).

requires that the rules of an exchange provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed TBT Report would further broaden the availability of U.S. options market data to investors consistent with the principles of Regulation NMS. The proposal also promotes increased transparency through the dissemination of the TBT Report. The proposed rule change would benefit investors by providing access to the TBT Report, which, as noted above, may aid subscribers in performing detailed transaction-level analysis, compliance checks, and historical market reconstruction. The TBT Report may also serve as a foundation for analytics on liquidity, price formation, and trade behavior at a trade-by-trade level. Additionally, trade-by-trade information regarding opening and closing activity across different option series may indicate investor sentiment, which can be helpful trading information. The Exchange emphasizes, however, that such data is not necessary for trading.

The proposed TBT Report is also similar to an existing EDGX Options data product, Open-Close Data. Open-Close Data is a data product that summarizes volume (contracts traded on EDGX Options) by origin (customer and firm orders), original order size, and the opening or closing position of the order, and is available on an end-of-day and intraday basis.[15] While there are some differences between Open-Close Data and the TBT Report (*e.g.,* level of detail and timing of delivery), the products serve similar purposes. Specifically, the TBT Report and Open-Close Data both provide information regarding options trading activity on EDGX Options, which, in turn, may be used by subscribers to create and test trading models and analytical strategies and provide comprehensive insight into trading on the Exchange. The functional differences are the level of granularity at which a subscriber may view executed options transactions and the timeline on which each product is delivered, *i.e.,* on an aggregated, summary level on an end-of-day or intraday basis (Open-Close Data), or, as proposed, on a trade-by-trade level delivered on a T+1 basis (the TBT Report). By offering the TBT Report as well as Open-Close Data, the Exchange will give subscribers an additional choice for historical trade data, and subscribers may choose to purchase the data that best suits their business needs. Given these similarities, and because the TBT Report is substantively identical to the TBT Report offered by Cboe Options,[16] the Exchange believes that the proposal does not present any new or novel issues.

The Exchange believes the proposed fees are reasonable. A subscriber may purchase a subscription to the TBT Report for $6,000 per month, and may purchase the TBT Report on an ad hoc basis for $4,000 per month of data. The Exchange currently assesses a fee of $500 per month for a subscription to Open-Close Data, which is the most comparable data product the Exchange offers, and $400 per month for ad hoc requests of historical Open-Close Data. The Exchange believes the higher proposed fees for the TBT Report are reasonable in light of the substantially greater content of the TBT Report. The TBT Report provides data on a trade-by-trade basis, while Open-Close Data provides data on an aggregated basis. While a subscriber to the TBT Report will not receive data intraday, the subscriber will receive additional data points because the data is not aggregated but covers every trade executed on EDGX Options, including the time, price, size, market context, side, transaction type, and origin of each trade. Further, the relationship between the proposed subscription fee and the proposed ad hoc fee for the TBT Report is consistent with the relationship between the corresponding Open-Close Data fees, in that the ad hoc fee for each product is lower than the subscription fee. The proposed fees are also lower than the fees Cboe Options assesses for its substantively identical TBT Report.[17] Furthermore, setting fees for the TBT Report that are not commensurate with its value relative to established fees for similar data products would simply serve to reduce demand for the Exchange's data product, which, as noted, is entirely optional. If a market participant views Open-Close Data as a more attractive offering for its specific business needs, then such market participant can merely choose to purchase Open-Close Data instead.

The Exchange also believes the proposed fees are reasonable as they would support the introduction of a new market data product that is designed to aid investors by providing further insight into trading on the Exchange. The Exchange believes the proposed fees are equitable and not unfairly discriminatory because they will apply uniformly to all subscribers, whether Options Members or non-Options Members.

The Exchange believes that the proposed free sample for Options Members and non-Options Members who have not previously purchased the TBT Report or previously received a free sample is reasonable because such users would not be subject to fees for End-of-Day Trade by Trade Historical Data for the period July 1, 2022 through July 31, 2022. The proposed free sample is also reasonable as it will give potential subscribers the ability to evaluate historical options trading data prior to purchasing the TBT Report and will therefore encourage and promote new users to purchase the TBT Report. The Exchange believes that the proposed free sample is equitable and not unfairly discriminatory because it will apply equally to all Options Members and non-Options Members who have not previously purchased the TBT Report or previously received a free sample. As noted above, Cboe Options is concurrently proposing the same free sample, and another exchange offers a free trial to new users of a similar data product.[18] Lastly, the purchase of this data product is discretionary and not compulsory.

The Exchange reiterates that the decision whether to purchase the TBT Report is entirely optional for all potential subscribers. No market participant is required to purchase the TBT Report, and the Exchange is not required to make the TBT Report available to all investors. Rather, the Exchange is voluntarily making the TBT Report available, as requested by customers, and market participants may choose to receive (and pay for) this data based on their own business needs. Potential purchasers may request the data at any time if they believe it to be valuable or may decline to purchase such data.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically,

[15] *See* Rule 21.15(b)(6).

[16] *See supra* note 5.

[17] *See supra* note 5.

[18] *See supra* note 10.

the Exchange notes that both Nasdaq PHLX LLC (''PHLX'') and The Nasdaq Stock Market LLC (''Nasdaq'') offer the PHLX Options Trade Outline (''PHOTO'') and Nasdaq Options Trade Outline (''NOTO'') products,[19] respectively, and that Cboe Options offers a substantively identical TBT Report.[20] In this regard, the Exchange believes that its proposal will promote competition by permitting the Exchange to offer a data product similar to those offered by other options exchanges, but that contains more granular data reporting details on a trade-by-trade basis, rather than on an aggregated basis. The Exchange believes the TBT Report represents the type of innovation and competition that Regulation NMS sought to create, and is proposing the TBT Report to keep pace with changes in the industry and evolving customer needs.

The Exchange also does not believe the proposed fees would cause any unnecessary or inappropriate burden on intermarket competition, as other exchanges are free to introduce their own comparable reports with additional data points and lower prices to better compete with the Exchange's offerings. The Exchange operates in a highly competitive environment, and its ability to price the TBT Report is constrained by competition among exchanges that offer similar products. Setting fees that are not commensurate with the value of the TBT Report relative to fees for similar data products would simply serve to reduce demand for the TBT Report, which market participants are under no obligation to purchase. In this competitive environment, potential purchasers are free to choose which, if any, similar product to purchase to satisfy their need for market information. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges.

The Exchange does not believe the proposed rule change would cause any unnecessary or inappropriate burden on intramarket competition. The TBT Report is entirely optional and available to anyone who believes the data will be helpful for their purposes, and the proposed fees apply uniformly to any purchaser, in that the Exchange does not differentiate between the different market participants that may purchase the report, other than through the free sample, which is available on equal terms to all eligible purchasers.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from Members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

A. significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. 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) of the Act[21] and Rule 19b–4(f)(6)[22] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeEDGX–2026–074 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeEDGX–2026–074. 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 filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeEDGX–2026–074 and should be submitted on or before November 27, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22654 Filed 11–5–26; 8:45 am]

BILLING CODE 8011–01–P

[19] PHOTO and NOTO include periodic, cumulative data for a particular trading session for a particular option series. Both reports include information regarding the aggregate number of trades to open a position, aggregate number of trades to close a position, and the origin of the trades based on the specific categories of market participants (*i.e.,* customers, broker-dealers, market makers, etc.). *See* Nasdaq PHLX Options—Trade Outline (PHOTO) Intraday, available at: *https://data.nasdaq.com/databases/PHOTO; see also* Nasdaq Options Market—Trade Outline (NOTO) Intraday, available at: *https://data.nasdaq.com/databases/NOTOI.*

[20] *See supra* note 5.

[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b–4(f)(6).

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 36377; File No. 812–15955]

83 Investment Group Income Fund, *et al.*

November 3, 2026.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of application for an order under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

Summary of Application: Applicants request an order to permit certain business development companies (''BDCs''), closed-end management investment companies, and open-end

management investment companies to co-invest in portfolio companies with each other and with certain affiliated investment entities.

Applicants: 83 Investment Group Income Fund, Morton Capital Management, LLC, RBE Capital Partners Fund LP and M83 Investment Group, LLC.

Filing Dates: The application was filed on December 16, 2025, and amended on June 11, 2026, and September 18, 2026.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. The email should include the file number referenced above. Hearing requests should be received by the Commission by 5:30 p.m., Eastern time, on November 30, 2026, and should be accompanied by proof of service on the Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Menachem Striks, *mstriks@mortonwealth.com;* Terrence Davis, Esq. and Tanya Boyle, Esq., DLA Piper, LLP, *terrence.davis@us.dlapiper.com* and *tanya.boyle@us.dlapiper.com.*

FOR FURTHER INFORMATION CONTACT: Rachel Loko, Senior Special Counsel, or Laura L. Solomon, Senior Counsel at (202) 551–6720 or *IMOCC@sec.gov* (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' second amended application, filed September 18, 2026, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at *https://www.sec.gov/search-filings.* You may also call the SEC's Office of Investor Education and Assistance at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22648 Filed 11–5–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106808; File No. SR–NasdaqTX–2026–051]

Self-Regulatory Organizations; Nasdaq Texas, LLC; Notice of Filing and Immediate Effectiveness of a Proposal To Amend Equity 4 To Remove All References to the CORE FIX Order Entry Protocol

November 3, 2026.

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 October 22, 2026, Nasdaq Texas, LLC (''Nasdaq Texas'' 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 Equity 4 to remove all references to the CORE FIX order entry protocol.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaqtx/rulefilings,* and at the principal office of the Exchange.

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

In September 2025 the Exchange added CORE FIX to its rulebook in Equity 4, in anticipation of making this new order entry protocol available to Exchange Participants in October of 2025.[3] In December 2025 the Exchange extended the implementation date for CORE FIX to the first quarter of 2026.[4] In March 2026 the Exchange extended the implementation date for CORE FIX to the end of 2026.[5]

In spite of its best efforts, the Exchange has been unable to generate interest in CORE FIX among Exchange Participants. Therefore, rather than deploy an order entry protocol that Participants are not even interested in testing, the Exchange proposes to abandon its plans to deploy CORE FIX.[6] This will allow the Exchange to better allocate its technological development resources. The Exchange notes that it will continue to offer all the order entry protocols that are currently available and operative on the Exchange—namely, OUCH, RASH, FLITE, and FIX.[7]

The Exchange proposes to eliminate all references to CORE FIX that are currently present in Equity 4.[8]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 103891 (Sept. 5, 2025), 90 FR 43705 (Sept. 10, 2025) (''Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Add the CORE FIX Order Entry Protocol and To Amend Nasdaq BX Equity 4, Rules 4120, 4702, 4703, and 4757'') (File No. SR–BX–2025–017). At the time of that filing, the Exchange was known by the name ''Nasdaq BX.''

[4] *See* Securities Exchange Act Release No. 104291 (Dec. 2, 2025), 90 FR 56218 (Dec. 5, 2025) (''Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend BX Equity 4, Rule 4702(b)(4)(C) To Specify That the 'Time-in-Force' Order Attribute of 'Immediate-or-Cancel' Is Not Available to Post-Only Orders Entered Through the CORE FIX protocol'') (File No. SR–BX–2025–029). At the time of that filing, the Exchange was known by the name ''Nasdaq BX.''

[5] *See* Securities Exchange Act Release No. 105128 (Mar. 31, 2025), 91 FR 17024 (Apr. 3, 2026) (''Notice of Filing and Immediate Effectiveness of a Proposal To Amend the Exchange's Anti-Internalization Functionality in Equity 4, Rule 4757, and To Extend the Implementation Date of the CORE FIX Order Entry Protocol'') (File No. SR–NasdaqTX–2026–012).

[6] The Exchange will also submit, in short order, a separate fee filing to remove references to CORE FIX found in Equity 7 (Pricing Schedule).

[7] *See* Equity 4, Rule 4702(a).

[8] The Exchange notes that its rulebook online, under the headings for Rules 4702, 4703, and 4757, contains the following disclaimer: 'References to ''CORE FIX'' will be implemented in 2026.'

Specifically, these references are found in Rules 4702 (Order Types), 4703 (Order Attributes), and 4757 (Book Processing).[9]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Section 6(b)(5) of the Act,[11] 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.

The Exchange believes that the proposed rule change is designed to promote just and equitable principles of trade because it will ensure that the Exchange's rulebook accurately reflects the order entry protocols that are available and operative on the Exchange. Removing references to CORE FIX, which the Exchange will not deploy, will avoid confusion among Participants and other market participants regarding the protocols available for order entry. The proposed rule change will not alter the operation of the Exchange's market, the treatment of orders, or the rights or obligations of Participants; the Exchange will continue to offer the OUCH, RASH, FLITE, and FIX protocols. Accordingly, the proposal will remove impediments to and perfect the mechanism of a free and open market and a national market system, and will protect investors and the public interest by providing clear and accurate information concerning the Exchange's order entry protocols.

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. The proposed rule change is not designed to address any competitive issue; instead, its purpose is to ensure that the Exchange's rulebook accurately reflects the protocols that are available and operative on the Exchange. Removing references to CORE FIX will not deprive any Participant of an available order entry protocol, because CORE FIX has not been deployed on the Exchange. Participants will continue to be able to choose among the OUCH, RASH, FLITE, and FIX protocols based on their trading needs. Accordingly, the proposal will not impose any burden on competition, either among Exchange Participants or between the Exchange and other trading venues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

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 Act[12] and subparagraph (f)(6) of Rule 19b–4 thereunder.[13]

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–NasdaqTX–2026–051 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–NasdaqTX–2026–051. 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 filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NasdaqTX–2026–051 and should be submitted on or before November 27, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22656 Filed 11–5–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106807; File No. SR–NASDAQ–2026–092]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of a Proposal To Amend Equity 4 to Remove All References to the CORE FIX Order Entry Protocol

November 3, 2026.

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 October 22, 2026, The Nasdaq Stock Market LLC

However, those are only online disclaimers that the Exchange did not add to its rule text. Those online-only disclaimers will be deleted once the other references to CORE FIX are deleted from the Exchange's rule text, pursuant to this filing.

[9] References to CORE FIX in Equity 4, Rule 4120 (Limit Up-Limit Down Plan and Trading Halts) are being deleted through a separate immediately effective filing that the Exchange filed on October 22, 2026 (File No. SR–NasdaqTX–2026–050). That other filing completely replaces Rule 4120, and the new text of that rule does not contain any references to CORE FIX.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 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.

[14] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

(''Nasdaq'' 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 Equity 4 to remove all references to the CORE FIX order entry protocol.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rulefilings,* and at the principal office of the Exchange.

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

In March 2025 the Exchange added CORE FIX to its rulebook in Equity 4, in anticipation of making this new order entry protocol available to Exchange Participants by the third quarter of 2025.[3] In March 2026 the Exchange extended the implementation date for CORE FIX to the end of 2026.[4]

In spite of its best efforts, the Exchange has been unable to generate interest in CORE FIX among Exchange Participants. Therefore, rather than deploy an order entry protocol that Participants are not even interested in testing, the Exchange proposes to abandon its plans to deploy CORE FIX.[5] This will allow the Exchange to better allocate its technological development resources. The Exchange notes that it will continue to offer all the order entry protocols that are currently available and operative on the Exchange—namely, OUCH, RASH, FLITE, and FIX.[6]

The Exchange proposes to eliminate all references to CORE FIX that are currently present in Equity 4. Specifically, these references are found in Rules 4120 (Limit Up-Limit Down Plan and Trading Halts), 4702 (Order Types), 4703 (Order Attributes), and 4757 (Book Processing).[7]

Finally, the Exchange proposes to use this filing to make a technical correction to Equity 4, Rule 4120(b)(1)(C)(ii)(e)(2). That rule provides that following a regulatory halt pursuant to the Limit Up-Limit Down Mechanism, ''limit-priced orders entered via the OUCH or CORE FIX protocols which are not assigned a Managed Pegging, Discretionary, or Reserve Order Attribute, the order shall be repriced upon entry only if the Price Bands are such that the price of the limit-priced interest to buy (sell) would be above (below) the Upper (Lower) Price Band.'' The reference to CORE FIX in that rule will be deleted as part of this filing. But the Exchange also wishes to correct this rule by adding the FLITE protocol, alongside the OUCH protocol. This is to reflect current Exchange functionality. In other words, the Exchange currently applies this rule to limit-priced orders entered via the OUCH of FLITE protocols, even though the FLITE protocol is not currently included in this rule. The Exchange proposes to correct this oversight in this filing. Therefore, pursuant to this filing, Equity 4, Rule 4120(b)(1)(C)(ii)(e)(2) will state that ''limit-priced orders entered via the OUCH or FLITE protocols which are not assigned a Managed Pegging, Discretionary, or Reserve Order Attribute, the order shall be repriced upon entry only if the Price Bands are such that the price of the limit-priced interest to buy (sell) would be above (below) the Upper (Lower) Price Band.''

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5) of the Act,[9] 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.

The Exchange believes that the proposed rule change is designed to promote just and equitable principles of trade because it will ensure that the Exchange's rulebook accurately reflects the order entry protocols that are available and operative on the Exchange. Removing references to CORE FIX, which the Exchange will not deploy, will avoid confusion among Participants and other market participants regarding the protocols available for order entry. The proposed technical correction to Rule 4120(b)(1)(C)(ii)(e)(2) will likewise make the rule text accurately reflect current Exchange functionality by adding the FLITE protocol alongside the OUCH protocol. The proposed rule change will not alter the operation of the Exchange's market, the treatment of orders, or the rights or obligations of Participants; the Exchange will continue to offer the OUCH, RASH, FLITE, and FIX protocols. Accordingly, the proposal will remove impediments to and perfect the mechanism of a free and open market and a national market system, and will protect investors and the public interest by providing clear and accurate information concerning the Exchange's order entry protocols and order handling 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. The proposed rule change is not designed to address any competitive issue; instead, its purpose is to ensure that the Exchange's rulebook accurately reflects the protocols that are available and

[3] *See* Securities Exchange Act Release No. 102661 (Mar. 13, 2025), 90 FR 12858 (Mar. 19, 2025) (''Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Equity 4, Rules 4120, 4702 4703, and 4757'') (File No. SR–NASDAQ–2025–027).

[4] *See* Securities Exchange Act Release No. 105129 (Mar. 31, 2026), 91 FR 17010 (Apr. 3, 2026) (''Notice of Filing and Immediate Effectiveness of a Proposal To Amend the Exchange's Anti-Internalization Functionality in Equity 4, Rule 4757, and To Extend the Implementation Date of the CORE FIX Order Entry Protocol'') (File No. SR–NASDAQ–2026–023).

[5] The Exchange will also submit, in short order, a separate fee filing to remove references to CORE FIX found in Equity 7 (Pricing Schedule).

[6] *See* Equity 4, Rule 4702(a).

[7] Additionally, in a recent filing, the Exchange added to the rule text of Equity 4, Rule 4120, the online rulebook disclaimer that 'References to ''CORE FIX'' will be implemented in 2026.' *See* Securities Exchange Act Release No. 106139 (Aug. 14, 2026), 91 FR 53677 (Aug. 19, 2026) (''Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Equity 4, Rule 4120 Regarding Trading Halts'') (File No. SR–NASDAQ–2026–064). Therefore, as part of this filing, the Exchange proposes to delete this disclaimer in Rule 4120. The same disclaimer is also found at the top of Rules 4702, 4703, and 4757. However, those are only online disclaimers that the Exchange did not add to its rule text. Those online-only disclaimers will be deleted once the other references to CORE FIX are deleted from the Exchange's rule text, pursuant to this filing.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

operative on the Exchange and the functionality currently provided through those protocols. Removing references to CORE FIX will not deprive any Participant of an available order entry protocol, because CORE FIX has not been deployed on the Exchange. The technical correction adding FLITE to Rule 4120(b)(1)(C)(ii)(e)(2) will not change the functionality available to Participants and will apply equally to all Participants. Participants will continue to be able to choose among the OUCH, RASH, FLITE, and FIX protocols based on their trading needs. Accordingly, the proposal will not impose any burden on competition, either among Exchange Participants or between the Exchange and other trading venues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

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 Act [10] and subparagraph (f)(6) of Rule 19b–4 thereunder.[11]

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–NASDAQ–2026–092 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–NASDAQ–2026–092. 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 filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NASDAQ–2026–092 and should be submitted on or before November 27, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22655 Filed 11–5–26; 8:45 am]

BILLING CODE 8011–01–P

[10] 15 U.S.C. 78s(b)(3)(A)(iii).

[11] 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.

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106802; File No. SR–CboeBZX–2026–089]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Introduce a Trade-by-Trade Report for BZX Options and To Amend Its Fee Schedule To Adopt Fees for the Trade-by-Trade Report

November 3, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 21, 2026, Cboe BZX Exchange, Inc. (''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (''BZX'' or the ''Exchange'') proposes to introduce a Trade-by-Trade report for BZX Options and to amend its fee schedule to adopt fees for the Trade-by-Trade report. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission's website (*https://www.sec.gov/rules/sro.shtml*), the Exchange's website (*https://www.cboe.com/us/equities/regulation/rule_filings/bzx/*), and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to introduce a Trade-by-Trade report (''TBT Report'') for its equity options platform (''BZX Options''), which will be available for purchase by Options Members and non-Options Members, and to amend the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

BZX Options fee schedule to adopt fees for the TBT Report, including a free sample. The proposed TBT Report is based on the TBT Report recently adopted by the Exchange's affiliated options exchange, Cboe Exchange, Inc. (''Cboe Options'').[5]

Trade-by-Trade Report

The TBT Report will provide subscribers with comprehensive trade-by-trade level detail for each options transaction executed on BZX Options. The TBT Report will be produced and updated at the end of each trading day and be made available to subscribers overnight after midnight Eastern Time (*i.e.,* T+1), ensuring that the data is strictly historical and cannot be used to influence intraday trading decisions.

Specifically, each row in the TBT Report will represent a single trade event and will include transaction time, underlying symbol, Options Symbology Initiative (''OSI'') details (*e.g.,* root, expiry, strike, call/put), trade size, trade price, market context indicators (*e.g.,* National Best Bid/National Best Offer, BZX Options best bid/best offer), side of the market (*i.e.,* buy or sell), transaction type (opening or closing), and origin (*i.e.,* the Capacity of the order, such as Priority Customer, Professional, broker-dealer, and Market-Maker),[6] as well as, for a subscriber that is an Options Member, that Options Member's execution IDs for both Simple Book[7] and Complex Order Book[8] trades, which will better allow for accurate linkage and reconstruction of trading activity.

The Exchange anticipates a wide variety of market participants would purchase the TBT Report, including, but not limited to, individual customers, buy-side investors, and investment banks. The Exchange believes the proposed TBT Report will aid subscribers in performing detailed transaction-level analysis, compliance checks, and historical market reconstruction. The TBT Report may also serve as a foundation for analytics on liquidity, price formation, and trade behavior at a trade-by-trade level. The proposed TBT Report is a completely voluntary product, in that the Exchange is not required by any rule or regulation to make this data available, and potential subscribers are not required to purchase the TBT Report and may do so only if they voluntarily choose to.

Proposed Fees

The Exchange proposes to provide in the BZX Options fee schedule that firms may purchase the TBT Report on a subscription basis or by ad hoc request for a specified month.[9] The Exchange proposes to assess a monthly fee of $6,000 for subscribing to the TBT Report. The Exchange also proposes to adopt a fee of $4,000 per month for ad hoc requests of the TBT Report. An ad hoc request can be for any number of months for which the data is available, beginning with March 1, 2019.

The Exchange also proposes to offer a free sample consisting of End-of-Day Trade by Trade Historical Data for the period July 1, 2022 through July 31, 2022. The free sample will be available to both Options Members and non-Options Members who have not previously purchased the TBT Report or previously received a free sample. The Exchange believes the proposed free sample will serve as an incentive for new subscribers to start purchasing such data. Particularly, the Exchange believes it will give potential subscribers the ability to evaluate historical options trading data before purchasing the TBT Report. The Exchange notes that Cboe Options is concurrently filing a proposed rule change to adopt the same free sample for its TBT Report. The Exchange also notes that another exchange offers a free trial for new subscribers of a similar data product.[10]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed fees are consistent with Section 6(b)(4) of the Act,[14] which requires that the rules of an exchange provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed TBT Report would further broaden the availability of U.S. options market data to investors consistent with the principles of Regulation NMS. The proposal also promotes increased transparency through the dissemination of the TBT Report. The proposed rule change would benefit investors by providing access to the TBT Report, which, as noted above, may aid subscribers in performing detailed transaction-level analysis, compliance checks, and historical market reconstruction. The TBT Report may also serve as a foundation for analytics on liquidity, price formation, and trade behavior at a trade-by-trade level. Additionally, trade-by-trade information regarding opening and closing activity across different option series may indicate investor sentiment, which can be helpful trading information. The Exchange emphasizes, however, that such data is not necessary for trading.

The proposed TBT Report is also similar to an existing BZX Options data product, Open-Close Data. Open-Close Data is a data product that summarizes volume (contracts traded on BZX Options) by origin (customer and firm orders), original order size, and the opening or closing position of the order, and is available on an end-of-day and

[5] *See* Securities Exchange Act Release No. 104415 (December 16, 2025), 90 FR 59603 (December 19, 2025) (SR–CBOE–2025–088); Securities Exchange Act Release No. 104795 (February 10, 2026), 91 FR 6940 (February 13, 2026) (SR–CBOE–2026–010).

[6] The term ''Capacity'' means the capacity in which a User submits an order, which the User specifies by applying the corresponding code to the order. *See* BZX Rule 16.1.

[7] The terms ''BZX Options Book'' and ''Simple Book'' mean the electronic book of simple options orders maintained by the Trading System. *See* Rule 16.1.

[8] *See* Rule 21.18 (defining the Complex Order Book).

[9] The Exchange proposes to make clear in the fee schedule that a mid-month subscription or an ad hoc historical request for specific dates (*e.g.,* March 17, 2023–March 31, 2023) will be prorated.

[10] *See* Nasdaq ISE, Options 7 Pricing Schedule, Section 10A, Market Data.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

[14] 15 U.S.C. 78f(b)(4).

intraday basis.[15] While there are some differences between Open-Close Data and the TBT Report (*e.g.,* level of detail and timing of delivery), the products serve similar purposes. Specifically, the TBT Report and Open-Close Data both provide information regarding options trading activity on BZX Options, which, in turn, may be used by subscribers to create and test trading models and analytical strategies and provide comprehensive insight into trading on the Exchange. The functional differences are the level of granularity at which a subscriber may view executed options transactions and the timeline on which each product is delivered, *i.e.,* on an aggregated, summary level on an end-of-day or intraday basis (Open-Close Data), or, as proposed, on a trade-by-trade level delivered on a T+1 basis (the TBT Report). By offering the TBT Report as well as Open-Close Data, the Exchange will give subscribers an additional choice for historical trade data, and subscribers may choose to purchase the data that best suits their business needs. Given these similarities, and because the TBT Report is substantively identical to the TBT Report offered by Cboe Options,[16] the Exchange believes that the proposal does not present any new or novel issues.

The Exchange believes the proposed fees are reasonable. A subscriber may purchase a subscription to the TBT Report for $6,000 per month, and may purchase the TBT Report on an ad hoc basis for $4,000 per month of data. The Exchange currently assesses a fee of $500 per month for a subscription to Open-Close Data, which is the most comparable data product the Exchange offers, and $400 per month for ad hoc requests of historical Open-Close Data. The Exchange believes the higher proposed fees for the TBT Report are reasonable in light of the substantially greater content of the TBT Report. The TBT Report provides data on a trade-by-trade basis, while Open-Close Data provides data on an aggregated basis. While a subscriber to the TBT Report will not receive data intraday, the subscriber will receive additional data points because the data is not aggregated but covers every trade executed on BZX Options, including the time, price, size, market context, side, transaction type, and origin of each trade. Further, the relationship between the proposed subscription fee and the proposed ad hoc fee for the TBT Report is consistent with the relationship between the corresponding Open-Close Data fees, in that the ad hoc fee for each product is lower than the subscription fee. The proposed fees are also lower than the fees Cboe Options assesses for its substantively identical TBT Report.[17] Furthermore, setting fees for the TBT Report that are not commensurate with its value relative to established fees for similar data products would simply serve to reduce demand for the Exchange's data product, which, as noted, is entirely optional. If a market participant views Open-Close Data as a more attractive offering for its specific business needs, then such market participant can merely choose to purchase Open-Close Data instead.

The Exchange also believes the proposed fees are reasonable as they would support the introduction of a new market data product that is designed to aid investors by providing further insight into trading on the Exchange. The Exchange believes the proposed fees are equitable and not unfairly discriminatory because they will apply uniformly to all subscribers, whether Options Members or non-Options Members.

The Exchange believes that the proposed free sample for Options Members and non-Options Members who have not previously purchased the TBT Report or previously received a free sample is reasonable because such users would not be subject to fees for End-of-Day Trade by Trade Historical Data for the period July 1, 2022 through July 31, 2022. The proposed free sample is also reasonable as it will give potential subscribers the ability to evaluate historical options trading data prior to purchasing the TBT Report and will therefore encourage and promote new users to purchase the TBT Report. The Exchange believes that the proposed free sample is equitable and not unfairly discriminatory because it will apply equally to all Options Members and non-Options Members who have not previously purchased the TBT Report or previously received a free sample. As noted above, Cboe Options is concurrently proposing the same free sample, and another exchange offers a free trial to new users of a similar data product.[18] Lastly, the purchase of this data product is discretionary and not compulsory.

The Exchange reiterates that the decision whether to purchase the TBT Report is entirely optional for all potential subscribers. No market participant is required to purchase the TBT Report, and the Exchange is not required to make the TBT Report available to all investors. Rather, the Exchange is voluntarily making the TBT Report available, as requested by customers, and market participants may choose to receive (and pay for) this data based on their own business needs. Potential purchasers may request the data at any time if they believe it to be valuable or may decline to purchase such data.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange notes that both Nasdaq PHLX LLC (''PHLX'') and The Nasdaq Stock Market LLC (''Nasdaq'') offer the PHLX Options Trade Outline (''PHOTO'') and Nasdaq Options Trade Outline (''NOTO'') products,[19] respectively, and that Cboe Options offers a substantively identical TBT Report.[20] In this regard, the Exchange believes that its proposal will promote competition by permitting the Exchange to offer a data product similar to those offered by other options exchanges, but that contains more granular data reporting details on a trade-by-trade basis, rather than on an aggregated basis. The Exchange believes the TBT Report represents the type of innovation and competition that Regulation NMS sought to create, and is proposing the TBT Report to keep pace with changes in the industry and evolving customer needs.

The Exchange also does not believe the proposed fees would cause any unnecessary or inappropriate burden on intermarket competition, as other exchanges are free to introduce their own comparable reports with additional data points and lower prices to better compete with the Exchange's offerings. The Exchange operates in a highly competitive environment, and its ability to price the TBT Report is constrained by competition among exchanges that offer similar products. Setting fees that are not commensurate with the value of the TBT Report relative to fees for

[15] *See* Rule 21.15(b)(5).

[16] *See supra* note 5.

[17] *See supra* note 5.

[18] *See supra* note 10.

[19] PHOTO and NOTO include periodic, cumulative data for a particular trading session for a particular option series. Both reports include information regarding the aggregate number of trades to open a position, aggregate number of trades to close a position, and the origin of the trades based on the specific categories of market participants (*i.e.,* customers, broker-dealers, market makers, etc.). *See* Nasdaq PHLX Options—Trade Outline (PHOTO) Intraday, available at: *https://data.nasdaq.com/databases/PHOTO*; *see also* Nasdaq Options Market—Trade Outline (NOTO) Intraday, available at: *https://data.nasdaq.com/databases/NOTOI.*

[20] *See supra* note 5.

similar data products would simply serve to reduce demand for the TBT Report, which market participants are under no obligation to purchase. In this competitive environment, potential purchasers are free to choose which, if any, similar product to purchase to satisfy their need for market information. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges.

The Exchange does not believe the proposed rule change would cause any unnecessary or inappropriate burden on intramarket competition. The TBT Report is entirely optional and available to anyone who believes the data will be helpful for their purposes, and the proposed fees apply uniformly to any purchaser, in that the Exchange does not differentiate between the different market participants that may purchase the report, other than through the free sample, which is available on equal terms to all eligible purchasers.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from Members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

A. significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. 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) of the Act [21] and Rule 19b–4(f)(6) [22] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–CboeBZX–2026–089 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeBZX–2026–089. 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 filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBZX–2026–089 and should be submitted on or before November 27, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22653 Filed 11–5–26; 8:45 am]

BILLING CODE 8011–01–P

[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b–4(f)(6).

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106800; File No. SR–C2–2026–029]

Self-Regulatory Organizations; Cboe C2 Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Introduce a Trade-by-Trade Report for C2 Options and To Amend Its Fee Schedule To Adopt Fees for the Trade-by-Trade Report

November 3, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 27, 2026, Cboe C2 Exchange, Inc. (''Exchange'' or ''C2'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe C2 Exchange, Inc. (''C2'' or the ''Exchange'') proposes to introduce a Trade-by-Trade report for C2 Options and to amend its fee schedule to adopt fees for the Trade-by-Trade report. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission's website (*https://www.sec.gov/rules/sro.shtml*), the Exchange's website (*https://www.cboe.com/us/options/regulation/rule_filings/ctwo/*), and at the principal office of the Exchange.

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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to introduce a Trade-by-Trade report (''TBT Report'') for its equity options platform (''C2 Options''), which will be available for purchase by Trading Permit Holders (''TPHs'') and non-TPHs, and to amend the C2 Options fee schedule to adopt fees for the TBT Report, including a free sample. The proposed TBT Report is based on the TBT Report recently adopted by the Exchange's affiliated options exchange, Cboe Exchange, Inc. (''Cboe Options'').[5]

Trade-by-Trade Report

The TBT Report will provide subscribers with comprehensive trade-by-trade level detail for each options transaction executed on C2 Options. The TBT Report will be produced and updated at the end of each trading day and be made available to subscribers overnight after midnight Eastern Time (*i.e.,* T+1), ensuring that the data is strictly historical and cannot be used to influence intraday trading decisions.

Specifically, each row in the TBT Report will represent a single trade event and will include transaction time, underlying symbol, Options Symbology Initiative (''OSI'') details (*e.g.,* root, expiry, strike, call/put), trade size, trade price, market context indicators (*e.g.,* National Best Bid/National Best Offer, C2 Options best bid/best offer), side of the market (*i.e.,* buy or sell), transaction type (opening or closing), and origin (*i.e.,* the Capacity of the order, such as Public Customer, Professional, broker-dealer, and Market-Maker),[6] as well as, for a subscriber that is a TPH, that TPH's execution IDs for both Simple Book[7] and Complex Order Book[8] trades, which will better allow for accurate linkage and reconstruction of trading activity.

The Exchange anticipates a wide variety of market participants would purchase the TBT Report, including, but not limited to, individual customers, buy-side investors, and investment banks. The Exchange believes the proposed TBT Report will aid subscribers in performing detailed transaction-level analysis, compliance checks, and historical market reconstruction. The TBT Report may also serve as a foundation for analytics on liquidity, price formation, and trade behavior at a trade-by-trade level. The proposed TBT Report is a completely voluntary product, in that the Exchange is not required by any rule or regulation to make this data available, and potential subscribers are not required to purchase the TBT Report and may do so only if they voluntarily choose to.

Proposed Fees

The Exchange proposes to provide in the C2 Options fee schedule that firms may purchase the TBT Report on a subscription basis or by ad hoc request for a specified month.[9] The Exchange proposes to assess a monthly fee of $5,000 for subscribing to the TBT Report. The Exchange also proposes to adopt a fee of $3,000 per month for ad hoc requests of the TBT Report. An ad hoc request can be for any number of months for which the data is available, beginning with March 1, 2019.

The Exchange also proposes to offer a free sample consisting of End-of-Day Trade by Trade Historical Data for the period July 1, 2022 through July 31, 2022. The free sample will be available to both TPHs and non-TPHs who have not previously purchased the TBT Report or previously received a free sample. The Exchange believes the proposed free sample will serve as an incentive for new subscribers to start purchasing such data. Particularly, the Exchange believes it will give potential subscribers the ability to evaluate historical options trading data before purchasing the TBT Report. The Exchange notes that Cboe Options is concurrently filing a proposed rule change to adopt the same free sample for its TBT Report. The Exchange also notes that another exchange offers a free trial for new subscribers of a similar data product.[10]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed fees are consistent with Section 6(b)(4) of the Act,[14] which requires that the rules of an exchange provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed TBT Report would further broaden the availability of U.S. options market data to investors consistent with the principles of Regulation NMS. The proposal also promotes increased transparency through the dissemination of the TBT Report. The proposed rule change would benefit investors by providing access to the TBT Report, which, as noted above, may aid subscribers in performing detailed transaction-level analysis, compliance checks, and historical market reconstruction. The TBT Report may also serve as a foundation for analytics on liquidity, price formation, and trade

[5] *See* Securities Exchange Act Release No. 104415 (December 16, 2025), 90 FR 59603 (December 19, 2025) (SR–CBOE–2025–088); Securities Exchange Act Release No. 104795 (February 10, 2026), 91 FR 6940 (February 13, 2026) (SR–CBOE–2026–010).

[6] The term ''Capacity'' means the capacity in which a User submits an order, which the User specifies by applying the corresponding code to the order. *See* C2 Rule 1.1.

[7] The terms ''Book'' and ''Simple Book'' mean the electronic book of simple orders and quotes maintained by the System on which orders and quotes may execute during the applicable trading session. *See* Rule 1.1.

[8] *See* Rule 5.33(a) (defining the Complex Order Book).

[9] The Exchange proposes to make clear in the fee schedule that a mid-month subscription or an ad hoc historical request for specific dates (*e.g.,* March 17, 2023–March 31, 2023) will be prorated.

[10] *See* Nasdaq ISE, Options 7 Pricing Schedule, Section 10A, Market Data.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

[14] 15 U.S.C. 78f(b)(4).

behavior at a trade-by-trade level. Additionally, trade-by-trade information regarding opening and closing activity across different option series may indicate investor sentiment, which can be helpful trading information. The Exchange emphasizes, however, that such data is not necessary for trading.

The proposed TBT Report is also similar to an existing C2 Options data product, Open-Close Data. Open-Close Data is a data product that summarizes volume (contracts traded on C2 Options) by origin (customer and firm orders), original order size, and the opening or closing position of the order, and is available on an end-of-day and intraday basis.[15] While there are some differences between Open-Close Data and the TBT Report (*e.g.,* level of detail and timing of delivery), the products serve similar purposes. Specifically, the TBT Report and Open-Close Data both provide information regarding options trading activity on C2 Options, which, in turn, may be used by subscribers to create and test trading models and analytical strategies and provide comprehensive insight into trading on the Exchange. The functional differences are the level of granularity at which a subscriber may view executed options transactions and the timeline on which each product is delivered, *i.e.,* on an aggregated, summary level on an end-of-day or intraday basis (Open-Close Data), or, as proposed, on a trade-by-trade level delivered on a T+1 basis (the TBT Report). By offering the TBT Report as well as Open-Close Data, the Exchange will give subscribers an additional choice for historical trade data, and subscribers may choose to purchase the data that best suits their business needs. Given these similarities, and because the TBT Report is substantively identical to the TBT Report offered by Cboe Options,[16] the Exchange believes that the proposal does not present any new or novel issues.

The Exchange believes the proposed fees are reasonable. A subscriber may purchase a subscription to the TBT Report for $5,000 per month, and may purchase the TBT Report on an ad hoc basis for $3,000 per month of data. The Exchange currently assesses a fee of $500 per month for a subscription to Open-Close Data, which is the most comparable data product the Exchange offers, and $400 per month for ad hoc requests of historical Open-Close Data. The Exchange believes the higher proposed fees for the TBT Report are reasonable in light of the substantially greater content of the TBT Report. The TBT Report provides data on a trade-by-trade basis, while Open-Close Data provides data on an aggregated basis. While a subscriber to the TBT Report will not receive data intraday, the subscriber will receive additional data points because the data is not aggregated but covers every trade executed on C2 Options, including the time, price, size, market context, side, transaction type, and origin of each trade. Further, the relationship between the proposed subscription fee and the proposed ad hoc fee for the TBT Report is consistent with the relationship between the corresponding Open-Close Data fees, in that the ad hoc fee for each product is lower than the subscription fee. The proposed fees are also lower than the fees Cboe Options assesses for its substantively identical TBT Report.[17] Furthermore, setting fees for the TBT Report that are not commensurate with its value relative to established fees for similar data products would simply serve to reduce demand for the Exchange's data product, which, as noted, is entirely optional. If a market participant views Open-Close Data as a more attractive offering for its specific business needs, then such market participant can merely choose to purchase Open-Close Data instead.

The Exchange also believes the proposed fees are reasonable as they would support the introduction of a new market data product that is designed to aid investors by providing further insight into trading on the Exchange. The Exchange believes the proposed fees are equitable and not unfairly discriminatory because they will apply uniformly to all subscribers, whether TPHs or non-TPHs.

The Exchange believes that the proposed free sample for TPHs and non-TPHs who have not previously purchased the TBT Report or previously received a free sample is reasonable because such users would not be subject to fees for End-of-Day Trade by Trade Historical Data for the period July 1, 2022 through July 31, 2022. The proposed free sample is also reasonable as it will give potential subscribers the ability to evaluate historical options trading data prior to purchasing the TBT Report and will therefore encourage and promote new users to purchase the TBT Report. The Exchange believes that the proposed free sample is equitable and not unfairly discriminatory because it will apply equally to all TPHs and non-TPHs who have not previously purchased the TBT Report or previously received a free sample. As noted above, Cboe Options is concurrently proposing the same free sample, and another exchange offers a free trial to new users of a similar data product.[18] Lastly, the purchase of this data product is discretionary and not compulsory.

The Exchange reiterates that the decision whether to purchase the TBT Report is entirely optional for all potential subscribers. No market participant is required to purchase the TBT Report, and the Exchange is not required to make the TBT Report available to all investors. Rather, the Exchange is voluntarily making the TBT Report available, as requested by customers, and market participants may choose to receive (and pay for) this data based on their own business needs. Potential purchasers may request the data at any time if they believe it to be valuable or may decline to purchase such data.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange notes that both Nasdaq PHLX LLC (''PHLX'') and The Nasdaq Stock Market LLC (''Nasdaq'') offer the PHLX Options Trade Outline (''PHOTO'') and Nasdaq Options Trade Outline (''NOTO'') products,[19] respectively, and that Cboe Options offers a substantively identical TBT Report.[20] In this regard, the Exchange believes that its proposal will promote competition by permitting the Exchange to offer a data product similar to those offered by other options exchanges, but that contains more granular data reporting details on a trade-by-trade basis, rather than on an aggregated basis. The Exchange believes the TBT Report represents the type of innovation and competition that Regulation NMS sought to create, and is proposing the TBT Report to keep pace with changes

[15] *See* Cboe C2 Fees Schedule, Cboe LiveVol, LLC Market Data Fees, Open-Close Data.

[16] *See supra* note 5.

[17] *See supra* note 5.

[18] *See supra* note 10.

[19] PHOTO and NOTO include periodic, cumulative data for a particular trading session for a particular option series. Both reports include information regarding the aggregate number of trades to open a position, aggregate number of trades to close a position, and the origin of the trades based on the specific categories of market participants (*i.e.,* customers, broker-dealers, market makers, etc.). *See* Nasdaq PHLX Options—Trade Outline (PHOTO) Intraday, available at: *https://data.nasdaq.com/databases/PHOTO; see also* Nasdaq Options Market—Trade Outline (NOTO) Intraday, available at: *https://data.nasdaq.com/databases/NOTOI.*

[20] *See supra* note 5.

in the industry and evolving customer needs.

The Exchange also does not believe the proposed fees would cause any unnecessary or inappropriate burden on intermarket competition, as other exchanges are free to introduce their own comparable reports with additional data points and lower prices to better compete with the Exchange's offerings. The Exchange operates in a highly competitive environment, and its ability to price the TBT Report is constrained by competition among exchanges that offer similar products. Setting fees that are not commensurate with the value of the TBT Report relative to fees for similar data products would simply serve to reduce demand for the TBT Report, which market participants are under no obligation to purchase. In this competitive environment, potential purchasers are free to choose which, if any, similar product to purchase to satisfy their need for market information. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges.

The Exchange does not believe the proposed rule change would cause any unnecessary or inappropriate burden on intramarket competition. The TBT Report is entirely optional and available to anyone who believes the data will be helpful for their purposes, and the proposed fees apply uniformly to any purchaser, in that the Exchange does not differentiate between the different market participants that may purchase the report, other than through the free sample, which is available on equal terms to all eligible purchasers.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from Trading Permit Holders or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

A. significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. 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) of the Act[21] and Rule 19b–4(f)(6)[22] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–C2–2026–029 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–C2–2026–029. 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 filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–C2–2026–029 and should be submitted on or before November 27, 2026.

[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b–4(f)(6).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22652 Filed 11–5–26; 8:45 am]

BILLING CODE 8011–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36958 (Sub-No. 1)]

Wilkes-Barre Terminal Railway Company—Acquisition, Operation and Change of Operator Exemption—Luzerne County Redevelopment Authority and Luzerne County Rail Corporation, and R.J. Corman Railroad Company/Luzerne & Susquehanna Line, LLC

Wilkes-Barre Terminal Railway Company (WBT), a noncarrier, has filed a supplemented and restated verified notice of exemption under 49 CFR 1150.31 to acquire approximately 59.65 miles of rail line (the Line) from the Luzerne County Redevelopment Authority (LCRA) and the operating rights from LCRA's non-operating subsidiary Luzerne County Rail Corporation (LCRC), in Luzerne County, Pa. WBT also seeks authority to terminate the leasehold common carrier operations for the incumbent operator, R.J. Corman Railroad Company/Luzerne & Susquehanna Line, LLC (RJLS), for a portion of the Line that it operates. *See R.J. Corman R.R. Co./Luzerne & Susquehanna Line—Change in Operators, Lease and Operation Exemption—Luzerne and Susquehanna Ry. Co. and Luzerne Cnty. Rail Corp.,* Docket No. FD 36429 (STB served Nov. 6, 2020).[1] The Line consists of the following in-service segments: (1) the Dunmore Secondary Track, between milepost 6.5, at Avoca, Pa., and milepost 10+/− North side Montage Road Crossing, a distance of 4.5 miles;[2] (2) the Avoca Industrial Track, between milepost 1.8, at Number 7 Junction, and milepost 6.5, at Avoca, a distance of 4.7

[23] 17 CFR 200.30–3(a)(12).

[1] WBT previously filed a verified notice of exemption for the acquisition and operation of the Line in Docket No. FD 36958. *See Wilkes-Barre Terminal Ry.—Acquis. & Operation Exemption—Luzerne Cnty. Redevelopment Auth. & Luzerne Cnty. Rail Corp.,* FD 36958 (STB served Oct. 15, 2026). The supplemented and restated verified notice adds the change in operator authority for WBT to replace RJLS as a common carrier on a portion of the Line.

[2] The portion of the Dunmore Secondary Track, between milepost 8.6, at Rocky Glen, Pa., and milepost 10+/− north side Montage Road crossing, a distance of 1.4 miles, is out of service.

miles,[3] including the connection with the track of Reading Blue Mountain & Northern Railroad Company (RBMN) between LB Junction and the switch of the Dunmore Secondary Track, a distance of 0.123 miles, and the Langcliff Connecting Track, between milepost 0.0, at Duryea, Pa., and the connection with Norfolk Southern Railway in the middle of York Avenue, at milepost 0.867, a distance of 0.867 miles; (3) the Suscon Industrial Track, between milepost 154.5, at Suscon, Pa., and milepost 158.7, at Hillside, Pa., a distance of 4.2 miles; (4) the Wilkes-Barre Secondary, between milepost 169.2, at Ashley, Pa., and milepost 185.5, at Pittston, Pa., a distance of 16.3 miles; (5) the GWBP Industrial Track, between milepost 0.0, at Ashley, and milepost 0.5, at Hanover Industrial Track, a distance of 0.5 miles; (6) the Brownsville Industrial Track, between milepost 0.0, at Hillside, and milepost 1.0, at Brownsville, Pa., a distance of 1.0 miles; (7) the Wilkes-Barre Industrial Track, between milepost 59.9, at Ferry Street, and milepost 62.9, at Wilkes-Barre, Pa., a distance of 3.0 miles; (8) the Kingston Industrial Track, between milepost 142.7, at Pittston Junction, and Railroad Station 8594+58, a distance of 8.1 miles; (9) the D&H Wilkes-Barre Connector, from milepost A–208.08, Hudson Yard, to Conyngham Avenue, City of Wilkes-Barre, Pa., a distance of 2.5 miles; and (10) the APC line, between milepost 0.0 and 0.6 in Wilkes-Barre, a distance of 0.6 miles.

The Line consists of the following out-of-service segments: (1) the West Pittston Running Track, between milepost 0.0, at West Pittston, Pa., and milepost 3.0, at Harding, Pa., a distance of 3.0 miles, and between milepost 186.4, at West Pittston, and milepost 190.2, at Wyoming, Pa., a distance of 3.8 miles, and between milepost 194.2, at Wyoming, and milepost 194.4, in Kingston, Pa., a distance of 0.2 miles; (2) the Nanticoke Industrial Track, between milepost 0.0, at Ashley, and milepost 2.6 at Central Scrap, a distance of 2.6 miles; (3) the Harry E. Breaker Spur, between milepost 0.1, at Maltby Junction, and milepost 0.5, a distance of 0.4 miles; (4) the Miner's Mills Industrial Track, between milepost 173.6, at North Wilkes-Barre, and milepost 176.1, at Hudson, Pa., a distance of 2.5 miles; and (5) the Pettibone Branch, between milepost 0.0 and milepost 0.759, at Dorranceton, Pa., a distance of 0.759 miles.[4]

According to the supplemented and restated verified notice, WBT will enter into an agreement with LCRA and LCRC for the acquisition of the Line and operating rights to ensure continued rail service to customers. WBT states that RJLS is currently the common carrier operator for approximately 41.19 miles of the Line pursuant to a lease that has expired. According to the supplemented and restated verified notice, RJLS will be replaced as the common carrier operator, and RJLS's common carrier status over the 41.9-mile portion will terminate.

According to the supplemented and restated verified notice, WBT will grant local trackage rights to RBMN to provide immediate rail service to customers on the Line following the expiration of the incumbent operator's lease. *See Reading Blue Mountain & Northern R.R.—Trackage Rights Exemption—Wilkes-Barre Terminal Ry.,* Docket No. FD 36959 (STB served Oct. 15, 2026), (authorizing RBMN to acquire local trackage rights over the in-service segments of the Line).[5]

According to WBT, the proposed transaction does not contain an interchange commitment. WBT certifies that its projected annual revenues resulting from the transaction will not exceed $5 million and will not result in WBT's becoming a Class I or Class II rail carrier.

Under 49 CFR 1150.32(b), a change in operator requires that notice be given to shippers. WBT certifies that it has contacted all customers on the Lines to advise them of the planned change in operators.[6] WBT also certifies that it conferred with RJLS concerning the termination of RJLS's common carrier status and that RJLS consents to the change of operator arrangement.

The earliest this transaction may be consummated is November 22, 2026, the effective date of the exemption (30 days after the verified notice was filed).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than November 13, 2026 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36958 (Sub-No. 1), must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on WBT's representative, Justin J. Marks, Clark Hill PLC., 601 13th Street NW, Suite 600, Washington, DC 20005.

According to WBT, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: November 3, 2026.

By the Board, Anika S. Cooper, Chief Counsel, Office of Chief Counsel.

Stefan Rice,

Clearance Clerk.

[FR Doc. 2026–22666 Filed 11–5–26; 8:45 am]

BILLING CODE 4915–01–P

[3] The portion of the Avoca Industrial Track, between milepost 1.8, at Number 7 Junction, and milepost 4, at Rock Street, a distance of 2.2 miles, is out of service.

[4] According to the verified notice, the out-of-service segments are included as part of the proposed transaction because WBT has found no regulatory history to suggest that these segments have been abandoned. WBT states that, although these segments are unlikely to be placed back into active service, WBT recognizes that it will have a common carrier obligation over the out-of-service segments.

[5] Upon consummation of its acquisition authority in this docket, WBT will become a Class III rail carrier. The trackage rights authority in Docket No. FD 36959 cannot be consummated until WBT has exercised its acquisition authority.

[6] WBT also states in its verified notice that it served each affected customer with a copy of the verified notice.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No: FAA–2026–13267]

Deadline for Submitting Intent To Use Airport Improvement Program (AIP) Apportioned Funds for Fiscal Year (FY) 2027

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

ACTION: Notice.

SUMMARY: Title 49 U.S.C. 47105(f) provides that every sponsor of an airport for which AIP funds are apportioned shall notify the Secretary, by such time and in a form prescribed by the Secretary, of its intent to submit a grant application for its available entitlement funds. This notice establishes the annual national deadline and requirements for every airport sponsor to signal their intent to submit applications for FY 2027 AIP entitlement funds. This is necessary to ensure the FAA has sufficient time to convert and carry over (protect) undeclared apportionment funds.

FOR FURTHER INFORMATION CONTACT: Airports AIP Program Branch, at *9-ASE-ARP-AIP-Airports@faa.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 49 U.S.C. 47105(f), each airport sponsor receiving apportioned funds must inform the Secretary of its intention to apply for these funds, including any unused funds from previous years (protected carryover). Each airport sponsor must submit notifications for each airport receiving an entitlement amount to their FAA Regional Airports Division/Airports District Office by the national deadline of February 26, 2027. This notification is essential for the efficient planning and management of the AIP. The FAA will carry over and protect any undeclared apportioned funds after this date. Undeclared apportioned funds will be unavailable to the sponsor until the next fiscal year.

The notification must be in writing and include the total amount planned for eligible projects during the FY and confirmation of which projects listed in their Capital Improvement Plans for the current FY will proceed.

State aviation agencies in the FAA's State Block Grant Program must also notify the FAA by this date, with information consistent with the latest Memorandum of Agreement. This should include a plan for both entitlement and state apportionment funds.

Funds from previous FYs that are still available may not be immediately accessible to sponsors when the FAA initiates the AIP for a new fiscal year. The FAA can only issue grants when sufficient funds are appropriated.

Airport sponsors must submit applications for entitlement-only grants on or before April 30, 2027. These applications should be based on construction bids (or negotiated agreements) but may be based on estimates. Final bid dates should be coordinated with your local Region or Airport District Office (ADO), as appropriate, to ensure all grants can be issued based on bids. The submitted applications must comply with statutory pre-grant requirements, including the National Environmental Policy Act and Buy American requirements. If you are unable to meet the required dates, please contact your ADO.

Issued in Washington, DC, on October 29, 2026.

William C. Garrison,

Director, Office of Airport Planning and Programming,

[FR Doc. 2026–22651 Filed 11–5–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent of Waiver With Respect to Land; Watertown Regional Airport, Watertown, South Dakota

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The FAA is considering a proposal to change approximately 4.99 acres of airport land from aeronautical use to non-aeronautical use and to authorize the sale of airport property located at the Watertown Regional Airport, Watertown, SD. The aforementioned land is not needed for aeronautical use. The subject property is made up of two parcels of airport property known as the Lot 4 (2.0 acres) and Dakota Tube (2.99 acres) parcels. These parcels are located north of the airport, along the east side of Airport Drive. Both properties are currently being used for industrial purposes and will continue to be used for the same purpose in the future.

DATES: Comments must be received on or before December 7, 2026.

ADDRESSES: All requisite and supporting documentation will be made available for review by appointment at the FAA Dakota-Minnesota Airports District Office, David Ferrell, Program Manager, 2301 University Drive, Building 23B, Bismarck, ND 58504, Telephone: (701) 323–7380.

Written comments on the Sponsor's request may be submitted using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* David Ferrell, Program Manager, Federal Aviation Administration, Dakota-Minnesota Airports District Office, 2301 University Drive, Building 23B, Bismarck, ND 58504.
- *Hand Delivery:* Deliver to mail address above between 8 a.m. and 4 p.m. Monday through Friday, excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: David Ferrell, Program Manager, Federal Aviation Administration, Dakota-Minnesota Airports District Office, 2301 University Drive, Building 23B, Bismarck, ND 58504. Telephone: (701) 323–7380.

SUPPLEMENTARY INFORMATION: In accordance with section 47107(h) of Title 49, United States Code, this notice is required to be published in the **Federal Register** 30 days before modifying the land-use assurance that requires the property to be used for an aeronautical purpose.

On November 4, 1947, the United States of America, acting by and through the War Assets Administrator, transferred the subject properties to the City of Watertown via quitclaim deed as surplus property. The properties are not needed for aeronautical purposes and are currently being used for commercial industrial purposes. They will continue to be used for commercial industrial purposes after the proposed sale of the properties. The Airport Sponsor will receive fair market value for the sale of the subject properties.

The disposition of proceeds from the sale of this airport property will be in accordance with sections 47125 and 47151 of Title 49, United States Code and 14 CFR part 155, Release of Airport Property From Surplus Property Disposal Restrictions.

This notice announces that the FAA is considering the release of the subject airport property at the Watertown Regional Airport, Watertown, SD, from federal land covenants, subject to a reservation for continuing right of flight as well as restrictions on the released property as required in FAA Order 5190.6C, section 22.13. Approval does not constitute a commitment by the FAA to financially assist in the disposal of the subject airport property nor a determination of eligibility for grant-in-aid funding from the FAA.

Property Descriptions

Plat of Lot 4 of Airport Industrial Addition to the Municipality of Watertown, South Dakota, Located in the South Half of Section 23—T117N–R53W of the 5th PM, Codington County, South Dakota.

Plat of Dakota Tube Airport Industrial Addition to the Municipality of Watertown, Located in the South half of Section 23—T117N–R53W, Codington County, South Dakota.

Issued in Minneapolis, Minnesota, on October 26, 2026.

E. Lindsay Terry,

Manager, Dakota-Minnesota Airports District Office, FAA, Great Lakes Region.

[FR Doc. 2026–22678 Filed 11–5–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2026–1784]

Request Notice: Use of Foreign-Built Small Passenger Vessel in United States Coastwise Trade, M/V JULIANA

AGENCY: Maritime Administration (MARAD), U.S. Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: The Secretary of Transportation, as represented by MARAD, is authorized to make determinations regarding the coastwise use of foreign built; certain U.S. built; and U.S. and foreign rebuilt vessels that solely carry no more than twelve passengers for hire. MARAD has received such a determination request and is publishing this notice to solicit comments to assist with determining whether the proposed use of the vessel set forth in the request would have an adverse effect on U.S. vessel builders or U.S. coastwise trade businesses that use U.S.-built vessels in those businesses. Information about the requestor's vessel, including a description of the proposed service, is in the **SUPPLEMENTARY INFORMATION** section below.

DATES: Submit comments on or before December 7, 2026.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2026–1784 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search the above DOT Docket Number and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include the DOT Docket Number, your name and a mailing address, an email address or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific DOT Docket Number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Ye Tian, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Mail Stop 2, MAR–620, Washington, DC 20590. Telephone: (202) 366–5400. Email: *smallvessels@dot.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 46 U.S.C. 12121(b), the U.S. Coast Guard may issue a certificate of documentation with a coastwise trade endorsement for eligible, small passenger vessels authorized to carry no more than 12 passengers for hire if MARAD, after notice and an opportunity for public comment, determines the use of the small passenger vessel in the coastwise trade will not adversely affect United States vessel builders or the coastwise trade business of any person that employs vessels built in the United States in that business.[1]

MARAD has received an eligibility determination request. Further details about the requester's vessel and its proposed operations may be found in the determination request posted in the DOT Docket Number listed in the **ADDRESSES** section above at *https://www.regulations.gov.* Interested parties may comment on the undue adverse effect this action may have on U.S. vessel builders or coastwise trade businesses in the U.S. that employ U.S.-built vessels in those businesses. Comments should refer to the vessel name, state the commenter's interest in the request, and demonstrate, with supporting documentation, the undue adverse effect on U.S. vessel builders and coastwise trade businesses.

Public Participation

How do I submit comments?

Please submit comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. It may take a few hours or even days for comments to be reflected on the docket. Comments must be written in English. Provide concise comments and attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

The docket online is located at *https://www.regulations.gov,* keyword search the DOT Docket Number list in the **ADDRESSES** section above or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). Please periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

You may request that MARAD treat your comments as commercially confidential by submitting them to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential treatment highlighting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

If MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 46 U.S.C. 12121, 49 CFR 1.93(a))

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2026–22699 Filed 11–5–26; 8:45 am]

BILLING CODE 4910–81–P

[1] The U.S. Coast Guard and MARAD have authority under 46 U.S.C. 12121(b) through the Secretary of the Department of Homeland Security and the Secretary of the Department of Transportation, respectively.

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2026–1750]

Request Notice: Use of Foreign-Built Small Passenger Vessel in United States Coastwise Trade, M/V ISLAND VIBEZ

AGENCY: Maritime Administration (MARAD), U.S. Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: The Secretary of Transportation, as represented by MARAD, is authorized to make determinations regarding the coastwise use of foreign built; certain U.S. built; and U.S. and foreign rebuilt vessels that solely carry no more than twelve passengers for hire. MARAD has received such a determination request and is publishing this notice to solicit comments to assist with determining whether the proposed use of the vessel set forth in the request would have an adverse effect on U.S. vessel builders or U.S. coastwise trade businesses that use U.S.-built vessels in those businesses. Information about the requestor's vessel, including a description of the proposed service, is in the **SUPPLEMENTARY INFORMATION** section below.

DATES: Submit comments on or before December 7, 2026.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2026–1750 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search the above DOT Docket Number and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include the DOT Docket Number, your name and a mailing address, an email address or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific DOT Docket Number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Ye Tian, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Mail Stop 2, MAR–620, Washington, DC 20590. Telephone: (202) 366–5400. Email: *smallvessels@dot.gov*

SUPPLEMENTARY INFORMATION: Pursuant to 46 U.S.C. 12121(b), the U.S. Coast Guard may issue a certificate of documentation with a coastwise trade endorsement for eligible, small passenger vessels authorized to carry no more than 12 passengers for hire if MARAD, after notice and an opportunity for public comment, determines the use of the small passenger vessel in the coastwise trade will not adversely affect United States vessel builders or the coastwise trade business of any person that employs vessels built in the United States in that business.[1]

MARAD has received an eligibility determination request. Further details about the requester's vessel and its proposed operations may be found in the determination request posted in the DOT Docket Number listed in the **ADDRESSES** section above at *https://www.regulations.gov.* Interested parties may comment on the undue adverse effect this action may have on U.S. vessel builders or coastwise trade businesses in the U.S. that employ U.S.-built vessels in those businesses. Comments should refer to the vessel name, state the commenter's interest in the request, and demonstrate, with supporting documentation, the undue adverse effect on U.S. vessel builders and coastwise trade businesses.

Public Participation

How do I submit comments?

Please submit comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. It may take a few hours or even days for comments to be reflected on the docket. Comments must be written in English. Provide concise comments and attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

The docket online is located at *https://www.regulations.gov,* keyword search the DOT Docket Number list in the **ADDRESSES** section above or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). Please periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

You may request that MARAD treat your comments as commercially confidential by submitting them to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential treatment highlighting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

If MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 46 U.S.C. 12121, 49 CFR 1.93(a))

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2026–22703 Filed 11–5–26; 8:45 am]

BILLING CODE 4910–81–P

[1] The U.S. Coast Guard and MARAD have authority under 46 U.S.C. 12121(b) through the Secretary of the Department of Homeland Security and the Secretary of the Department of Transportation, respectively.

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2026–1816]

Request for Comments on the Renewal of a Previously Approved Information Collection: Generic Clearance of Customer Satisfaction Surveys

AGENCY: Maritime Administration (MARAD), U.S. Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: MARAD invites public comments on its intention to request Office of Management and Budget (OMB) approval to renew an information collection in accordance with the Paperwork Reduction Act of 1995. The proposed collection OMB 2133–0546 (Generic Clearance of Customer Satisfaction Surveys) is used to obtain feedback about customer service delivery. MARAD is required to publish this notice in the **Federal Register** to obtain comments from the public and affected agencies.

ADDRESSES: Written comments and recommendations for the proposed information collections 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: Tamelia Bolton, 202–366–4623, Office of Management and Administrative Services, Maritime Administration, Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, Email: *Tamelia.Bolton@dot.gov.*

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance of Customer Satisfaction Surveys.

OMB Control Number: 2133–0546.

Type of Request: Extension without change of currently approved information collection.

Abstract: OMB 2133–0546 (Generic Clearance Customer Satisfaction Surveys) enables MARAD to garner customer and stakeholder feedback in an efficient and timely manner, in accordance with our commitment to improve service delivery. The collected information ensures that users have an effective, efficient, and satisfying experience with the agency's programs. This feedback also provides insight into customer or stakeholder perceptions, identifies issues with service delivery, and focuses attention on areas where communication, training, and/or changes in operations might improve customer service experience. Additionally, this collection will facilitate ongoing, collaborative, and actionable communication between MARAD and its customers and stakeholders. Public feedback is also expected to contribute directly to the improvement of program operations that directly affect the public.

Respondents: Individuals and households, business and organizations, State, local or Tribal government.

Estimated Number of Respondents: 5,900.

Estimated Number of Responses: 5,900.

Annual Estimated Total Annual Burden Hours: 1,758.

Frequency of Response: per request.

A 60-day **Federal Register** Notice soliciting comments on this information collection was published on September 3, 2026 (91 FR 56719). The posting received one non-substantive comment that the publication dates for the 60-day **Federal Register** Notice were incorrect. However, MARAD reviewed and verified the publication date for the **Federal Register** Notice and notified the commenter that no correction was needed.

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.49.)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.

Secretary, Maritime Administration.

[FR Doc. 2026–22704 Filed 11–5–26; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2026–1783]

Request Notice: Use of Foreign-built Small Passenger Vessel in United States Coastwise Trade, M/V NIUHI 2

AGENCY: Maritime Administration (MARAD), U.S. Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: The Secretary of Transportation, as represented by MARAD, is authorized to make determinations regarding the coastwise use of foreign built; certain U.S. built; and U.S. and foreign rebuilt vessels that solely carry no more than twelve passengers for hire. MARAD has received such a determination request and is publishing this notice to solicit comments to assist with determining whether the proposed use of the vessel set forth in the request would have an adverse effect on U.S. vessel builders or U.S. coastwise trade businesses that use U.S.-built vessels in those businesses. Information about the requestor's vessel, including a description of the proposed service, is in the **SUPPLEMENTARY INFORMATION** section below.

DATES: Submit comments on or before December 7, 2026.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2026–1783 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search the above DOT Docket Number and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include the DOT Docket Number, your name and a mailing address, an email address or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific DOT Docket Number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Ye Tian, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Mail Stop 2, MAR–620, Washington, DC 20590. Telephone: (202) 366–5400. Email: *smallvessels@dot.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 46 U.S.C. 12121(b), the U.S. Coast Guard may issue a certificate of documentation with a coastwise trade endorsement for eligible, small passenger vessels authorized to carry no more than 12 passengers for hire if MARAD, after notice and an opportunity for public comment, determines the use of the small passenger vessel in the coastwise trade

will not adversely affect United States vessel builders or the coastwise trade business of any person that employs vessels built in the United States in that business.[1]

MARAD has received an eligibility determination request. Further details about the requester's vessel and its proposed operations may be found in the determination request posted in the DOT Docket Number listed in the **ADDRESSES** section above at *https://www.regulations.gov.* Interested parties may comment on the undue adverse effect this action may have on U.S. vessel builders or coastwise trade businesses in the U.S. that employ U.S.-built vessels in those businesses. Comments should refer to the vessel name, state the commenter's interest in the request, and demonstrate, with supporting documentation, the undue adverse effect on U.S. vessel builders and coastwise trade businesses.

Public Participation

How do I submit comments?

Please submit comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. It may take a few hours or even days for comments to be reflected on the docket. Comments must be written in English. Provide concise comments and attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

The docket online is located at *https://www.regulations.gov,* keyword search the DOT Docket Number list in the **ADDRESSES** section above or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). Please periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

You may request that MARAD treat your comments as commercially confidential by submitting them to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential treatment highlighting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

If MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 46 U.S.C. 12121, 49 CFR 1.93(a))

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2026–22702 Filed 11–5–26; 8:45 am]

BILLING CODE 4910–81–P

[1] The U.S. Coast Guard and MARAD have authority under 46 U.S.C. 12121(b) through the Secretary of the Department of Homeland Security and the Secretary of the Department of Transportation, respectively.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Information Collection Activities; Comment Request Concerning Procedures for Requesting Competent Authority Assistance Under Tax Treaties

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of information collection; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the IRS is inviting comments on the information collection request outlined in this notice.

DATES: Written comments should be received on or before January 5, 2027 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Include ''OMB Control No. 1545–2044'' in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this collection should be directed to Jason Schoonmaker, (801) 620–6008.

SUPPLEMENTARY INFORMATION: The IRS, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the IRS assess the impact and minimize the burden of its information collection requirements. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record, and viewable on relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Title: Procedures for Requesting Competent Authority Assistance Under Tax Treaties.

OMB Control Number: 1545–2044.

Regulation: Revenue Procedure 2015–40.

Abstract: Taxpayers who believe that the actions of the United States, a treaty country, or both, result or will result in taxation that is contrary to the provisions of an applicable tax treaty are required to submit the requested information in order to received assistance from the IRS official acting as the U.S. competent authority. The information is used to assist the taxpayer in reaching a mutual agreement with the IRS and the appropriate foreign competent authority.

Current Actions: There is no change to the previously approved information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, business or other for-profit organizations.

Estimated Number of Responses: 280.

Estimated Time per Response: 30 hours.

Estimated Total Annual Burden Hours: 8,400.

Dated: November 4, 2026.

Jason M. Schoonmaker,

Tax Analyst.

[FR Doc. 2026–22701 Filed 11–5–26; 8:45 am]

BILLING CODE 4831–GV–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Information Collection Activities; Requesting Comment Notice of Taxpayer Statement Regarding Refund

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of information collection; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the IRS is inviting comments on the information collection request outlined in this notice.

DATES: Written comments should be received on or before January 5, 2027 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Include ''OMB Control No. 1545–1384'' in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this collection should be directed to Jason Schoonmaker, (801) 620–6008.

SUPPLEMENTARY INFORMATION: The IRS, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the IRS assess the impact and minimize the burden of its information collection requirements. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record, and viewable on relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Title: Taxpayer Statement Regarding Refund.

OMB Control Number: 1545–1384.

Form Number: 3911.

Abstract: Form 3911 is used by taxpayers to notify the IRS that a tax refund previously claimed has not been received. The form is normally completed by the taxpayer as the result of an inquiry in which the taxpayer claims non-receipt, loss, theft, or destruction of a tax refund and IRS research shows that the refund has been issued. The information on the form is needed to clearly identify the refund to be traced.

Current Actions: There is no change to the previously approved information collection. However, the time burden has been recalculated for a better estimate.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, business or other for-profit organizations, and not-for-profit institutions.

Estimated Number of Responses: 200,000.

Estimated Time per Response: 13 minutes.

Estimated Total Annual Burden Hours: 46,000.

Dated: November 3, 2026.

Jason M. Schoonmaker,

Tax Analyst.

[FR Doc. 2026–22675 Filed 11–5–26; 8:45 am]

BILLING CODE 4831–GV–P



FEDERAL REGISTER

Vol. 91 Friday,
No. 214 November 6, 2026

Part II

Environmental Protection Agency

40 CFR Part 52
Air Plan Approval; California; Revised Format for Materials Incorporated by Reference; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2024–0527; FRL–13582–01–R9]

Air Plan Approval; California; Revised Format for Materials Incorporated by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; administrative change.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is revising the format for materials submitted by the State of California that are incorporated by reference into the California State Implementation Plan (SIP). The regulations and other materials affected by this format change have all been previously submitted by the State of California and approved by the EPA. This format revision will primarily affect the ''Identification of plan—in part'' sections, as well as the format of the SIP materials that will be available for public inspection at the EPA Regional Office and the National Archives and Records Administration (NARA). This action, which only relates to rules applicable within six California air districts, is the fifth and final of a series of actions intended to change the format for the entire California SIP.

DATES: This rule is effective on November 6, 2026.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2024–0527. SIP materials which are incorporated by reference into 40 CFR part 52 are available for inspection by appointment at Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901. For information on the availability of this material at the EPA Regional Office, please contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document.

FOR FURTHER INFORMATION CONTACT: Doris Lo, EPA Region IX, 75 Hawthorne St., San Francisco, CA; telephone number: (415) 972–3959; email address: *lo.doris@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, the terms ''we'', ''us,'' and ''our'' refer to the EPA. This **SUPPLEMENTARY INFORMATION** section is organized as follows:

Table of Contents

I. Background
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B. How the EPA Enforces SIPs
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H. When a SIP Revision Becomes Federally Enforceable
I. The Historical Record of SIP Revision Approvals
II. What the EPA Is Doing in This Action
III. Incorporation by Reference
IV. Statutory and Executive Order Reviews

I. Background

A. Description of a SIP

Each State has a SIP containing, among other things, the control measures and strategies used to attain and maintain the national ambient air quality standards (NAAQS). The SIP is extensive, containing such elements as air pollution control regulations, emission inventories, monitoring networks, attainment demonstrations, and enforcement mechanisms.

B. How the EPA Enforces SIPs

Each State must formally adopt the control measures and strategies to attain and maintain the NAAQS after the public has had an opportunity to comment on them. They are then submitted to the EPA as requested SIP revisions upon which the EPA must formally act. Once these control measures and strategies are approved by the EPA, after notice and comment rulemaking, they are incorporated into the federally approved SIP and are identified in part 52 (Approval and Promulgation of Implementation Plans), title 40 of the Code of Federal Regulations (40 CFR part 52). The EPA uses the process of incorporation by reference (IBR) to incorporate material into the CFR by referencing the original document(s) without publishing the full text of the material. The actual State regulations approved by the EPA are not reproduced in their entirety in 40 CFR part 52 but are ''incorporated by reference,'' which means that the EPA has approved a given State regulation with a specific effective date. This format allows both the EPA and the public to know which measures are contained in a given SIP and to help determine whether the State is enforcing the regulations. This format also assists the EPA and the public in taking enforcement action, should a State not enforce its SIP-approved regulations.

C. How the State and the EPA Update the SIP

The SIP is a dynamic document, which the State can revise as necessary to address the unique air pollution problems in the State. Therefore, the EPA must periodically take action on State SIP revisions containing new and/or revised regulations and other materials in order to make them part of the federally-approved SIP. The EPA establishes a docket for its actions using a unique Docket Identification Number, which is listed in each action. These dockets and the complete submissions are available for viewing on *http://www.regulations.gov.*

On May 22, 1997 (62 FR 27968), the EPA revised the formatting procedures for incorporating by reference federally-approved SIP revisions, as a result of consultations between the EPA and the Office of the Federal Register. These procedures include: (1) a revised SIP document for each State that would use the IBR process under the provisions of title 1 CFR part 51; (2) a revised mechanism for announcing the EPA's approval of revisions to an applicable SIP and updating both the document that has gone through the IBR process and the CFR; and (3) a revised format of the ''Identification of Plan'' sections for each applicable subpart in 40 CFR part 52 to reflect these revised IBR procedures. The description of the revised SIP document, IBR procedures, and ''Identification of plan'' format are discussed in further detail in the May 22, 1997 (62 FR 27968) **Federal Register** document. We have taken action to revise the format for many State SIPs, *see, e.g.,* 40 CFR 52.1470 and 52.1490 (''Identification of plan'' and ''Original identification of plan'' sections for the State of Nevada SIP), and take a fifth and final step today toward revising the format of the California SIP.

D. How the EPA Compiles the SIPs

Under the revised SIP format, the federally-approved regulations, source-specific requirements, and nonregulatory provisions (entirely or portions of) submitted by each State agency have been compiled by the EPA into a ''SIP compilation.'' The SIP compilation contains the regulations, source-specific requirements, and nonregulatory and quasi-regulatory provisions approved by the EPA through previous rulemaking actions published in the **Federal Register**.

E. How the EPA Organizes the SIP Compilation

Each compilation contains three parts. Part one contains the regulations, part

two contains the source-specific requirements, and part three contains the nonregulatory and quasi-regulatory provisions that have been approved by the EPA as part of the SIP. Each part consists of a table or tables of identifying information for each SIP-approved regulation, each SIP-approved source-specific requirement, and each nonregulatory or quasi-regulatory SIP provision. The EPA Regional Offices have the primary responsibility for updating the compilations and ensuring their accuracy.

F. Where You Can Find a Copy of the SIP Compilation

EPA Region IX has developed and will maintain the SIP compilation for California. A copy of the full text of California's regulatory and source-specific SIP compilation will also be maintained at NARA.

G. The Format of the California Identification of Plan Sections

Given the size of the California SIP, the EPA is revising the format of the California SIP in a phased manner. On May 26, 2016 (81 FR 33397), the EPA took the first action to revise the format of the ''Identification of plan'' section in subpart F in accordance with the revised format described in section I.C. of this document. Through the first action, we revised the heading of 40 CFR 52.220 to read, ''Identification of plan—in part,'' and added an introductory paragraph to convey our division of the California ''Identification of plan'' section into two sections:

- Amended 40 CFR 52.220 (renamed ''Identification of plan—in part''), which would continue for the time being to function as it has in the past to list past and newly-approved air district rules, local ordinances, source-specific requirements, and nonregulatory and quasi-regulatory provisions and which lists State statutes and State regulations approved on or prior to April 1, 2016; and
- New 40 CFR 52.220a (''Identification of plan—in part''), which lists the State statutes and State regulations approved as part of the California SIP as of April 1, 2016, using the new table format.

This meant that subsequent EPA approvals of air district rules, local ordinances, source-specific requirements, and nonregulatory and quasi-regulatory provisions would continue to be promulgated in 40 CFR 52.220 using the paragraph format whereas subsequent EPA approvals of State statutes and State regulations would be promulgated in 40 CFR 52.220a using the table format. In preparation for future actions to revise the format of the remaining portions of the California SIP, the May 26, 2016 action also organized 40 CFR 52.220a into five paragraphs: (a) Purpose and scope; (b) Incorporation by reference; (c) EPA-approved regulations; (d) EPA-approved source-specific requirements; and (e) EPA-approved nonregulatory provisions and quasi-regulatory measures. ''Nonregulatory provisions and quasi-regulatory measures'' refers to items such as transportation control measures, certain nonregulatory statutory provisions, control strategies, and monitoring networks.

Our phased approach to converting the format of the California SIP anticipated that, over time, as the EPA completes further rulemaking actions to convert the format of the California SIP, 40 CFR 52.220a would include a growing number of air district rules, local ordinances, source-specific requirements, and nonregulatory and quasi-regulatory provisions. On June 4, 2025 (90 FR 23618), the EPA took a second action to revise the format of the California SIP by converting the format for local ordinances and air district rules approved on or prior to April 17, 2025, for the following air districts: Amador Air District, Antelope Valley Air Quality Management District (AQMD), Bay Area AQMD, Butte County AQMD, Calaveras County Air Pollution Control District (APCD), Colusa County APCD, Eastern Kern APCD, and El Dorado County AQMD.

A third action was taken on July 7, 2025 (90 FR 29934) that converted the format for the nonregulatory provisions and quasi-regulatory measures portion of the California SIP approved on or prior to July 3, 2025. On August 21, 2025 (90 FR 40896), the EPA took a fourth action to revise the format of the California SIP by converting the format for source-specific requirements and air district rules approved on or prior to June 30, 2025, for the following air districts: Feather River Air Quality Management District (AQMD), Glenn County Air Pollution Control District (APCD), Great Basin Unified APCD, Imperial County APCD, Lake County AQMD, Lassen County APCD, Mariposa County APCD, Mendocino County AQMD, Modoc County APCD, Monterey Bay Air Resources District, North Coast Unified AQMD, Northern Sierra AQMD, Northern Sonoma County APCD, San Diego County APCD, San Luis Obispo County APCD, Santa Barbara County APCD, Shasta County AQMD, Siskiyou County APCD, Tehama County APCD, Tuolumne County APCD, and Yolo-Solano County AQMD.

In this fifth action to revise the format of the California SIP, we are converting the format and publishing the tables listing EPA-approved rules adopted by the following six California air districts: Mojave Desert AQMD, Placer County APCD, Sacramento Metropolitan AQMD, San Joaquin Valley Unified APCD, South Coast AQMD, and Ventura County APCD. This format revision involves materials approved on or before August 31, 2026 that are part of the current applicable SIP.

Through this fifth and final action, the EPA is completing the conversion process for the California SIP. As anticipated in the earlier actions, the EPA is redesignating 40 CFR 52.220a as 40 CFR 52.220 and renaming it simply ''Identification of plan.'' All subsequent actions by the EPA to approve California SIP revisions will be promulgated using the new table format. The revised format does not affect federal enforceability of the SIP and is consistent with the requirements of section 110(h)(1) of the Clean Air Act (CAA) concerning comprehensive SIP publication.

H. When a SIP Revision Becomes Federally Enforceable

All revisions to the applicable SIP become federally enforceable as of the effective date of the revisions to paragraphs (c), (d), or (e) of the applicable Identification of Plan section found in each subpart of 40 CFR part 52.

I. The Historical Record of SIP Revision Approvals

To facilitate enforcement of previously-approved SIP provisions and provide a smooth transition to the new SIP processing system, the EPA is redesignating the ''Identification of plan—in part'' section for California appearing in 40 CFR 52.220 as 40 CFR 52.250 and renaming the newly-redesignated section as ''Original identification of plan.'' After an initial one or two-year period, the EPA will review its experience with the new SIP processing system and decide whether to retain the ''Original identification of plan'' section for some further period.

II. What the EPA Is Doing in This Action

In this action, the EPA is revising the format for portions of the applicable California SIP related to the rules from the following six air districts: Mojave Desert AQMD, Placer County APCD, Sacramento Metropolitan AQMD, San Joaquin Valley Unified APCD, South Coast AQMD, and Ventura County APCD. This format revision involves materials approved on or before August

31, 2026, that are part of the current applicable SIP.

This action constitutes a ''housekeeping'' exercise to ensure that all EPA-approved revisions to the State programs that have occurred are accurately reflected in 40 CFR part 52. The requirements that apply to States and that relate to SIPs and SIP revisions are set forth in the Clean Air Act and in the EPA's regulations at 40 CFR part 51. When the EPA receives a formal SIP revision request, the Agency must publish the proposed revision in the **Federal Register** and provide for public comment before approval.

The EPA has determined that this rule falls under the ''good cause'' exemption in section 553(b)(B) of the Administrative Procedure Act (APA) which, upon finding ''good cause,'' authorizes agencies to dispense with public participation and section 553(d)(3) which allows an agency to make a rule effective immediately, thereby avoiding the 30-day delayed effective date otherwise provided for in the APA. This action simply reformats and recodifies provisions which are already in effect as a matter of law in Federal and approved State programs. Under section 553 of the APA, an agency may find good cause where notice and public procedure are ''impractical, unnecessary, or contrary to the public interest.'' Public comment is ''unnecessary'' and ''contrary to the public interest'' for this action because the EPA is merely reformatting and recodifying existing law. Immediate notice in the CFR benefits the public by removing outdated citations and making the IBR format clearer and more user-friendly.

III. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is reformatting the materials incorporated by reference in previous rulemakings on submittals of the California SIP and SIP revisions, as described in section II of this preamble. The EPA has made, and will continue to make, these documents generally available through *www.regulations.gov* and at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

A. General Requirements

This action does not impose additional requirements beyond those previously approved into the SIP and already 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 Order 12866 (58 FR 51735, October 4, 1993);
- Is not an Executive Order 14192 (90 FR 9065, February 6, 2025) regulatory action because this action is not significant under Executive Order 12866;
- 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, as 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 subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is an administrative action related to State program approval;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- 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.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the 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).

B. Submission to Congress and the Comptroller General

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. 5 U.S.C. 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This action simply reformats and recodifies provisions that are already in effect as a matter of law in Federal and approved State programs (*See* 5 U.S.C. 802(2)). As stated previously, the EPA has made such a good cause finding, including the basis for that finding, and established an effective date of November 6, 2026. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

The EPA has also determined that the provisions of section 307(b)(1) of the CA A pertaining to petitions for judicial review are not applicable to this action. Prior EPA rulemaking actions for each individual component of the California SIP compilation had previously afforded interested parties the opportunity to file a petition for judicial review in the United States Court of Appeals for the appropriate circuit within 60 days of such rulemaking action. Thus, the EPA believes judicial review of this action under section 307(b)(1) is not available.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon oxides, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen oxides, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: October 29, 2026.

Michael Martucci,

Acting Regional Administrator, Region IX.

For the reasons stated in the preamble, the Environmental Protection Agency amends part 52, chapter I, title 40 of the Code of Federal Regulations as follows:

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 F—California

■ 2. Section 52.220 is redesignated as § 52.250 and the newly-redesignated section is amended by:

■ a. Revising the section heading;
■ b. Removing the introductory text; and
■ c. Revising paragraph (a).
The revisions read as follows:

§ 52.250 Original identification of plan.

(a) This section identified the original ''The State of California Implementation Plan for Achieving and Maintaining the National Ambient Air Quality Standards'' and all revisions to California statutes and State regulations submitted by the State of California and approved as part of the California State implementation plan on or prior to April 1, 2016; all new or amended local ordinances approved on or prior to April 17, 2025; all new or amended air district rules approved on or prior to April 17, 2025 for the following air districts: Amador Air District, Antelope Valley Air Quality Management District, Bay Area Air Quality Management District, Butte County Air Quality Management District, Calaveras County Air Pollution Control District, Colusa County Air Pollution Control District, Eastern Kern Air Pollution Control District, and El Dorado County Air Quality Management District; all new or amended nonregulatory materials approved on or prior to July 3, 2025; all new or amended source-specific requirements approved on or prior to June 30, 2025; all new or amended air district rules approved on or prior to June 30, 2025 for the following air districts: Feather River Air Quality Management District, Glenn County Air Pollution Control District, Great Basin Unified Air Pollution Control District, Imperial County Air Pollution Control District, Lake County Air Quality Management District, Lassen County Air Pollution Control District, Mariposa County Air Pollution Control District, Mendocino County Air Quality Management District, Modoc County Air Pollution Control District, Monterey Bay Air Resources District, North Coast Unified Air Quality Management District, Northern Sierra Air Quality Management District, Northern Sonoma County Air Pollution Control District, San Diego County Air Pollution Control District, San Luis Obispo County Air Pollution Control District, Santa Barbara County Air Pollution Control District, Shasta County Air Quality Management District, Siskiyou County Air Pollution Control District, Tehama County Air Pollution Control District, Tuolumne County Air Pollution Control District, and Yolo-Solano County Air Quality Management District; and all new or amended air district rules approved on or prior to August 31, 2026 for the following air districts: Mojave Desert Air Quality Management District, Placer County Air Pollution Control District, Sacramento Metropolitan Air Quality Management District, San Joaquin Valley Unified Air Pollution Control District, South Coast Air Quality Management District, and Ventura County Air Pollution Control District.

* * * * *

■ 3. Section 52.220a is redesignated as § 52.220 and the newly redesignated section is amended by:
■ a. Revising the section heading;
■ b. Revising paragraphs (b)(1) introductory text, (b)(1)(xxi), (b)(1)(xxvi), (b)(1)(xxvii), (b)(1)(xxix), (b)(1)(xxxiv) and (b)(1)(xxxvii);
■ c. Adding paragraph (b)(1)(xxxix);
■ d. Revising paragraph (c) introductory text, and tables 21, 26, 27, 29, 34 and 37 to paragraph (c); and
■ e. Revising paragraphs (d) introductory and (e) introductory text.
The revisions and addition read as follows:

§ 52.220 Identification of plan.

* * * * *

(b) * * *

(1) Material listed in paragraphs (c) and (d) of this section with an EPA approval date on or prior to the dates listed in this paragraph (b)(1) was approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Material is incorporated as it exists on the date of the approval and notice of any change in the material will be published in the **Federal Register**. Entries in tables 1 through 38 to paragraph (c) of this section and paragraph (d) of this section with EPA approval dates after the dates listed in this paragraph (b)(1) have been approved by the EPA for inclusion in the State implementation plan and will be incorporated by reference in the next update to the SIP compilation.

* * * * *

(xxi) *EPA-Approved Mojave Desert Air Quality Management District Regulations (District-Wide, Riverside County Portion of District, And San Bernardino County Portion of District).* Material listed in Table 21 to paragraph (c) of this section was approved by EPA for inclusion in the SIP on August 31, 2026.

* * * * *

(xxvi) *EPA-Approved Placer County Air Pollution Control District Regulations.* Material listed in Table 26 to paragraph (c) of this section was approved by EPA for inclusion in the SIP on August 31, 2026.

(xxvii) *EPA-Approved Sacramento Metropolitan Air Quality Management District Regulations.* Material listed in Table 27 to paragraph (c) of this section was approved by EPA for inclusion in the SIP on April 22, 2026.

* * * * *

(xxix) *EPA-Approved San Joaquin Valley Unified Air Pollution Control District Regulations; Fresno County Air Pollution Control District Regulations; Kern County Air Pollution Control District Regulations; Kings County Air Pollution Control District Regulations; Madera County Air Pollution Control District Regulations; Merced County Air Pollution Control District Regulations; San Joaquin County Air Pollution Control District Regulations; Stanislaus County Air Pollution Control District Regulations; Tulare County Air Pollution Control District Regulations.* Material listed in Table 29 to paragraph (c) of this section was approved by EPA for inclusion in the SIP on August 31, 2026.

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(xxxiv) *EPA-Approved South Coast Air Quality Management District Regulations; Los Angeles County Air Pollution Control District Regulations; Orange County Air Pollution Control District Regulations; Riverside County Air Pollution Control District Regulations; San Bernardino County Air Pollution Control District Regulations.* Material listed in Table 34 to paragraph (c) of this section was approved by EPA for inclusion in the SIP on August 31, 2026.

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(xxxvii) *EPA-Approved Ventura County Air Pollution Control District Regulations.* Material listed in Table 37 to paragraph (c) of this section was approved by EPA for inclusion in the SIP on August 31, 2026.

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(xxxix) *EPA-Approved Source-Specific Requirements.* Material listed in paragraph (d) of this section was approved by EPA for inclusion in the SIP on June 30, 2025.

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(c) *EPA-approved regulations.* References to paragraphs in 40 CFR 52.220 in entries in tables 1 through 38 to paragraph (c) should be understood to refer to the corresponding paragraphs in 40 CFR 52.250.

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TABLE 21—EPA-APPROVED MOJAVE DESERT AIR QUALITY MANAGEMENT DISTRICT REGULATIONS

[District-Wide, Riverside County Portion of District, and San Bernardino County Portion of District]

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
Rules and Regulations (District-Wide)				
Regulation I—General Provisions				
102	Definition of Terms	September 28, 2020	January 8, 2026, 91 FR 607.	Submitted on March 12, 2021 as an attachment to a letter dated March 10, 2021. See 40 CFR 52.220(c)(587)(i)(B)(*1*).
103	Description of District Boundaries	June 28, 1995	June 3, 1999, 64 FR 29790.	Submitted by CARB on August 10, 1995. See 40 CFR 52.220(c)(224)(i)(C)(*2*).
104	Reporting of Source Test Data and Analyses.	December 19, 1988	December 4, 2024, 89 FR 96103.	Submitted by CARB on October 13, 2023. See 40 CFR 52.220(c)(622)(i)(A)(*1*).
Regulation II—Permits				
206	Posting of Permit to Operate	February 22, 2021	June 30, 2023, 88 FR 42258.	Submitted by CARB on October 15, 2021 as an attachment to a letter dated October 14, 2021. See 40 CFR 52.220(c)(601)(i)(A)(*1*).
219	Equipment Not Requiring a Permit	January 25, 2021	June 30, 2023, 88 FR 42258.	Submitted by CARB on July 23, 2021 as an attachment to a letter dated July 22, 2021. See 40 CFR 52.220(c)(600)(i)(A)(*1*).
221	Federal Operating Permit Requirement.	December 21, 1994	February 5, 1996, 61 FR 4217.	Submitted by CARB on March 31, 1995. See 40 CFR 52.220(c)(216)(i)(A)(*2*).
222	Limitations on Potential to Emit	July 31, 1995	August 31, 2004, 69 FR 53005.	Submitted by CARB on October 13, 1995. See 40 CFR 52.220(c)(225)(i)(H)(*1*).
Regulation IV—Prohibitions				
403.1	Fugitive Dust Control for the Searles Valley Planning Area.	November 25, 1996	August 13, 2009, 74 FR 40750.	Submitted by CARB on March 3, 1997. See 40 CFR 52.220(c)(244)(i)(C)(*2*).
404	Particulate Matter—Concentration	July 25, 1977	December 4, 2024, 89 FR 96103.	Submitted electronically by CARB on May 11, 2023 as an attachment to a letter dated May 10, 2023. See 40 CFR 52.220(c)(610)(i)(D)(*1*).
405	Solid Particulate Matter—Weight	July 25, 1977	December 4, 2024, 89 FR 96103.	Submitted electronically by CARB on May 11, 2023 as an attachment to a letter dated May 10, 2023. See 40 CFR 52.220(c)(610)(i)(D)(*2*).
407	Liquid and Gaseous Air Contaminants	July 25, 1977	December 4, 2024, 89 FR 96103.	Submitted by CARB on September 23, 2022. See 40 CFR 52.220(c)(620)(i)(A)(*1*).
408	Circumvention	July 25, 1977	December 4, 2024, 89 FR 96103.	Submitted electronically by CARB on May 11, 2023 as an attachment to a letter dated May 10, 2023. See 40 CFR 52.220(c)(610)(i)(D)(*3*).
409	Combustion Contaminants	July 25, 1977	December 4, 2024, 89 FR 96103.	Submitted electronically by CARB on May 11, 2023 as an attachment to a letter dated May 10, 2023. See 40 CFR 52.220(c)(610)(i)(D)(*4*).
442	Usage of Solvents	February 27, 2006	September 17, 2007, 72 FR 52791.	Submitted by CARB on October 5, 2006. See 40 CFR 52.220(c)(347)(i)(C)(*1*).
443	Labeling of Solvents	July 25, 1977	December 4, 2024, 89 FR 96103.	Submitted electronically by CARB on May 11, 2023 as an attachment to a letter dated May 10, 2023. See 40 CFR 52.220(c)(610)(i)(D)(*5*).
444	Open Outdoor Fires	September 25, 2006	October 31, 2007, 72 FR 61525.	Submitted by CARB on May 8, 2007. See 40 CFR 52.220(c)(350)(i)(B)(*1*).
461	Gasoline Transfer and Dispensing	January 22, 2018	May 1, 2020, 85 FR 25293.	Submitted by CARB on May 23, 2018. See 40 CFR 52.220(c)(518)(i)(A)(*3*).
462	Organic Liquid Loading	January 22, 2018	May 1, 2020, 85 FR 25293.	Submitted by CARB on May 23, 2018. See 40 CFR 52.220(c)(518)(i)(A)(*4*).
463	Storage of Organic Liquids	January 22, 2018	May 1, 2020, 85 FR 25293.	Submitted by CARB on May 23, 2018. See 40 CFR 52.220(c)(518)(i)(A)(*5*).
464	Oil-Water Separators	June 23, 2014	June 5, 2015, 80 FR 32026.	Submitted by CARB on November 6, 2014. See 40 CFR 52.220(c)(457)(i)(B)(*1*).
468	Sulfur Recovery Units	July 25, 1977	December 4, 2024, 89 FR 96103.	Submitted electronically by CARB on November 30, 2022 as an attachment to a letter dated November 22, 2022. See 40 CFR 52.220(c)(621)(i)(A)(*1*).
469	Sulfur Acid Units	July 25, 1977	December 4, 2024, 89 FR 96103.	Submitted electronically by CARB on November 30, 2022 as an attachment to a letter dated November 22, 2022. See 40 CFR 52.220(c)(621)(i)(A)(*2*).
471	Asphalt Roofing Operations	December 21, 1994	February 29, 1996, 61 FR 7706.	Submitted by CARB on December 22, 1994. See 40 CFR 52.220(c)(210)(i)(C)(*2*).
472	Reduction of Animal Matter	July 25, 1977	December 4, 2024, 89 FR 96103.	Submitted electronically by CARB on May 11, 2023 as an attachment to a letter dated May 10, 2023. See 40 CFR 52.220(c)(610)(i)(D)(*6*).
474	Fuel Burning Equipment	August 25, 1997	January 11, 1999, 64 FR 1517.	Submitted by CARB on March 10, 1998. See 40 CFR 52.220(c)(254)(i)(H)(*1*).
475	Electric Power Generating Equipment	August 25, 1997	January 11, 1999, 64 FR 1517.	Submitted by CARB on March 10, 1998. See 40 CFR 52.220(c)(254)(i)(H)(*1*).
476	Steam Generating Equipment	August 25, 1997	January 11, 1999, 64 FR 1517.	Submitted by CARB on March 10, 1998. See 40 CFR 52.220(c)(254)(i)(H)(*1*).

TABLE 21—EPA-APPROVED MOJAVE DESERT AIR QUALITY MANAGEMENT DISTRICT REGULATIONS—Continued
[District-Wide, Riverside County Portion of District, and San Bernardino County Portion of District]

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
Regulation VII—Emergencies				
701	Air Pollution Emergency Contingency Actions.	September 26, 2022	January 8, 2026, 91 FR 613.	Submitted electronically on May 11, 2023 as an attachment to a letter dated May 10, 2023. See 40 CFR 52.220(c)(610)(i)(D)(7).
Regulation XI—Source Specific Standards				
1102	Fugitive Emissions of VOCs from Components at Pipeline Transfer Stations.	October 26, 1994	September 27, 1995, 60 FR 49772.	Submitted by CARB on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(D)(*1*).
1103	Cutback and Emulsified Asphalt	December 21, 1994	February 5, 1996, 61 FR 4215.	Submitted by CARB on December 22, 1994. See 40 CFR 52.220(c)(210)(i)(C)(*1*).
1104	Organic Solvent Degreasing Operations.	April 23, 2018	July 2, 2019, 84 FR 31682.	Submitted by CARB on July 16, 2018. See 40 CFR 52.220(c)(519)(i)(A)(*1*).
1106	Marine Coating Operations	October 24, 2016	February 12, 2018, 83 FR 5940.	Submitted by CARB on May 8, 2007. See 40 CFR 52.220(c)(498)(i)(B)(*1*).
1113	Architectural Coatings	April 23, 2012	January 3, 2014, 79 FR 364.	Submitted by CARB on February 6, 2013. See 40 CFR 52.220(c)(428)(i)(C)(*1*).
1114	Wood Products Coating Operations	August 24, 2020	July 28, 2021, 86 FR 40335.	Submitted on November 18, 2020 by CARB as an attachment to a letter dated November 17, 2020. See 40 CFR 52.220(c)(558)(i)(A)(*1*).
1115	Metal Parts and Products Coating Operations.	June 8, 2020	May 9, 2022, 87 FR 27526.	Submitted on July 24, 2020 by the Governor's designee as an attachment to a letter dated July 23, 2020. See 40 CFR 52.220(c)(571)(i)(A)(*1*).
1116	Automotive Refinishing Operations	August 23, 2010	August 9, 2012, 77 FR 47536.	Submitted by CARB on April 5, 2011. See 40 CFR 52.220(c)(388)(i)(F)(*1*).
1117	Graphic Arts and Paper, Film, Foil and Fabric Coatings.	September 28, 2009	March 1, 2012, 77 FR 12495.	Submitted by CARB on July 20, 2010. See 40 CFR 52.220(c)(381)(i)(H)(*1*).
1118	Aerospace Assembly, Rework and Component Manufacturing Operations.	October 26, 2015	June 21, 2017, 82 FR 28240.	Submitted by CARB on April 21, 2016. See 40 CFR 52.220(c)(485)(i)(B)(*1*).
1157	Boilers and Process Heaters	September 25, 2023	May 19, 2025, 90 FR 21236.	Submitted electronically on January 10, 2024, as an attachment to a letter dated December 27, 2023. See 40 CFR 52.220(c)(626)(i)(A)(*1*).
1158	Electric Power Generating Facilities	August 25, 1997	July 20, 1999, 64 FR 38832.	Submitted by CARB on March 10, 1998. See 40 CFR 52.220(c)(254)(i)(H)(*2*).
1159	Stationary Gas Turbines	September 28, 2009	October 25, 2012, 77 FR 65133.	Submitted by CARB on May 17, 2010. See 40 CFR 52.220(c)(379)(i)(E)(*1*).
1160	Internal Combustion Engines	January 23, 2023	August 28, 2025, 90 FR 41895.	Submitted electronically on March 3, 2023, as an attachment to a letter dated February 17, 2023. See 40 CFR 52.220(c)(628)(i)(A)(1).
1161	Portland Cement Kilns	January 22, 2018	June 2, 2023, 88 FR 36249.	Submitted by CARB on May 23, 2018. See 40 CFR 52.220(c)(518)(i)(A)(*9*).
1162	Polyester Resin Operations	April 23, 2018	February 27, 2020, 85 FR 11812.	Submitted by CARB on July 16, 2018. See 40 CFR 52.220(c)(519)(i)(A)(*2*).
1165	Glass Melting Furnaces	August 25, 2008	July 2, 2012, 77 FR 39181.	Submitted by CARB on December 23, 2008. See 40 CFR 52.220(c)(364)(i)(D)(*1*).
Regulation XIII—New Source Review				
1300	New Source Review General	March 22, 2021	June 30, 2023, 88 FR 42258.	Submitted by CARB on July 23, 2021 as an attachment to a letter dated July 22, 2021. See 40 CFR 52.220(c)(600)(i)(A)(*2*).
1301	New Source Review Definitions	March 25, 2024	March 23, 2026, 91 FR 13774.	Submitted by CARB on August 7, 2024. See 40 CFR 52.220(c)(631)(i)(A)(*1*).
1302 (except subsections 1302(C)(5) and 1302(C)(7)(c)).	New Source Review Procedure	March 25, 2024	March 23, 2026, 91 FR 13774.	Submitted by CARB on August 7, 2024. See 40 CFR 52.220(c)(631)(i)(A)(*2*).
1303	New Source Review Requirements	March 25, 2024	March 23, 2026, 91 FR 13774.	Submitted by CARB on August 7, 2024. See 40 CFR 52.220(c)(631)(i)(A)(*3*).
1304	New Source Review Emissions Calculations.	March 25, 2024	March 23, 2026, 91 FR 13774.	Submitted by CARB on August 7, 2024. See 40 CFR 52.220(c)(631)(i)(A)(*4*).
1305	New Source Review Emissions Offsets.	March 25, 2024	March 23, 2026, 91 FR 13774.	Submitted by CARB on August 7, 2024. See 40 CFR 52.220(c)(631)(i)(A)(*5*).
1306	New Source Review for Electric Energy Generating Facilities.	March 22, 2021	June 30, 2023, 88 FR 42258.	Submitted by CARB on July 23, 2021 as an attachment to a letter dated July 22, 2021. See 40 CFR 52.220(c)(600)(i)(A)(*8*).
Regulation XIV—Emission Reduction Credit Banking				
1400	General	June 28, 1995	January 22, 1997, 62 FR 3215.	Submitted by CARB on August 10, 1995. See 40 CFR 52.220(c)(224)(i)(C)(*1*).
1401	Definitions	June 28, 1995	January 22, 1997, 62 FR 3215.	Submitted by CARB on August 10, 1995. See 40 CFR 52.220(c)(224)(i)(C)(*1*).
1402	Emission Reduction Credit Registry	May 19, 1997	June 30, 2023, 88 FR 42258.	Submitted by CARB on August 1, 1997. See 40 CFR 52.220(c)(248)(i)(D)(*3*).

TABLE 21—EPA-APPROVED MOJAVE DESERT AIR QUALITY MANAGEMENT DISTRICT REGULATIONS—Continued
[District-Wide, Riverside County Portion of District, and San Bernardino County Portion of District]

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
1404	Emission Reduction Credit Calculation	June 28, 1995	January 22, 1997, 62 FR 3215.	Submitted by CARB on August 10, 1995. See 40 CFR 52.220(c)(224)(i)(C)(*1*).
Regulation XX—Conformity				
2002	General Federal Actions Conformity	October 26, 1994	April 23, 1999, 64 FR 19916.	Submitted by CARB on May 10, 1996. See 40 CFR 52.220(c)(231)(i)(C)(*1*).
Rules and Regulations (Applicable within the Riverside County portion of District only)				
Original Codification of Rules and Regulations				
53	Specific Air Contaminants	June 10, 1975	June 14, 1978, 43 FR 25684.	Adopted by the Riverside County APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on July 22, 1975. See 40 CFR 52.220(c)(28)(x)(A).
56	Scavenger Plants	June 13, 1972	September 22, 1972, 37 FR 19812.	Adopted by the Riverside County APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on June 30, 1972. See 40 CFR 52.220(c)(6).
58	Disposal of Solid and Liquid Wastes	March 28, 1972	September 22, 1972, 37 FR 19812.	Adopted by the Riverside County APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on June 30, 1972. See 40 CFR 52.220(c)(6).
Recodification of Rules and Regulations				
Regulation I—General Provisions				
101	Title	April 1, 1977	December 19, 1978, 43 FR 59065.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on October 13, 1977. See 40 CFR 52.220(c)(41)(xiv)(A).
106	Increments of Progress	January 9, 1976	June 14, 1978, 43 FR 25684.	Adopted by the Southern California APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(B).
107	Determination of Volatile Organic Compounds in Coating Material.	January 8, 1982	October 11, 1983, 48 FR 46046.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on March 1, 1982. See 40 CFR 52.220(c)(121)(i)(B).
108	Alternative Emission Control Plans (AECPs).	April 6, 1990	August 30, 1993, 58 FR 45445.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on December 31, 1990. See 40 CFR 52.220(c)(182)(i)(A)(*3*).
109	Recordkeeping for Volatile Organic Compound Emissions.	May 5, 1989	August 30, 1993, 58 FR 45444.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on December 31, 1990. See 40 CFR 52.220(c)(182)(i)(A)(*2*).
Regulation II—Permits				
201	Permit to Construct	January 9, 1976	November 9, 1978, 43 FR 52237.	Adopted by the Southern California APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(C).
202(a) and (b)	Temporary Permit to Operate	January 9, 1976	November 9, 1978, 43 FR 52237.	Adopted by the Southern California APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(C).
202(c)	Temporary Permit to Operate	May 7, 1976	November 9, 1978, 43 FR 52237.	Adopted by the Southern California APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on August 2, 1976. See 40 CFR 52.220(c)(32)(iv)(C).
203	Permit to Operate	January 9, 1976	November 9, 1978, 43 FR 52237.	Adopted by the Southern California APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(C).
204	Permit Conditions	January 9, 1976	November 9, 1978, 43 FR 52237.	Adopted by the Southern California APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(C).
205	Cancellation of Applications	January 9, 1976	November 9, 1978, 43 FR 52237.	Adopted by the Southern California APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(C).

TABLE 21—EPA-APPROVED MOJAVE DESERT AIR QUALITY MANAGEMENT DISTRICT REGULATIONS—Continued
[District-Wide, Riverside County Portion of District, and San Bernardino County Portion of District]

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
207	Altering or Falsifying of Permit	January 9, 1976	November 9, 1978, 43 FR 52237.	Adopted by the Southern California APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(C).
208	Permit for Open Burning	October 8, 1976	September 8, 1978, 43 FR 40011.	Adopted by the Southern California APCD but submitted on behalf of the Riverside County APCD. Submitted on June 6, 1977. See 40 CFR 52.220(c)(39)(iv)(C).
209	Transfer and Voiding of Permits	January 9, 1976	November 9, 1978, 43 FR 52237.	Adopted by the Southern California APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(C).
210	Applications	January 9, 1976	November 9, 1978, 43 FR 52237.	Adopted by the Southern California APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(C).
211	Action on Permits	January 9, 1976	November 9, 1978, 43 FR 52237.	Adopted by the Southern California APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(C).
212	Standards for Approving Permits	May 1, 1987	February 3, 1989, 54 FR 5448.	Adopted by the SCAQMD and applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on September 1, 1987. See 40 CFR 52.220(c)(174)(i)(A)(1).
214	Denial of Permits	January 9, 1976	November 9, 1978, 43 FR 52237.	Adopted by the Southern California APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(C).
215	Permits Deemed Denied	January 9, 1976	November 9, 1978, 43 FR 52237.	Adopted by the Southern California APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(C).
216	Appeals	January 9, 1976	November 9, 1978, 43 FR 52237.	Adopted by the Southern California APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(C).
217	Provision for Sampling and Testing Facilities.	January 9, 1976	November 9, 1978, 43 FR 52237.	Adopted by the Southern California APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(C).
218	Stack Monitoring	August 7, 1981	July 6, 1982, 47 FR 29231.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on October 23, 1981. See 40 CFR 52.220(c)(103)(xviii)(A).
220	Exemption—Net Increase in Emissions.	August 7, 1981	July 6, 1982, 47 FR 29231.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on October 23, 1981. See 40 CFR 52.220(c)(103)(xviii)(A).
221	Plans	January 4, 1985	April 17, 1987, 52 FR 12522.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on November 12, 1985. See 40 CFR 52.220(c)(165)(i)(B)(*1*).
	Regulation IV—Prohibitions			
401	Visible Emissions	March 2, 1984	January 29, 1985, 50 FR 3906.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on July 10, 1984. See 40 CFR 52.220(c)(155)(iv)(B).
403	Fugitive Dust	May 7, 1976	June 14, 1978, 43 FR 25684.	Adopted by the Southern California APCD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on August 2, 1976. See 40 CFR 52.220(c)(32)(iv)(A).
404	Particulate Matter—Concentration	October 5, 1979	September 28, 1981, 46 FR 47451.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on December 17, 1979. See 40 CFR 52.220(c)(58)(ii)(B).
407	Liquid and Gaseous Contaminants	April 2, 1982	November 10, 1982, 47 FR 50864.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on August 6, 1982. See 40 CFR 52.220(c)(124)(iv)(A).
431.1	Sulfur Content of Gaseous Fuels	May 6, 1983	October 19, 1984, 49 FR 41028.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on July 19, 1983. See 40 CFR 52.220(c)(137)(vii)(B).

TABLE 21—EPA-APPROVED MOJAVE DESERT AIR QUALITY MANAGEMENT DISTRICT REGULATIONS—Continued
[District-Wide, Riverside County Portion of District, and San Bernardino County Portion of District]

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
431.2	Sulfur Content of Liquid Fuels	October 20, 1978	September 28, 1981, 46 FR 47451.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on July 25, 1979. See 40 CFR 52.220(c)(65)(ii).
431.2(c)(5)	Sulfur Content of Liquid Fuels	February 2, 1979	September 28, 1981, 46 FR 47451.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on April 23, 1980. See 40 CFR 52.220(c)(69)(ii).
431.3	Sulfur Content of Fossil Fuels	December 2, 1977	September 28, 1981, 46 FR 47451.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on July 25, 1979. See 40 CFR 52.220(c)(65)(ii).
465	Vacuum Producing Devices or Systems.	December 7, 1990	August 11, 1992, 57 FR 35758.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on May 13, 1991. See 40 CFR 52.220(c)(184)(i)(B)(*2*).
481	Spray Coating Operations	May 5, 1978	January 21, 1981, 46 FR 5965.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on January 2, 1979. See 40 CFR 52.220(c)(47)(i)(B).
	Regulation XI—Source-Specific Standards			
1102	Petroleum Solvent Dry Cleaners	December 7, 1990	March 24, 1992, 57 FR 10136.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on May 13, 1991. See 40 CFR 52.220(c)(184)(i)(B)(1).
1102.1	Perchloroethylene Cry Cleaning Systems.	December 7, 1990	March 24, 1992, 57 FR 10136.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on May 13, 1991. See 40 CFR 52.220(c)(184)(i)(B)(*1*).
1103	Pharmaceuticals and Cosmetic Manufacturing Operations.	April 4, 1980	July 8, 1982, 47 FR 29668.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on April 23, 1980. See 40 CFR 52.220(c)(69)(iii).
1105	Fluid Catalytic Cracking Units—Oxides of Sulfur.	September 21, 1984	July 12, 1990, 55 FR 28624.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on February 6, 1985. See 40 CFR 52.220(c)(159)(v)(C).
1111	NO_X Emissions from Natural-Gas-Fired, Fan-Type Central Furnaces.	July 8, 1983	May 3, 1984, 49 FR 18830.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on October 27, 1983. See 40 CFR 52.220(c)(148)(vi)(A).
1115	Motor Vehicle Assembly Line Coating Operations.	March 6, 1992	December 20, 1993, 58 FR 66282.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on September 14, 1992. See 40 CFR 52.220(c)(189)(i)(A)(*1*).
1119	Petroleum Coke Calcining Operations—Oxides of Sulfur.	March 2, 1979	September 28, 1981, 46 FR 47451.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on July 25, 1980. See 40 CFR 52.220(c)(88)(iii)(A).
1120	Asphalt Pavement Heaters	August 4, 1978	September 28, 1981, 46 FR 47451.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on July 25, 1979. See 40 CFR 52.220(c)(65)(ii).
1121	Control of Nitrogen Oxides from Residential Type Natural Gas-Fired Water Heaters.	December 1, 1978	September 28, 1981, 46 FR 47451.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on April 2, 1980. See 40 CFR 52.220(c)(67)(i)(B).
1123	Refinery Process Turnarounds	December 7, 1990	August 11, 1992, 57 FR 35758.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on May 13, 1991. See 40 CFR 52.220(c)(184)(i)(B)(*2*).
1125	Metal Container, Closure, and Coil Coating Operations.	August 2, 1991	April 14, 1994, 59 FR 17697.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on May 13, 1993. See 40 CFR 52.220(c)(189)(i)(A)(*4*), but note that approval should have promulgated under 40 CFR 52.220(c)(193) rather than 40 CFR 52.220(c)(189).
1126	Magnet Wire Coating Operations	March 6, 1992	December 20, 1993, 58 FR 66285.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on September 14, 1992. See 40 CFR 52.220(c)(189)(i)(A)(*2*).
1140	Abrasive Blasting	February 1, 1980	September 28, 1981, 46 FR 47451.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on April 2, 1980. See 40 CFR 52.220(c)(67)(i)(B).

TABLE 21—EPA-APPROVED MOJAVE DESERT AIR QUALITY MANAGEMENT DISTRICT REGULATIONS—Continued
[District-Wide, Riverside County Portion of District, and San Bernardino County Portion of District]

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
1141	Control of Volatile Organic Compound Emissions from Resin Manufacturing.	April 3, 1992	December 20, 1993, 58 FR 66286.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on September 14, 1992. See 40 CFR 52.220(c)(189)(i)(A)(*3*).
1141.1	Coatings and Ink Manufacturing	November 4, 1983	January 24, 1985, 50 FR 3338.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on March 14, 1984. See 40 CFR 52.220(c)(153)(vii)(A).
1141.2	Surfactant Manufacturing	July 6, 1984	January 15, 1987, 52 FR 1627.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on October 19, 1984. See 40 CFR 52.220(c)(156)(vii)(A).
1145	Plastic, Rubber, and Glass Coating Operations.	January 10, 1992	December 20, 1993, 58 FR 66286.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on January 11, 1993. See 40 CFR 52.220(c)(191)(i)(A)(*1*).
1148	Thermally Enhanced Oil Recovery Wells.	November 5, 1982	October 19, 1984, 49 FR 41028.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on February 3, 1983. See 40 CFR 52.220(c)(127)(vii)(C).
1151	Motor Vehicle and Mobile Equipment Non-Assembly Line Coating Operations.	September 6, 1991	December 20, 1993, 58 FR 66285.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on May 13, 1993. See 40 CFR 52.220(c)(193)(i)(A)(*1*).
1153	Commercial Bakery Ovens	January 4, 1991	September 29, 1993, 58 FR 50850.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on May 13, 1991. See 40 CFR 52.220(c)(184)(i)(B)(*3*).
1158	Storage, Handling, and Transport of Petroleum Coke.	December 2, 1983	January 15, 1987, 52 FR 1627.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on March 14, 1984. See 40 CFR 52.220(c)(153)(vii)(B).
1159	Nitric Acid Units—Oxides of Nitrogen	December 6, 1985	July 12, 1990, 55 FR 28622.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on February 10, 1986. See 40 CFR 52.220(c)(168)(i)(H)(*1*).
1164	Semiconductor Manufacturing Operations.	December 7, 1990	September 29, 1993, 58 FR 50850.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on May 13, 1991. See 40 CFR 52.220(c)(184)(i)(B)(*3*).
1173	Fugitive Emissions of Volatile Organic Compounds.	December 7, 1990	October 26, 1992, 57 FR 48457; corrected on January 16, 2004, 69 FR 2509.	Adopted by the SCAQMD. Applicable within the Riverside County portion of the Mojave Desert AQMD. Submitted by CARB on May 13, 1991. See 40 CFR 52.220(c)(184)(i)(B)(*10*).
Rules and Regulations (Applicable within the San Bernardino County portion of District only)				
Original Codification of Rules and Regulations				
5(a)	Public Availability of Emission Data	February 13, 1973	June 14, 1978, 43 FR 25684.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on July 25, 1973. See 40 CFR 52.220(c)(21)(xv)(A).
53A, paragraph (c) only	Specific Contaminants	February 13, 1973	June 14, 1978, 43 FR 25684.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on July 25, 1973. See 40 CFR 52.220(c)(21)(xv)(A). Paragraphs (a) and (b) were superseded by approval of San Bernardino County APCD Rule 53–A(a) (Specific Contaminants) (later Rule 406(a)) and Rule 409 (Combustion Contaminants).
73	Dry Sandblasting	January 28, 1975	June 14, 1978, 43 FR 25684.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on April 10, 1975. See 40 CFR 52.220(c)(27)(v)(A).
Recodification of Rules and Regulations				
Regulation I—General Provisions				
101	Title	December 19, 1988	November 27, 1990, 55 FR 49281.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on March 26, 1990. See 40 CFR 52.220(c)(179)(i)(B)(*1*).

TABLE 21—EPA-APPROVED MOJAVE DESERT AIR QUALITY MANAGEMENT DISTRICT REGULATIONS—Continued
[District-Wide, Riverside County Portion of District, and San Bernardino County Portion of District]

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
106	Increments of Progress	December 19, 1988	November 27, 1990, 55 FR 49281.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on March 26, 1990. See 40 CFR 52.220(c)(179)(i)(B)(*1*).
107	Certifications and Emission Statements.	September 14, 1992	May 26, 2004, 69 FR 29880.	Adopted by the San Bernardino County APCD. Submitted by CARB on November 12, 1992 prior to the date (July 1, 1994) on which the Palo Verde Valley area in Riverside County joined the MDAQMD. See 40 CFR 52.220(c)(190)(i)(F)(*1*).
Regulation II—Permits				
201	Permit to Construct	February 1, 1977	November 9, 1978, 43 FR 52237.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on June 6, 1977. See 40 CFR 52.220(c)(39)(ii)(B).
202	Temporary Permit to Operate	February 1, 1977	November 9, 1978, 43 FR 52237.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on June 6, 1977. See 40 CFR 52.220(c)(39)(ii)(B).
203	Permit to Operate	February 1, 1977	November 9, 1978, 43 FR 52237.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on June 6, 1977. See 40 CFR 52.220(c)(39)(ii)(B).
204	Permit Conditions	February 1, 1977	November 9, 1978, 43 FR 52237.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on June 6, 1977. See 40 CFR 52.220(c)(39)(ii)(B).
205	Cancellation of Applications	February 1, 1977	November 9, 1978, 43 FR 52237.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on June 6, 1977. See 40 CFR 52.220(c)(39)(ii)(B).
207	Altering or Falsifying of Permit	February 1, 1977	November 9, 1978, 43 FR 52237.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on June 6, 1977. See 40 CFR 52.220(c)(39)(ii)(B).
208	Permit for Open Burning	February 1, 1977	September 8, 1978, 43 FR 40011.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on June 6, 1977. See 40 CFR 52.220(c)(39)(ii)(C).
209	Transfer and Voiding of Permits	February 1, 1977	November 9, 1978, 43 FR 52237.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on June 6, 1977. See 40 CFR 52.220(c)(39)(ii)(B).
212	Standard for Approving Permits	February 1, 1977	November 9, 1978, 43 FR 52237.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on June 6, 1977. See 40 CFR 52.220(c)(39)(ii)(B).
217	Provision for Sampling and Testing Facilities.	February 1, 1977	November 9, 1978, 43 FR 52237.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on June 6, 1977. See 40 CFR 52.220(c)(39)(ii)(B).
218	Stack Monitoring	February 1, 1977	September 8, 1978, 43 FR 40011.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on June 6, 1977. See 40 CFR 52.220(c)(39)(ii)(C).
Regulation IV—Prohibitions				
401	Visible Emissions	February 1, 1977	September 8, 1978, 43 FR 40011.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on June 6, 1977. See 40 CFR 52.220(c)(39)(ii)(C).

TABLE 21—EPA-APPROVED MOJAVE DESERT AIR QUALITY MANAGEMENT DISTRICT REGULATIONS—Continued
[District-Wide, Riverside County Portion of District, and San Bernardino County Portion of District]

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
403	Fugitive Dust	February 1, 1977	September 8, 1978, 43 FR 40011.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on June 6, 1977. See 40 CFR 52.220(c)(39)(ii)(C).
406(a)	Specific Contaminants	July 25, 1977	December 21, 1978, 43 FR 59489.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. No action was taken on paragraph (b) at 43 FR 59489 (December 21, 1978). Submitted by CARB on November 4, 1977. See 40 CFR 52.220(c)(42)(xiii)(A).
431	Sulfur Content of Fuels	February 1, 1977	September 8, 1978, 43 FR 40011.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on June 6, 1977. See 40 CFR 52.220(c)(39)(ii)(C).
465	Vacuum Producing Devices or Systems.	February 1, 1977	September 8, 1978, 43 FR 40011.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on June 6, 1977. See 40 CFR 52.220(c)(39)(ii)(C).
473	Disposal of Liquid and Solid Wastes ..	February 1, 1977	September 8, 1978, 43 FR 40011.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on June 6, 1977. See 40 CFR 52.220(c)(39)(ii)(C).
Regulation VII—Emergencies				
707	Plans	February 1, 1977	June 3, 1980, 45 FR 37428.	Adopted by the San Bernardino County APCD and applicable within the San Bernardino County portion of the Mojave Desert AQMD. Submitted by CARB on June 6, 1977. See 40 CFR 52.220(c)(39)(ii)(E).

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TABLE 26—EPA-APPROVED PLACER COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
RULES AND REGULATIONS (DISTRICT–WIDE APPLICABILITY)				
Regulation 1—General Provisions				
101	Title	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
102	Definitions	November 12, 1974	June 14, 1978, 43 FR 25684.	Submitted on January 10, 1975. See 40 CFR 52.220(c)(26)(xvii)(A). Most of the definitions have been superseded by subsequent approvals of Rule 102 but not all.
102	Definitions	June 11, 2020	May 9, 2022, 87 FR 27526.	Submitted on July 24, 2020 by the Governor's designee as an attachment to a letter dated July 23, 2020. See 40 CFR 52.220(c)(571)(i)(B)(*1*).
103	Validity	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
Regulation 2—Prohibitions				
201	Coverage	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
202	Visible Emissions	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
203	Exceptions to Rule 202	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
204	Wet Plumes	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
206	Incinerator Burning	October 13, 2016	December 19, 2017, 82 FR 60119.	Submitted on January 24, 2017. See 40 CFR 52.220(c)(497)(i)(B)(*1*).
208	Orchard or Citrus Heaters	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
209	Fossil Fuel-Steam Facility	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
210	Specific Contaminants	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).

TABLE 26—EPA-APPROVED PLACER COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
211	Process Weight	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
212	Storage of Organic Liquids	June 19, 1997	June 11, 2009, 74 FR 27714.	Submitted on July 18, 2008. See 40 CFR 52.220(c)(359)(i)(C)(*1*).
213	Gasoline Transfer into Stationary Storage Containers.	February 21, 2013	February 10, 2015, 80 FR 7345.	Submitted on February 10, 2014. See 40 CFR 52.220(c)(442)(i)(D)(*1*).
214	Transfer of Gasoline into Vehicle Fuel Tanks.	February 21, 2013	February 10, 2015, 80 FR 7345.	Submitted on February 10, 2014. See 40 CFR 52.220(c)(442)(i)(D)(*2*).
215	Transfer of Gasoline Into Trucks, Trailers, and Railroad Tank Cars at Loading Facilities.	June 19, 1997	January 31, 2011, 76 FR 5277.	Submitted on July 18, 2008. See 40 CFR 52.220(c)(359)(i)(C)(*3*).
216	Organic Solvent Cleaning and Degreasing Operations.	December 11, 2003	May 5, 2010, 75 FR 24406.	Submitted on July 18, 2008. See 40 CFR 52.220(c)(359)(i)(C)(*2*).
217	Cutback and Emulsified Asphalt Paving Materials.	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
218	Architectural Coatings	October 14, 2010	December 5, 2011, 76 FR 75795.	Submitted on April 5, 2011. See 40 CFR 52.220(c)(388)(i)(E)(*3*).
219	Organic Solvents	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
220	Abrasive Blasting	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
221	Compliance Tests	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
222	Reduction of Animal Matter	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
223	Metal Container Coating	October 6, 1994	March 23, 1995, 60 FR 15241.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*1*).
225	Wood Fired Appliances	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*). Applies within the Squaw Valley portion of the district.
226	Sulfur Content of Fuels—Lake Tahoe Air Basin.	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
228	Fugitive Dust—Lake Tahoe Air Basin	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
231	Industrial, Institutional and Commercial Boiler, Steam Generator and Process Heaters.	October 9, 1997	November 1, 2011, 76 FR 67366.	Submitted on March 17, 2009. See 40 CFR 52.220(c)(363)(i)(D)(*1*).
233	Biomass Boilers	June 14, 2012	August 29, 2013, 78 FR 53249.	Submitted on September 21, 2012. See 40 CFR 52.220(c)(423)(i)(A)(*7*).
234	Automotive Refinishing Operations	July 1, 2011	December 5, 2011, 76 FR 75795.	Submitted on April 5, 2011. See 40 CFR 52.220(c)(388)(i)(E)(*4*).
235	Adhesives	October 11, 2012	August 30, 2013, 78 FR 53680.	Submitted on February 6, 2013. See 40 CFR 52.220(c)(428)(i)(A)(*1*).
236	Wood Products and Coating Operations.	July 1, 2011	November 21, 2011, 76 FR 71886.	Submitted on April 5, 2011. See 40 CFR 52.220(c)(388)(i)(E)(*1*).
238	Factory Coating of Flat Wood Paneling.	July 1, 2011	November 21, 2011, 76 FR 71886.	Submitted on April 5, 2011. See 40 CFR 52.220(c)(388)(i)(E)(*2*).
239	Graphic Arts Operations	October 11, 2012	March 13, 2014, 79 FR 14178.	Submitted on February 6, 2013. See 40 CFR 52.220(c)(428)(i)(A)(*2*).
240	Surface Preparation and Cleanup	December 11, 2003	March 13, 2014, 79 FR 14178.	Submitted on September 24, 2013. See 40 CFR 52.220(c)(434)(i)(A)(*1*).
242	Stationary Internal Combustion Engines.	April 10, 2003	November 1, 2011, 76 FR 67366.	Submitted on December 7, 2010. See 40 CFR 52.220(c)(389)(i)(B)(*2*).
243	Polyester Resin Operations	April 10, 2003	October 3, 2011, 76 FR 61057.	Submitted on December 7, 2010. See 40 CFR 52.220(c)(389)(i)(B)(*5*). Also see 85 FR 42728 (July 15, 2020).
244	Semiconductor Manufacturing Operations.	February 9, 1995	July 25, 1996, 61 FR 38571.	Submitted on May 24, 1995. See 40 CFR 52.220(c)(220)(i)(B)(*3*).
245	Surface Coating of Metal Parts and Products.	August 20, 2009	May 24, 2011, 76 FR 30025.	Submitted on January 10, 2010. See 40 CFR 52.220(c)(378)(i)(B)(*1*).
246	Natural Gas-Fired Water Heaters	June 19, 1997	November 1, 2011, 76 FR 67366.	Submitted on December 7, 2010. See 40 CFR 52.220(c)(389)(i)(B)(*3*).
247	Natural Gas-Fired Water Heaters, Small Boilers and Process Heaters.	February 13, 2014	October 7, 2014, 79 FR 60347.	Submitted on May 13, 2014. See 40 CFR 52.220(c)(441)(i)(B)(*2*).
249	Surface Coating of Plastic Parts and Products.	August 8, 2013	March 27, 2015, 80 FR 16289.	Submitted on May 13, 2014. See 40 CFR 52.220(c)(441)(i)(B)(*3*).
250	Stationary Gas Turbines	October 8, 2015	August 1, 2016, 81 FR 50348.	Submitted on March 11, 2016. See 40 CFR 52.220(c)(474)(i)(A)(*1*).
	Regulation 3—Open Burning			
301	Nonagricultural Burning Smoke Management.	August 9, 2018	July 28, 2021, 86 FR 40336.	Submitted on November 21, 2018. See 40 CFR 52.220(c)(527)(i)(C)(*1*).
302	Agricultural Waste Burning Smoke Management.	August 9, 2018	July 28, 2021, 86 FR 40336.	Submitted on November 21, 2018. See 40 CFR 52.220(c)(527)(i)(C)(*2*).
303	Prescribed Burning Smoke Management.	February 9, 2012	January 31, 2013, 78 FR 6736.	Submitted on September 21, 2012. See 40 CFR 52.220(c)(423)(i)(A)(*3*).
304	Land Development Burning Smoke Management.	February 9, 2012	January 31, 2013, 78 FR 6736.	Submitted on September 21, 2012. See 40 CFR 52.220(c)(423)(i)(A)(*4*).

TABLE 26—EPA-APPROVED PLACER COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
305	Residential Allowable Burning	October 11, 2018	July 28, 2021, 86 FR 40336.	Submitted on January 31, 2019 by CARB as an attachment to a letter dated January 23, 2019. See 40 CFR 52.220(c)(545)(i)(C)(*1*).
306	Open Burning of Nonindustrial Wood Waste at Designated Disposal Sites.	February 9, 2012	January 31, 2013, 78 FR 6736.	Submitted on September 21, 2012. See 40 CFR 52.220(c)(423)(i)(A)(*6*).
Regulation 4—Miscellaneous Provisions				
401	Responsibility	May 24, 1977	November 15, 1978, 43 FR 53035.	Submitted on October 13, 1977. See 40 CFR 52.220(c)(41)(x)(A).
405	Separation of Emissions	November 12, 1974	June 14, 1978, 43 FR 25684.	Submitted on January 10, 1975. See 40 CFR 52.220(c)(26)(xvii)(A).
406	Combination of Emissions	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
407	Circumvention	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
408	Source Record Keeping and Reporting.	October 19, 1993	April 30, 1997, 62 FR 23365.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(A)(*2*).
409	Public Records	May 24, 1977	November 15, 1978, 43 FR 53035.	Submitted on October 13, 1977. See 40 CFR 52.220(c)(41)(x)(A).
410	Recordkeeping for Volatile Organic Compound Emissions.	November 3, 1994	May 23, 1995, 60 FR 15241.	Submitted on December 19, 1994. See 40 CFR 52.220(c)(208)(i)(A)(*1*).
Regulation 5—Permits				
501	General Permit Requirements	April 8, 2021	September 26, 2023, 88 FR 65816.	Submitted on October 6, 2021. See 40 CFR 52.220(c)(495)(i)(A)(*1*).
502	New Source Review	June 13, 2024	January 6, 2026, 91 FR 337.	Submitted electronically on November 15, 2024 as an attachment to a letter dated November 13, 2024. See 40 CFR 52.220(c)(630)(i)(A)(*1*).
503	Emission Statement	October 8, 2020	July 29, 2022, 87 FR 45657.	Submitted on December 15, 2020 as an attachment to a letter dated December 14, 2020. See 40 CFR 52.220(c)(576)(i)(B)(*1*).
508	General Conformity	November 3, 1994	April 23, 1999, 64 FR 19916.	Submitted on December 22, 1994. See 40 CFR 52.220(c)(210)(i)(G)(*1*).
515	Stationary Rail Yard Control Emission Reduction Credits.	February 19, 2015	November 6, 2015, 80 FR 68766.	Submitted on June 26, 2015. See 40 CFR 52.220(c)(463)(i)(A)(*1*).
516	Rice Straw Emission Reduction Credits.	February 19, 2009	July 3, 2014, 79 FR 37956.	Submitted on April 6, 2009. See 40 CFR 52.220(c)(366)(i)(D)(*1*).
518	Prevention of Significant Deterioration (PSD) Permit Program.	October 13, 2016	August 28, 2018, 83 FR 43765.	Submitted on January 24, 2017. See 40 CFR 52.220(c)(497)(i)(A))(*2*).
Ozone Emergency Episode Plan				
No Citation	Ozone Emergency Episode Plan	June 11, 2015	December 8, 2015, 80 FR 76230.	Submitted on July 15, 2015. See 40 CFR 52.220(c)(465)(i)(A)(*1*).
RULES AND REGULATIONS (LAKE TAHOE AIR BASIN PORTION OF DISTRICT)				
Regulation 2—Prohibitions				
206	Incinerator Burning and Pathological Incinerator.	June 19, 1979	May 18, 1981, 46 FR 27115.	Paragraph A is titled ''Incinerator Burning'' and paragraph B is titled ''Pathological Incinerator.'' Submitted on August 21, 1979. See 40 CFR 52.220(c)(80)(i)(A).
207	Particulate Matter	June 19, 1979	May 18, 1981, 46 FR 27115.	Submitted on August 21, 1979. See 40 CFR 52.220(c)(80)(i)(A).
RULES AND REGULATIONS (MOUNTAIN COUNTIES AIR BASIN AND SACRAMENTO VALLEY AIR BASIN PORTION OF DISTRICT)				
Regulation 2—Prohibitions				
207	Particulate Matter	May 24, 1977	November 15, 1978, 43 FR 53035.	Submitted on October 13, 1977. See 40 CFR 52.220(c)(41)(x)(A). Originally adopted for district-wide applicability but superseded in the Lake Tahoe Air Basin portion of the county by approval of Rule 207 at 46 FR 27115 (May 18, 1981).

TABLE 27—EPA-APPROVED SACRAMENTO METROPOLITAN AIR QUALITY MANAGEMENT DISTRICT REGULATIONS

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
Original Codification of Rules and Regulations				
7	Ringelmann Chart	April 19, 1983	February 1, 1984, 49 FR 3987.	Submitted on July 19, 1983. See 40 CFR 52.220(c)(137)(iii)(A).
22a	Open Fires	August 3, 1977	August 4, 1978, 43 FR 34468.	Submitted on November 4, 1977. See 40 CFR 52.220(c)(42)(ii)(A).
Re-Codification of Rules and Regulations				
Regulation 1—General				
101	General Provisions and Definitions	October 27, 2011	August 9, 2012, 77 FR 47535.	Submitted on February 23, 2012. See 40 CFR 52.220(c)(411)(i)(A)(*2*).
102	Circumvention	November 29, 1983	December 5, 1984, 49 FR 47490.	Submitted on April 19, 1984. See 40 CFR 52.220(c)(154)(iii)(A).
103	Exceptions	November 29, 1983	December 5, 1984, 49 FR 47490.	Submitted on April 19, 1984. See 40 CFR 52.220(c)(154)(iii)(A).
104	General Conformity	November 3, 1994	April 23, 1999, 64 FR 19916.	Submitted on December 22, 1994. See 40 CFR 52.220(c)(210)(i)(H)(*1*).
105	Emission Statement	September 5, 1996	June 6, 2008, 73 FR 32240.	Submitted on May 18, 1998. See 40 CFR 52.220(c)(255)(i)(A)(*6*).
Regulation 2—Permits				
201	General Permit Requirements	November 20, 1984	July 13, 1987, 52 FR 26148.	Submitted on February 6, 1985. See 40 CFR 52.220(c)(159)(iv)(A).
203	Prevention of Significant Deterioration	January 27, 2011	July 20, 2011, 76 FR 43183.	Submitted on January 28, 2011. See 40 CFR 52.220(c)(390)(i)(A)(*1*).
214	Federal New Source Review	August 23, 2012	August 29, 2013, 78 FR 53270.	Submitted on September 26, 2012. See 40 CFR 52.220(c)(427)(i)(A)(*1*).
217	Public Notice Requirements for Permits.	August 23, 2012	August 29, 2013, 78 FR 53270.	Submitted on September 26, 2012. See 40 CFR 52.220(c)(427)(i)(A)(*2*).
Regulation 3—Fees				
307	Clean Air Act Penalty Fees	March 23, 2023	March 6, 2024, 89 FR 15962.	Submitted electronically on May 11, 2023 as an attachment to a letter dated May 10, 2023. See 40 CFR 52.220(c)(610)(i)(A)(*1*).
Regulation 4—Prohibitory Rules				
403	Fugitive Dust	November 29, 1983	December 5, 1984, 49 FR 47490.	Submitted on April 19, 1984. See 40 CFR 52.220(c)(154)(iii)(A).
404	Particulate Matter	November 20, 1984	July 13, 1987, 52 FR 26148.	Submitted on February 6, 1985. See 40 CFR 52.220(c)(159)(iv)(A).
405	Dust and Condensed Fumes	November 29, 1983	December 5, 1984, 49 FR 47490.	Submitted on April 19, 1984. See 40 CFR 52.220(c)(154)(iii)(A).
406	Specific Contaminants	November 29, 1983	December 5, 1984, 49 FR 47490.	Submitted on April 19, 1984. See 40 CFR 52.220(c)(154)(iii)(A).
407	Open Burning	November 29, 1983	December 5, 1984, 49 FR 47490.	Submitted on April 19, 1984. See 40 CFR 52.220(c)(154)(iii)(A).
408	Incinerator Burning	November 29, 1983	December 5, 1984, 49 FR 47490.	Submitted on April 19, 1984. See 40 CFR 52.220(c)(154)(iii)(A).
409	Orchard Heaters	November 29, 1983	December 5, 1984, 49 FR 47490.	Submitted on April 19, 1984. See 40 CFR 52.220(c)(154)(iii)(A).
410	Reduction of Animal Matter	November 29, 1983	December 5, 1984, 49 FR 47490.	Submitted on April 19, 1984. See 40 CFR 52.220(c)(154)(iii)(A).
411	NO_X from Boilers, Process Heaters and Steam Generators.	August 23, 2007	May 6, 2009, 74 FR 20880.	Submitted on March 7, 2008. See 40 CFR 52.220(c)(354)(i)(C)(*1*).
412	Stationary Internal Combustion Engines Located at Major Stationary Sources of NO_X.	June 1, 1995	April 30, 1996, 61 FR 18959.	Submitted on June 16, 1995. See 40 CFR 52.220(c)(222)(i)(C)(*3*).
413	Stationary Gas Turbines	March 24, 2005	January 10, 2008, 73 FR 1819.	Submitted on September 5, 2007. See 40 CFR 52.220(c)(352)(i)(A)(*1*).
414	Water Heaters, Boilers and Process Heaters Rated Less Than 1,000,000 BTU per hour.	October 25, 2018	July 13, 2021, 86 FR 36665.	Submitted on January 31, 2019 as an attachment to a letter dated January 23, 2019. See 40 CFR 52.220(c)(545)(i)(B)(*1*).
417	Wood Burning Appliances	October 26, 2006	April 11, 2013, 78 FR 21540.	Submitted on September 21, 2012. See 40 CFR 52.220(c)(423)(i)(B)(*1*).
420	Sulfur Content of Fuels	November 29, 1983	December 5, 1984, 49 FR 47490.	Submitted on April 19, 1984. See 40 CFR 52.220(c)(154)(iii)(A).
421 (excluding section 402).	Mandatory Episodic Curtailment of Wood and Other Solid Fuel Burning.	September 24, 2009	March 16, 2015, 80 FR 13495.	Approval of Rule 421 excludes section 402 (''Penalties''). Submitted on September 21, 2012. See 40 CFR 52.220(c)(423)(i)(B)(*2*). The Financial Hardship Exemption Decision Tree, dated December 12, 2007, was also approved and is included in the tables in paragraph (e) listing the nonregulatory and quasi-regulatory portion of the California SIP.

TABLE 27—EPA-APPROVED SACRAMENTO METROPOLITAN AIR QUALITY MANAGEMENT DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
441	Organic Solvents	November 29, 1983	January 24, 1985, 50 FR 3338.	Submitted on April 19, 1984. See 40 CFR 52.220(c)(154)(iii)(B).
442	Architectural Coatings	September 24, 2015	October 4, 2016, 81 FR 68320.	Submitted on March 11, 2016. See 40 CFR 52.220(c)(474)(i)(B)(*1*).
443	Leaks from Synthetic Organic Chemical and Polymer Manufacturing.	September 5, 1996	November 9, 1998, 63 FR 60214.	Submitted on May 18, 1998. See 40 CFR 52.220(c)(255)(i)(A)(*2*).
444	Petroleum Solvent Dry Cleaning	November 29, 1983	January 24, 1985, 50 FR 3338.	Submitted on April 19, 1984. See 40 CFR 52.220(c)(154)(iii)(B).
446	Storage of Petroleum Products	November 16, 1993	September 16, 1994, 59 FR 47544.	Submitted on March 29, 1994. See 40 CFR 52.220(c)(196)(i)(A)(*1*).
447	Organic Liquid Loading	April 2, 1998	November 26, 1999, 64 FR 66393.	Submitted on June 23, 1998. See 40 CFR 52.220(c)(256)(i)(G)(*1*).
448	Gasoline Transfer into Stationary Storage Containers.	February 26, 2009	January 7, 2013, 78 FR 897.	Submitted on April 5, 2011. See 40 CFR 52.220(c)(388)(i)(D)(*4*).
449	Transfer of Gasoline into Vehicle Fuel Tanks.	February 26, 2009	January 7, 2013, 78 FR 897.	Submitted on April 5, 2011. See 40 CFR 52.220(c)(388)(i)(D)(*5*).
450	Graphic Arts Operations	October 23, 2008	April 9, 2010, 75 FR 18068.	Submitted on April 29, 2009. See 40 CFR 52.220(c)(362)(i)(C)(*1*).
451	Surface Coating of Miscellaneous Metal Parts and Products.	October 28, 2010	November 21, 2011, 76 FR 71886.	Submitted on April 5, 2011. See 40 CFR 52.220(c)(388)(i)(D)(*3*).
452	Can Coating	September 25, 2008	April 9, 2010, 75 FR 18068.	Submitted on September 15, 2009. See 40 CFR 52.220(c)(377)(i)(A)(*1*).
453	Cutback and Emulsified Asphalt Paving Materials.	November 29, 1983	January 24, 1985, 50 FR 3338.	Submitted on April 19, 1984. See 40 CFR 52.220(c)(154)(iii)(B).
454	Degreasing Operations	September 25, 2008	April 9, 2010, 75 FR 18068.	Submitted on September 15, 2009. See 40 CFR 52.220(c)(377)(i)(A)(*1*).
456	Aerospace Assembly and Component Coating Operations.	October 23, 2008	July 14, 2010, 75 FR 40726.	Submitted on September 15, 2009. See 40 CFR 52.220(c)(377)(i)(A)(*3*).
458	Large Commercial Bread Bakeries	September 5, 1996	November 9, 1998, 63 FR 60214.	Submitted on May 18, 1998. See 40 CFR 52.220(c)(255)(i)(A)(*2*).
459	Automotive, Mobile Equipment, and Associated Parts and Components Coating Operations.	August 25, 2011	August 9, 2012, 77 FR 47536.	Submitted on February 23, 2012. See 40 CFR 52.220(c)(411)(i)(A)(*1*).
463	Wood Products Coatings	September 25, 2008	April 9, 2010, 75 FR 18068.	Submitted on September 15, 2009. See 40 CFR 52.220(c)(377)(i)(A)(*1*).
464	Organic Chemical Manufacturing Operations.	April 28, 2016	December 4, 2017, 82 FR 57123.	Submitted on August 22, 2016. See 40 CFR 52.220(c)(488)(i)(C)(*1*).
465	Polyester Resin Operations	September 25, 2008	July 26, 2011, 76 FR 44493.	Submitted on September 15, 2009. See 40 CFR 52.220(c)(377)(i)(A)(*4*).
466	Solvent Cleaning	October 28, 2010	September 29, 2011, 76 FR 60376.	Submitted on April 5, 2011. See 40 CFR 52.220(c)(388)(i)(D)(*1*).
468	Surface Coating of Plastic Parts and Products.	March 22, 2018	November 19, 2020, 85 FR 73640.	Submitted on May 23, 2018. See 40 CFR 52.220(c)(518)(i)(C)(*1*).
Regulation 5—Agricultural Burning				
501	Agricultural Burning	November 29, 1983	December 5, 1984, 49 FR 47490.	Submitted on April 19, 1984. See 40 CFR 52.220(c)(154)(iii)(A).
Regulation 7—Emergency Episode Plan				
701	Emergency Episode Plan	May 27, 1999	September 5, 2000, 65 FR 53602.	Submitted on March 28, 2000. See 40 CFR 52.220(c)(277)(i)(B)(*1*).

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TABLE 29—EPA-APPROVED SAN JOAQUIN VALLEY UNIFIED AIR POLLUTION CONTROL DISTRICT REGULATIONS; FRESNO COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; KERN COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; KINGS COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; MADERA COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; MERCED COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; SAN JOAQUIN COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; STANISLAUS COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; TULARE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
Rules and Regulations (District-Wide Applicability)				
Original Codification of Rules and Regulations				
461.2	Vegetable Oil Processing Operations	April 11, 1991	January 18, 1994, 59 FR 2535.	Submitted on May 30, 1991. See 40 CFR 52.220(c)(185)(i)(C)(*5*).
Recodification of Rules and Regulations				
Regulation I—General Provisions				
1010	Title	June 18, 1992	June 3, 1999, 64 FR 29790; corrected on June 30, 1999, 64 FR 35002.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*5*).
1020	Definitions	February 21, 2013	October 2, 2014, 79 FR 59433.	Submitted on February 10, 2014. See 40 CFR 52.220(c)(442)(i)(B)(*1*).
1040	Enforcement	December 17, 1992	July 1, 2014, 79 FR 37224.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*10*).
1050	Order of Abatement	December 17, 1992	July 1, 2014, 79 FR 37224.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*10*).
1070	Inspections	December 17, 1992	July 1, 2014, 79 FR 37224.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*10*).
1080	Stack Monitoring	December 17, 1992	April 26, 2004, 69 FR 22441.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*8*).
1081	Source Sampling	December 16, 1993	April 26, 2004, 69 FR 22441.	Submitted on May 24, 1994. See 40 CFR 52.220(c)(197)(i)(C)(*5*).
1090	Penalty	December 17, 1992	July 1, 2014, 79 FR 37224.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*10*).
1110	Circumvention	December 17, 1992	July 23, 1999, 64 FR 39920.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*6*).
1130	Severability	December 17, 1992	June 3, 1999, 64 FR 29790; corrected on June 30, 1999, 64 FR 35002.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*5*).
1140	Applicability of Emission Limits	December 17, 1992	July 23, 1999, 64 FR 39920.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*6*).
1150	Separation and Combination	December 17, 1992	July 23, 1999, 64 FR 39920.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*6*).
1160	Emission Statements	November 18, 1992	February 12, 2019, 84 FR 3302.	Submitted on January 11, 1993. See 40 CFR 52.220(c)(191)(i)(E)(*1*).
Regulation II—Permits				
2010	Permits Required	December 17, 1992	July 23, 1999, 64 FR 39920.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*6*).
2020	Exemptions	August 18, 2011	September 17, 2014, 79 FR 55637.	Submitted on September 28, 2011. See 40 CFR 52.220(c)(440)(i)(A)(*1*).
2021	Experimental Research Operations	December 17, 1992	November 17, 2021, 86 FR 64071.	Submitted on November 18, 1993. See 40 CFR 52.220(c)(194)(i)(C)(*6*).
2031	Transfer of Permits	December 17, 1992	July 23, 1999, 64 FR 39920.	Submitted on November 18, 1993. See 40 CFR 52.220(c)(194)(i)(C)(*4*).
2050	Cancellation of Application	December 16, 1993	October 24, 2008, 73 FR 63382.	Submitted on May 24, 1994. See 40 CFR 52.220(c)(197)(i)(C)(*6*).
2070	Standards for Granting Applications	December 17, 1992	July 23, 1999, 64 FR 39920.	Submitted on November 18, 1993. See 40 CFR 52.220(c)(194)(i)(C)(*4*).
2080	Conditional Approval	December 17, 1992	July 23, 1999, 64 FR 39920.	Submitted on November 18, 1993. See 40 CFR 52.220(c)(194)(i)(C)(*4*).
2092	Standards for Permits to Operate	December 17, 1992	July 23, 1999, 64 FR 39920.	Submitted on November 18, 1993. See 40 CFR 52.220(c)(194)(i)(C)(*4*).
2201	New and Modified Stationary Source Review Rule.	August 15, 2019	July 10, 2023, 88 FR 43434.	Submitted on November 20, 2019 as an attachment to a letter dated November 15, 2019. See 40 CFR 52.220(c)(598)(i)(A)(*1*).
2250	Permit-Exempt Equipment Registration.	October 19, 2006	September 14, 2020, 85 FR 56521.	Submitted on April 30, 2020. See 40 CFR 52.220(c)(540)(i)(A)(*1*).

TABLE 29—EPA-APPROVED SAN JOAQUIN VALLEY UNIFIED AIR POLLUTION CONTROL DISTRICT REGULATIONS; FRESNO COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; KERN COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; KINGS COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; MADERA COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; MERCED COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; SAN JOAQUIN COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; STANISLAUS COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; TULARE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
2410	Prevention of Significant Deterioration	November 26, 2012	October 26, 2012, 77 FR 65305.	Submitted on August 23, 2011. See 40 CFR 52.220(c)(415)(i)(A)(*1*). Final approval of this rule is based, in part, on the clarifications contained in a May 18, 2012 letter from the San Joaquin Valley Unified Air Pollution Control District regarding specific implementation of parts of the Prevention of Significant Deterioration program. The letter is included in the table listing the nonregulatory portions of the California SIP.
2530	Federally Enforceable Potential to Emit.	June 10, 2010	May 11, 2010, 75 FR 26102.	Submitted on March 17, 2009. See 40 CFR 52.220(c)(363)(i)(A)(*6*).
Regulation III—Fees				
3170	Federally Mandated Ozone Nonattainment Fee.	May 19, 2011	August 20, 2012, 77 FR 50021.	Submitted on June 14, 2011. See 40 CFR 52.220(c)(412)(i)(A)(*1*).
3171	Federally Mandated Ozone Nonattainment Fee—1997 8-Hour Standard.	October 19, 2023	January 6, 2026, 91 FR 336.	Submitted electronically on January 10, 2024 as an attachment to a letter dated December 27, 2023. See 40 CFR 52.220(c)(626)(i)(C)(*1*).
3172	Federally Mandated Ozone Nonattainment Fee—2008 8-Hour Standard.	December 21, 2023	July 30, 2026, 91 FR 47962.	Submitted electronically on March 13, 2024 as an attachment to a letter dated March 7, 2024. See 40 CFR 52.220(c)(632)(i)(A)(1).
3173	Federally Mandated Ozone Nonattainment Fee—2015 8-Hour Standard.	December 21, 2023	July 30, 2026, 91 FR 47962.	Submitted electronically on March 13, 2024 as an attachment to a letter dated March 7, 2024. See 40 CFR 52.220(c)(632)(i)(A)(2).
Regulation IV—Prohibitions				
4101	Visible Emissions	February 17, 2005	August 11, 2005, 70 FR 46770.	Submitted on April 26, 2005. See 40 CFR 52.220(c)(336)(i)(A)(*1*).
4103	Open Burning	June 1, 2010	January 4, 2012, 77 FR 214.	Submitted on April 5, 2011. See 40 CFR 52.220(c)(388)(i)(B)(*2*).
4104	Reduction of Animal Matter	December 17, 1992	March 9, 2010, 75 FR 10690.	Submitted on August 24, 2007. See 40 CFR 52.220(c)(351)(i)(C)(*1*).
4106	Prescribed Burning and Hazard Reduction Burning.	June 21, 2001	February 27, 2002, 67 FR 8894.	Submitted on October 30, 2001. See 40 CFR 52.220(c)(288)(i)(A)(*1*).
4201	Particulate Matter Concentration	December 17, 1992	April 4, 2002, 67 FR 16026.	Submitted on November 18, 1993. See 40 CFR 52.220(c)(194)(i)(C)(*5*).
4202	Particulate Matter—Emission Rate	December 17, 1992	April 21, 2000, 65 FR 21347.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*7*).
4204	Cotton Gins	February 17, 2005	November 9, 2006, 71 FR 65740.	Submitted on July 15, 2005. See 40 CFR 52.220(c)(337)(i)(A)(*3*).
4301	Fuel Burning Equipment	December 17, 1992	May 18, 1999, 64 FR 26876.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*4*).
4302	Incinerator Burning	December 16, 1993	August 19, 1999, 64 FR 45170.	Submitted on May 24, 1994. See 40 CFR 52.220(c)(197)(i)(C)(*3*).
4303	Orchard Heaters	December 16, 1993	August 19, 1999, 64 FR 45170.	Submitted on May 24, 1994. See 40 CFR 52.220(c)(197)(i)(C)(*3*).
4304	Equipment Tuning Procedure for Boilers, Steam Generators and Process Heaters.	October 19, 1995	November 16, 2001, 66 FR 57666.	Submitted on March 26, 1996. See 40 CFR 52.220(c)(230)(i)(D)(*2*).
4305	Boilers, Steam Generators and Process Heaters—Phase 2.	August 21, 2003	May 18, 2004, 69 FR 28061.	Submitted on September 29, 2003. See 40 CFR 52.220(c)(325)(i)(A)(*1*).
4306	Boilers, Steam Generators and Process Heaters-Phase 3.	October 16, 2008	January 13, 2010, 75 FR 1715.	Submitted on March 17, 2009. See 40 CFR 52.220(c)(363)(i)(A)(*3*).
4307	Boilers, Steam Generators, and Process Heaters—2.0 MMBtu/hr to 5.0 MMBtu/hr.	April 21, 2016	August 14, 2017, 82 FR 37817.	Submitted on August 22, 2016. See 40 CFR 52.220(c)(488)(i)(B)(*1*).
4308	Boilers, Steam Generators, and Process Heaters-0.075 MMBtu/hr to less than 2.0 MMBtu/hr.	November 14, 2013	February 12, 2015, 80 FR 7803.	Submitted on May 13, 2014. See 40 CFR 52.220(c)(441)(i)(D)(*3*).
4309	Dryers, Dehydrators and Ovens	December 15, 2005	May 30, 2007, 72 FR 29886.	Submitted on March 10, 2006. See 40 CFR 52.220(c)(344)(i)(C)(*1*).
4311	Flares	December 17, 2020	December 28, 2022, 87 FR 79806.	Submitted on March 12, 2021 as an attachment to a letter dated March 10, 2021. See 40 CFR 52.220(c)(587)(i)(A)(*1*).
4313	Lime Kilns	March 27, 2003	September 4, 2003, 68 FR 52510.	Submitted on June 5, 2003. See 40 CFR 52.220(c)(316)(i)(B)(*1*).
4320	Advanced Emission Reduction Options for Boilers, Steam Generators and Process Heaters greater than 5.0 MMbtu/hr.	October 16, 2008	March 25, 2011, 76 FR 16696.	Submitted on March 17, 2009. See 40 CFR 52.220(c)(363)(i)(A)(*7*).
4351	Boilers, Steam Generators and Process Heaters—Phase 1.	August 21, 2003	May 18, 2004, 69 FR 28061.	Submitted on September 29, 2003. See 40 CFR 52.220(c)(325)(i)(A)(*1*).

TABLE 29—EPA-APPROVED SAN JOAQUIN VALLEY UNIFIED AIR POLLUTION CONTROL DISTRICT REGULATIONS; FRESNO COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; KERN COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; KINGS COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; MADERA COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; MERCED COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; SAN JOAQUIN COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; STANISLAUS COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; TULARE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
4352	Solid Fuel Fired Boilers, Steam Generators and Process Heaters.	December 15, 2011	November 6, 2012, 77 FR 66548.	Submitted on February 23, 2012. See 40 CFR 52.220(c)(411)(i)(B)(*4*).
4354	Glass Melting Furnaces	May 19, 2011	January 31, 2013, 78 FR 6740.	Submitted on September 27, 2011. See 40 CFR 52.220(c)(404)(i)(D)(*1*).
4401	Steam-Enhanced Crude Oil Production Wells.	June 15, 2023	May 29, 2026, 91 FR 31918.	Submitted electronically on October 16, 2023 as an attachment to a letter dated October 13, 2023. See 40 CFR 52.220(c)(619)(i)(A)(*2*).
4402	Crude Oil Production Sumps	December 15, 2011	October 22, 2012, 77 FR 64427.	Submitted on February 23, 2012. See 40 CFR 52.220(c)(411)(i)(B)(*2*).
4404	Heavy Oil Test Station—Kern County	December 17, 1992	March 9, 2010, 75 FR 10690.	Submitted on August 24, 2007. See 40 CFR 52.220(c)(351)(i)(C)(*1*).
4407	In-Situ Combustion Well Vents	May 19, 1994	March 6, 1995, 60 FR 12121.	Submitted on July 13, 1994. See 40 CFR 52.220(c)(198)(i)(C)(*1*).
4408	Glycol Dehydration Systems	December 19, 2002	August 26, 2003, 68 FR 51187.	Submitted on April 1, 2003. See 40 CFR 52.220(c)(315)(i)(B)(*1*).
4409	Components at Light Crude Oil Production Facilities, Natural Gas Production Facilities, and Natural Gas Processing Facilities.	June 15, 2023	May 29, 2026, 91 FR 31918.	Submitted electronically on October 16, 2023 as an attachment to a letter dated October 13, 2023. See 40 CFR 52.220(c)(619)(i)(A)(*3*).
4453	Refinery Vacuum Producing Devices or Systems.	December 17, 1992	September 23, 2010, 75 FR 57862.	Submitted on August 24, 2007. See 40 CFR 52.220(c)(351)(i)(C)(*3*).
4454	Refinery Process Unit Turnaround	December 17, 1992	September 23, 2010, 75 FR 57862.	Submitted on August 24, 2007. See 40 CFR 52.220(c)(351)(i)(C)(*4*).
4455	Components at Petroleum Refineries, Gas Liquids Processing Facilities, and Chemical Plants.	April 20, 2005	March 23, 2006, 71 FR 14652.	Submitted on July 15, 2005. See 40 CFR 52.220(c)(337)(i)(A)(*2*).
4550	Conservation Management Practices	August 19, 2004	February 14, 2006, 71 FR 7683.	Submitted on September 23, 2004. See 40 CFR 52.220(c)(334)(i)(B)(*1*).
[4550—CMP List]	List of Conservation Management Practices.	August 19, 2004	February 14, 2006, 71 FR 7683.	Submitted on September 23, 2004. See 40 CFR 52.220(c)(334)(i)(B)(*1*).
4565	Biosolids, Animal Manure, and Poultry Litter Operations.	March 15, 2007	January 17, 2012, 77 FR 2228.	Submitted on August 24, 2007. See 40 CFR 52.220(c)(351)(i)(C)(*7*).
4566	Organic Material Composting Operations.	August 18, 2011	November 29, 2012, 77 FR 71129.	Submitted on November 18, 2011. See 40 CFR 52.220(c)(416)(i)(A)(*2*).
4570	Confined Animal Facilities	October 21, 2010	January 17, 2012, 77 FR 2228; corrected on March 28, 2018, 83 FR 13190.	Submitted on April 5, 2011. See 40 CFR 52.220(c)(388)(i)(B)(*6*).
4601	Architectural Coatings	April 16, 2020	December 22, 2022, 87 FR 78544.	Submitted on April 23, 2020. See 40 CFR 52.220(c)(592)(i)(A)(*1*).
4602	Motor Vehicle Assembly Coatings	September 17, 2009	November 1, 2011, 76 FR 67369.	Submitted on May 17, 2010. See 40 CFR 52.220(c)(379)(i)(C)(*3*).
4603	Surface Coating of Metal Parts and Products, Plastic Parts and Products and Pleasure Crafts.	September 17, 2009	November 1, 2011, 76 FR 67369.	Submitted on May 17, 2010. See 40 CFR 52.220(c)(379)(i)(C)(*4*).
4604	Can and Coil Coating Operations	September 20, 2007	January 19, 2010, 75 FR 2796.	Submitted on March 7, 2008. See 40 CFR 52.220(c)(354)(i)(E)(*9*).
4605	Aerospace Assembly and Component Coating Operations.	June 16, 2011	November 16, 2011, 76 FR 70886.	Submitted on July 28, 2011. See 40 CFR 52.220(c)(402)(i)(A)(*2*).
4606	Wood Products and Flat Wood Paneling Product Coating Operations.	October 16, 2008	October 15, 2009, 74 FR 52894.	Submitted on December 23, 2008. See 40 CFR 52.220(c)(364)(i)(A)(*1*).
4607	Graphic Arts and Paper, Film, Foil, and Fabric Coatings.	December 18, 2008	October 15, 2009, 74 FR 52894.	Submitted on March 17, 2009. See 40 CFR 52.220(c)(363)(i)(A)(*2*).
4610	Glass Coating Operations	April 17, 2003	October 14, 2004, 69 FR 60962.	Submitted on June 3, 2004. See 40 CFR 52.220(c)(331)(i)(A)(*1*).
4612	Motor Vehicle and Mobile Equipment Coating.	October 21, 2010	February 13, 2012, 77 FR 7536; corrected on March 28, 2018, 83 FR 13190.	Submitted on April 5, 2011. See 40 CFR 52.220(c)(388)(i)(B)(*7*).
4621	Gasoline Transfer into Stationary Storage Containers, Delivery Vessels, and Bulk Plants.	December 19, 2013	February 10, 2015, 80 FR 7345.	Submitted on May 13, 2014. See 40 CFR 52.220(c)(441)(i)(D)(*1*).
4622	Gasoline Transfer into Motor Vehicle Fuel Tanks.	December 19, 2013	February 10, 2015, 80 FR 7345.	Submitted on May 13, 2014. See 40 CFR 52.220(c)(441)(i)(D)(*2*).
4623	Storage of Organic Liquids	June 15, 2023	May 29, 2026, 91 FR 31918.	Submitted electronically on October 16, 2023 as an attachment to a letter dated October 13, 2023. See 40 CFR 52.220(c)(619)(i)(A)(*4*).
4624	Transfer of Organic Liquid	December 20, 2007	October 15, 2009, 74 FR 52894.	Submitted on March 7, 2008. See 40 CFR 52.220(c)(354)(i)(E)(*3*).

TABLE 29—EPA-APPROVED SAN JOAQUIN VALLEY UNIFIED AIR POLLUTION CONTROL DISTRICT REGULATIONS; FRESNO COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; KERN COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; KINGS COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; MADERA COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; MERCED COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; SAN JOAQUIN COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; STANISLAUS COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; TULARE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
4625	Wastewater Separators	December 15, 2011	October 22, 2012, 77 FR 64427.	Submitted on February 23, 2012. See 40 CFR 52.220(c)(411)(i)(B)(*3*).
4641	Cutback, Slow Cure, and Emulsified Asphalt, Paving and Maintenance Operations.	December 17, 1992	March 9, 2010, 75 FR 10690.	Submitted on August 24, 2007. See 40 CFR 52.220(c)(351)(i)(C)(*2*).
4642	Solid Waste Disposal Sites	April 16, 1998	July 26, 2001, 66 FR 38939.	Submitted on September 29, 1998. See 40 CFR 52.220(c)(266)(i)(B)(*4*).
4651	Soil Decontamination Operations	September 20, 2007	October 30, 2009, 74 FR 56120.	Submitted on March 7, 2008. See 40 CFR 52.220(c)(354)(i)(E)(*8*).
4653	Adhesives and Sealants	September 16, 2010	February 13, 2012, 77 FR 7536; corrected on March 28, 2018, 83 FR 13190.	Submitted on April 5, 2011. See 40 CFR 52.220(c)(388)(i)(B)(*8*).
4661	Organic Solvents	September 20, 2007	May 5, 2010, 75 FR 24406.	Submitted on March 7, 2008. See 40 CFR 52.220(c)(354)(i)(E)(*13*).
4662	Organic Solvent Degreasing Operations.	September 20, 2007	July 30, 2009, 74 FR 37948.	Submitted on March 7, 2008. See 40 CFR 52.220(c)(354)(i)(E)(*1*).
4663	Organic Solvent Cleaning, Storage, and Disposal.	September 20, 2007	July 30, 2009, 74 FR 37948.	Submitted on March 7, 2008. See 40 CFR 52.220(c)(354)(i)(E)(*2*).
4672	Petroleum Solvent Dry Cleaning Operations.	December 17, 1992	March 9, 2010, 75 FR 10690.	Submitted on August 24, 2007. See 40 CFR 52.220(c)(351)(i)(C)(*2*).
4681	Rubber Tire Manufacturing	December 16, 1993	August 17, 1998, 63 FR 43881.	Submitted on May 24, 1994. See 40 CFR 52.220(c)(197)(i)(C)(*2*).
4682	Polystyrene, Polyethylene, and Polypropylene Products Manufacturing.	December 15, 2011	September 20, 2012, 77 FR 58312.	Submitted on February 23, 2012. See 40 CFR 52.220(c)(411)(i)(B)(*1*).
4684	Polyester Resin Operations	August 18, 2011	February 6, 2012, 77 FR 5709.	Submitted on August 26, 2011. See 40 CFR 52.220(c)(405)(i)(A)(*1*).
4692	Commercial Charbroiling	June 21, 2018	September 14, 2020, 85 FR 56521.	Submitted on November 21, 2018. See 40 CFR 52.220(c)(527)(i)(B)(*1*).
4693	Bakery Ovens	May 16, 2002	April 26, 2004, 69 FR 22441.	Submitted on August 6, 2002. See 40 CFR 52.220(c)(303)(i)(C)(*3*).
4694 (Section 1.0, except for the words ''fermentation and'' and ''or achieve equivalent reductions from alternative emission sources''; Section 2.0, except for the words ''fermenting wine and/or''; Section 3.0, paragraphs 3.1, 3.2, 3.18, 3.19, 3.21, 3.22, 3.27, 3.29, 3.33, 3.35, and 3.36; Section 4.0, paragraph 4.2; Section 5.0, paragraph 5.2-Storage Tanks; and Section 6.0, paragraph 6.4-Monitoring and Recordkeeping, introductory text and paragraph 6.4.2.).	Wine Fermentation and Storage Tanks.	December 15, 2005	November 29, 2012, 77 FR 71108.	Submitted on November 18, 2011. See 40 CFR 52.220(c)(416)(i)(A)(*1*). As noted, only certain portions of sections 1.0 (Purpose), 2.0 (Applicability), 3.0 (Definitions), 4.0 (Exemptions), 5.0 Requirements), and 6.0 (Administrative Requirements) were submitted and approved as part of the SIP. Approved definitions include paragraphs 3.1 (Air Pollution Control Officer (APCO)), 3.2 (Air Resources Board (ARB or CARB)), 3.18 (Gas Leak), 3.19 (Gas-Tight), 3.21 (Must), 3.22 (Operator), 3.27 (Storage Tank), 3.29 (Tank), 3.33 (Volatile Organic Compound (VOC)), 3.35 (Wine), and 3.36 (Winery).
4695	Brandy Aging and Wine Aging Operations.	September 17, 2009	August 4, 2011, 76 FR 47076.	Submitted on May 17, 2010. See 40 CFR 52.220(c)(379)(i)(C)(*2*).
4701	Internal Combustion Engines—Phase 1.	August 21, 2003	May 18, 2004, 69 FR 28061.	Submitted on October 9, 2003. See 40 CFR 52.220(c)(326)(i)(A)(*1*).
4702	Internal Combustion Engines	November 14, 2013	April 25, 2016, 81 FR 24029.	Submitted on May 13, 2014. See 40 CFR 52.220(c)(441)(i)(D)(*4*).
4703	Stationary Gas Turbines	September 20, 2007	October 21, 2009, 74 FR 53888.	Submitted on March 7, 2008. See 40 CFR 52.220(c)(354)(i)(E)(*5*).
4802	Sulfuric Acid Mist	December 17, 1992	June 8, 1999, 64 FR 30396.	Submitted on November 18, 1993. See 40 CFR 52.220(c)(194)(i)(C)(*3*).
4901	Wood Burning Fireplaces and Wood Burning Heaters.	May 18, 2023	October 4, 2024, 89 FR 80749.	Submitted electronically on June 8, 2023 as an attachment to a letter dated June 7, 2023. See 40 CFR 52.220(c)(618)(i)(A)(*1*).
4902	Residential Water Heaters	March 19, 2009	May 5, 2010, 75 FR 24408.	Submitted on April 29, 2009. See 40 CFR 52.220(c)(362)(i)(D)(*1*).

TABLE 29—EPA-APPROVED SAN JOAQUIN VALLEY UNIFIED AIR POLLUTION CONTROL DISTRICT REGULATIONS; FRESNO COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; KERN COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; KINGS COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; MADERA COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; MERCED COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; SAN JOAQUIN COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; STANISLAUS COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; TULARE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
4905	Natural-Gas-Fired, Fan-Type Central Furnaces.	January 22, 2015	March 29, 2016, 81 FR 17390.	Submitted on April 7, 2015. See 40 CFR 52.220(c)(461)(i)(D)(*1*).
Regulation VI—Air Pollution Emergency Contingency Plan				
6010	General Statement	December 17, 1992	March 18, 1999, 64 FR 13351.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*3*).
6020	Applicable Areas	December 17, 1992	March 18, 1999, 64 FR 13351.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*3*).
6030	Episode Criteria Levels	November 13, 1996	March 18, 1999, 64 FR 13351.	Submitted on March 3, 1997. See 40 CFR 52.220(c)(244)(i)(E)(*1*).
6040	Episode Stages	December 17, 1992	March 18, 1999, 64 FR 13351.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*3*).
6050	Division of Responsibility	December 17, 1992	March 18, 1999, 64 FR 13351.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*3*).
6060	Administration of Emergency Program	December 17, 1992	March 18, 1999, 64 FR 13351.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*3*).
6070	Advisory of High Air Pollution Potential.	December 17, 1992	March 18, 1999, 64 FR 13351.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*3*).
6080	Declaration of Episode	December 17, 1992	March 18, 1999, 64 FR 13351.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*3*).
6081	Episode Action—Health Advisory	December 17, 1992	March 18, 1999, 64 FR 13351.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*3*).
6090	Episode Action Stage 1 (Health Advisory—Alert).	December 17, 1992	March 18, 1999, 64 FR 13351.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*3*).
6100	Episode Action Stage 2 (Warning)	December 17, 1992	March 18, 1999, 64 FR 13351.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*3*).
6110	Episode Action Stage 3 (Emergency)	December 17, 1992	March 18, 1999, 64 FR 13351.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*3*).
6120	Episode Termination	December 17, 1992	March 18, 1999, 64 FR 13351.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*3*).
6130	Stationary Source Curtailment Plans and Traffic Abatement Plans.	December 17, 1992	March 18, 1999, 64 FR 13351.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*3*).
6140	Episode Abatement Plan	December 17, 1992	March 18, 1999, 64 FR 13351.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*3*).
6150	Enforcement	December 17, 1992	March 18, 1999, 64 FR 13351.	Submitted on September 28, 1994. See 40 CFR 52.220(c)(199)(i)(D)(*3*).
Regulation VIII—Fugitive PM_{10} Prohibitions				
8011	General Requirements	August 19, 2004	February 17, 2006, 71 FR 8461.	Submitted on September 23, 2004. See 40 CFR 52.220(c)(334)(i)(B)(*2*).
8021	Construction, Demolition, Excavation, Extraction, and Other Earthmoving Activities.	August 19, 2004	February 17, 2006, 71 FR 8461.	Submitted on September 23, 2004. See 40 CFR 52.220(c)(334)(i)(B)(*2*).
8031	Bulk Materials	August 19, 2004	February 17, 2006, 71 FR 8461.	Submitted on September 23, 2004. See 40 CFR 52.220(c)(334)(i)(B)(*2*).
8041	Carryout and Trackout	August 19, 2004	February 17, 2006, 71 FR 8461.	Submitted on September 23, 2004. See 40 CFR 52.220(c)(334)(i)(B)(*2*).
8051	Open Areas	September 21, 2023	October 4, 2024, 89 FR 80749.	Submitted electronically on October 16, 2023, as an attachment to a letter dated October 13, 2023. See 40 CFR 52.220(c)(619)(i)(A)(*1*).
8061	Paved and Unpaved Roads	August 19, 2004	February 17, 2006, 71 FR 8461.	Submitted on September 23, 2004. See 40 CFR 52.220(c)(334)(i)(B)(*2*).
8071	Unpaved Vehicle/Equipment Traffic Areas.	September 16, 2004	February 17, 2006, 71 FR 8461.	Submitted on September 23, 2004. See 40 CFR 52.220(c)(334)(i)(B)(*2*).
8081	Agricultural Sources	September 16, 2004	February 17, 2006, 71 FR 8461.	Submitted on September 23, 2004. See 40 CFR 52.220(c)(334)(i)(B)(*2*).
Regulation IX—Mobile and Indirect Sources				
9110	General Conformity	October 20, 1994	April 23, 1999, 64 FR 19916.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(G)(*1*).
9310	School Bus Fleets	September 21, 2006	March 8, 2010, 75 FR 10420.	Submitted on December 29, 2006. See 40 CFR 52.220(c)(348)(i)(A)(*2*).
9410	Employer Based Trip Reduction	December 17, 2009	February 9, 2016, 81 FR 6761.	Submitted on May 17, 2010. See 40 CFR 52.220(c)(379)(i)(C)(*7*).
9510	Indirect Source Review (ISR)	March 21, 2018	June 25, 2021, 86 FR 33542.	Amended by the District on December 21, 2017. Submitted by CARB on May 23, 2018. See 40 CFR 52.220(c)(518)(i)(E)(*1*).
9610	State Implementation Plan Credit for Emission Reductions Generated through Incentive Programs.	June 20, 2013	April 9, 2015, 80 FR 19020.	Submitted on June 26, 2013. See 40 CFR 52.220(c)(455)(i)(A)(*1*).

TABLE 29—EPA-APPROVED SAN JOAQUIN VALLEY UNIFIED AIR POLLUTION CONTROL DISTRICT REGULATIONS; FRESNO COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; KERN COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; KINGS COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; MADERA COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; MERCED COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; SAN JOAQUIN COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; STANISLAUS COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; TULARE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
Materials Related to Implementation of Rule 4103 (Open Burning)				
Table 2–1 of the Supplemental Report and Recommendations on Agricultural Burning.	Accelerated Reductions by Crop Category.	June 17, 2021	June 16, 2022, 87 FR 36222.	Submitted on November 29, 2021 as an attachment to a letter dated November 24, 2021. See 40 CFR 52.220(c)(572)(i)(A)(*1*).
San Joaquin Valley Air Pollution Control District, Resolution 21–06–12.	Approve Supplemental Report and Recommendations on Agricultural Burning.	June 17, 2021	June 16, 2022, 87 FR 36222.	Submitted on November 29, 2021 as an attachment to a letter dated November 24, 2021. See 40 CFR 52.220(c)(572)(i)(A)(*2*).
California Air Resources Board, Resolution 21–4.	San Joaquin Valley Agricultural Burning Assessment.	February 25, 2021	June 16, 2022, 87 FR 36222.	Submitted on November 29, 2021 as an attachment to a letter dated November 24, 2021. See 40 CFR 52.220(c)(572)(i)(B)(*1*).
Letter dated June 18, 2021, from Richard W. Corey, Executive Officer, CARB, to Samir Sheikh, Executive Director, SJVUAPCD.	Not applicable	June 17, 2021	June 16, 2022, 87 FR 36222.	Through the letter, CARB concurred on the SJVUAPCD Supplemental Report and Recommendations on Agricultural Burning. Submitted on November 29, 2021 as an attachment to a letter dated November 24, 2021. See 40 CFR 52.220(c)(572)(i)(B)(*2*).
Rules and Regulations (Fresno County portion of the District)				
Original Codification of Rules and Regulations				
4:1	Prohibitions under State Law	June 2, 1969	May 31, 1972, 37 FR 10842.	Submitted on February 21, 1972. See 40 CFR 52.220(b).
Recodification of Rules and Regulations				
103	Confidential Information	July 30, 1974	August 22, 1977, 42 FR 42219.	Submitted on October 23, 1974. See 40 CFR 52.220(c)(25)(i)(A).
106	Land Use	March 28, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
406	Sulfur Compounds	November 9, 1982	November 18, 1983, 48 FR 52451.	Submitted on February 3, 1983. See 40 CFR 52.220(c)(127)(ii)(A).
407.1	Disposal of Solid and Liquid Wastes	March 28, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
Rules and Regulations (Kern County portion of the District)				
Original Codification of Rules and Regulations				
4.1	Prohibitions under State Law	January 25, 1971	May 31, 1972, 37 FR 10842.	Submitted on February 21, 1972. See 40 CFR 52.220(b).
Recodification of Rules and Regulations				
103	Confidential Information	November 10, 1976	March 22, 1978, 43 FR 11816.	Submitted on November 10, 1976. See 40 CFR 52.220(c)(35)(xiii)(A).
103.1	Inspection of Public Records	November 10, 1976	March 22, 1978, 43 FR 11816.	Submitted on November 10, 1976. See 40 CFR 52.220(c)(35)(xiii)(A).
106	Land Use	April 18, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
406.2	Process Weight—Portland Cement Kilns.	April 18, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
407	Sulfur Compounds	April 18, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
407.1	Disposal of Solid and Liquid Wastes	April 18, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
424	Sulfur Compounds from Oil Field Steam Generators.	July 18, 1983	May 3, 1984, 49 FR 18824.	Submitted on August 30, 1983. See 40 CFR 52.220(c)(140)(ii)(A).
425	Oxides of Nitrogen Emissions from Steam Generators Used in Thermally Enhanced Oil Recovery.	April 5, 1982	May 3, 1984, 49 FR 18822.	Submitted on June 28, 1982. See 40 CFR 52.220(c)(132)(i)(A).
426	Experimental Research Operations	December 15, 1980	July 6, 1982, 47 FR 29231.	Submitted on March 23, 1981. See 40 CFR 52.220(c)(95)(i)(C).

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District citation	Title/subject	State effective date	EPA approval date	Additional explanation
Rules and Regulations (Kings County portion of the District)				
Original Codification of Rules and Regulations				
24–7	Prohibitions Supplemental to State Law.	October 7, 1971	May 31, 1972, 37 FR 10842.	Submitted on February 21, 1972. See 40 CFR 52.220(b).
Recodification of Rules and Regulations				
103	Confidential Information	November 4, 1977	August 4, 1978, 43 FR 34467.	Submitted on November 4, 1977. See 40 CFR 52.220(c)(42)(iii)(A).
103.1	Inspection of Public Records	November 4, 1977	August 4, 1978, 43 FR 34467.	Submitted on November 4, 1977. See 40 CFR 52.220(c)(42)(iii)(A).
106	Land Use	May 1, 1973	August 22, 1977, 42 FR 42219.	Submitted on July 25, 1973. See 40 CFR 52.220(c)(21)(ix)(A).
407	Sulfur Compounds	June 30, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
407.1	Disposal of Solid and Liquid Wastes	June 30, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
409	Fuel Burning Equipment—Oxides of Nitrogen.	November 4, 1977	August 4, 1978, 43 FR 34467.	Submitted on November 4, 1977. See 40 CFR 52.220(c)(42)(iii)(A).
Rules and Regulations (Madera County portion of the District)				
Original Codification of Rules and Regulations				
4.1	Prohibitions under State Law	June 24, 1969	May 31, 1972, 37 FR 10842.	Submitted on February 21, 1972. See 40 CFR 52.220(b).
Recodification of Rules and Regulations				
103	Confidential Information	February 15, 1983	November 18, 1983, 48 FR 52450.	Submitted on April 11, 1983. See 40 CFR 52.220(c)(138)(v)(A).
104	Inspection of Public Records	February 15, 1983	November 18, 1983, 48 FR 52450.	Submitted on April 11, 1983. See 40 CFR 52.220(c)(138)(v)(A).
107	Land Use	February 15, 1983	November 18, 1983, 48 FR 52450.	Submitted on April 11, 1983. See 40 CFR 52.220(c)(138)(v)(A).
403	Particulate Matter Emissions from the Incineration of Combustible Refuse.	January 5, 1988	April 16, 1991, 56 FR 15286.	Submitted on February 7, 1989. See 40 CFR 52.220(c)(177)(i)(D)(*1*).
404	Sulfur Compound Emissions (General).	May 8, 1984	January 29, 1985, 50 FR 3906.	Submitted on July 10, 1984. See 40 CFR 52.220(c)(155)(iii)(B).
405	Fuel Burning Equipment	February 15, 1983	November 18, 1983, 48 FR 52450.	Submitted on April 11, 1983. See 40 CFR 52.220(c)(138)(v)(A). Rule 405 was superseded in part by approval of SJVUAPCD Rule 4301 (Fuel Burning Equipment) at 64 FR 26876 (May 18, 1999).
Rules and Regulations (Merced County portion of the District)				
Original Codification of Rules and Regulations				
4:1	Prohibitions under State Law	December 2, 1969	May 31, 1972, 37 FR 10842.	Submitted on February 21, 1972. See 40 CFR 52.220(b).
Recodification of Rules and Regulations				
103	Confidential Information	June 1, 1976	June 14, 1978, 43 FR 25689.	Submitted on August 2, 1976. See 40 CFR 52.220(c)(32)(iii)(C).
103.1	Inspection of Public Records	June 1, 1976	June 14, 1978, 43 FR 25689.	Submitted on August 2, 1976. See 40 CFR 52.220(c)(32)(iii)(C).
106	Land Use	May 2, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
109 (paragraphs (A), (B), and (D)–(I)).	Equipment Breakdown	May 22, 1979	December 9, 1981, 46 FR 60202.	Submitted on October 15, 1979. See 40 CFR 52.220(c)(52)(vi)(B).
109 (paragraph (C))	Equipment Breakdown	May 22, 1979	June 18, 1982, 47 FR 26384.	Submitted on October 15, 1979. See 40 CFR 52.220(c)(52)(vi)(C).
407	Sulfur Compounds	March 1, 1983	February 1, 1984, 49 FR 3987.	Submitted on July 19, 1983. See 40 CFR 52.220(c)(137)(ii)(A).
407.1	Disposal of Solid or Liquid Wastes	May 2, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).

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District citation	Title/subject	State effective date	EPA approval date	Additional explanation
408.1	Fuel Burning Equipment—Oxides of Nitrogen.	June 1, 1976	June 14, 1978, 43 FR 25689.	Submitted on August 2, 1976. See 40 CFR 52.220(c)(32)(iii)(C).
421 (paragraph (a))	Burning Reports	June 1, 1976	June 14, 1978, 43 FR 25689.	Submitted on August 2, 1976. See 40 CFR 52.220(c)(32)(iii)(C).
Rules and Regulations (San Joaquin County portion of the District)				
Original Codification of Rules and Regulations				
4.1	Prohibitions under State Law	January 1, 1970	May 31, 1972, 37 FR 10842.	Submitted on February 21, 1972. See 40 CFR 52.220(b).
Recodification of Rules and Regulations				
103	Confidential Information	July 6, 1976	October 4, 1977, 42 FR 53961.	Submitted on November 10, 1976. See 40 CFR 52.220(c)(35)(v)(A).
103.1	Inspection of Public Records	July 6, 1976	October 4, 1977, 42 FR 53961.	Submitted on November 10, 1976. See 40 CFR 52.220(c)(35)(v)(A).
106	Land Use	May 30, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
110	Equipment Breakdown	September 27, 1983	December 5, 1984, 49 FR 47490.	Submitted on March 14, 1984. See 40 CFR 52.220(c)(153)(iv)(A).
209.4	Implementation Plans	May 29, 1979	June 18, 1982, 47 FR 26384.	Submitted on October 15, 1979. See 40 CFR 52.220(c)(52)(vii)(C).
407	Sulfur Compounds	September 27, 1983	December 5, 1984, 49 FR 47490.	Submitted on March 14, 1984. See 40 CFR 52.220(c)(153)(iv)(A).
407.1	Disposal of Solid or Liquid Waste	May 30, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
408.1	Fuel Burning Equipment—Oxides of Nitrogen.	January 1, 1975	August 22, 1977, 42 FR 42219.	Submitted on October 23, 1974. See 40 CFR 52.220(c)(25)(ii)(A).
420.1	Burning Reports	January 1, 1975	August 22, 1977, 42 FR 42219.	Submitted on October 23, 1974. See 40 CFR 52.220(c)(25)(ii)(A).
Rules and Regulations (Stanislaus County portion of the District)				
Original Codification of Rules and Regulations				
I	Introduction	January 20, 1970	May 31, 1972, 37 FR 10842.	Submitted on February 21, 1972. See 40 CFR 52.220(b).
Recodification of Rules and Regulations				
103	Confidential Information	June 17, 1980	December 9, 1981, 46 FR 60202.	Submitted on July 25, 1980. See 40 CFR 52.220(c)(88)(i)(B).
103.1	Inspection of Public Records	July 19, 1977	August 18, 1978, 43 FR 36624.	Submitted on November 4, 1977. See 40 CFR 52.220(c)(42)(iv)(A).
106	Land Use	April 25, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
213	Violation of Permit Prohibited	July 12, 1983	May 3, 1984, 49 FR 18824.	Submitted on August 30, 1983. See 40 CFR 52.220(c)(140)(iii)(A).
407	Sulfur Compounds	April 25, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
407.1	Disposal of Solid and Liquid Wastes	May 4, 1976	May 18, 1977, 42 FR 25501; corrected on August 22, 1977, 42 FR 42219.	Submitted on August 2, 1976. See 40 CFR 52.220(c)(32)(ii)(A).
Rules and Regulations (Tulare County portion of the District)				
Original Codification of Rules and Regulations				
203	Referrals by Planning Department	February 10, 1970	May 31, 1972, 37 FR 10842.	Submitted on February 21, 1972. See 40 CFR 52.220(b).
306 (paragraph (b))	Sulfur and Fluorine Compounds	February 10, 1970	May 31, 1972, 37 FR 10842.	Submitted on February 21, 1972. See 40 CFR 52.220(b). Paragraph (a) establishes a sulfur compound emission limit, and it was superseded by approval of Rule 407 (Sulfur Compounds) at 37 FR 19812 (September 22, 1972).

TABLE 29—EPA-APPROVED SAN JOAQUIN VALLEY UNIFIED AIR POLLUTION CONTROL DISTRICT REGULATIONS; FRESNO COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; KERN COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; KINGS COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; MADERA COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; MERCED COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; SAN JOAQUIN COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; STANISLAUS COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; TULARE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
Recodification of Rules and Regulations				
103	Confidential Information	August 31, 1976	September 21, 1977, 42 FR 47556.	Submitted on November 10, 1976. See 40 CFR 52.220(c)(35)(vi)(A).
103.1	Inspection of Public Records	August 31, 1976	September 21, 1977, 42 FR 47556.	Submitted on November 10, 1976. See 40 CFR 52.220(c)(35)(vi)(A).
106	Land Use	May 18, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
406	Process Weight—Portland Cement Plants.	October 23, 1974	August 22, 1977, 42 FR 42219.	Submitted on October 23, 1974. See 40 CFR 52.220(c)(25)(iv)(A).
407	Sulfur Compounds	May 18, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
407.1 (excluding paragraph (b)).	Disposal of Solid or Liquid Waste	August 31, 1976	September 21, 1977, 42 FR 47556.	Paragraph (b) was disapproved at 42 FR 47556 (September 21, 1977). Submitted on November 10, 1976. See 40 CFR 52.220(c)(35)(vi)(A).
409	Fuel Burning Equipment—Oxides of Nitrogen.	August 31, 1976	September 21, 1977, 42 FR 47556.	Submitted on November 10, 1976. See 40 CFR 52.220(c)(35)(vi)(A).

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TABLE 34—EPA-APPROVED SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT REGULATIONS; LOS ANGELES COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; ORANGE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; RIVERSIDE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; SAN BERNARDINO COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
Rules and Regulations (District-Wide Applicability)				
Regulation I—General Provisions				
101	Title	April 1, 1977	December 19, 1978, 43 FR 59065.	Submitted on October 13, 1977. See 40 CFR 52.220(c)(41)(xiv)(A).
102	Definition of Terms	January 10, 2020	July 9, 2021, 86 FR 36227.	Submitted on September 16, 2020. See 40 CFR 52.220(c)(556)(i)(A)(1).
103	Definition of Geographical Areas	January 9, 1976	June 14, 1978, 43 FR 25684.	Adopted by the Southern California Air Pollution Control District and remains applicable throughout the SCAQMD. Submitted on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(B).
104	Reporting of Source Test Data and Analyses.	January 9, 1976	June 14, 1978, 43 FR 25684.	Adopted by the Southern California Air Pollution Control District and remains applicable throughout the SCAQMD. Submitted on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(B).
106	Increments of Progress	January 9, 1976	June 14, 1978, 43 FR 25684.	Adopted by the Southern California Air Pollution Control District and remains applicable throughout the SCAQMD. Submitted on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(B).
108	Alternative Emission Control Plans	April 6, 1990	August 30, 1993, 58 FR 45445.	Submitted on December 31, 1990. See 40 CFR 52.220(c)(182)(i)(A)(3).
109	Recordkeeping for Volatile Organic Compound Emissions.	May 2, 2003	January 22, 2004, 69 FR 3018.	Submitted on August 11, 2003. See 40 CFR 52.220(c)(320)(i)(B)(1).
Regulation II—Permits				
201	Permit to Construct	January 5, 1990	May 13, 1999, 64 FR 25828.	Submitted on May 13, 1991. See 40 CFR 52.220(c)(184)(i)(B)(7).
201.1	Permit Conditions in Federally Issued Permits to Construct.	January 5, 1990	May 13, 1999, 64 FR 25828.	Submitted on May 13, 1991. See 40 CFR 52.220(c)(184)(i)(B)(7).
202 (excluding paragraph (c)).	Temporary Permit to Operate	January 9, 1976	November 9, 1978, 43 FR 52237.	Adopted by the Southern California Air Pollution Control District and remains applicable throughout the SCAQMD. Submitted on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(C).

TABLE 34—EPA-APPROVED SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT REGULATIONS; LOS ANGELES COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; ORANGE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; RIVERSIDE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; SAN BERNARDINO COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
202 (paragraph (c))	Temporary Permit to Operate	May 7, 1976	November 9, 1978, 43 FR 52237.	Adopted by the Southern California Air Pollution Control District and remains applicable throughout the SCAQMD. Submitted on August 2, 1976. See 40 CFR 52.220(c)(32)(iv)(C).
203	Permit to Operate	January 5, 1990	May 13, 1999, 64 FR 25828.	Submitted on May 13, 1991. See 40 CFR 52.220(c)(184)(i)(B)(7).
204	Permit Conditions	October 8, 1993	May 13, 1999, 64 FR 25828.	Submitted on February 28, 1994. See 40 CFR 52.220(c)(217)(i)(C)(1).
205	Expiration of Permits to Construct	January 5, 1990	May 13, 1999, 64 FR 25828.	Submitted on May 13, 1991. See 40 CFR 52.220(c)(184)(i)(B)(7).
206	Posting of Permit to Operate	October 8, 1993	May 13, 1999, 64 FR 25828.	Submitted on February 28, 1994. See 40 CFR 52.220(c)(217)(i)(C)(1).
207	Altering or Falsifying of Permit	January 9, 1976	November 9, 1978, 43 FR 52237.	Adopted by the Southern California Air Pollution Control District and remains applicable throughout the SCAQMD. Submitted on April 21, 1976. See 40 CFR 52.220(c)(31)(vi)(C).
208	Permit and Burn Authorization for Open Burning.	December 21, 2001	April 8, 2002, 67 FR 16644.	Submitted on January 22, 2002. See 40 CFR 52.220(c)(293)(i)(A)(1).
209	Transfer and Voiding of Permits	January 5, 1990	May 13, 1999, 64 FR 25828.	Submitted on May 13, 1991. See 40 CFR 52.220(c)(184)(i)(B)(7).
210	Applications	October 8, 1993	May 13, 1999, 64 FR 25828.	Submitted on February 28, 1994. See 40 CFR 52.220(c)(217)(i)(C)(1).
212	Standards for Approving Permits	December 7, 1995	December 4, 1996, 61 FR 64291.	Submitted on August 28, 1996. See 40 CFR 52.220(c)(240)(i)(A)(1).
217	Provision for Sampling and Testing Facilities.	January 5, 1990	May 13, 1999, 64 FR 25828.	Submitted on May 13, 1991. See 40 CFR 52.220(c)(184)(i)(B)(7).
218	Continuous Emission Monitoring	May 14, 1999	June 8, 2010, 75 FR 32293.	Submitted on July 23, 1999. See 40 CFR 52.220(c)(268)(i)(A)(2).
218.1	Continuous Emission Monitoring Performance Specifications.	May 14, 1999	June 8, 2010, 75 FR 32293.	Submitted on July 23, 1999. See 40 CFR 52.220(c)(268)(i)(A)(3).
219	Equipment Not Requiring a Written Permit Pursuant to Regulation II.	September 4, 1981	July 6, 1982, 47 FR 29231.	Submitted on October 23, 1981. See 40 CFR 52.220(c)(103)(xviii)(A).
220	Exemption—Net Increase in Emissions.	August 7, 1981	July 6, 1982, 47 FR 29231.	Submitted on October 23, 1981. See 40 CFR 52.220(c)(103)(xviii)(A).
221	Plans	January 4, 1985	April 17, 1987, 52 FR 12522.	Submitted on November 12, 1985. See 40 CFR 52.220(c)(165)(i)(B)(1).
223	Emission Reduction Permits for Large Confined Animal Facilities.	June 2, 2006	July 13, 2015, 80 FR 39966.	Submitted on March 17, 2009. See 40 CFR 52.220(c)(363)(i)(F)(1).
	Regulation III—Fees			
301 (paragraphs (e)(1), except (e)(1)(C), (e)(2), (5) and (8) only).	Permitting and Associated Fees	July 12, 2019	October 1, 2019, 84 FR 52005.	Submitted on August 5, 2019. See 40 CFR 52.220(c)(526)(i)(A)(1).
317	Clean Air Act Non-Attainment Fees	February 4, 2011	December 14, 2012, 77 FR 74372.	Submitted on April 22, 2011. See 40 CFR 52.220(c)(418)(i)(A)(1).
317.1	Clean Air Act Nonattainment Fees For 8-Hour Ozone Standards	June 7, 2024	December 11, 2025, 90 FR 57364.	Submitted on August 13, 2024. See 40 CFR 52.220(c)(629)(i)(A)(1).
	Regulation IV—Prohibitions			
401	Visible Emissions	March 2, 1984	January 29, 1985, 50 FR 3906.	Submitted on July 10, 1984. See 40 CFR 52.220(c)(155)(iv)(B).
403	Fugitive Dust	June 3, 2005	March 10, 2008, 73 FR 12639.	Submitted on October 20, 2005. See 40 CFR 52.220(c)(342)(i)(C)(4).
403 Implementation Handbook (Chapters 5, 7 and 8).	Fugitive Dust	April 2, 2004	November 14, 2005, 70 FR 69081.	Submitted on November 16, 2004. See 40 CFR 52.220(c)(340)(i)(A)(1).
403.1 (excluding paragraph (j)).	Supplemental Fugitive Dust Control Requirements for Coachella Valley Sources.	April 2, 2004	November 14, 2005, 70 FR 69081.	Paragraph (j) relates to fees. Submitted on July 29, 2004. See 40 CFR 52.220(c)(333)(i)(A)(2).
403.1 Implementation Handbook (Chapters 2, 3, 4 and 7).	Supplemental Fugitive Dust Control Requirements for Coachella Valley Sources.	April 2, 2004	November 14, 2005, 70 FR 69081.	Submitted on November 16, 2004. See 40 CFR 52.220(c)(340)(i)(A)(1).
404 (excluding table 404(a)).	Particulate Matter—Concentration	February 7, 1986	September 2, 1998, 63 FR 46659.	Submitted on June 4, 1986. See 40 CFR 52.220(c)(169)(i)(A)(1). The submittal did not include table 404(a).
404 (table 404(a))	Particulate Matter—Concentration	October 15, 1979	September 28, 1981, 46 FR 47451.	Submitted on December 17, 1979. See 40 CFR 52.220(c)(58)(ii)(B).
405 (excluding table 405(a)).	Solid Particulate Matter—Weight	February 7, 1986	September 2, 1998, 63 FR 46659.	Submitted on June 4, 1986. See 40 CFR 52.220(c)(169)(i)(A)(1). The submittal did not include table 405(a).
405 (table 405(a))	Solid Particulate Matter—Weight	May 7, 1976	September 28, 1981, 46 FR 47451.	Submitted on April 23, 1980. See 40 CFR 52.220(c)(69)(ii).

TABLE 34—EPA-APPROVED SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT REGULATIONS; LOS ANGELES COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; ORANGE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; RIVERSIDE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; SAN BERNARDINO COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
407	Liquid and Gaseous Air Contaminants	April 2, 1982	November 10, 1982, 47 FR 50864.	Submitted on August 6, 1982. See 40 CFR 52.220(c)(124)(iv)(A).
408	Circumvention	May 7, 1976	June 14, 1978, 43 FR 25684.	Adopted by the Southern California Air Pollution Control District and remains applicable throughout the SCAQMD. Submitted on August 2, 1976. See 40 CFR 52.220(c)(32)(iv)(A).
409	Combustion Contaminants	August 7, 1981	July 6, 1982, 47 FR 29231.	Submitted on October 23, 1981. See 40 CFR 52.220(c)(103)(xviii)(A).
431.1	Sulfur Content of Gaseous Fuels	June 12, 1998	December 3, 1999, 64 FR 67787.	Submitted on September 29, 1998. See 40 CFR 52.220(c)(266)(i)(A)(2).
431.2	Sulfur Content of Liquid Fuels	May 4, 1990	June 8, 1999, 64 FR 30396.	Submitted on December 31, 1990. See 40 CFR 52.220(c)(182)(i)(A)(5).
431.3	Sulfur Content of Fossil Fuels	December 2, 1977	September 28, 1981, 46 FR 47451.	Submitted on July 25, 1979. See 40 CFR 52.220(c)(65)(ii).
442	Usage of Solvents	December 15, 2000	May 23, 2002, 67 FR 36105.	Submitted on May 8, 2001. See 40 CFR 52.220(c)(284)(i)(B)(3).
443	Labeling of Solvents	January 1, 1977	June 14, 1978, 43 FR 25684.	Adopted by the Southern California Air Pollution Control District and remains applicable throughout the SCAQMD. Submitted on August 2, 1976. See 40 CFR 52.220(c)(32)(iv)(A).
443.1	Labeling of Materials Containing Organic Solvents.	December 5, 1986	September 12, 2001, 66 FR 47392.	Submitted on June 9, 1987. See 40 CFR 52.220(c)(173)(i)(F)(1).
444 (excluding paragraph (g)).	Open Burning	May 3, 2013	September 26, 2013, 78 FR 59249.	Paragraph (g) (''Fees'') was not included as part of the SIP revision. Submitted on June 11, 2013. See 40 CFR 52.220(c)(430)(i)(A)(1).
445 (excluding paragraph (g), ''Ozone Contingency Measures,'' and paragraph (k), ''Penalties'').	Wood-Burning Devices	October 27, 2020	March 8, 2022, 87 FR 12866.	Submitted on October 29, 2020. See 40 CFR 52.220(c)(570)(i)(A)(1).
461	Gasoline Transfer and Dispensing	April 6, 2012	April 11, 2013, 78 FR 21542.	Submitted on September 21, 2012. See 40 CFR 52.220(c)(423)(i)(C)(1).
462	Organic Liquid Loading	May 14, 1999	July 21, 1999, 64 FR 39037.	Submitted on June 3, 1999. See 40 CFR 52.220(c)(264)(i)(A)(1).
463	Organic Liquid Storage	May 5, 2023	May 29, 2026, 91 FR 31918.	Submitted electronically on October 16, 2023 as an attachment to a letter dated October 13, 2023. See 40 CFR 52.220(c)(619)(i)(B)(1).
464	Wastewater Separators	December 7, 1990	February 24, 1997, 62 FR 8171.	Submitted on May 13, 1991. See 40 CFR 52.220(c)(184)(i)(B)(6).
465	Refinery Vacuum-Producing Devices or Systems.	August 13, 1999	March 1, 2000, 65 FR 10944.	Submitted on October 29, 1999. See 40 CFR 52.220(c)(270)(i)(C)(1).
466	Pumps and Compressors	October 7, 1983	January 15, 1987, 52 FR 1627.	Submitted on December 2, 1983. See 40 CFR 52.220(c)(166)(i)(A)(1).
466.1	Valves and Flanges	May 2, 1980	July 8, 1982, 47 FR 29668.	Submitted on June 2, 1980. See 40 CFR 52.220(c)(79)(iv)(B).
467	Pressure Relief Devices	March 5, 1982	November 16, 1983, 58 FR 52054.	Submitted on May 20, 1982. See 40 CFR 52.220(c)(125)(ii)(D).
468	Sulfur Recovery Units	October 8, 1976	June 14, 1978, 43 FR 25684.	Adopted by the Southern California Air Pollution Control District and remains applicable throughout the SCAQMD. Submitted on February 10, 1977. See 40 CFR 52.220(c)(37)(i)(A).
469	Sulfuric Acid Units	October 8, 1976	June 14, 1978, 43 FR 25684.	Adopted by the Southern California Air Pollution Control District and remains applicable throughout the SCAQMD. Submitted on February 10, 1977. See 40 CFR 52.220(c)(37)(i)(A).
470	Asphalt Air Blowing	May 7, 1976	June 14, 1978, 43 FR 25684.	Adopted by the Southern California Air Pollution Control District and remains applicable throughout the SCAQMD. Submitted on August 2, 1976. See 40 CFR 52.220(c)(32)(iv)(A).
472	Reduction of Animal Matter	May 7, 1976	June 14, 1978, 43 FR 25684.	Adopted by the Southern California Air Pollution Control District and remains applicable throughout the SCAQMD. Submitted on August 2, 1976. See 40 CFR 52.220(c)(32)(iv)(A).
474	Fuel Burning Equipment—Oxides of Nitrogen.	December 4, 1981	July 6, 1982, 47 FR 29231.	Submitted on March 1, 1982. See 40 CFR 52.220(c)(121)(i)(A).
475	Electric Power Generating Equipment	October 8, 1976	June 14, 1978, 43 FR 25684.	Adopted by the Southern California Air Pollution Control District and remains applicable throughout the SCAQMD. Submitted on February 10, 1977. See 40 CFR 52.220(c)(37)(i)(A).
476	Steam Generating Equipment	October 8, 1976	June 14, 1978, 43 FR 25684.	Adopted by the Southern California Air Pollution Control District and remains applicable throughout the SCAQMD. Submitted on February 10, 1977. See 40 CFR 52.220(c)(37)(i)(A).

TABLE 34—EPA-APPROVED SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT REGULATIONS; LOS ANGELES COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; ORANGE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; RIVERSIDE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; SAN BERNARDINO COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
481	Spray Coating Operations	January 11, 2002	August 26, 2003, 68 FR 51181.	Submitted on May 21, 2002. See 40 CFR 52.220(c)(310)(i)(B)(1).
Regulation V—Procedure Before the Hearing Board				
518.2	Federal Alternative Operating Conditions.	December 21, 2001	September 13, 2002, 67 FR 57954.	Submitted on March 15, 2002. See 40 CFR 52.220(c)(297)(i)(C)(2).
Regulation VII—Emergencies				
701	Air Pollution Emergency Contingency Actions.	June 13, 1997	March 25, 1999, 64 FR 14391.	Submitted on September 8, 1997. See 40 CFR 52.220(c)(249)(i)(A)(2).
Regulation XI—Source Specific Standards				
1101	Secondary Lead Smelters—Sulfur Oxides.	October 7, 1977	September 2, 1981, 46 FR 43968.	Submitted on August 15, 1980. See 40 CFR 52.220(c)(70)(i)(B).
1102	Dry Cleaners Using Solvent Other Than Perchloroethylene.	November 17, 2000	July 17, 2002, 67 FR 46876.	Submitted on May 8, 2001. See 40 CFR 52.220(c)(284)(i)(B)(4).
1102.1	Perchloroethylene Dry Cleaning Systems.	December 7, 1990	March 24, 1992, 57 FR 10136.	Submitted on May 13, 1991. See 40 CFR 52.220(c)(184)(i)(B)(1).
1103	Pharmaceuticals and Cosmetics Manufacturing Operations.	March 12, 1999	July 21, 1999, 64 FR 39037.	Submitted on May 13, 1999. See 40 CFR 52.220(c)(263)(i)(A)(1).
1104	Wood Flat Stock Coating Operations	August 13, 1999	March 22, 2000, 65 FR 15240.	Submitted on October 29, 1999. See 40 CFR 52.220(c)(270)(i)(C)(2).
1105	Fluid Catalytic Cracking Units—Oxides of Sulfur.	September 21, 1984	July 12, 1990, 55 FR 28624.	Submitted on February 6, 1985. See 40 CFR 52.220(c)(159)(v)(C).
1105.1	Reduction of PM_{10} and Ammonia Emissions from Fluid Catalytic Cracking Units.	November 7, 2003	January 4, 2006, 71 FR 241.	Submitted on June 3, 2004. See 40 CFR 52.220(c)(331)(i)(B)(2).
1106	Marine Coating Operations	January 13, 1995	July 14, 1995, 60 FR 36227.	Submitted on February 24, 1995. See 40 CFR 52.220(c)(215)(i)(A)(3).
1106.1	Pleasure Craft Coating Operations	February 12, 1999	August 31, 1999, 64 FR 47392.	Submitted on June 3, 1999. See 40 CFR 52.220(c)(264)(i)(A)(2).
1107	Coating of Metal Parts and Products	January 6, 2006	November 24, 2008, 73 FR 70883.	Submitted on May 8, 2007. See 40 CFR 52.220(c)(350)(i)(D)(1).
1108	Cutback Asphalt	February 1, 1985	July 12, 1990, 55 FR 28624.	Submitted on April 12, 1985. See 40 CFR 52.220(c)(160)(i)(E)(1).
1108.1	Emulsified Asphalt	November 4, 1983	January 24, 1985, 50 FR 3338.	Submitted on March 14, 1984. See 40 CFR 52.220(c)(153)(vii)(A).
1110.2	Emissions from Gaseous- and Liquid-Fueled Engines.	February 1, 2008	April 27, 2009, 74 FR 18995.	Submitted on May 20, 2008. See 40 CFR 52.220(c)(360)(i)(A)(1).
1111	Reduction of NO_X Emissions From Natural-Gas-Fired, Fan-Type Central Furnaces.	September 5, 2014	March 29, 2016, 81 FR 17390.	Submitted on April 7, 2015. See 40 CFR 52.220(c)(461)(i)(C)(2).
1112.1	Emissions of Particulate Matter and Carbon Monoxide from Cement Kilns.	December 4, 2009	March 13, 2014, 79 FR 14176.	Submitted on July 20, 2010. See 40 CFR 52.220(c)(381)(i)(K)(1).
1113 (excluding the final sentence of paragraphs (b)(8), and (b)(25)).	Architectural Coatings	February 5, 2016	November 29, 2018, 83 FR 61326.	Submitted on August 22, 2016. See 40 CFR 52.220(c)(488)(i)(D)(1).
1114	Petroleum Refinery Coking Operations.	May 3, 2013	January 20, 2015, 80 FR 2609.	Submitted on February 10, 2014. See 40 CFR 52.220(c)(442)(i)(C)(1).
1115	Motor Vehicle Assembly Line Coating Operations.	May 12, 1995	July 14, 1995, 60 FR 36227.	Submitted on June 16, 1995. See 40 CFR 52.220(c)(222)(i)(A)(1).
1117	Emissions of Oxides of Nitrogen from Glass Melting Furnaces.	January 6, 1984	July 12, 1990, 55 FR 28624.	Submitted on February 6, 1985. See 40 CFR 52.220(c)(159)(v)(D).
1118	Control of Emissions from Refinery Flares.	January 6, 2023	October 21, 2024, 89 FR 84083.	Submitted on May 11, 2023 as an attachment to a letter dated May 10, 2023. See 40 CFR 52.220(c)(610)(i)(B)(1).
1118.1	Control of Emissions from Non-Refinery Flares.	January 4, 2019	December 28, 2022, 87 FR 79806.	Submitted on April 24, 2019. See 40 CFR 52.220(c)(564)(i)(A)(2).
1119	Petroleum Coke Calcining Operations—Oxides of Sulfur.	March 2, 1979	September 28, 1981, 46 FR 47451.	Submitted on July 25, 1980. See 40 CFR 52.220(c)(88)(iii)(A).
1120	Asphalt Pavement Heaters	August 4, 1978	September 28, 1981, 46 FR 47451.	Submitted on July 25, 1979. See 40 CFR 52.220(c)(65)(ii).
1121	Control of Nitrogen Oxides from Residential Type, Natural Gas-Fired Water Heaters.	September 3, 2004	May 6, 2009, 74 FR 20880.	Submitted on July 18, 2008. See 40 CFR 52.220(c)(359)(i)(B)(1).
1122	Solvent Degreasers	October 1, 2004	February 8, 2006, 71 FR 6350.	Submitted on January 13, 2005. See 40 CFR 52.220(c)(335)(i)(D)(1).
1123	Refinery Process Turnarounds	December 7, 1990	August 11, 1992, 57 FR 35758.	Submitted on May 13, 1991. See 40 CFR 52.220(c)(184)(i)(B)(2).

TABLE 34—EPA-APPROVED SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT REGULATIONS; LOS ANGELES COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; ORANGE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; RIVERSIDE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; SAN BERNARDINO COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
1124	Aerospace Assembly and Component Manufacturing Operations.	September 21, 2001	August 13, 2002, 67 FR 52611.	Submitted on January 22, 2002. See 40 CFR 52.220(c)(293)(i)(A)(2).
1125	Metal Container, Closure, and Coil Coating Operations.	March 7, 2008	December 21, 2009, 74 FR 67821.	Submitted on April 6, 2009. See 40 CFR 52.220(c)(366)(i)(B)(1).
1126	Magnet Wire Coating Operations	January 13, 1995	June 13, 1995, 60 FR 31081.	Submitted on February 24, 1995. See 40 CFR 52.220(c)(215)(i)(A)(1).
1127	Emissions Reductions from Livestock Waste.	August 6, 2004	May 23, 2013, 78 FR 30768.	Submitted on October 5, 2006. See 40 CFR 52.220(c)(347)(i)(B)(2).
1128	Paper, Fabric, and Film Coating Operations.	March 8, 1996	May 4, 1999, 64 FR 23774.	Submitted on July 23, 1996. See 40 CFR 52.220(c)(239)(i)(B)(1).
1130	Graphic Arts	May 2, 2014	July 14, 2015, 80 FR 40915.	Submitted on November 6, 2014. See 40 CFR 52.220(c)(457)(i)(E)(1).
1130.1	Screen Printing Operations	December 13, 1996	August 21, 1998, 63 FR 44792.	Submitted on March 3, 1997. See 40 CFR 52.220(c)(244)(i)(D)(1).
1131	Food Product Manufacturing and Processing Operations.	June 6, 2003	January 22, 2004, 69 FR 3018.	Submitted on August 11, 2003. See 40 CFR 52.220(c)(320)(i)(B)(1).
1132	Further Control of VOC Emissions From High-Emitting Spray Booth Facilities.	May 5, 2006	July 26, 2011, 76 FR 44493.	Submitted on January 10, 2010. See 40 CFR 52.220(c)(378)(i)(A)(2).
1133	Composting and Related Operations—General Administrative Requirements.	January 10, 2003	July 21, 2004, 69 FR 43518.	Submitted on June 5, 2003. See 40 CFR 52.220(c)(316)(i)(D)(1).
1133.1	Chipping and Grinding Activities	July 8, 2011	November 29, 2012, 77 FR 71129.	Submitted on November 18, 2011. See 40 CFR 52.220(c)(416)(i)(B)(1).
1133.2	Emission Reductions from Co-Composting Operations.	January 10, 2003	July 21, 2004, 69 FR 43518.	Submitted on June 5, 2003. See 40 CFR 52.220(c)(316)(i)(D)(1).
1133.3	Emission Reductions from Greenwaste Composting Operations.	July 8, 2011	November 29, 2012, 77 FR 71129.	Submitted on November 18, 2011. See 40 CFR 52.220(c)(416)(i)(B)(2).
1134	Emissions of Oxides of Nitrogen from Stationary Gas Turbines.	August 8, 1997	August 1, 2000, 65 FR 46873.	Submitted on March 10, 1998. See 40 CFR 52.220(c)(254)(i)(D)(4).
1135	Emissions of Oxides of Nitrogen from Electric Power Generating Systems.	July 19, 1991	August 11, 1998, 63 FR 42721.	Submitted on January 28, 1992. See 40 CFR 52.220(c)(187)(i)(C)(2).
1136	Wood Products Coatings	June 14, 1996	August 18, 1998, 63 FR 44132.	Submitted on August 28, 1996. See 40 CFR 52.220(c)(240)(i)(A)(5).
1137	PM_{10} Emission Reductions from Woodworking Operations.	February 1, 2002	January 22, 2004, 69 FR 3018.	Submitted on November 19, 2002. See 40 CFR 52.220(c)(307)(i)(D)(1).
1138	Control of Emissions from Restaurant Operations.	November 14, 1997	July 11, 2001, 66 FR 36170.	Submitted on March 10, 1998. See 40 CFR 52.220(c)(254)(i)(D)(5).
1140	Abrasive Blasting	August 2, 1985	December 10, 2014, 79 FR 73203.	Submitted on November 12, 1985. See 40 CFR 52.220(c)(165)(i)(B)(2).
1141	Control of Volatile Organic Compound Emissions from Resin Manufacturing.	November 17, 2000	August 13, 2002, 67 FR 52611.	Submitted on March 14, 2001. See 40 CFR 52.220(c)(286)(i)(A)(3).
1141.1	Coatings and Ink Manufacturing	November 17, 2000	February 12, 2002, 67 FR 6410.	Submitted on March 14, 2001. See 40 CFR 52.220(c)(286)(i)(A)(1).
1141.2	Surfactant Manufacturing	January 11, 2002	August 26, 2003, 68 FR 51181.	Submitted on May 21, 2002. See 40 CFR 52.220(c)(310)(i)(B)(1).
1142	Marine Tank Vessel Operations	July 19, 1991	December 13, 1994, 59 FR 64132.	Submitted on January 28, 1992. See 40 CFR 52.220(c)(187)(i)(C)(1).
1143	Consumer Paint Thinners & Multi-Purpose Solvents.	December 3, 2010	November 16, 2011, 76 FR 70888.	Submitted on April 5, 2011. See 40 CFR 52.220(c)(388)(i)(A)(1).
1144	Metal Working Fluids and Direct-Contact Lubricants.	July 9, 2010	November 16, 2011, 76 FR 70888.	Submitted on April 5, 2011. See 40 CFR 52.220(c)(388)(i)(A)(2).
1145	Plastic, Rubber, Leather, and Glass Coatings.	December 4, 2009	July 14, 2010, 75 FR 40726.	Submitted on May 17, 2010. See 40 CFR 52.220(c)(379)(i)(A)(2).
1146	Emissions of Oxides of Nitrogen from Industrial, Institutional, and Commercial Boilers, Steam Generators, and Process Heaters.	November 1, 2013	September 25, 2014, 79 FR 57442.	Submitted on May 13, 2014. See 40 CFR 52.220(c)(441)(i)(A)(1).
1146.1	Emissions of Oxides of Nitrogen from Small Industrial, Institutional, and Commercial Boilers, Steam Generators, and Process Heaters.	November 1, 2013	September 25, 2014, 79 FR 57442.	Submitted on May 13, 2014. See 40 CFR 52.220(c)(441)(i)(A)(2).
1146.2	Emissions of Oxides of Nitrogen From Large Water Heaters and Small Boilers and Process Heaters.	May 5, 2006	December 5, 2008, 73 FR 74027.	Submitted on March 7, 2008. See 40 CFR 52.220(c)(354)(i)(A)(4).
1147	NO_X Reductions from Miscellaneous Sources.	September 9, 2011	December 28, 2016, 81 FR 95472.	Submitted on February 6, 2013. See 40 CFR 52.220(c)(428)(i)(D)(2).
1148	Thermally Enhanced Oil Recovery Wells.	November 5, 1982	October 19, 1984, 49 FR 41028.	Submitted on February 3, 1983. See 40 CFR 52.220(c)(127)(vii)(C).
1148.1	Oil and Gas Production Wells	March 5, 2004	September 29, 2011, 76 FR 60376.	Submitted on January 10, 2010. See 40 CFR 52.220(c)(378)(i)(A)(3).
1149	Storage Tank and Pipeline Cleaning and Degassing.	May 2, 2008	December 21, 2009, 74 FR 67821.	Submitted on April 6, 2009. See 40 CFR 52.220(c)(366)(i)(B)(2).

TABLE 34—EPA-APPROVED SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT REGULATIONS; LOS ANGELES COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; ORANGE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; RIVERSIDE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; SAN BERNARDINO COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
1150.1	Control of Gaseous Emissions from Municipal Solid Waste Landfills.	April 1, 2011	May 23, 2013, 78 FR 30768.	Submitted on September 27, 2011. See 40 CFR 52.220(c)(404)(i)(A)(4).
1151	Motor Vehicle and Mobile Equipment Non-Assembly Line Coating Operations.	September 5, 2014	December 8, 2015, 80 FR 76219.	Submitted on April 7, 2015. See 40 CFR 52.220(c)(461)(i)(C)(1).
1153	Commercial Bakery Ovens	January 13, 1995	August 8, 1995, 60 FR 40285.	Submitted on February 24, 1995. See 40 CFR 52.220(c)(215)(i)(A)(2).
1153.1	Emissions of Oxides of Nitrogen from Commercial Food Ovens.	November 7, 2014	December 28, 2016, 81 FR 95472.	Submitted on April 7, 2015. See 40 CFR 52.220(c)(461)(i)(C)(3).
1155	Particulate Matter (PM) Control Devices.	May 2, 2014	March 16, 2015, 80 FR 13495.	Submitted on July 25, 2014. See 40 CFR 52.220(c)(447)(i)(C)(1).
1156	Further Reductions of Particulate Emissions from Cement Manufacturing Facilities.	March 6, 2009	September 4, 2012, 77 FR 53773.	Submitted on April 29, 2009. See 40 CFR 52.220(c)(362)(i)(B)(2).
1157	PM_{10} Emission Reductions from Aggregate and Related Operations.	September 8, 2006	March 7, 2012, 77 FR 13495.	Submitted on May 17, 2010. See 40 CFR 52.220(c)(379)(i)(A)(5).
1158	Storage, Handling, and Transport of Coke, Coal and Sulfur.	July 11, 2008	November 10, 2009, 74 FR 57907.	Submitted on December 23, 2008. See 40 CFR 52.220(c)(364)(i)(B)(1).
1159	Nitric Acid Units—Oxides of Nitrogen	December 6, 1985	July 12, 1990, 55 FR 28622.	Submitted on February 10, 1986. See 40 CFR 52.220(c)(168)(i)(H)(1).
1162	Polyester Resin Operations	July 8, 2005	July 26, 2011, 76 FR 44493.	Submitted on April 6, 2009. See 40 CFR 52.220(c)(366)(i)(B)(3).
1164	Semiconductor Manufacturing	January 13, 1995	February 1, 1996, 61 FR 3579.	Submitted on February 24, 1995. See 40 CFR 52.220(c)(215)(i)(A)(4).
1166	Volatile Organic Compound Emissions from Decontamination of Soil.	July 14, 1995	August 17, 1998, 63 FR 43881.	Submitted on October 13, 1995. See 40 CFR 52.220(c)(225)(i)(A)(3).
1168	Adhesive and Sealant Applications	October 6, 2017	February 24, 2021, 86 FR 11130; corrected on March 11, 2021, 86 FR 13819.	Submitted on May 23, 2018. See 40 CFR 52.220(c)(518)(i)(D)(1).
1171	Solvent Cleaning Operations	February 1, 2008	September 29, 2011, 76 FR 60376.	Submitted on April 5, 2011. See 40 CFR 52.220(c)(388)(i)(A)(5).
1173	Control of Volatile Organic Compound Leaks and Releases from Components at Petroleum Facilities and Chemical Plants.	February 6, 2009	May 5, 2010, 75 FR 24406.	Submitted on January 10, 2010. See 40 CFR 52.220(c)(378)(i)(A)(1).
1174	Control of Volatile Organic Compound Emissions from the Ignition of Barbeque Charcoal.	October 5, 1990	October 4, 1994, 59 FR 50498.	Submitted on May 13, 1991. See 40 CFR 52.220(c)(184)(i)(B)(4).
1175	Control of Emissions from the Manufacture of Polymeric Cellular (Foam) Products.	November 5, 2010	August 4, 2011, 76 FR 47074.	Submitted on April 5, 2011. See 40 CFR 52.220(c)(388)(i)(A)(3).
1176	VOC Emissions from Wastewater Systems.	September 13, 1996	October 7, 2002, 67 FR 62376.	Submitted on November 26, 1996. See 40 CFR 52.220(c)(242)(i)(B)(2).
1177	Liquefied Petroleum Gas Transfer and Dispensing.	June 1, 2012	January 3, 2014, 79 FR 364.	Submitted on February 6, 2013. See 40 CFR 52.220(c)(428)(i)(D)(1).
1178	Further Reductions of VOC Emissions from Storage Tanks at Petroleum Facilities.	September 1, 2023	May 29, 2026, 91 FR 31918.	Submitted electronically on February 14, 2024 as an attachment to a letter dated February 9, 2024. See 40 CFR 52.220(c)(612)(i)(B)(1).
1179	Publicly Owned Treatment Works Operations.	March 6, 1992	October 4, 1994, 59 FR 50498.	Submitted on September 14, 1992. See 40 CFR 52.220(c)(189)(i)(A)(5).
1186	PM_{10} Emissions from Paved and Unpaved Roads, and Livestock Operations.	July 11, 2008	March 7, 2012, 77 FR 13495.	Submitted on December 23, 2008. See 40 CFR 52.220(c)(364)(i)(B)(2).
1189	Emissions from Hydrogen Plant Process Vents.	January 21, 2000	June 8, 2001, 66 FR 30815.	Submitted on July 26, 2000. See 40 CFR 52.220(c)(280)(i)(A)(1).
	Regulation XIII—New Source Review			
1301	General	December 7, 1995	December 4, 1996, 61 FR 64291.	Submitted on August 28, 1996. See 40 CFR 52.220(c)(240)(i)(A)(1).
1302	Definitions	June 13, 1997	March 19, 1999, 64 FR 13514.	Submitted on March 10, 1998. See 40 CFR 52.220(c)(254)(i)(D)(3).
1303	Requirements	May 10, 1996	December 4, 1996, 61 FR 64291.	Submitted on August 28, 1996. See 40 CFR 52.220(c)(240)(i)(A)(1).
1304	Exemptions	June 14, 1996	December 4, 1996, 61 FR 64291.	Submitted on August 28, 1996. See 40 CFR 52.220(c)(240)(i)(A)(1).
1306	Emission Calculations	June 14, 1996	December 4, 1996, 61 FR 64291.	Submitted on August 28, 1996. See 40 CFR 52.220(c)(240)(i)(A)(1).
1309	Emission Reduction Credits	December 7, 1995	December 4, 1996, 61 FR 64291.	Submitted on August 28, 1996. See 40 CFR 52.220(c)(240)(i)(A)(1).
1309.1	Priority Reserve	May 3, 2002	June 19, 2006, 71 FR 35157.	Submitted on December 23, 2002. See 40 CFR 52.220(c)(311)(i)(A)(3).
1310	Analysis and Reporting	December 7, 1995	December 4, 1996, 61 FR 64291.	Submitted on August 28, 1996. See 40 CFR 52.220(c)(240)(i)(A)(1).

TABLE 34—EPA-APPROVED SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT REGULATIONS; LOS ANGELES COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; ORANGE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; RIVERSIDE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; SAN BERNARDINO COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
1313	Permits to Operate	December 7, 1995	December 4, 1996, 61 FR 64291.	Submitted on August 28, 1996. See 40 CFR 52.220(c)(240)(i)(A)(1).
1315 (excluding paragraph (b)(2) and subdivisions (g) and (h)).	Federal New Source Review Tracking System.	February 4, 2011	May 25, 2012, 77 FR 31200.	Submitted on March 2, 2011. See 40 CFR 52.220(c)(403)(i)(A)(1).
1325	Federal $PM_{2.5}$ New Source Review Program.	January 4, 2019	October 22, 2021, 86 FR 58592.	Submitted on April 24, 2019. See 40 CFR 52.220(c)(564)(i)(A)(1).
Regulation XIV—Toxics and Other Non-Criteria Pollutants				
1420.1	Emissions Standard For Lead From Large Lead-Acid Battery Recycling Facilities.	November 5, 2010	January 25, 2013, 78 FR 5305.	Submitted on September 27, 2011. See 40 CFR 52.220(c)(404)(i)(A)(2).
Regulation XVI—Mobile Source Offset Programs				
1612.1	Mobile Source Credit Generation Pilot Program.	March 16, 2001	February 7, 2002, 67 FR 5729.	Submitted on May 8, 2001. See 40 CFR 52.220(c)(284)(i)(B)(1).
1631	Pilot Credit Generation Program for Marine Vessels.	October 4, 2002	November 24, 2003, 68 FR 65845.	Submitted on December 12, 2002. See 40 CFR 52.220(c)(308)(i)(D)(1).
1632	Pilot Credit Generation Program for Hotelling Operations.	May 11, 2001	February 7, 2002, 67 FR 5729.	Submitted on May 31, 2001. See 40 CFR 52.220(c)(282)(i)(A)(1).
1633	Pilot Credit Generation Program for Truck/Trailer Refrigeration Units.	May 11, 2001	February 7, 2002, 67 FR 5729.	Submitted on May 31, 2001. See 40 CFR 52.220(c)(282)(i)(A)(1).
1634	Pilot Credit Generation Program for Truck Stops.	November 9, 2001	November 24, 2003, 68 FR 65845.	Submitted on January 22, 2002. See 40 CFR 52.220(c)(293)(i)(A)(3).
Regulation XVII—Prevention of Significant Deterioration (PSD)				
1714	Prevention of Significant Deterioration for Greenhouse Gases.	November 5, 2010	December 10, 2012, 77 FR 73320.	Submitted on December 30, 2010. See 40 CFR 52.220(c)(421)(i)(A)(1). The approval is based on clarifications provided in a letter dated August 15, 2012 from Mohsen Nazemi, SCAQMD, to Gerardo Rios, EPA Region 9, which is listed in the tables for the nonregulatory portions of the applicable California SIP.
Regulation XIX—Federal Conformity Regulations				
1901	General Conformity	September 9, 1994	April 23, 1999, 64 FR 19916.	Submitted on November 30, 1994. See 40 CFR 52.220(c)(207)(i)(I)(1).
Regulation XX—Regional Clean Air Incentives Market (RECLAIM)				
2000	General	May 6, 2005	August 29, 2006, 71 FR 51120.	Submitted on October 20, 2005. See 40 CFR 52.220(c)(342)(i)(C)(2).
2001	Applicability	December 4, 2015	September 14, 2017, 82 FR 43176.	Submitted on March 17, 2017. See 40 CFR 52.220(c)(491)(i)(A)(1).
2002	Allocations for Oxides of Nitrogen (NO_X) and Oxides of Sulfur (SO_X).	October 7, 2016	September 14, 2017, 82 FR 43176.	Submitted on March 17, 2017. See 40 CFR 52.220(c)(491)(i)(A)(2).
2004	Requirements	April 6, 2007	July 3, 2008, 73 FR 38122.	Submitted on March 7, 2008. See 40 CFR 52.220(c)(354)(i)(A)(1).
2005	New Source Review for RECLAIM	December 4, 2015	September 14, 2017, 82 FR 43176.	Submitted on March 17, 2017. See 40 CFR 52.220(c)(491)(i)(A)(3).
2006	Permits	May 11, 2001	September 4, 2003, 68 FR 52512.	Submitted on May 31, 2001. See 40 CFR 52.220(c)(282)(i)(A)(2).
2007	Trading Requirements	April 6, 2007	July 3, 2008, 73 FR 38122.	Submitted on March 7, 2008. See 40 CFR 52.220(c)(354)(i)(A)(2).
2008	Mobile Source Credits	October 15, 1993	November 8, 1996, 61 FR 57775.	Submitted on March 21, 1994. See 40 CFR 52.220(c)(232)(i)(A)(1).
2010	Administrative Remedies and Sanctions.	April 6, 2007	July 3, 2008, 73 FR 38122.	Submitted on March 7, 2008. See 40 CFR 52.220(c)(354)(i)(A)(3).
2011	Requirements for Monitoring, Reporting, and Recordkeeping for Oxides of Sulfur (SO_X) Emissions.	January 7, 2005	August 29, 2006, 71 FR 51120.	Submitted on July 15, 2005. See 40 CFR 52.220(c)(337)(i)(C)(1).
2011 Protocol—Appendix A, Chapter 1.	Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Sulfur (SO_X) Emissions.	May 6, 2005	August 29, 2006, 71 FR 51120.	Chapter 1 is titled ''Overview.'' Submitted on October 20, 2005. See 40 CFR 52.220(c)(342)(i)(C)(2).
2011 Protocol—Appendix A, Chapter 2.	Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Sulfur (SO_X) Emissions.	January 7, 2005	August 29, 2006, 71 FR 51120.	Chapter 2 is titled ''Major Sources—Continuous Emission Monitoring System (CEMS).'' Submitted on July 15, 2005. See 40 CFR 52.220(c)(337)(i)(C)(1).

TABLE 34—EPA-APPROVED SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT REGULATIONS; LOS ANGELES COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; ORANGE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; RIVERSIDE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; SAN BERNARDINO COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
2011 Protocol—Appendix A, Chapter 3.	Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Sulfur (SO_X) Emissions.	December 4, 2015	September 14, 2017, 82 FR 43176.	Chapter 3 is titled ''Process Units—Periodic Reporting and Rule 219 Equipment.'' Submitted on March 17, 2017. See 40 CFR 52.220(c)(491)(i)(A)(5).
2011 Protocol—Appendix A, Chapters 4, 5 and 6.	Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Sulfur (SO_x) Emissions.	January 7, 2005	August 29, 2006, 71 FR 51120.	Chapters 4, 5 and 6 are titled ''Process Units—Source Testing,'' ''Remote Terminal Unit (RTU)—Electronic Reporting'' and ''Reference Methods,'' respectively. Submitted on July 15, 2005. See 40 CFR 52.220(c)(337)(i)(C)(1).
2011 Protocol—Appendix A, Attachments A and B.	Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Sulfur (SO_x) Emissions.	January 7, 2005	August 29, 2006, 71 FR 51120.	Attachments A, B, D and F are titled ''1 N Procedure,'' and ''Bias Test,'' respectively. Submitted on July 15, 2005. See 40 CFR 52.220(c)(337)(i)(C)(1).
2011 Protocol—Appendix A, Attachment C.	Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Sulfur (SO_x) Emissions.	December 4, 2015	September 14, 2017, 82 FR 43176.	Attachment C is titled ''Quality Assurance and Quality Control Procedures.'' Submitted on March 17, 2017. See 40 CFR 52.220(c)(491)(i)(A)(4).
2011 Protocol—Appendix A, Attachment D.	Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Sulfur (SO_x) Emissions.	January 7, 2005	August 29, 2006, 71 FR 51120.	Attachment D is titled ''List of Acronyms and Abbreviations.'' Submitted on July 15, 2005. See 40 CFR 52.220(c)(337)(i)(C)(1).
2011 Protocol—Appendix A, Attachment E.	Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Sulfur (SO_x) Emissions.	February 5, 2016	September 14, 2017, 82 FR 43176.	Attachment E is titled ''Definitions.'' Submitted on March 17, 2017. See 40 CFR 52.220(c)(491)(i)(A)(8).
2011 Protocol—Appendix A, Attachment F.	Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Sulfur (SO_x) Emissions.	January 7, 2005	August 29, 2006, 71 FR 51120.	Attachment F is titled ''Supplemental and Alternative CEMS Performance Requirements for Low SO_x Concentrations.'' Submitted on July 15, 2005. See 40 CFR 52.220(c)(337)(i)(C)(1).
2012	Requirements for Monitoring, Reporting, and Recordkeeping for Oxides of Nitrogen (NO_X) Emissions.	January 7, 2005	August 29, 2006, 71 FR 51120.	Submitted on July 15, 2005. See 40 CFR 52.220(c)(337)(i)(C)(1).
Rule 2012(j)(3)—Testing Guidelines (Protocol).	Rule 2012(j)(3)—Testing Guidelines (Protocol) for Alternative Nitrogen Oxides Emission Rate Determination at Process Units.	December 7, 1995	June 15, 1998, 63 FR 32621.	The Protocol is dated March 31, 1994. Submitted on August 28, 1996. See 40 CFR 52.220(c)(240)(i)(A)(3).
2012 Protocol—Appendix A, Chapter 1.	Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Nitrogen (NO_X) Emissions.	May 6, 2005	August 29, 2006, 71 FR 51120.	Chapter 1 is titled ''Overview.'' Submitted on October 20, 2005. See 40 CFR 52.220(c)(342)(i)(C)(2).
2012 Protocol—Appendix A, Chapters 2 and 3.	Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Nitrogen (NO_X) Emissions.	January 7, 2005	August 29, 2006, 71 FR 51120.	Chapters 2 and 3 are titled ''Major Sources—Continuous Emission Monitoring System (CEMS)'' and ''Large Sources—Continuous Process Monitoring System (CPMS),'' respectively. Submitted on July 15, 2005. See 40 CFR 52.220(c)(337)(i)(C)(1).
2012 Protocol—Appendix A, Chapter 4.	Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Nitrogen (NO_X) Emissions.	December 4, 2015	September 14, 2017, 82 FR 43176.	Chapter 4 is titled ''Process Units—Periodic Reporting and Rule 219 Equipment.'' Submitted on March 17, 2017. See 40 CFR 52.220(c)(491)(i)(A)(7).
2012 Protocol—Appendix A, Chapters 5, 6, 7 and 8.	Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Nitrogen (NO_X) Emissions.	January 7, 2005	August 29, 2006, 71 FR 51120.	Chapters 5, 6, 7 and 8 are titled ''Large Sources and Process Units—Source Testing,'' ''All Sources and Units—Determining Source Category Status,'' ''Remote Terminal Unit (RTU)—Electronic Reporting'' and ''Reference Methods,'' respectively. Submitted on July 15, 2005. See 40 CFR 52.220(c)(337)(i)(C)(1).
2012 Protocol—Appendix A, Attachments A and B.	Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Nitrogen (NO_X) Emissions.	January 7, 2005	August 29, 2006, 71 FR 51120.	Attachments A and B are titled ''1 N Procedures'' and ''Bias Test,'' respectively. Submitted on July 15, 2005. See 40 CFR 52.220(c)(337)(i)(C)(1).
2012 Protocol—Appendix A, Attachment C.	Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Nitrogen (NO_X) Emissions.	December 4, 2015	September 14, 2017, 82 FR 43176.	Attachment C is titled ''Quality Assurance and Quality Control Procedures.'' Submitted on March 17, 2017. See 40 CFR 52.220(c)(491)(i)(A)(6).
2012 Protocol—Appendix A, Attachments D and E.	Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Nitrogen (NO_X) Emissions.	January 7, 2005	August 29, 2006, 71 FR 51120.	Attachments D and E are titled ''Equipment Tuning Procedures,'' and ''List of Acronyms and Abbreviations,'' respectively. Submitted on July 15, 2005. See 40 CFR 52.220(c)(337)(i)(C)(1).
2012 Protocol—Appendix A, Attachment F.	Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Nitrogen (NO_X) Emissions.	February 5, 2016	September 14, 2017, 82 FR 43176.	Attachment F is titled ''Definitions.'' Submitted on March 17, 2017. See 40 CFR 52.220(c)(491)(i)(A)(9).
2012 Protocol—Appendix A, Attachment G.	Protocol for Monitoring, Reporting, and Recordkeeping for Oxides of Nitrogen (NO_X) Emissions.	January 7, 2005	August 29, 2006, 71 FR 51120.	Attachment G is titled ''Supplemental and Alternative CEMS Performance Requirements for Low NO_X Concentrations.'' Submitted on July 15, 2005. See 40 CFR 52.220(c)(337)(i)(C)(1).
2015	Backstop Provisions	June 4, 2004	December 21, 2004, 69 FR 76417.	Submitted on July 29, 2004. See 40 CFR 52.220(c)(333)(i)(A)(1).
2020	RECLAIM Reserve	May 11, 2001	September 4, 2003, 68 FR 52512.	Submitted on May 31, 2001. See 40 CFR 52.220(c)(282)(i)(A)(2).

TABLE 34—EPA-APPROVED SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT REGULATIONS; LOS ANGELES COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; ORANGE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; RIVERSIDE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; SAN BERNARDINO COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
Regulation XXIII—Facility Based Mobile Source Measures				
2305	Warehouse Indirect Source Rule—Warehouse Actions and Investments to Reduce Emissions (WAIRE) Program.	May 7, 2021	September 11, 2024, 89 FR 73568.	Submitted on August 13, 2021. See 40 CFR 52.220(c)(616)(i)(A)(1).
Regulation XXIV—In-Use Mobile Source Emission Reduction Programs				
2449	Control of Oxides of Nitrogen Emissions from Off-Road Diesel Vehicles.	July 11, 2014	November 21, 2016, 81 FR 83154.	Submitted on September 5, 2014. See 40 CFR 52.220(c)(482)(i)(A)(1).
Regulation XXV—Intercredit Trading				
2507	Pilot Credit Generation Program for Agricultural Pumps.	May 11, 2001	February 7, 2002, 67 FR 5729.	Submitted on May 31, 2001. See 40 CFR 52.220(c)(282)(i)(A)(1).
Rules and Regulations (Los Angeles County portion of the District)				
53	Sulfur Compounds—Concentration	June 30, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
58	Disposal of Solid and Liquid Wastes	June 30, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
67	Fuel Burning Equipment	June 30, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6). Deletion approved in part at 46 FR 27116 (May 18, 1981). The emission limits of Rule 67 are partially retained, applicable only to (existing) sources, granted permits prior to June 17, 1981—see 40 CFR 52.280(c)(1)(i).
Rules and Regulations (Orange County portion of the District)				
53 (paragraph (c))	Specific Contaminants	May 24, 1967	May 31, 1972, 37 FR 10842.	Submitted on February 21, 1972. See 40 CFR 52.220(b). Paragraph (a) was superseded by approval of Rule 53 (Sulfur Compounds—Concentration) at 37 FR 19812 (September 22, 1972). Paragraph (b) was disapproved at 37 FR 10842, at 10852 (May 31, 1972). Paragraph (c) relates to fluorine emissions.
53	Sulfur Compounds—Concentration	June 18, 1975	September 8, 1978, 43 FR 40011.	Submitted on July 22, 1975. See 40 CFR 52.220(c)(28)(xi)(A).
58	Disposal of Solid and Liquid Wastes	April 25, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
67	Fuel Burning Equipment	December 23, 1969	May 31, 1972, 37 FR 10842.	Submitted on February 21, 1972. See 40 CFR 52.220(b). Deletion approved in part at 46 FR 27116 (May 18, 1981). The emission limits of Rule 67 are partially retained, applicable only to (existing) sources, granted permits prior to June 17, 1981—see 40 CFR 52.280(c)(1)(i).
74	Lead Content of Motor Fuels	October 27, 1971	May 31, 1972, 37 FR 10842.	Submitted on February 21, 1972. See 40 CFR 52.220(b).
Rules and Regulations (Riverside County portion of the District)				
53	Specific Air Contaminants	June 10, 1975	June 14, 1978, 43 FR 25684.	Submitted on July 22, 1975. See 40 CFR 52.220(c)(28)(x)(A).
56	Scavenger Plants	June 13, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
58	Disposal of Solid and Liquid Wastes	March 28, 1972	September 22, 1972, 37 FR 19812.	Paragraphs (b), (c), (d) are effective on January 1, 1974. Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
72	Fuel Burning Equipment	May 8, 1970	May 31, 1972, 37 FR 10842.	Submitted on February 21, 1972. See 40 CFR 52.220(b). Deletion approved in part at 46 FR 27116 (May 18, 1981). The emission limits of Rule 72 are partially retained, applicable only to (existing) sources, granted permits prior to June 17, 1981—see 40 CFR 52.280(c)(1)(i).

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District citation	Title/subject	State effective date	EPA approval date	Additional explanation
Rules and Regulations (San Bernardino County portion of the District)				
2	Definitions	November 17, 1970	May 31, 1972, 37 FR 10842.	Part of Regulation I (General Provisions). Submitted on February 21, 1972. See 40 CFR 52.220(b). Superseded except for the definitions for the terms used in Regulation VI (Orchard or Citrus Grove Heaters), which remains part of the applicable SIP.
5 (paragraph (a))	Public Availability of Emission Data	May 30, 1972	June 14, 1978, 43 FR 25684.	Submitted on July 25, 1973. See 40 CFR 52.220(c)(21)(xv)(A).
53A	Specific Contaminants	May 30, 1972	June 14, 1978, 43 FR 25684.	Submitted on July 25, 1973. See 40 CFR 52.220(c)(21)(xv)(A).
53.1	Scavenger Plants	May 30, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
58–A	Disposal of Solid and Liquid Wastes—South Coast Air Basin.	May 30, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
67	Fuel Burning Equipment	December 23, 1969	May 31, 1972, 37 FR 10842.	Submitted on February 21, 1972. See 40 CFR 52.220(b). Deletion approved in part at 46 FR 27116 (May 18, 1981). The emission limits of Rule 67 are partially retained, applicable only to (existing) sources, granted permits prior to June 17, 1981—see 40 CFR 52.280(c)(1)(i).
100	Definition	November 17, 1970	May 31, 1972, 37 FR 10842.	Part of Regulation VI (Orchard or Citrus Grove Heaters). Submitted on February 21, 1972. See 40 CFR 52.220(b). Cites the definitions in Rule 2.
101	Exceptions	November 17, 1970	May 31, 1972, 37 FR 10842.	Part of Regulation VI (Orchard or Citrus Grove Heaters). Submitted on February 21, 1972. See 40 CFR 52.220(b). Cites the definitions in Rule 2.
102	Permits Required	November 17, 1970	May 31, 1972, 37 FR 10842.	Part of Regulation VI (Orchard or Citrus Grove Heaters). Submitted on February 21, 1972. See 40 CFR 52.220(b). Cites the definitions in Rule 2.
104	Standards for Granting Permits	November 17, 1970	May 31, 1972, 37 FR 10842.	Part of Regulation VI (Orchard or Citrus Grove Heaters). Submitted on February 21, 1972. See 40 CFR 52.220(b). Cites the definitions in Rule 2.
109	Denial of Applications	November 17, 1970	May 31, 1972, 37 FR 10842.	Part of Regulation VI (Orchard or Citrus Grove Heaters). Submitted on February 21, 1972. See 40 CFR 52.220(b). Cites the definitions in Rule 2.
110	Appeals	November 17, 1970	May 31, 1972, 37 FR 10842.	Part of Regulation VI (Orchard or Citrus Grove Heaters). Submitted on February 21, 1972. See 40 CFR 52.220(b). Cites the definitions in Rule 2.
130	Classification of Orchard Heaters	November 17, 1970	May 31, 1972, 37 FR 10842.	Part of Regulation VI (Orchard or Citrus Grove Heaters). Submitted on February 21, 1972. See 40 CFR 52.220(b). Cites the definitions in Rule 2.
131	Class I Heaters Designated	November 17, 1970	May 31, 1972, 37 FR 10842.	Part of Regulation VI (Orchard or Citrus Grove Heaters). Submitted on February 21, 1972. See 40 CFR 52.220(b). Cites the definitions in Rule 2.
132	Class II Heaters Designated	November 17, 1970	May 31, 1972, 37 FR 10842.	Part of Regulation VI (Orchard or Citrus Grove Heaters). Submitted on February 21, 1972. See 40 CFR 52.220(b). Cites the definitions in Rule 2.
133	Identification of Heaters	November 17, 1970	May 31, 1972, 37 FR 10842.	Part of Regulation VI (Orchard or Citrus Grove Heaters). Submitted on February 21, 1972. See 40 CFR 52.220(b). Cites the definitions in Rule 2.
134	Use of Incomplete Heaters Prohibited	November 17, 1970	May 31, 1972, 37 FR 10842.	Part of Regulation VI (Orchard or Citrus Grove Heaters). Submitted on February 21, 1972. See 40 CFR 52.220(b). Cites the definitions in Rule 2.
135	Cleaning, Repairs	November 17, 1970	May 31, 1972, 37 FR 10842.	Part of Regulation VI (Orchard or Citrus Grove Heaters). Submitted on February 21, 1972. See 40 CFR 52.220(b). Cites the definitions in Rule 2.
136	Authority to Classify Orchard Heaters	November 17, 1970	May 31, 1972, 37 FR 10842.	Part of Regulation VI (Orchard or Citrus Grove Heaters). Submitted on February 21, 1972. See 40 CFR 52.220(b). Cites the definitions in Rule 2.

TABLE 34—EPA-APPROVED SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT REGULATIONS; LOS ANGELES COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; ORANGE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; RIVERSIDE COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; SAN BERNARDINO COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
137	Enforcement	November 17, 1970	May 31, 1972, 37 FR 10842.	Part of Regulation VI (Orchard or Citrus Grove Heaters). Submitted on February 21, 1972. See 40 CFR 52.220(b). Cites the definitions in Rule 2.

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TABLE 37—EPA-APPROVED VENTURA COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
Regulation I—General				
1	Title	July 2, 1968	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
2	Definitions	April 9, 2019	November 12, 2020, 85 FR 71846.	Submitted on August 19, 2019. See 40 CFR 52.220(c)(542)(i)(B)(1).
4	Rules Supplemental	March 9, 1976	August 15, 1977, 42 FR 41121.	Submitted on April 21, 1976. See 40 CFR 52.220(c)(31)(xiii)(A).
5	Effective Date	April 13, 2004	May 19, 2014, 79 FR 28612.	Submitted on July 19, 2004. See 40 CFR 52.220(c)(332)(i)(B)(4).
6	Severability	November 21, 1978	June 18, 1982, 47 FR 26388.	Submitted on May 23, 1979. See 40 CFR 52.220(c)(51)(xx)(A).
7	Zone Boundaries	June 14, 1977	March 20, 1979, 44 FR 16912.	Submitted on June 22, 1978. See 40 CFR 52.220(c)(44)(iii)(A).
Regulation II—Permits				
10	Permits Required	April 13, 2004	December 3, 2019, 84 FR 66074.	Submitted on July 19, 2004. See 40 CFR 52.220(c)(332)(i)(B)(5).
11	Definitions for Regulation II	March 14, 2006	October 24, 2008, 73 FR 63382.	Submitted on June 16, 2006. See 40 CFR 52.220(c)(345)(i)(C)(1).
12	Applications for Permits	June 13, 1995	December 7, 2000, 65 FR 76567.	Submitted on October 13, 1995. See 40 CFR 52.220(c)(225)(i)(G)(2).
13	Action on Applications for an Authority to Construct.	June 13, 1995	December 7, 2000, 65 FR 76567.	Submitted on October 13, 1995. See 40 CFR 52.220(c)(225)(i)(G)(2).
14	Action on Applications for a Permit to Operate.	June 13, 1995	December 7, 2000, 65 FR 76567.	Submitted on October 13, 1995. See 40 CFR 52.220(c)(225)(i)(G)(2).
15	Standards for Permit Issuance	June 13, 1995	December 7, 2000, 65 FR 76567.	Submitted on October 13, 1995. See 40 CFR 52.220(c)(225)(i)(G)(2).
15.1	Sampling and Testing Facilities	October 12, 1993	December 7, 2000, 65 FR 76567.	Submitted on March 29, 1994. See 40 CFR 52.220(c)(196)(i)(B)(2).
16	BACT Certification	June 13, 1995	December 7, 2000, 65 FR 76567.	Submitted on October 13, 1995. See 40 CFR 52.220(c)(225)(i)(G)(2).
19	Posting of Permits	May 23, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
20	Transfer of Permit	May 23, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
23	Exemptions from Permit	November 12, 2013	July 14, 2015, 80 FR 40909.	Submitted on May 13, 2014. See 40 CFR 52.220(c)(441)(i)(C)(3).
24	Source Recordkeeping, Reporting and Emission Statements.	September 15, 1992	December 7, 2000, 65 FR 76567.	Submitted on November 12, 1992. See 40 CFR 52.220(c)(190)(i)(A)(3).
26	New Source Review—General	March 14, 2006	January 11, 2010, 75 FR 1282.	Submitted on June 16, 2006. See 40 CFR 52.220(c)(345)(i)(C)(2).
26.1	New Source Review—Definitions	November 14, 2006	January 11, 2010, 75 FR 1282.	Submitted on May 8, 2007. See 40 CFR 52.220(c)(350)(i)(E)(1).
26.2	New Source Review—Requirements	March 14, 2006	January 11, 2010, 75 FR 1282.	Submitted on June 16, 2006. See 40 CFR 52.220(c)(345)(i)(C)(2).
26.3	New Source Review—Exemptions	March 14, 2006	January 11, 2010, 75 FR 1282.	Submitted on June 16, 2006. See 40 CFR 52.220(c)(345)(i)(C)(2).
26.4	New Source Review—Emission Banking.	March 14, 2006	January 11, 2010, 75 FR 1282.	Submitted on June 16, 2006. See 40 CFR 52.220(c)(345)(i)(C)(2).
26.5	New Source Review—Essential Public Service Bank.	March 14, 2006	January 11, 2010, 75 FR 1282.	Submitted on June 16, 2006. See 40 CFR 52.220(c)(345)(i)(C)(2).
26.6	New Source Review—Calculations	March 14, 2006	January 11, 2010, 75 FR 1282.	Submitted on June 16, 2006. See 40 CFR 52.220(c)(345)(i)(C)(2).
26.7	New Source Review—Notification	December 22, 1992	December 7, 2000, 65 FR 76567.	Submitted on May 13, 1993. See 40 CFR 52.220(c)(193)(i)(E)(1).
26.8	New Source Review—Permit to Operate.	October 22, 1991	December 7, 2000, 65 FR 76567.	Submitted on January 28, 1992. See 40 CFR 52.220(c)(187)(i)(B)(4).

TABLE 37—EPA-APPROVED VENTURA COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
26.9	New Source Review—Power Plants ..	October 22, 1991 ...	December 7, 2000, 65 FR 76567.	Submitted on January 28, 1992. See 40 CFR 52.220(c)(187)(i)(B)(4).
26.11	New Source Review—ERC Evaluation at Time of Use.	May 14, 2002	February 28, 2003, 68 FR 9561.	Submitted on May 20, 2002. See 40 CFR 52.220(c)(305)(i)(A)(1).
26.13	New Source Review—Prevention of Significant Deterioration (PSD).	November 10, 2015	March 10, 2017, 82 FR 13243.	Submitted on March 11, 2016. See 40 CFR 52.220(c)(474)(i)(D)(1).
28	Revocation of Permits	May 23, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
29	Conditions on Permits	March 14, 2006	October 24, 2008, 73 FR 63382.	Submitted on June 16, 2006. See 40 CFR 52.220(c)(345)(i)(C)(1).
30	Permit Renewal	May 30, 1989	December 7, 2000, 65 FR 76567.	Submitted on March 26, 1990. See 40 CFR 52.220(c)(179)(i)(D)(2).
31	Public Disclosure of Data	January 29, 1974 ...	August 15, 1977, 42 FR 41121.	Submitted on July 19, 1974. See 40 CFR 52.220(c)(24)(x)(A).
34	Acid Deposition Control	March 14, 1995	May 20, 2004, 69 FR 29074.	Submitted on May 24, 1995. See 40 CFR 52.220(c)(220)(i)(E)(1).
	Regulation IV—Prohibitions			
50	Opacity	April 13, 2004	August 9, 2005, 70 FR 46090.	Submitted on July 19, 2004. See 40 CFR 52.220(c)(332)(i)(B)(2).
52	Particulate Matter—Concentration (Grain Loading).	April 13, 2004	August 9, 2005, 70 FR 46090.	Submitted on July 19, 2004. See 40 CFR 52.220(c)(332)(i)(B)(2).
53	Particulate Matter—Process Weight ...	April 13, 2004	August 9, 2005, 70 FR 46090.	Submitted on July 19, 2004. See 40 CFR 52.220(c)(332)(i)(B)(2).
54	Sulfur Compounds	January 14, 2014 ...	January 20, 2015, 80 FR 2609.	Submitted on May 13, 2014. See 40 CFR 52.220(c)(441)(i)(C)(1).
56	Open Burning	November 11, 2003	February 22, 2005, 70 FR 8516.	Submitted on January 15, 2004. See 40 CFR 52.220(c)(328)(i)(A)(2).
57	Incinerators	January 11, 2005 ...	November 9, 2006, 71 FR 65740.	Submitted on July 15, 2005. See 40 CFR 52.220(c)(337)(i)(B)(2).
57.1	Particulate Matter Emissions from Fuel Burning Equipment.	January 11, 2005 ...	November 9, 2006, 71 FR 65740.	Submitted on July 15, 2005. See 40 CFR 52.220(c)(337)(i)(B)(2).
58	Reduction of Animal Matter	May 23, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
59	Electrical Power Generating Equipment—Oxides of Nitrogen Emissions.	July 15, 1997	July 20, 1999, 64 FR 38832.	Submitted on March 10, 1998. See 40 CFR 52.220(c)(254)(i)(K)(1).
62	Hazardous Materials	May 23, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
62.6	Ethylene Oxide—Sterilization and Aeration.	July 16, 1991	August 4, 1994, 59 FR 39690.	Submitted on October 25, 1991. See 40 CFR 52.220(c)(186)(i)(D)(1).
63	Separation and Combination of Emissions.	November 21, 1978	June 18, 1982, 47 FR 26388.	Submitted on May 23, 1979. See 40 CFR 52.220(c)(51)(xx)(A).
64	Sulfur Content of Fuels	April 13, 1999	December 3, 1999, 64 FR 67787.	Submitted on June 3, 1999. See 40 CFR 52.220(c)(264)(i)(C)(1).
68	Carbon Monoxide	April 13, 2004	August 9, 2005, 70 FR 46090.	Submitted on July 19, 2004. See 40 CFR 52.220(c)(332)(i)(B)(3).
69	Asphalt Air Blowing	July 5, 1983	April 17, 1987, 52 FR 12522.	Submitted on October 16, 1985. See 40 CFR 52.220(c)(164)(i)(C)(1).
70	Storage and Transfer of Gasoline	April 1, 2009	January 31, 2011, 76 FR 5277.	Submitted on September 15, 2009. See 40 CFR 52.220(c)(377)(i)(C)(1).
71	Crude Oil and Reactive Organic Compound Liquids.	May 11, 2021	August 15, 2024, 89 FR 66232.	Submitted on October 15, 2021 as an attachment to a letter dated October 14, 2021. See 40 CFR 52.220(c)(601)(i)(B)(1).
71.1	Crude Oil Production and Separation	July 11, 2023	May 29, 2026, 91 FR 31918.	Submitted on January 10, 2024. See 40 CFR 52.220(c)(626)(i)(B)(1).
71.2	Storage of Reactive Organic Compound Liquids.	September 26, 1989	December 6, 1993, 58 FR 64157.	Submitted on October 16, 1990. See 40 CFR 52.220(c)(181)(i)(A)(1).
71.3	Transfer of Reactive Organic Compound Liquids.	June 16, 1992	August 4, 1994, 59 FR 39690.	Submitted on September 14, 1992. See 40 CFR 52.220(c)(189)(i)(B)(1).
71.4	Petroleum Sumps, Pits, Ponds and Well Cellars.	June 8, 1993	December 14, 1994, 59 FR 64330.	Submitted on November 18, 1993. See 40 CFR 52.220(c)(194)(i)(A)(1).
71.5	Glycol Dehydrators	December 13, 1994	February 29, 1996, 61 FR 7706.	Submitted on February 24, 1995. See 40 CFR 52.220(c)(215)(i)(B)(2).
74.1	Abrasive Blasting	November 12, 1991	December 7, 1998, 63 FR 67419.	Submitted on January 28, 1992. See 40 CFR 52.220(c)(187)(i)(B)(2).
74.2	Architectural Coatings	November 10, 2020	March 6, 2023, 88 FR 13713.	Submitted on July 26, 2021. See 40 CFR 52.220(c)(569)(i)(A)(3).
74.3	Paper, Fabric and Film Coating Operations.	December 10, 1991	September 7, 1995, 60 FR 46535.	Submitted on June 19, 1992. See 40 CFR 52.220(c)(188)(i)(D)(3).
74.4	Cutback Asphalt	July 5, 1983	April 17, 1987, 52 FR 12522.	Submitted on October 16, 1985. See 40 CFR 52.220(c)(164)(i)(C)(1).
74.5.1	Petroleum Solvent Dry Cleaning	December 4, 1990	March 24, 1992, 57 FR 10136.	Submitted on April 5, 1991. See 40 CFR 52.220(c)(183)(i)(B)(1).
74.5.2	Synthetic Solvent Dry Cleaning	May 9, 1995	April 5, 2000, 65 FR 17768.	Submitted on August 10, 1995. See 40 CFR 52.220(c)(224)(i)(B)(3).

TABLE 37—EPA-APPROVED VENTURA COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
74.6	Surface Cleaning and Degreasing	November 10, 2020	February 24, 2022, 87 FR 10311.	Submitted on July 26, 2021. See 40 CFR 52.220(c)(569)(i)(A)(1).
74.6.1	Batch Loaded Vapor Degreasers	November 10, 2020	February 24, 2022, 87 FR 10311.	Submitted on July 26, 2021. See 40 CFR 52.220(c)(569)(i)(A)(2).
74.7	Fugitive Emissions of Reactive Organic Compounds (ROC) at Petroleum Refineries and Chemical Plants.	October 10, 1995	July 25, 1996, 61 FR 38571.	Submitted on March 26, 1996. See 40 CFR 52.220(c)(230)(i)(A)(1).
74.8 (paragraphs (A) and (B)).	Refinery Vacuum Producing Systems, Wastewater Separators and Process Turnarounds.	June 19, 1979	July 1, 1982, 47 FR 28617.	Submitted on October 18, 1979. See 40 CFR 52.220(c)(77)(ii)(B). Paragraphs (C) and (D) were superseded by approval of amended Rule 74.8 at 52 FR 12522 (April 17, 1987).
74.8 (paragraphs (C) and (D)).	Refinery Vacuum Producing Systems, Wastewater Separators and Process Turnarounds.	July 5, 1983	April 17, 1987, 52 FR 12522.	Submitted on October 16, 1985. See 40 CFR 52.220(c)(164)(i)(C)(1).
74.9	Stationary Internal Combustion Engines.	November 8, 2005	July 30, 2008, 73 FR 44155.	Submitted on March 10, 2006. See 40 CFR 52.220(c)(344)(i)(D)(1).
74.10	Components at Crude Oil and Natural Gas Production and Processing Facilities.	March 10, 1998	August 19, 1999, 64 FR 45175.	Submitted on June 23, 1998. See 40 CFR 52.220(c)(256)(i)(F)(1).
74.11	Natural Gas-Fired Water Heaters	May 11, 2010	October 29, 2019, 84 FR 57826.	Submitted on June 21, 2011. See 40 CFR 52.220(c)(391)(i)(D)(1).
74.11.1	Large Water Heaters and Small Boilers.	September 11, 2012	May 19, 2014, 79 FR 28612.	Submitted on April 22, 2013. See 40 CFR 52.220(c)(429)(i)(A)(2).
74.12	Surface Coating of Metal Parts and Products.	April 8, 2008	May 24, 2011, 76 FR 30025.	Submitted on January 10, 2010. See 40 CFR 52.220(c)(378)(i)(C)(1).
74.13	Aerospace Assembly and Component Manufacturing Operations.	September 11, 2012	July 1, 2014, 79 FR 37222.	Submitted on April 22, 2013. See 40 CFR 52.220(c)(429)(i)(A)(4).
74.14	Polyester Resin Material Operations	April 12, 2005	February 1, 2006, 71 FR 5172.	Submitted on July 15, 2005. See 40 CFR 52.220(c)(337)(i)(B)(1).
74.15	Boilers, Steam Generators, and Process Heaters.	November 8, 1994	February 9, 1996, 61 FR 4887.	Submitted on January 24, 1995. See 40 CFR 52.220(c)(214)(i)(D)(1).
74.15.1	Boilers, Steam Generators, and Process Heaters.	June 23, 2015	August 1, 2016, 81 FR 50348.	Submitted on November 13, 2015. See 40 CFR 52.220(c)(472)(i)(B)(1).
74.16	Oilfield Drilling Operations	January 8, 1991	April 20, 1999, 64 FR 19277.	Submitted on April 5, 1991. See 40 CFR 52.220(c)(183)(i)(B)(4).
74.18	Motor Vehicle and Mobile Equipment Coating Operations.	November 11, 2008	September 24, 2013, 78 FR 58459.	Submitted on March 17, 2009. See 40 CFR 52.220(c)(363)(i)(E)(1).
74.19	Graphic Arts	June 14, 2011	September 24, 2013, 78 FR 58459.	Submitted on September 27, 2011. See 40 CFR 52.220(c)(404)(i)(C)(2).
74.19.1	Screen Printing Operations	November 11, 2003	October 25, 2005, 70 FR 61561.	Submitted on April 26, 2005. See 40 CFR 52.220(c)(336)(i)(B)(1).
74.20	Adhesives and Sealants	October 9, 2018	February 24, 2021, 86 FR 11130.	Submitted on January 23, 2019. See 40 CFR 52.220(c)(545)(i)(A)(1).
74.21	Semiconductor Manufacturing	April 6, 1993	February 29, 1996, 61 FR 7706.	Submitted on November 18, 1993. See 40 CFR 52.220(c)(194)(i)(A)(4).
74.22	Natural Gas-Fired, Fan-Type Central Furnaces.	November 9, 1993	April 30, 1996, 61 FR 18959.	Submitted on February 11, 1994. See 40 CFR 52.220(c)(195)(i)(B)(1).
74.23	Stationary Gas Turbines	January 8, 2002	June 3, 2003, 68 FR 33018.	Submitted on March 15, 2002. See 40 CFR 52.220(c)(297)(i)(A)(4).
74.24	Marine Coating Operations	September 11, 2012	July 1, 2014, 79 FR 37222.	Submitted on April 22, 2013. See 40 CFR 52.220(c)(429)(i)(A)(5).
74.24.1	Pleasure Craft Coating and Commercial Boatyard Operations.	January 8, 2002	August 13, 2002, 67 FR 52611.	Submitted on March 15, 2002. See 40 CFR 52.220(c)(297)(i)(A)(3).
74.25	Restaurant Cooking Operations	October 12, 2004	August 9, 2005, 70 FR 46090.	Submitted on January 13, 2005. See 40 CFR 52.220(c)(335)(i)(C)(1).
74.26	Crude Oil Storage Tank Degassing Operations.	November 8, 1994	May 6, 1996, 61 FR 20145.	Submitted on January 24, 1995. See 40 CFR 52.220(c)(214)(i)(D)(2).
74.27	Gasoline and ROC Liquid Storage Tank Degassing Operations.	November 8, 1994	May 6, 1996, 61 FR 20145.	Submitted on January 24, 1995. See 40 CFR 52.220(c)(214)(i)(D)(2).
74.28	Asphalt Roofing Operations	January 1, 1995	February 29, 1996, 61 FR 7706.	Submitted on July 13, 1994. See 40 CFR 52.220(c)(198)(i)(J)(1).
74.29	Soil Decontamination Operations	July 1, 2008	October 3, 2011, 76 FR 61057.	Submitted on January 10, 2010. See 40 CFR 52.220(c)(378)(i)(C)(2).
74.30	Wood Products Coatings	June 27, 2006	July 16, 2008, 73 FR 40754.	Submitted on October 5, 2006. See 40 CFR 52.220(c)(347)(i)(D)(1).
74.31	Metalworking Fluids and Direct-Contact Lubricants.	November 12, 2013	March 27, 2015, 80 FR 16289.	Submitted on May 13, 2014. See 40 CFR 52.220(c)(441)(i)(C)(2).
74.33	Liquefied Petroleum Gas Transfer or Dispensing.	January 13, 2015	September 25, 2015, 80 FR 57725.	Submitted on April 7, 2015. See 40 CFR 52.220(c)(461)(i)(B)(1).
74.34	NO_X Reductions from Miscellaneous Sources.	December 13, 2016	December 19, 2017, 82 FR 60119.	Submitted on February 24, 2017. See 40 CFR 52.220(c)(498)(i)(A)(1).
75	Circumvention	November 21, 1978	June 18, 1982, 47 FR 26388.	Submitted on May 23, 1979. See 40 CFR 52.220(c)(51)(xx)(A).

TABLE 37—EPA-APPROVED VENTURA COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS—Continued

District citation	Title/subject	State effective date	EPA approval date	Additional explanation
Regulation V—Orchard Heaters				
80	Permits	July 5, 1983	April 17, 1987, 52 FR 12522.	Submitted on October 16, 1985. See 40 CFR 52.220(c)(164)(i)(C)(1).
81	Condition of Heaters	October 30, 1979	June 18, 1982, 47 FR 26388.	Submitted on February 25, 1980. See 40 CFR 52.220(c)(54)(i)(C).
82	Burning Rubber and Other Substances.	May 23, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
83	Orchard Heaters: Permitted Types	May 23, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
85	Prohibition of Sale of Heaters	May 23, 1972	September 22, 1972, 37 FR 19812.	Submitted on June 30, 1972. See 40 CFR 52.220(c)(6).
Regulation VI—Source Testing and Stack Monitoring				
101	Sampling and Testing Facilities	May 23, 1972	August 15, 1977, 42 FR 41121.	Submitted on July 25, 1973. See 40 CFR 52.220(c)(21)(xiii)(A).
102	Source Tests	April 13, 2004	August 9, 2005, 70 FR 46090.	Submitted on July 19, 2004. See 40 CFR 52.220(c)(332)(i)(B)(3).
103	Continuous Monitoring Systems	February 9, 1999	December 9, 2002, 67 FR 72842.	Submitted on June 3, 1999. See 40 CFR 52.220(c)(264)(i)(C)(2).
Regulation VIII—Emergency Action				
150	General	September 17, 1991	March 18, 1999, 64 FR 13351.	Submitted on January 28, 1992. See 40 CFR 52.220(c)(187)(i)(B)(3).
151	Episode Criteria	September 17, 1991	March 18, 1999, 64 FR 13351.	Submitted on January 28, 1992. See 40 CFR 52.220(c)(187)(i)(B)(3).
152	Episode Notification Procedures	September 17, 1991	March 18, 1999, 64 FR 13351.	Submitted on January 28, 1992. See 40 CFR 52.220(c)(187)(i)(B)(3).
153	Health Advisory Episode Actions	September 17, 1991	March 18, 1999, 64 FR 13351.	Submitted on January 28, 1992. See 40 CFR 52.220(c)(187)(i)(B)(3).
154	Stage 1 Episode Actions	September 17, 1991	March 18, 1999, 64 FR 13351.	Submitted on January 28, 1992. See 40 CFR 52.220(c)(187)(i)(B)(3).
155	Stage 2 Episode Actions	September 17, 1991	March 18, 1999, 64 FR 13351.	Submitted on January 28, 1992. See 40 CFR 52.220(c)(187)(i)(B)(3).
156	Stage 3 Episode Actions	September 17, 1991	March 18, 1999, 64 FR 13351.	Submitted on January 28, 1992. See 40 CFR 52.220(c)(187)(i)(B)(3).
157	Air Pollution Disaster	September 17, 1991	March 18, 1999, 64 FR 13351.	Submitted on January 28, 1992. See 40 CFR 52.220(c)(187)(i)(B)(3).
158	Source Abatement Plans	September 17, 1991	March 18, 1999, 64 FR 13351.	Submitted on January 28, 1992. See 40 CFR 52.220(c)(187)(i)(B)(3).
159	Traffic Abatement Procedures	September 17, 1991	March 18, 1999, 64 FR 13351.	Submitted on January 28, 1992. See 40 CFR 52.220(c)(187)(i)(B)(3).
Regulation IX—Public Records				
200	Public Records	January 29, 1974	August 15, 1977, 42 FR 41121.	Submitted on July 19, 1974. See 40 CFR 52.220(c)(24)(x)(A).
201	District's Request for Information	March 9, 1976	August 15, 1977, 42 FR 41121.	Submitted on April 21, 1976. See 40 CFR 52.220(c)(31)(xiii)(A).
202	Inspection of Public Records—Disclosure Policy.	March 9, 1976	August 15, 1977, 42 FR 41121.	Submitted on April 21, 1976. See 40 CFR 52.220(c)(31)(xiii)(A).
203	Inspection of Public Records—Disclosure Procedure.	January 29, 1974	August 15, 1977, 42 FR 41121.	Submitted on July 19, 1974. See 40 CFR 52.220(c)(24)(x)(A).
204	Trade Secrets	January 29, 1974	August 15, 1977, 42 FR 41121.	Submitted on July 19, 1974. See 40 CFR 52.220(c)(24)(x)(A).
Regulation XI—Conformity				
220	General Conformity	May 9, 1995	April 23, 1999, 64 FR 19916.	Submitted on August 10, 1995. See 40 CFR 52.220(c)(224)(i)(B)(2).

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(d) *EPA-approved source-specific requirements.* References to paragraphs in 40 CFR 52.220 in entries to paragraph (d) should be understood to refer to the corresponding paragraphs in 40 CFR 52.250.

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(e) *EPA-approved California nonregulatory provisions and quasi-regulatory measures.* References to paragraphs in 40 CFR 52.220 in entries in tables 1 through 10 to paragraph (e) should be understood to refer to the corresponding paragraphs in 40 CFR 52.250.

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[FR Doc. 2026–22671 Filed 11–5–26; 8:45 am]

BILLING CODE 6569–60–P



FEDERAL REGISTER

Vol. 91 Friday,
No. 214 November 6, 2026

Part III

Department of Labor

29 CFR Parts 29 and 30
Prohibiting Illegal Discrimination in Registered Apprenticeship Programs; Final Rule

DEPARTMENT OF LABOR

29 CFR Parts 29 and 30

[Docket No. ETA–2025–0006]

RIN 1205–AC21

Prohibiting Illegal Discrimination in Registered Apprenticeship Programs

AGENCY: Employment and Training Administration, Labor.

ACTION: Final rule.

SUMMARY: The Department of Labor (DOL or the Department) is issuing this final rule to remove the onerous and legally questionable affirmative action requirements that were previously imposed by the Department on Registered Apprenticeship program sponsors. This final rule also streamlines and simplifies nondiscrimination obligations for all program sponsors, while clarifying that sponsors are accountable for compliance with Federal and State nondiscrimination protections. It also makes conforming, technical changes to the Department's regulation that addresses Labor Standards for the Registration of Apprenticeship Programs.

DATES: This final rule is effective January 5, 2027.

FOR FURTHER INFORMATION CONTACT: Luke Murren, Acting Administrator, Office of Policy Development and Research, U.S. Department of Labor, Employment and Training Administration, 200 Constitution Avenue NW, Room N–5641, Washington, DC 20210, Telephone: 202–693–3700 (voice) (this is not a toll-free number). For persons with a hearing or speech disability who need assistance using the telephone system, please dial 711 to access telecommunications relay services.

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Acronyms and Abbreviations

ADA Americans with Disabilities Act
WIOA Workforce Innovation and Opportunity Act
ADEA Age Discrimination in Employment Act
APA Administrative Procedure Act
BLS Bureau of Labor Statistics
DOL Department of Labor
EEO Equal Employment Opportunity
EEOC Equal Employment Opportunity Commission
ETA Employment and Training Administration
FCC Federal Communications Commission
FEPA Fair Employment Practices Agency
FY Fiscal Year

I. Executive Summary

This final rule, *Prohibiting Illegal Discrimination in Registered Apprenticeship Programs,* removes burdensome requirements for Registered Apprenticeship program sponsors contained in the regulation at 29 CFR part 30, and replaces the part 30 regulation's complicated array of apprenticeship-specific nondiscrimination requirements with a more straightforward requirement that all Registered Apprenticeship program sponsors comply with all Federal and State laws and regulations prohibiting discrimination. In addition, the final rule provides clarity to apprenticeship stakeholders regarding the appropriate forums for advancing and remediating issues relating to alleged discrimination in Registered Apprenticeship programs.

Under this final rule, Registered Apprenticeship program sponsors will no longer be required to comply with the burdensome administrative requirements contained in the part 30 regulation, which included a general duty for all sponsors to engage in affirmative action and meet equal employment opportunity (EEO) obligations. The part 30 regulation's general duty to engage in affirmative action included mandates to designate an individual to manage the program's EEO policy, to conduct anti-harassment training, and to post an equal opportunity pledge, among other burdensome requirements. The final rule also removes the burdensome and legally questionable regulatory mandate that sponsors with five or more apprentices comply with more extensive affirmative action requirements, which included conducting utilization analyses and setting numerical goals for hiring apprentices based upon their race, sex, and ethnicity. The Department expects that removing these obligations will significantly reduce administrative burdens for sponsors and will also support the growth of Registered Apprenticeship programs, in alignment with the Department's and Administration's goals and priorities.

In their place, this final rule substitutes a streamlined requirement that all Registered Apprenticeship program sponsors comply fully with all applicable Federal and State laws and regulations prohibiting illegal

discrimination. This requirement, along with a revised regulatory framework for discrimination-related complaints, provides needed clarity to apprenticeship stakeholders on the most appropriate and effective course of action for apprentices to raise and seek remediation of discrimination-related issues. Finally, the final rule includes a requirement that any State seeking new or continued recognition from the Department's Office of Apprenticeship (OA) as a State Apprenticeship Agency (SAA) must establish State laws and regulations that conform to the revised part 30 regulation, so that Registered Apprenticeship programs throughout the National Apprenticeship System are subject to a consistent set of requirements related to nondiscrimination in apprenticeship.

II. Background and Purpose of the Revised Part 30 Regulation

A. Legal Authority To Promulgate Registered Apprenticeship Regulations

The National Apprenticeship Act (NAA) (also known as the Fitzgerald Act), 50 Stat. 664,[1] was enacted by Congress in 1937. Among other things, the NAA authorizes the Secretary of the Department of Labor to ''formulate and promote the furtherance of labor standards necessary to safeguard the welfare of apprentices, to extend the application of such standards by inclusion thereof in contracts of apprenticeship, to bring together employers and labor for the formulation of programs of apprenticeship, [and] to cooperate with State agencies engaged in the formulation and promotion of standards of apprenticeship.'' 50 Stat. 664.[2] The NAA forms the basis of the Department's legal authority to oversee the National Apprenticeship System and develop and advance labor standards, in conjunction with apprenticeship stakeholders throughout industry, labor, and State and local jurisdictions, for Registered Apprenticeship programs. Pursuant to this statutory authority, the Department has designated OA, within the Department's Employment and Training Administration (ETA), as the office responsible for conducting oversight, establishing rules and policies related to Registered Apprenticeship, and promoting the success and expansion of the Registered Apprenticeship model.

To implement the aims of the NAA, OA has promulgated regulations, found at 29 CFR parts 29 and 30, to formalize labor standards that all Registered Apprenticeship programs must meet, and establish processes to conduct National Apprenticeship System oversight in coordination with State and local jurisdictions. The Department's legal authority to promulgate regulations related to Registered Apprenticeship, as well as the scope and content of such regulations, is rooted in the NAA. Under such authority, the Department must also periodically revisit the governing regulations at 29 CFR parts 29 and 30 in light of evolving economic conditions, changes impacting the labor market, or other developments impacting workforce development and apprenticeship.

The regulation at 29 CFR part 29 (part 29) implements the NAA's statutory directive to the Department to establish labor standards for Registered Apprenticeship programs and safeguard the welfare of apprentices. The first version of a regulation that set forth standards of apprenticeship was issued by the Department in 1977, and the last major revision to the part 29 regulations was issued in 2008. The part 29 regulation, and the labor standards that it established, serve as the primary regulatory framework for Registered Apprenticeship programs. The part 29 regulatory requirements for Registered Apprenticeship programs are intended to allow sponsors of such programs to tailor programs to meet their workforce needs while maintaining the high quality that has characterized Registered Apprenticeship for decades.

The regulation at part 30 requiring nondiscrimination and equality of opportunity in Registered Apprenticeship programs was first issued by the Department in 1963, and was subsequently updated by the Department in 1971, 1978, and 2016. Across these iterations, the part 30 regulation evolved from a prohibition against discrimination (also described as a requirement for sponsors to select apprentices ''solely on the basis of their qualifications compared to those of other applicants''), to include various other requirements for sponsors and State agencies. For sponsors, additional requirements imposed by the part 30 regulation included: developing and posting a policy committing to equal opportunity; conducting anti-harassment training; providing a written notice to apprentices informing them of their right to file discrimination complaints and the process for doing so; and (for those Registered Apprenticeship programs enrolling five or more apprentices) conducting utilization analyses as part of their affirmative action plans and inviting apprentices to voluntarily disclose their disability status. The part 30 regulation also included a requirement for State agencies to develop a ''State EEO plan'' in order to seek or maintain recognition as an SAA, among other requirements.

Acting on the Department's authority to promulgate apprenticeship regulations under the NAA, the Department issued a Notice of Proposed Rulemaking (NPRM) entitled *Prohibiting Illegal Discrimination in Registered Apprenticeship Programs* in the **Federal Register** on July 2, 2025, (90 FR 28947) as the first step in a transparent process to update the part 30 regulation.[3] This first step of the rulemaking process for Federal agencies, which is governed by the Administrative Procedure Act (APA), as amended, at 5 U.S.C. 553, supports transparent policymaking by allowing the Department to publish its proposed approach to updating the regulation and explain its rationale for the proposed changes, and by allowing the public to examine, assess, and provide public comments in response to the Department's proposal. In the NPRM, the Department proposed to update and significantly streamline the part 30 regulation to return to a more straightforward nondiscrimination requirement for Registered Apprenticeship program sponsors and clarify the most appropriate and effective processes and forums for raising and remediating issues related to alleged illegal discrimination in Registered Apprenticeship programs. The Department assessed public comments on its proposal and reexamined its rationale and goals for the rulemaking in light of the views, arguments, and data shared by public commenters, in developing this final rule in accordance with the APA.

B. Registered Apprenticeship: Opportunities for Expansion

For nearly a century, the Department has supported the administration of Registered Apprenticeship programs and overseen the National Apprenticeship System. Registered Apprenticeship is a proven workforce development strategy that combines paid on-the-job learning (OJL) and related instruction, providing tangible benefits to employers and career-seekers alike. Registered Apprenticeship enables employers to design training programs that meet their workforce development needs, empowers apprentices to advance their careers

[1] 29 U.S.C. 50.

[2] 29 U.S.C. 50.

[3] The Department's NPRM can be found at *https://www.federalregister.gov/documents/2025/07/02/2025-12317/prohibiting-illegal-discrimination-in-registered-apprenticeship-programs.*

through structured training that develops critical occupational skills and competencies and ultimately leads to an apprentice becoming proficient in an occupation. What began as a training strategy for the skilled trades has evolved and expanded to include a wider range of occupations across industries, including growth sectors such as information technology, health care, and financial services.

At the end of fiscal year (FY) 2025, according to OA data on Registered Apprenticeship programs nationwide, 26,628 active Registered Apprenticeship programs provided training to more than 700,000 apprentices.[4] These programs provide training in more than 1,000 occupations determined to be ''apprenticeable'' [5] across industries ranging from advanced manufacturing and construction to education, financial services, information technology, and health care. The number of apprentices has grown steadily over the past decade; the total number of active apprentices at the end of FY 2025 represented a 77% increase from the 395,764 active apprentices in FY 2016. Since 2016,[6] the Department has expanded its role in administering the National Apprenticeship System to include targeted investments to support Registered Apprenticeship growth. These investments have grown from around $90 million in FY 2016 to $185 million in FY 2021, $235 million in FY 2022,[7] and $285 million in FYs 2023, 2024, 2025, and 2026.[8]

Despite the steady growth of the National Apprenticeship System, the Department recognizes that Registered Apprenticeship's impact on the U.S. economy, overall, remains limited. Registered Apprenticeship is underutilized as a workforce development solution in the United States when compared to the impact of apprenticeship in other developed nations. In the United States, apprentices comprise a significantly smaller share of the overall workforce than in other countries with strong and established apprenticeship systems (such as Australia, Canada, Germany, and the United Kingdom).[9] Given this underutilization of apprenticeship in the United States, the Department is determined to address factors that serve to limit the accelerated expansion and utilization of the model, including removing burdensome regulatory requirements like the complex and legally questionable set of requirements contained in the existing part 30 regulation.

While the Department is supportive of efforts to expand Registered Apprenticeship into new sectors and occupations where the training model is not currently widespread, the preponderance of Registered Apprenticeship programs remain within the skilled trades. In 2026, OA's data on apprenticeship participation by industry indicates there are nearly 270,000 apprentices in Registered Apprenticeship programs in the construction sector, a significant plurality compared to other industries.[10] This concentration of programs in the skilled trades limits Registered Apprenticeship's potential economy-wide impact and contributes to the false narrative that this training model is only suitable for that sector. Registered Apprenticeship's combination of structured OJL and related instruction is a proven training strategy that has consistently benefited both employers and career-seekers and can be adapted across industries (including growth sectors like information technology and healthcare).

The Registered Apprenticeship model has significant potential to meet the workforce development needs of more employers and provide more apprentices with opportunities to develop their careers, and as such, the Department views the expansion of the model as a pathway to greater economic prosperity in the United States. In a 2023 report (updated in February 2026), the U.S. Chamber of Commerce analyzed economic trends in job openings, labor force participation, and other labor market indicators.[11] This analysis showed that over the past two decades, job openings have increased, on average, while the number of unemployed workers has decreased, resulting in a persistent shortage of workers available to fill open positions. The analysis shows that while the gap between job openings and available workers has evened out following economic shocks and disruptions related to the COVID–19 pandemic (when unemployment spiked to 23 million unemployed workers in 2020), State-level economic data indicates that some States face significant challenges in filling job openings. South Dakota, for example, had 41 available workers for every 100 open jobs, and nationwide, only ten States report a surplus of available workers.

In general, labor force participation has been on the decline for the past two decades, due to a range of factors including retirements, an aging workforce, and reliance on means-tested public benefits. Further, employers increasingly point to a mismatch in the skills they need for their workforce and the skills possessed by job seekers when describing challenges in filling open positions. Surveys and analyses of hiring trends indicate that, while many employers have open positions and are seeking to hire employees, they struggle to fill these positions because they struggle to find candidates that possess the skills they need. One recent analysis estimates a potential shortage of approximately 5.25 million workers with education and training beyond high school through 2032, including projected shortages in several occupations that have historically relied on work-based training.[12]

[4] Data discussed in this paragraph are available to the public on OA's website, ''Apprenticeship—Data and Statistics,'' *https://www.apprenticeship.gov/data-and-statistics.*

[5] Part 29 defines an ''apprenticeable'' occupation as an occupation that must involve skills customarily learned through structured, systematic OJL, must be clearly identified and commonly recognized throughout an industry, must involve the progressive attainment of skills that would require the completion of at least 2,000 hours of OJL to attain, and must require a related instruction component to supplement OJL. *See* 29 CFR 29.4, *https://www.ecfr.gov/current/title-29/subtitle-A/part-29#29.4.*

[6] Prior to 2016, the Department invested around $30 million per year to support Registered Apprenticeship. Since 2016, these investments have steadily increased and diversified, and are supplemented by State funds supporting the Registered Apprenticeship expansion goal. *See* the Urban Institute's analysis of strategic investment in Registered Apprenticeship, ''Strategic Investments to Expand Apprenticeships in the US,'' *https://www.urban.org/sites/default/files/2025-03/Strategic_Investments_to_Advance_Apprenticeships_in_the_US.pdf.*

[7] Congressional Research Service, ''Registered Apprenticeship: Federal Role and Recent Federal Efforts,'' Feb. 7, 2025, *https://www.congress.gov/crs-product/R45171#_Toc190349619.*

[8] H.R.7148—119th Congress (2025–2026): Consolidated Appropriations Act, 2026.

[9] *See* Keith Rolland, ''Apprenticeships and their potential in the U.S.,'' Federal Reserve Bank of Philadelphia, Winter 2015, *https://www.philadelphiafed.org/community-development/workforce-and-economic-development/apprenticeships-and-their-potential-in-the-us* (citing a presentation by Professor Robert I. Lerman of the Urban Institute, which noted that apprentices constituted only 0.2% of the U.S. labor force, compared with 2.2% in Canada, 2.7% in Great Britain, and 3.7% in Australia and Germany). *See also* Robert I. Lerman, ''Proposal 7: Expand Apprenticeship Opportunities in the United States,'' The Hamilton Project of the Brookings Institution, 2015, at p. 3, *https://www.hamiltonproject.org/assets/legacy/files/downloads_and_links/expand_apprenticeship_opportunities_united_states_lerman.pdf.*

[10] DOL, ''Apprenticeship—Data and Statistics,'' *https://www.apprenticeship.gov/data-and-statistics/apprentices-by-state-dashboard* (last visited June 26, 2026).

[11] U.S. Chamber of Commerce, ''Understanding America's Labor Shortage,'' Nov. 21, 2023, *https://www.uschamber.com/workforce/understanding-americas-labor-shortage.*

[12] Georgetown University Center on Education and the Workforce, Falling Behind: How Skills Shortages Threaten Future Jobs (2025), available at

The Department sees Registered Apprenticeship as a critical strategy for increasing job seekers' skills and empowering employers to design training programs that develop in-demand skill sets. Registered Apprenticeship programs' training plans are based on industry training standards, meaning that industry leaders have input into the skills and competencies needed for an occupation. Sponsors of Registered Apprenticeship programs use these industry-derived inputs in designing programs that fit their specific needs (or the needs of employers who participate in the program). During the past two decades, the Registered Apprenticeship model has expanded into industries beyond the skilled trades, but still accounts for a small share of the overall labor force that lags far behind other advanced economies.[13] The Department views Registered Apprenticeship as a successful strategy for helping more employers meet their workforce development needs, a view that is more pronounced and relevant in the labor market of 2026, when job openings increasingly require higher levels of technical and specialized skills. As such, the Trump Administration has made the expansion of Registered Apprenticeship a top priority.

Registered Apprenticeship stakeholders, including those with established programs and those interested in starting programs, have pointed to the administrative burdens and direct costs of starting and operating a program as factors that limit the expansion and uptake of the model.[14] While Federal and State funds have helped mitigate these challenges, stakeholders still report impediments, including compliance with the administrative requirements found in Federal and State regulation. The Department has determined that substantially reducing the regulatory burdens that were imposed upon program sponsors by the part 30 regulation is an indispensable prerequisite for achieving the Department's ongoing goal of expanding Registered Apprenticeship to meet the needs of the labor market.

The Department's determination to update the part 30 regulation with this final rule also aligns with the Administration's priorities for the Department and Registered Apprenticeship. On January 31, 2025, in the first days of his Administration, President Trump signed E.O. 14192, *Unleashing Prosperity Through Deregulation,* which directed Federal agencies to identify opportunities to review and revise or rescind any regulations that impose undue burdens on Americans and American businesses, with the goal of increasing flexibility for businesses and accelerating economic prosperity.[15] The President also issued E.O. 14278, *Preparing Americans for High-Paying Skilled Trade Jobs of the Future,* which directed Federal agencies to prioritize investments and develop strategies to support workforce development, and specifically instructed the Departments of Labor, Education, and Commerce to develop a plan to achieve 1,000,000 active apprentices in Registered Apprenticeship programs.[16] The Department views this final rule rescinding the burdensome and legally questionable elements of the part 30 regulation as a critical step towards meeting the Administration's directives, growing Registered Apprenticeship's footprint in the broader economy, and supporting economic prosperity for employers and job seekers in the modern labor market.

C. Historical Background on Part 30 and on Prohibiting Illegal Discrimination in Apprenticeship

In issuing this final rule, the Department has determined that it can fulfill the NAA's statutory mandate to ''safeguard the welfare of apprentices'' by simply requiring that sponsors comply with already applicable Federal and State employment nondiscrimination laws. The importance of establishing clarity and consistency in the laws and policies governing nondiscrimination in Registered Apprenticeship programs is best understood by tracing the evolution of the part 30 regulation, the pertinent provisions of applicable Federal nondiscrimination laws, and relevant Supreme Court decisions relating to the constitutionality of group-based preferences generally.

The original version of the 29 CFR part 30 regulation [17] (issued by the Department in December 1963) barred Registered Apprenticeship program sponsors from engaging in discrimination against apprentices on the basis of race, color, creed, or national origin in all phases of apprenticeship, stipulated that the selection of apprentices by programs be made ''solely on the basis of their qualifications compared to those of other applicants,'' and provided for the deregistration of apprenticeship programs that failed to comply with those mandates.[18] In effect, the Department's issuance of the 1963 part 30 regulation prohibiting illegal discrimination by Registered Apprenticeship programs formulated a new minimum standard of apprenticeship designed to safeguard the welfare of apprentices, one that was later supplemented by the establishment of additional labor standards of apprenticeship (at 29 CFR part 29) concerning, among other things, the payment of progressive wages and the provision of safe working environments to apprentices. However, it is important to note that neither the 1963 part 30 regulation nor its later iterations (in 1971, 1978, and 2016) provided apprentices with meaningful, individualized remedies (such as make-whole relief) to address instances of illegal discriminatory conduct against such persons by a program sponsor.

The absence of such individualized remedies for illegal discrimination against apprentices under the part 30 regulation, however, was addressed in the following year, when Congress enacted the Civil Rights Act of 1964, 78 Stat. 257 (the Act). Title VII of the Act (which applies to employers with 15 or more employees, among other covered

https://cew.georgetown.edu/wp-content/uploads/cew-falling_behind-fr.pdf.

[13] A white paper discussing the potential to expand Registered Apprenticeship states that apprentices accounted for just 0.3% of the labor force in the United States in 2020, far below rates of apprentice makeup of the labor force in other advanced economies that utilize the model. Robert I. Lerman, ''The State of Apprenticeship in the US: A Plan for Scale,'' Apprenticeships for America, July 2022, *https://apprenticeshipsforamerica.org/resources/afa-publications/19/the-state-of-apprenticeship-in-the-us-a-plan-for-scale.*

[14] Bhavani Arabandi and Leslee Haisma, ''Strategic Investments to Advance Apprenticeships in the US,'' The Urban Institute, Mar. 25, 2025, *https://www.urban.org/sites/default/files/2025-03/Strategic_Investments_to_Advance_Apprenticeships_in_the_US.pdf.*

[15] E.O. 14192, ''Unleashing Prosperity Through Deregulation,'' Jan. 31, 2025, *https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation.*

[16] E.O. 14278, ''Preparing Americans for High-Paying Skilled Jobs of the Future,'' Apr. 23, 2025, *https://www.federalregister.gov/documents/2025/04/28/2025-07369/preparing-americans-for-high-paying-skilled-trade-jobs-of-the-future.*

[17] See 28 FR 13775 (Dec. 18, 1963).

[18] This potential deregistration sanction against sponsors who are found to have engaged in program-wide discriminatory conduct against apprentices on the basis of protected characteristics has been retained in all subsequent iterations of the part 30 regulation, including the latest version contained in this final rule. As a Registration Agency's grant of registration to an apprenticeship program serves as an official recognition of that program's overall quality and represents the conferral of a valuable governmental benefit upon the program sponsor, the Department maintains that the potential deregistration of an apprenticeship program is an appropriate sanction against those sponsors that have been shown to operate their programs in a discriminatory manner and that have failed to address or rectify such illegal conduct.

entities) prohibits employment discrimination against individuals on the basis of their race, color, religion, national origin, and sex. In particular, section 703(d) of the Act states that ''[i]t shall be an unlawful employment practice for any employer, labor organization, or joint labor-management committee controlling apprenticeship or other training or retraining, including on-the-job training programs to discriminate against any individual because of his race, color, religion, sex, or national origin in admission to, or employment in, any program established to provide apprenticeship or other training.'' [19] Section 706(g) of the Act further authorizes a wide range of remedies for employees (including apprentices) who have experienced discrimination at the hands of a covered entity based upon their race, color, religion, sex, or national origin.[20] The Act also established the Equal Employment Opportunity Commission (EEOC), a specialized Federal agency vested by Congress with the authority to receive and investigate complaints from job applicants and employees (including apprentices) alleging violations of Title VII (as well as alleged violations of other Federal employment discrimination statutes subsequently enacted by Congress).

Significantly, the text of Title VII contains no provision requiring employers or apprenticeship programs to adopt a compulsory, nonremedial scheme of group-based preferences (such as affirmative action arrangements) in hiring or employment that takes into consideration the race, color, religion, sex, or national origin of job applicants.[21] The absence of such a general mandate in Title VII is highlighted by the inclusion (at section 703(j) of the Act [22]) of a proscriptive rule of statutory construction specifically governing the provisions of Title VII. Section 703(j) stipulates, in relevant part, that nothing contained in Title VII shall be interpreted to require any employer, employment agency, labor organization, or joint labor-management committee subject to the title ''to grant preferential treatment'' to any individual or to any group based on the race, color, religion, sex, or national origin of such individual or group in order to address an imbalance which may exist in the demographic composition of an employer's or other covered entity's work force or membership, including those individuals ''admitted to, or employed in, any apprenticeship or training program,'' as compared to the demographic composition ''in any community, State, section, or other area, or in the available work force in any community, State, section, or other area.''

In effect, the language of section 703(j) precludes governmental entities, such as Federal courts and relevant Federal administrative agencies, from interpreting Title VII's provisions in such a way as to require an employer or an apprenticeship program subject to the Act to grant preferential treatment to individuals or groups in hiring and employment based upon their race, color, religion, sex, or national origin for the purpose of achieving or maintaining demographic ''balance'' in that employer's or apprenticeship program's workforce. However, in those limited instances where a court finds that an employer or apprenticeship program has intentionally engaged in illegal, discriminatory employment practices under Title VII, the court has the discretion under section 706(g) of the Act to impose a narrowly tailored, time-limited affirmative action plan to remedy such discriminatory conduct. *See Loc. 28 of Sheet Metal Workers' Int'l Ass'n* v. *E.E.O.C.,* 478 U.S. 421, 444–45 (1986) (plurality opinion); *id.* at 483 (Powell, J., concurring in part and concurring in judgment) (finding that the District Court had acted within the remedial authority under section 706(g) in establishing a numerical membership goal based on the percentage of nonwhites in the relevant labor pool where the union had repeatedly and egregiously violated Title VII and ignored prior judicial orders).

Taken together, the foregoing provisions of Title VII established a comprehensive statutory framework under which Congress outlawed all employment discrimination in apprenticeship and training programs covered by the Act based upon race, color, religion, sex, or national origin; provided effective remedies to individual apprentices who were subjected to such forms of illegal discrimination by covered employers and apprenticeship programs; precluded interpreting Title VII to require the utilization of nonremedial, group-based preferences by covered apprenticeship and training programs to address imbalances in the demographic composition of a program's workforce; and established a Federal agency (the EEOC) with the statutory authority and subject-matter expertise to investigate discrimination complaints by apprentices and to identify violations of Title VII by covered apprenticeship programs. The express inclusion of apprentices and apprenticeship and training programs within the scope of Title VII's statutory protections demonstrates that Congress was concerned about the prevalence of discrimination in these programs in the early 1960s, and was intentional in enacting legislation specifically prohibiting program sponsors from engaging in such egregious employment practices.[23]

In 1971, subsequent to the enactment of Title VII, the Department modified the part 30 regulation by adding sex as a protected category with respect to nondiscrimination by program sponsors; this particular amendment effectively aligned the text of part 30 with the protected nondiscrimination categories that were established by Congress in Title VII. However, the 1971 version of the part 30 regulation also introduced and imposed upon apprenticeship programs enrolling five or more apprentices a compulsory, nonremedial affirmative action requirement of indefinite duration, and mandated the establishment of numerical hiring goals by such programs in the selection of apprentices from minority groups.[24] Clearly, the Department's 1971 issuance of a regulation mandating the establishment by such apprenticeship programs of a permanent system of nonremedial, nonvoluntary, group-based preferences in the selection of apprentices was fundamentally at odds with the unambiguous policy direction charted by Congress in sections 703(d) and (j) of Title VII regarding apprenticeship: namely, that *all* employment discrimination against

[19] 42 U.S.C. 2000e–2(d).

[20] 42 U.S.C. 2000e–5(g).

[21] During the lengthy floor debate preceding the Senate's passage of the bill (H.R. 7152) that became the Act, Senator Edmund Muskie of Maine defended the Title VII provisions of the legislation, noting that the measure ''seeks to afford to all Americans equal opportunity in employment without discrimination. Not equal pay. Not 'racial balance.' Only equal opportunity.'' Senator Muskie further stated that ''[d]iscrimination in this bill means just what it means anywhere: a distinction in treatment given to different individuals because of their race.'' 110 Cong. Rec. 12617 (1964). Senator Hubert Humphrey of Minnesota, the floor manager of the bill in the Senate, maintained during the debate that ''Title VII prohibits discrimination. In effect, it says that race, religion, and national origin are not to be used as the basis for hiring and firing. Title VII is designed to encourage hiring on the basis of ability and qualifications, not race or religion.'' 110 Cong. Rec. 6549 (1964).

[22] 42 U.S.C. 2000e–2(j).

[23] Congressional concern about discrimination in apprenticeship programs led to the convening of hearings on the topic a few years before the enactment of Title VII. See ''Equal Opportunity in Apprenticeship Programs: Hearings Before the Special Subcommittee on Labor of the House Committee on Education and Labor,'' 87th Congress, 1st Session, Aug. 21, 22, and 23, 1961, *https://books.google.com/books?id=mSy_Rm9wF7oC&pg=PP1#v=onepage&q&f=false.*

[24] See 36 FR 6810 (Apr. 8, 1971).

apprentices based upon their race, color, religion, sex, or national origin is illegal, and that the use of group-based preferences to adjust demographic imbalances which may exist in an apprenticeship program's workforce must never be required (unless such preferences are temporarily imposed by a court to remedy proven instances of manifest, intentional discriminatory conduct by a program). In a broader sense, however, the Department's regulatory imposition of affirmative action requirements for certain Registered Apprenticeship programs in the 1971 part 30 regulation—and the retention of these requirements in the 1978 and 2016 versions of the regulation—effectively substituted the policy preferences of an agency of the administrative state for the considered legislative judgments of the nation's elected representatives in delineating the appropriate scope and content of Federal employment nondiscrimination laws and policies relating to apprenticeship.

On June 29, 2023, the Supreme Court of the United States handed down a decision in a landmark case involving the use of race-based preferences in university admissions, *Students for Fair Admissions, Inc.* v. *President and Fellows of Harvard College,* 600 U.S. 181 (2023) (*SFFA*). In *SFFA,* the Supreme Court held that the use of such racial preferences by Harvard and the University of North Carolina in their admissions processes violated the Equal Protection Clause of the Fourteenth Amendment to the Constitution. Several NPRM commenters mischaracterized the extent to which the Department relied upon the decision in *SFFA* in proposing to rescind the race-, sex-, and ethnicity-based affirmative action provisions contained in part 30. To be clear, the Department did not and does not claim that *SFFA's* holding regarding race-based admissions in higher education *compels* the rescission of part 30's affirmative action provisions. Nevertheless, the Department considers the Supreme Court's decision in *SFFA* to be relevant to this rulemaking insofar as it signals the Court's apparent willingness to revisit the constitutionality of race-based selection and admissions procedures that it had previously upheld in earlier decisions. In his *SFFA* opinion striking down these types of preferences, Chief Justice Roberts opined that ''[e]liminating racial discrimination means eliminating all of it,'' 600 U.S. at 206, and further observed that the Court has ''time and time again forcefully rejected the notion that governmental actors may intentionally allocate preferences to those 'who may have little in common with each other but the color of their skin,' '' *id.* at 220 (quoting *Shaw* v. *Reno,* 509 U.S. 630, 647 (1993)). These categorical and pointed expositions of nondiscrimination and equal protection principles by the Chief Justice in *SFFA*—as well as similar viewpoints expressed by other justices in their concurring opinions—certainly do not augur well for the Court's future sanctioning of mandatory, nonremedial race-, ethnic-, and sex-based affirmative action efforts in Registered Apprenticeship.

Recognizing that government-mandated, group-based affirmative action schemes such as those contained in the 1971, 1978, and 2016 versions of the part 30 regulation ''violate the text and spirit of our longstanding Federal civil-rights laws,'' President Trump issued E.O. 14173, ''Ending Illegal Discrimination and Restoring Merit-Based Opportunity,'' on January 21, 2025.[25] Among other things, section 2 of E.O. 14173 directed ''all executive departments and agencies to terminate all discriminatory and illegal preferences, mandates, policies, programs, activities, guidance, regulations, enforcement actions, consent orders, and requirements.'' Noting that longstanding Federal civil rights laws such as Title VII ''protect individuals from discrimination based on race, color, religion, sex, or national origin'' and serve ''as a bedrock supporting equality of opportunity for all Americans,'' E.O. 14173 affirmed that the President of the United States has ''a solemn duty to ensure that these laws are enforced for the benefit of all Americans.'' The issuance of this final rule by the Department prohibiting all illegal discrimination in Registered Apprenticeship programs fulfills President Trump's directive in E.O. 14173; moreover, it demonstrates appropriate respect for, and deference to, the nondiscrimination policies relating to apprenticeship that were enacted by Congress as part of Title VII of the Act.

In revising the content and scope of the part 30 regulation, the Department has determined that the affirmative action provisions described above are administratively burdensome and likely unlawful. Moreover, the Department is convinced that affirmative action schemes tend to promote the development of pernicious and divisive group-based preferences within our society, thereby undermining the goal of ensuring equality of opportunity for every American participating in the workforce. Accordingly, in issuing this final rule, the Department affirms that all applicants seeking admission to a Registered Apprenticeship program should be evaluated and selected strictly on the basis of individual merit and demonstrated potential, and that a person's race, color, religion, sex, or national origin must never be considered by a sponsor as a basis for either rejecting or granting preferential treatment to anyone seeking admission to a Registered Apprenticeship program.

D. Need for the Rulemaking: The Burdens and Challenges Imposed on Sponsors by the Part 30 Regulation

The Department has known for some time that, as its Task Force on Apprenticeship Expansion reported, ''many employers choose to establish apprenticeship programs outside of the registered apprenticeship program, in part because of the paperwork and process involved in registering a program.'' Apprenticeship Programs, Labor Standards for Registration, Amendment of Regulations, 85 FR 14294, 14295 (Mar. 11, 2020). The Department has determined that this final rule updating the part 30 regulation is necessary to accomplish the Department's and Administration's goals of eliminating unnecessary and burdensome regulatory requirements and accelerating the expansion of Registered Apprenticeship. The part 30 regulation contains the type of onerous regulatory requirements targeted by the Administration's deregulatory directive contained in E.O. 14192; in particular, the Department has identified the affirmative action requirements of the part 30 regulation as illustrative of the complicated, burdensome, and ineffective regulations that Federal agencies are directed to rescind or revise under the E.O.

Accordingly, the Department has determined that revising the part 30 regulation is necessary to discontinue the regulatory imposition of a legally questionable, nonremedial, group-based preference scheme for certain Registered Apprenticeship program sponsors. Moreover, the Department has determined that this final rule is necessary to achieve cost savings for Registered Apprenticeship stakeholders and reduce the cost and administrative burden of establishing and maintaining Registered Apprenticeship programs. As outlined in the Regulatory Impact Analysis (RIA) accompanying this final rule, over a 10-year period, Registered Apprenticeship stakeholders stand to save more than $1 billion on costs related to compliance with the part 30

[25] See 90 FR 8633 (Jan. 31, 2025).

regulation, including developing and maintaining affirmative action programs and complying with other part 30 requirements. The E.O. directing Federal agencies to identify opportunities for increased regulatory flexibility established the potential for financial relief for the regulated community as a criterion for targeting burdensome regulations. Eliminating the costs of compliance with the part 30 regulation further informs the Department's determination that this final rule's significant revisions to the part 30 regulation are necessary.

E. Goals of the Revised Part 30 Regulation

The fundamental aims of this final rule are threefold: (1) to simplify sponsors' obligations with respect to nondiscrimination in apprenticeship by affirming the applicability and sufficiency of existing Federal and State laws governing nondiscrimination in the workplace; (2) to rescind the regulatory, nonremedial affirmative action mandate that the Department has imposed upon program sponsors since 1971—a mandate that the Department is concerned would not survive legal challenge and that was plainly inconsistent with the policies underlying the statutory, apprenticeship-related, nondiscrimination provisions of Title VII applicable to many of these same sponsors; and (3) to reduce the regulatory and administrative burdens on Registered Apprenticeship program sponsors—burdens that could inhibit the accelerated establishment and expansion of such vital workforce development programs—by removing all onerous, conflicting, duplicative, or unnecessary requirements found in the part 30 regulation.

The Legal and Practical Challenges Imposed Upon Program Sponsors by the Affirmative Action Provisions of the Part 30 Regulation

Alleviating the legal and practical challenges imposed on program sponsors by the affirmative action provisions of the part 30 regulation is a primary objective of the Department's final rule. As stated in the foregoing section, the part 30 regulation's affirmative action mandate for certain apprenticeship programs imposed an onerous administrative burden upon these program sponsors and is inconsistent with this Administration's efforts to enforce merit-based opportunity, as the requirements may induce these sponsors to engage in the unequal and illegal treatment of individual apprentices (as well as applicants for apprenticeship) based upon their race, sex, or ethnicity.

In the public comments submitted to the Department in response to the NPRM, several commenters discounted or glossed over the significant and self-evident administrative burdens that the affirmative action provisions of the part 30 regulation imposed upon certain program sponsors, particularly those that operate small- and medium-sized enterprises. These commenters opined that the affirmative action provisions of the part 30 regulation imposed no undue burdens, simply requiring certain sponsors (*i.e.,* those that employ five or more apprentices) to identify imbalances in the demographic composition of the sponsor's apprenticeship workforce, to set ''aspirational'' hiring goals based upon that analysis, and to make ''good faith'' efforts to address such imbalances, while simultaneously adhering to the general prohibition on making apprenticeship hiring decisions based upon an applicant's race, ethnicity, or sex. These commenters, however, failed to either recognize or acknowledge that the part 30 regulation's nondiscrimination and affirmative action provisions, taken together, imposed fundamentally contradictory and irreconcilable legal mandates upon apprenticeship programs.

The internally inconsistent regulatory requirements contained in the part 30 regulation are illustrated by examining the content of the affirmative action provisions of that regulation at § 30.4. While § 30.4(a)(5) states that the ''commitments made in an affirmative action program are not intended and must not be used to discriminate against any qualified applicant or apprentice'' on the basis of race, color, religion, sex, disability, age or national origin, § 30.4(a)(2) admonishes sponsors that ''if women, individuals with disabilities, or individuals from a particular minority group . . . are not being admitted into apprenticeship at a rate to be expected given their availability in the relevant labor pool, the sponsor's affirmative action program must include specific, practical steps designed to address any barriers to equal opportunity that may be contributing to this underutilization.'' Such ''practical steps'' will frequently involve the establishment of ''utilization goals'' based upon an individual's race, sex, and ethnicity to address such demographic imbalances in the apprenticeship program's workforce (see § 30.4(d)).

The fundamental policy premise underlying the affirmative action provisions contained in the part 30 regulation was that ''absent discrimination, over time a sponsor's apprenticeship program, generally, will reflect the sex, race, ethnicity, and disability profile of the labor pools from which the [apprenticeship] sponsor recruits and selects.'' *See* 29 CFR 30.4(a)(2). This premise was and is constitutionally dubious, however, and the Department's concomitant regulatory requirement of setting utilization goals in the hiring of apprentices based upon the race, sex, and ethnicity of a program applicant had the effect of inducing program sponsors to meet such numerical targets. The mandating of such numerical hiring goals, combined with the prospect of apprenticeship program deregistration for failing to take ''good faith efforts'' to meet such goals, plainly incentivized employers to engage in legally questionable, group-based preferential hiring practices in order to prevent an administrative finding by the Department that they had failed to engage in such affirmative action efforts.

The part 30 regulation (at 29 CFR 30.5(b)) further stipulated that sponsors with 5 or more apprentices enrolled in their programs conduct, at least once every 3 years, detailed demographic and utilization analyses to assess and address the existence of imbalances with respect to certain demographic groups enrolled in their programs. By requiring the permanent, ongoing conduct of such analyses by certain program sponsors—and potentially requiring the establishment of group-based numerical hiring goals based upon the results—this regulatory provision constituted a mandate that such sponsors not only strive to achieve, but also continuously maintain, a demographic ''balance'' in their apprenticeship programs based upon race, sex, and ethnicity. Such a regulatory purpose, however, was and is plainly contrary to the fundamental policy thrust of Title VII, as demonstrated by the text of section 703(j) of the Act (discussed *supra*) and by the following passage contained in an interpretative, joint memorandum drafted by Senators Joseph Clark of Pennsylvania and Clifford Case of New Jersey that was addressed to their Senate colleagues at the time of the floor debate on H.R. 7152 (the bill that was later enacted by Congress as the Act): ''There is no requirement in Title VII that an employer maintain a racial balance in his work force. On the contrary, any deliberate attempt to maintain a racial balance, whatever such a balance may be, would involve a violation of Title VII because maintaining such a balance

would require an employer to hire or refuse to hire on the basis of race . . .'' 110 Cong. Rec. 7213 (1964). This joint statement by Senators Clark and Case neatly encapsulates the inescapable legal and practical dilemmas faced by Title VII-covered Registered Apprenticeship programs that attempted to comply in good faith with the open-ended, compulsory, nonremedial, and legally questionable affirmative action requirements that were contained in the part 30 regulation.

Accordingly, by rescinding the affirmative action requirements contained in the part 30 regulation, this final rule relieves Registered Apprenticeship program sponsors from vexing legal and practical dilemmas, while ensuring that an individual's admission to a Registered Apprenticeship program is made on a nondiscriminatory basis and solely on the basis of their qualifications compared to those of other applicants. The Department is confident that the provision of such regulatory relief to a large segment of program sponsors will accelerate the establishment and expansion of Registered Apprenticeship programs, resulting in a more skilled and productive American workforce.

Alleviating Undue Regulatory Burdens for Registered Apprenticeship Stakeholders

The Department has determined that the changes to the part 30 regulation codified in this final rule serve the Department's ongoing policy goal of expanding the Registered Apprenticeship model and its imprint on the national economy, a goal which aligns with the Administration's directive to the Department to expand Registered Apprenticeship and to achieve and surpass 1 million active apprentices. The part 30 regulation included a wide range of requirements that imposed administrative and financial burdens on Registered Apprenticeship program sponsors, and the Department expects that the rescission of these requirements will have a significant impact on Registered Apprenticeship program expansion. In particular, the Department expects that the rescission of the general obligation to engage in affirmative action for all sponsors, and the affirmative action program requirement for programs with five or more apprentices, will attract new sponsors to the National Apprenticeship System and encourage existing sponsors to expand their programs by substantially reducing the administrative burden necessary to establish and maintain a Registered Apprenticeship program.

E.O. 14192 directed Federal agencies to identify and rescind regulations that impose significant administrative or financial burdens (including on American businesses). The burdensome administrative requirements of the part 30 regulation began impacting Registered Apprenticeship programs from their very inception, even before they are registered with a Registration Agency. Registration of a program depends on compliance with the requirements at parts 29 and 30, and sponsors must review both parts to understand what elements they need to develop or commit to at the program development stage. Under the part 30 regulation, all prospective program sponsors were required to identify their process for the selection of apprentices (per § 30.10); identify staff responsible for overseeing the program's commitment to equal opportunity (per § 30.3(b)(1)); develop and disseminate an equal opportunity policy, including posting the Equal Opportunity pledge in the program's standards and at sites where apprentices are trained (per § 30.3(b)(2)); and plan for and address various other requirements, all before their program was even registered. These requirements presented challenges for prospective sponsors new to the system in designing Registered Apprenticeship programs that satisfied all of the requirements contained in parts 29 and 30.

In Registered Apprenticeship, compulsory affirmative action programs were the clearest example of regulatory requirements that imposed significant administrative and financial burdens on the regulated community, without providing tangible benefits to either the regulated entities, the individuals they serve, or the Federal Government. Under the part 30 regulation, all sponsors had a general duty to engage in affirmative action. In addition, sponsors with five or more apprentices were required to develop and adhere to affirmative action programs, including creating and updating a written document that memorializes the affirmative action program (per § 30.4(e)). The part 30 regulation required sponsors to include in their written affirmative action program, and adopt as an ongoing operational practice, a utilization analysis examining race, sex, and ethnicity, utilization goals for race, sex, and ethnicity; a utilization analysis and goal for individuals with disabilities; targeted outreach, recruitment, and retention policies; ongoing review of personnel policies; and annual reminders to apprentices to voluntarily disclose their disability status. These requirements were detailed at §§ 30.4 through 30.9 and 30.11 of the part 30 regulation.

Developing and maintaining an affirmative action program was a significant undertaking for Registered Apprenticeship program sponsors under the existing part 30 regulation, and OA provided significant technical assistance to both prospective and existing programs to explain these requirements. As affirmed by commenters in the public comments received in response to the Department's NPRM, some commenters reported investing significant administrative and financial resources in-house (or even externally, with consultants or outside legal assistance) to train staff, conduct the required analyses objectively and accurately, and address any legal issues related to apprentice recruitment, hiring, and retention policies. The development of an affirmative action program has been a resource-intensive undertaking for many sponsors (even with the 2-year timeframe from the point of program registration that new sponsors were allowed to develop the plan at § 30.4(e)(1)(ii)), a mandate which significantly complicated the efforts of sponsors in establishing and maintaining their apprenticeship programs. Many sponsors also faced ongoing and significant administrative burdens related to establishing and maintaining affirmative action programs, including conducting the required analyses, and updating their written plan every time the sponsor completes such analyses.

Aside from the foregoing administrative elements of developing and maintaining affirmative action programs, the part 30 regulation imposed regulatory burdens on Registered Apprenticeship program sponsors by dictating key aspects of their recruitment, hiring, and retention policies through utilization analyses that incentivized them to consider arbitrary aspects of applicants' backgrounds—namely, their group-based demographic characteristics. In the case of individuals with disabilities, the requirement even extended to setting a fixed percentage utilization goal that sponsors were charged with meeting, which created an even more prescriptive framework that infringed on a sponsor's freedom to make hiring decisions based purely on their business and workforce needs.

Several commenters advocated for the retention of the existing part 30 regulation, asserting that its requirements were instrumental in raising rates of participation in

Registered Apprenticeship programs by women and minority groups. However, as detailed later in this preamble, the Department maintains that the correlation posited by these commenters between post-2016 participation outcomes for certain demographic groups and the part 30 regulation's affirmative action requirements is inconclusive. Moreover, such statistical inferences do not alter the fundamental and inescapable reality that compulsory, nonremedial, group-based preferences and affirmative action schemes are inherently discriminatory—and therefore legally suspect—because they treat individuals differently based upon their race, sex, or ethnicity. Accordingly, any arguments advanced to justify affirmative action arrangements that are based upon the general notion of achieving and maintaining greater demographic ''balance'' or ''diversity'' in the apprenticeship workforce are not only contrary to the principle of hiring individuals solely on the basis of merit and without reference to their ancestry or group identity, but are also unlikely to withstand legal scrutiny by the courts. Even a noted proponent of affirmative action based upon race, Professor Randall Kennedy of the Harvard Law School, has candidly acknowledged that ''[r]acial affirmative action *does* distinguish between people on a racial basis. It *does* discriminate. It *does* redistribute resources. It *does* favor preferred racial categories of candidates . . . It *does* generate stigma and resentment. These issues cannot be hidden for long behind verbal tricks (emphasis in original).'' [26] Similarly, any system of group-based hiring preferences that makes distinctions among individuals based upon their sex or ethnicity is inherently discriminatory in its purpose and effect.

In issuing this final rule prohibiting illegal discrimination in Registered Apprenticeship programs, the Department seeks to ensure that a candidate's admission to such a training program is based solely upon their individual merit and their demonstrated potential for success. Accordingly, such an approach necessitates the rescission of all of the part 30 regulatory provisions that imposed affirmative action requirements on sponsors (such as those setting numerical, nonremedial hiring goals in the selection of apprentices based upon an individual's race, sex, ethnicity, religion, or national origin), as such mandates are contrary to the fundamental goal of guaranteeing genuine equality of opportunity for each and every American who participates in the workforce. At a time when the accelerated expansion of Registered Apprenticeship training is needed to equip American workers of all backgrounds with the occupational skills they need to succeed in a competitive global marketplace, it is essential that the Department rescind such burdensome and legally vulnerable regulatory provisions that could effectively inhibit the growth of this proven workforce development model.

III. Overview of the Revised Part 30 Regulation

A. Summary of the Final Rule's Provisions

This final rule rescinds or significantly revises the burdensome requirements of the part 30 regulation and replaces them with a more straightforward Federal standard for nondiscrimination in Registered Apprenticeship. The final rule explains how Registration Agencies will monitor and enforce program sponsors' compliance with the revised part 30 regulation. The final rule also changes requirements for SAAs related to the part 30 regulation and clarifies the Department's expectation that Registered Apprenticeship program sponsors must not be subject to inhibitive or contradictory nondiscrimination requirements in apprenticeship laws or regulations across States. With this final rule, the Department eliminates the apprenticeship-specific framework for EEO and nondiscrimination contained in the part 30 regulation. Under the part 30 regulation as revised by this final rule, program sponsors are still bound by a firm nondiscrimination requirement that clearly incorporates applicable Federal and State laws and regulations prohibiting illegal discrimination on the basis of race, color, religion, national origin, sex, age, genetic information, or disability. Under this final rule, Registered Apprenticeship program sponsors are no longer bound by a separate, apprenticeship-specific, and administratively burdensome nondiscrimination framework.

This final rule's purpose and applicability section, at 29 CFR 30.1, lays out the Department's intent for the part 30 regulation going forward—to establish a ''uniform Federal standard prohibiting illegal discrimination against apprentices (including applicants for apprenticeship)'' and to clarify the scope of enforcement and compliance assistance by Registration Agencies (either OA or an SAA). Section 30.1 also clarifies that the part 30 regulation applies to all sponsors of Registered Apprenticeship programs, whether registered by OA or an SAA. It eliminates the prior part 30 regulation's § 30.1(c) on the regulation's ''relationship to other laws,'' which is covered under the revised § 30.3. The final rule also rescinds definitions specific to the part 30 regulation and instead clarifies that definitions contained in the part 29 regulation (at 29 CFR 29.2) also apply to part 30. The prior part 30 regulation's definition section contained definitions already established in the part 29 regulation, or definitions specific to the prior part 30 regulation's requirements that are being rescinded in this final rule.

This final rule establishes the streamlined and clarified nondiscrimination requirement for all Registered Apprenticeship program sponsors at 29 CFR 30.3. The updated § 30.3 language requires that Registered Apprenticeship program sponsors must comply with all applicable Federal and State laws prohibiting illegal discrimination on the basis of race, color, religion, national origin, sex, age (40 or older), genetic information, or disability. The Department notes that these protected characteristics align with the Federal nondiscrimination protections contained in Title VII of the Act and subsequent nondiscrimination statutes enacted by Congress, including the Age Discrimination in Employment Act of 1967 (ADEA),[27] the Americans with Disabilities Act of 1990 (ADA),[28] and title II of the Genetic Information Nondiscrimination Act of 2008.[29] This section also lays out, at a high level, the consequences of a failure to comply with this nondiscrimination requirement, which include enforcement actions up to and including deregistration of the Registered Apprenticeship program. Under § 30.3, apprentices and applicants for apprenticeship are protected from discrimination ''with respect to any benefit, term, or condition of employment associated with an apprenticeship.''

This final rule eliminates the EEO requirements applicable to all sponsors contained in part 30 regulation at § 30.3, as well as the regulation's affirmative action program requirements which are referenced at § 30.3 and elaborated on at §§ 30.4 through 30.9 and 30.11. These sections included a description of the

[26] Randall Kennedy, *For Discrimination: Race, Affirmative Action, and the Law* (Pantheon Books, New York, 2013), pp. 18–19.

[27] 29 U.S.C. ch. 14.

[28] 42 U.S.C. ch. 126.

[29] 42 U.S.C. ch. 21F.

rule's prohibition on discrimination and discrimination standards and defenses; the general duty to engage in affirmative action applicable to all sponsors; the requirement to develop and disseminate an equal opportunity policy and post an Equal Opportunity pledge; universal outreach and recruitment requirements applicable to all sponsors; a prohibition on harassment, intimidation, and retaliation specific to apprenticeship; and the requirement for sponsors with five or more apprentices to establish demographic utilization goals (when appropriate) and maintain an affirmative action program.

This final rule eliminates the part 30 regulation's requirement (at § 30.11) that sponsors invite apprentices to voluntarily disclose their disability status upon enrollment in the program and annually thereafter. Under this final rule, however, apprentices are not precluded from voluntarily disclosing their disability status to Registered Apprenticeship program sponsors and are encouraged to do so, especially if they need to request reasonable accommodation related to their disability. In rescinding the part 30 regulation's affirmative action program requirements, the Department also eliminates the requirement that Registered Apprenticeship program sponsors conduct utilization analyses for individuals with disabilities and pursue a utilization goal for such persons established by the Administrator. The final rule also rescinds the part 30 regulation's requirements for sponsors related to the procedure for the selection of apprentices (at § 30.10), the recordkeeping requirements related to the part 30 regulation (at § 30.12), and the apprenticeship-specific prohibition against intimidation and retaliation (at § 30.17).

The final rule updates the part 30 regulation's section on complaints to clarify that complaints alleging illegal discrimination against apprentices should be referred to the EEOC or another relevant enforcement agency with the jurisdiction and expertise to adequately investigate and potentially remedy the issue. Under current practice, apprentices may submit complaints alleging instances of discrimination or other violations of part 30 requirements through ETA Form 9039 to the Registration Agency. In practice, Registration Agencies then forward complaints to the most relevant nondiscrimination enforcement agency, including the EEOC, the U.S. Attorney General, or a State-level Fair Employment Practices Agency (FEPA). The part 30 regulation contained a requirement for Registration Agencies to conduct investigations and provide written notice of findings to the respondent and the complainant, along with other regulatory requirements outlining who can file complaints, what information must be included in the complaint, a requirement for sponsors to provide written notice to apprentices of their right to file complaints, and a requirement for the Registration Agency to ''attempt to resolve the matter quickly . . . whenever appropriate'' (at § 30.14(c)(2)).

The revised part 30 regulation's section on complaints, at § 30.4 of this final rule, removes the investigative requirements for Registration Agencies and the notice requirement for program sponsors. The final rule establishes a simpler and less duplicative process that recognizes that the investigation and adjudication of complaints alleging illegal discrimination should be conducted by the appropriate investigative and enforcement agency. The revised section on complaints at § 30.4 of this final rule states that Registration Agencies in receipt of complaints alleging illegal discrimination against apprentices will ''immediately'' refer the complainant to the EEOC, the U.S. Attorney General, a State FEPA, or another appropriate enforcement entity. In accordance with this change to the part 30 regulation, the Department is also rescinding ETA Form 9039.

The part 30 regulation, as finalized in this rulemaking, also revises the process for Registration Agencies to assess compliance with part 30 requirements. The section on nondiscrimination compliance reviews and enforcement, at § 30.5 of this final rule, revises the current part 30 regulation's section on EEO compliance reviews (at § 30.13) to align with the content of the updated part 30 regulation and its streamlined nondiscrimination in apprenticeship requirement for program sponsors. Section 30.5 of this final rule clarifies that Registration Agency reviews for part 30 compliance will occur when a program is assessed for compliance with the part 29 regulation. The final rule's revised compliance review and enforcement section stipulates that a Registration Agency may initiate enforcement actions against a sponsor for failing to comply with the final rule's nondiscrimination requirement at § 30.3 when a final determination of a violation of an applicable nondiscrimination law (without any remaining right to appeal) has been made by an enforcement agency or court with jurisdiction over the matter and the authority to issue such final determinations.

This revision aligns with the change in the complaints section that eliminates the Registration Agency's duplicative role in investigating and adjudicating instances of alleged illegal discrimination against apprentices. Registration Agency staff, whether employed by OA or an SAA, lack the subject-matter background, expertise, and jurisdictional authority to investigate or adjudicate potential violations of Federal or State nondiscrimination law that FEPAs or courts possess. This final rule therefore returns this function and responsibility to the agencies and courts that do possess such authority. To provide additional clarity on the compliance framework for the part 30 regulation, the Department has added a provision in this final rule that requires sponsors to disclose to the Registration Agency any instances when a relevant enforcement entity or court has made a final determination that an applicable nondiscrimination violation has occurred with respect to an apprentice or applicant for apprenticeship in their Registered Apprenticeship program. This addition in the final rule is responsive to public comments that requested additional clarity on the compliance framework and will promote transparency and accountability regarding Registered Apprenticeship programs' adherence to applicable nondiscrimination laws.

Section 30.5(c) of this final rule stipulates that the Registration Agency may work with a sponsor who is the subject of a final determination from an enforcement entity or court to develop a compliance action plan, in alignment with any remedies prescribed by the enforcement entity or court. A sponsor's failure to adhere to such compliance action plans may lead to additional enforcement actions, including the suspension of the sponsor's right to register new apprentices or the initiation of full deregistration proceedings (as described in the part 29 regulation at § 29.8). In addition to requiring sponsors to disclose any final determinations to the Registration Agency, the Department has added a provision requiring sponsors to disclose to the Registration Agency any remedies prescribed by the enforcement entity or court that issued the final determination.

Section 30.6 of this final rule carries forward the reinstatement of the program registration section of the part 30 regulation (at § 30.16). This section allows programs that have been deregistered pursuant to a violation of

the part 30 nondiscrimination requirement to present evidence in support of reinstatement and permits Registration Agencies to reinstate programs in instances where such evidence is determined to be adequate.

This final rule also includes significant revisions to the part 30 regulation's requirements for SAAs, which are contained in § 30.7 of this final rule. This section stipulates that, within 1 year of the effective date of this final rule, State agencies seeking to obtain or maintain recognition as an SAA must submit a State plan for nondiscrimination in apprenticeship that demonstrates that the State's laws, regulations, policies, and operational procedures specific to nondiscrimination or equal opportunity in apprenticeship conform to the requirements of the part 30 regulation. In this final rule, the Department updated the language at § 30.7 based, in part, on public comments received on the NPRM, which proposed that States' laws and regulations conform only to the part 30 regulation. To better align with the Department's intention to create a more uniform set of requirements for all Registered Apprenticeship programs as set forth in the NPRM, this final rule clarifies that State laws and regulations must conform to the part 30 Federal standard, and that the Department will only assess State laws and regulations specific to nondiscrimination or equal opportunity in apprenticeship for conformity with part 30.

A primary goal motivating the Department's determination to update the part 30 regulation is the establishment of a uniform Federal standard for nondiscrimination in apprenticeship. Registered Apprenticeship stakeholders, particularly those with a national or multi-regional interest and operational imprint, have long requested that the Department promote a more coherent National Apprenticeship System, where Registered Apprenticeship stakeholders are not faced with conflicting or contradictory requirements depending on where their program operates. The Department has determined that establishing a uniform Federal standard for nondiscrimination in apprenticeship serves this goal and will work with States to identify discrepancies in nondiscrimination requirements for apprenticeship stakeholders that must be resolved under this final rule's requirement that State laws and regulations conform to the Federal standard in the part 30 regulation.

Section 30.7 of this final rule requires States seeking new or continued recognition as a SAA to submit their State laws and regulations in a State plan for nondiscrimination in apprenticeship and lays out the required elements and the Department's process for reviewing State plans. To determine whether the State plan conforms to the part 30 regulation, the Department will consider whether the State's laws and regulations include nondiscrimination or equal opportunity elements that constitute a separate, State-level legal or regulatory compliance framework specific to apprenticeship, and whether such laws and regulations would serve to restrict the growth and impact of Registered Apprenticeship in the State by imposing administrative barriers, excessive costs, or requirements that conflict with Federal or State nondiscrimination laws. OA will review State laws and regulations on a case-by-case basis and will provide technical assistance to States as needed to identify which elements of State laws and regulations do or do not conform to the Federal part 30 regulation.

The Department's decision to modify the regulatory language proposed in the NPRM to require that State laws and regulations ''conform to'' (rather than ''conform only to'') the part 30 regulation aligns with the existing regulatory language found in the part 29 regulation governing labor standards for Registered Apprenticeship programs and the recognition of SAAs. Specifically, this change aligns with the regulatory language at 29 CFR 29.13(a)(1), which provides that States' apprenticeship laws and regulations ''conform to'' the requirements of the part 29 regulation. At § 29.13(a)(5), the part 29 regulation requires that States submit ''a description of policies and operating procedures which depart from or impose requirements in addition to those prescribed in [the part 29 regulation].'' The Department will apply this same approach in determining whether State laws and regulations pertaining specifically to nondiscrimination or equal opportunity in apprenticeship conform to the Federal nondiscrimination in apprenticeship standard in this final rule. State plans for nondiscrimination in apprenticeship must conform to the revised part 30 regulation's prohibition on illegal discrimination stated at § 30.3, and must also describe any laws, regulations, or policies that depart from or impose additional requirements on Registered Apprenticeship program sponsors, including any apprenticeship-specific equal employment laws or regulations. Examples of nonconforming State laws or regulations include any laws or regulations that establish unlawful compulsory, nonremedial group-based preference schemes for sponsors, such as affirmative action programs, or laws or regulations that establish burdensome restrictions or administrative requirements specific to apprenticeship that could restrict or inhibit the growth of Registered Apprenticeship programs or that may conflict with the nondiscrimination requirements contained in this final rule and in applicable Federal laws.

This final rule retains the exemptions provision from the part 30 regulation, redesignating the provision as § 30.8 of this final rule. This provision allows sponsors to request exemptions from the part 30 regulation, ''or any part thereof,'' in writing, to the Registration Agency, which may grant exemptions for good cause. The provision also stipulates that SAAs must receive approval from the Department before granting any exemptions to program sponsors in their State. Finally, the final rule adds a severability provision (at § 30.9). This provision stipulates that, should a court of competent jurisdiction find that any provision of the revised part 30 regulation is invalid, the finding will not impact any other provision of the regulation.

B. The Role of Registration Agencies Under the Final Rule

The Department expects that this final rule will significantly reduce administrative burdens for both Registered Apprenticeship program sponsors and Registration Agency staff. The Department recognizes that Registration Agency staff expertise is rooted in analyzing labor standards for Registered Apprenticeship programs and providing technical assistance to program sponsors. The prior requirements of the 2016 version of the part 30 regulation introduced an entirely separate set of issues that required a distinct expertise—namely, the ability to provide technical assistance and oversight on affirmative action programs and nondiscrimination and EEO matters. The removal of these requirements in this final rule allows Registration Agency staff to focus on the issues they know best—supporting quality across all Registered Apprenticeship programs—and leaves the investigation and adjudication of issues pertaining to nondiscrimination and EEO to the agencies and courts that do possess the appropriate expertise and jurisdiction.

The revised part 30 regulation requires that all sponsors of Registered Apprenticeship programs adhere to applicable Federal and State laws and

regulations prohibiting illegal discrimination. This streamlined nondiscrimination requirement applies with respect to both apprentices and applicants to an apprenticeship program, and covers any benefit, term, or condition of employment associated with an apprenticeship. Registration Agencies must begin enforcing this requirement on the effective date of this final rule. Such enforcement will primarily occur through program reviews, and a review for compliance with the revised part 30 regulation will occur when the Registration Agency conducts program reviews for compliance with the part 29 regulation. Registered Apprenticeship programs will be deemed out of compliance with the revised part 30 regulation only if a final determination of a violation of an applicable nondiscrimination law against an apprentice or an applicant to an apprenticeship program, without any remaining right to appeal, is made by an enforcement agency or court with jurisdiction over the matter.

To support accountability and transparency, the Department added a provision to this final rule requiring sponsors to disclose any final determinations from a relevant enforcement entity or court regarding violations of applicable nondiscrimination law with respect to an apprentice or applicant for apprenticeship to the Registration Agency, as well as any remedies provided by such entities. To further support awareness of any such final determinations regarding Registered Apprenticeship programs, the Department recommends that Registration Agencies consider establishing Memoranda of Understanding (MOUs) or other arrangements with these governmental enforcement agencies to maintain awareness of any final determinations concerning nondiscrimination violations against apprentices or applicants to an apprenticeship program by Registered Apprenticeship programs in their State. Registration Agencies may also consider contacting such enforcement agencies when a program comes up for review to identify any instances of final determinations concerning nondiscrimination violations.

When such a final determination has been issued, the Registration Agency may work with the program sponsor in question to develop a compliance action plan to address and remedy the issue. Any such plans must align with any remedies prescribed by the enforcement entity or court that issued the final determination. The Department's addition of a disclosure requirement in this final rule is intended to facilitate alignment of compliance action plans with the remedies for nondiscrimination violations prescribed by relevant enforcement entities. Under this final rule, the Registration Agency must monitor the sponsor's progress in implementing the compliance action plan and remediating the issue. If the Registration Agency determines that the sponsor is not following or implementing the compliance action plan, the Registration Agency may initiate enforcement actions, including suspension of the right to register new apprentices or the initiation of deregistration proceedings. This framework ultimately reflects a more efficient and fair approach to addressing instances of illegal discrimination in Registered Apprenticeship that incorporates the expertise, transparency, and due process protocols associated with enforcement entities or courts with jurisdiction over such matters.

Under this final rule, Registration Agencies will no longer investigate complaints alleging instances of illegal discrimination in Registered Apprenticeship programs and will instead forward any such complaints they receive to the relevant enforcement agency or court. These entities include the EEOC, State-level FEPAs or their equivalents, the U.S. Attorney General, or another appropriate enforcement entity. Registration Agency staff are not equipped to conduct such investigations, which require legal interpretations of both the substance of the alleged complaint as well as any relevant nondiscrimination laws or regulations.

Finally, SAAs, the State agencies recognized to perform the functions of Registration Agencies under 29 CFR 29.13, must submit State plans for nondiscrimination in apprenticeship that show their State's laws, regulations, and policies pertaining specifically to nondiscrimination or equal opportunity in apprenticeship conform to the revised Federal part 30 regulation. With this final rule, the Department requires any State seeking new or continued recognition as an SAA to revise any aspects of State law, regulation, or policy pertaining specifically to nondiscrimination or equal opportunity in apprenticeship that do not conform to the Federal part 30 regulation. This includes repealing, rescinding, or revising any such laws, regulations, or policies that undermine the goals of this rulemaking, such as overly burdensome requirements that may impede Registered Apprenticeship expansion or requirements specific to nondiscrimination or equal opportunity in apprenticeship that are inconsistent with existing Federal or State nondiscrimination laws. The Department expects that the Federal standard established in this final rule will promote the expansion and success of Registered Apprenticeship programs nationwide, and the Department will examine State laws and regulations pertaining specifically to nondiscrimination or equal opportunity in apprenticeship to verify that any additional State-level requirements do not impose undue burdens on sponsors and do not adversely impact efforts to expand Registered Apprenticeship.

C. Transition Timelines

This final rule is effective on January 5, 2027, 60 days from its publication in the **Federal Register**. Registered Apprenticeship program sponsors must comply with the final rule's streamlined nondiscrimination requirement by this date, and Registration Agencies must assess programs' compliance with this final rule starting on the final rule's effective date. The Department determined that this compliance timeline would be feasible because sponsors were already required to comply with applicable Federal and State nondiscrimination requirements, which is retained as the core nondiscrimination requirement at § 30.3 of this final rule. State agencies seeking new or continued recognition as an SAA must submit State plans for nondiscrimination in apprenticeship that conform to the final rule within 1 year of the final rule's effective date. The Department will provide technical assistance to all Registered Apprenticeship stakeholders, including program sponsors and SAAs, on all aspects of this final rule, including its transition timelines and the process for requesting extension for good cause.

IV. Public Comments Received on the Proposed Rule

A. General Description of Comments

The Department received 372 public comment submissions, which included a form letter campaign that accounted for 311 comments, and 56 unique comments. Additionally, five comments were duplicates or not related to the subject of this rulemaking. The commenters represented a range of stakeholders from the public, non-profit, and private sectors. Public sector commenters included State and local government agencies and elected officials. Non-profit sector commenters included think tanks, advocacy groups, national and local labor unions,

professional associations, and trade associations. Private sector commenters included employers, employer associations, and program sponsors. The Department also received comments from individuals and anonymous commenters. Below, the Department addresses general comments on the proposed rule and the rulemaking process, and the section-by-section discussion of this final rule (sections V and VI) addresses comments about the specific regulatory changes the Department proposed in the NPRM.

B. Requests To Extend the Comment Period and Comments on Public Participation

Requests for Comment Period Extension

Comments: A commenter requested that the Department extend the comment period for the proposed rule by 30 days to ensure that interested parties have a meaningful opportunity to participate in the rulemaking process. Another commenter requested a 45-day extension of the comment period to allow them to develop more comprehensive and well-supported commentary in support of the proposed rule.

Department Response: The Department maintains that the 60-day comment period for public comments on the NPRM afforded stakeholders and any interested members of the public with sufficient time and opportunity to review the Department's proposal and rationale and develop critical public comments. The Department notes that the 60-day comment period aligns with the length of the comment period established for its previous NPRM, *National Apprenticeship System Enhancements* (89 FR 3118, Jan. 17, 2024), which was a longer and more complex rule that proposed additional regulatory requirements alongside rationale for such additions. The Department further notes that a 30-day comment period is generally considered to be the minimum period sufficient to provide the public with a meaningful opportunity to comment on a Federal agency rulemaking, and that Federal agencies often adhere to this minimum timeframe. The Department's 60-day comment period for this rulemaking is twice the length of this generally adhered to minimum timeframe under the APA. Accordingly, the Department rejected requests to extend the comment period and communicated this decision to public commenters by posting a response letter to the public docket for the NPRM indicating that the Department had received, and was rejecting, requests to extend the comment period. This response provided stakeholders with notice on the Department's decision with respect to the comment period early in the comment period and affirmed that commenters must submit their comments by September 2, 2025, as communicated in the NPRM.

Comments on Public Participation and Other Concerns

Comments: A commenter expressed concern that the Department is issuing overlapping regulations at an aggressive pace, and that this makes it difficult for the public to provide meaningful assessments of the proposals. The commenter recommended pausing the current suite of regulatory efforts and taking time to assess their collective impact if implemented, including by conducting a community impact assessment. Similarly, another commenter expressed concern about the cumulative impact of these rulemakings on women.

A commenter requested that the Department extend the comment period for the proposed rule, particularly because the Department issued six proposed rules on July 1 and 2, and stakeholders for those rules significantly overlap; the commenter reasoned that this timing undermines stakeholders' ability to assess and respond to the proposals. The commenter recommended that the Department double the length of the comment periods for each rule, or stagger their deadlines to be no less than 21 days apart.

A commenter opposed the Department's statement that it ''reserves the right to redact or refrain from posting sensitive information, libelous, or otherwise inappropriate comments, including those that contain obscene, indecent, or profane language; that contain threats or defamatory statements; or that contain hate speech.'' The commenter reasoned that terms like ''hate speech'' and ''inappropriate comments'' are vague and provide officials with too much discretion over what commentary to publish, and that the First Amendment protects such expression anyway.

Department Response: The Department maintains that the 60-day comment period provided Registered Apprenticeship stakeholders with ample time and opportunity to provide comprehensive reactions and criticisms to its proposal to revise the part 30 regulation, and is in keeping with the Department's practice of providing 60 days to comment on apprenticeship NPRMs. The Department does not consider the issuance of other NPRMs unrelated to the Registered Apprenticeship regulations as sufficient rationale for extending the comment period for this rulemaking, and rejected requests to extend the comment period beyond the 60 days communicated in the NPRM early in the comment period for this rulemaking.

The Department's statement that it reserves the right to redact certain sensitive, libelous, or inappropriate information in posting public comments reflects longstanding practice that is motivated by several factors, including the need to redact personally identifiable information or other sensitive personal information. In addition, while commenters are free to submit comments that include profane or indecent language, the Department is not obligated to post any such language publicly. While the Department favors transparency in the rulemaking process and has sought to establish transparency, as appropriate, throughout the process, such comments are not suitable for public posting and do not advance the public discourse on the proposal.

C. General Comments on the Proposed Rule

General Support

Comments: The Department received several general comments in support of the proposed rule from public commenters, with some commenters agreeing with the Department's assertions in the NPRM that revising the part 30 regulation would reduce administrative burdens on Registered Apprenticeship program sponsors and stimulate growth throughout the National Apprenticeship System. Supportive commenters argued that eliminating the part 30 regulation's affirmative action requirements would make Registered Apprenticeship more attractive for prospective program sponsors, especially for smaller businesses and other stakeholders who view the extensive and complicated part 30 regulation as a barrier to entry into the National Apprenticeship System.

Some supportive commenters remarked that the part 30 regulation may have fostered discriminatory race- and sex-based preferences in Registered Apprenticeship programs and expressed appreciation for the Department's proposal to move to a merit-based system. Some commenters characterized the proposal as a needed step towards achieving equal opportunity in Registered Apprenticeship by removing what they referred to as race-and sex-based mandates, with one commenter suggesting that employers in their

industry were already incentivized to recruit inclusively due to business needs or economic factors like labor shortages. Some commenters supportive of the proposal also appreciated that, under the Department's proposal to remove documentation and reporting requirements related to affirmative action programs, sponsors would be free to focus on developing quality training programs that serve the needs of both employers and apprentices.

Department Response: The Department appreciates the comments received in support of the proposed rule and the Department's objective to streamline and align part 30 with existing Federal nondiscrimination laws. The Department agrees with commenters who asserted that the proposed rule would reduce unnecessary administrative burdens on program sponsors, and with commenters who supported the Department's goal of establishing a robust, merit-based framework for all qualified Americans to enroll in an apprenticeship program.

The Department is committed to reducing duplicative or overlapping requirements that fail to directly serve the National Apprenticeship System. The Department agrees with commenters who agreed that apprenticeship stakeholders should focus on the development of strong, skills-based apprenticeship programs that effectively serve both employers and apprentices. The Department further agrees with the observation made by one commenter that competitive labor market conditions found in a number of industries, including construction, already necessitate broad recruitment from the available talent pool, independent of regulatory reporting mandates. The Department concurs that a streamlined regulatory framework that eliminates the requirement to establish affirmative action plans, among other things, will allow sponsors to focus on program quality.

General Opposition

Comments: The Department received comments opposing the proposed rule, including some commenters who urged the Department to withdraw the proposed rule. Some commenters generally argued that the Department's proposal would undermine progress in expanding access to Registered Apprenticeship for underrepresented groups. Some commenters who opposed the proposed rule urged the Department to maintain the EEO, affirmative action, or other requirements contained in the part 30 regulation, asserting that these requirements have made a difference in increasing access to Registered Apprenticeship for underrepresented groups. Some commenters urged the Department to focus more of its efforts on implementing and enforcing the requirements contained in the part 30 regulation to maximize their impact.

Department Response: The Department considered all public comments received in response to the NPRM and acknowledges that some commenters opposed the proposal and urged the Department to retain or strengthen the part 30 regulation. As explained later in this final rule's section-by-section discussion, the Department maintains that data on demographic trends in Registered Apprenticeship is inconclusive with respect to the correlation between the extensive EEO and affirmative action requirements contained in the part 30 regulation and any increases in participation by certain demographic groups. More fundamentally, however, the Department maintains that any arguments advanced to justify the retention of requirements intended to increase diversity in Registered Apprenticeship are contrary to the underlying purpose of this rulemaking, which is to ensure that apprentices are hired and retained based solely on the basis of individual merit without consideration of their race, sex, or ethnic origin. This final rule also reflects the Department's position that establishing a clear, consistent nondiscrimination standard for Registered Apprenticeship program sponsors provides a more legally sound and practical framework to support equal access to apprenticeship opportunities for all qualified individuals.

General Comments on the Department's Rationale

Comments: Commenters provided general reactions to the Department's rationale for the proposal, with some commenters arguing that the Department had overstated or exaggerated the administrative burdens associated with the part 30 regulation. Other commenters asserted that the proposal would increase the prevalence of illegal discrimination in Registered Apprenticeship, and that the Department was incorrect in asserting that the proposal would clarify and strengthen nondiscrimination requirements in Registered Apprenticeship. Some commenters asserted that the proposal would restrict growth in Registered Apprenticeship by removing affirmative action requirements contained in the part 30 regulation, which the commenters described as a necessary tool for establishing widespread and equitable access to Registered Apprenticeship. One commenter critical of the proposal argued that the Department sought to return to a ''bygone era'' when discrimination was permissible and prevalent in Registered Apprenticeship.

Department Response: The Department does not agree with commenters who asserted that the NPRM overstated the administrative burden associated with the part 30 regulation. The Department's conclusion that the current regulatory framework imposes significant compliance costs on program sponsors, as communicated in the NPRM and reinforced in this final rule, is supported by ongoing analysis of empirical data, including the economic analysis required under the rulemaking process. The Department's conclusion that the part 30 regulation imposes excessive administrative burdens on program sponsors is also supported by OA's experience overseeing the administration of Registered Apprenticeship programs. The Department has received consistent feedback from sponsors and other apprenticeship stakeholders on the administrative burden imposed by the part 30 regulation, including in the public comments received in response to the NPRM. Registered Apprenticeship stakeholders have consistently noted that program sponsors must dedicate substantial staff time and resources to meet the extensive requirements of the part 30 regulation.

Further, the Department maintains that some requirements contained in the part 30 regulation may have improperly induced sponsors to hire an apprentice based solely on their race, sex, or other demographic characteristics. The Department has determined that establishing a clearer and more concise nondiscrimination requirement for all Registered Apprenticeship programs aligns the apprenticeship regulations more closely with Federal nondiscrimination laws, and that clarifying and simplifying regulatory compliance requirements for program sponsors will support the expedited growth of Registered Apprenticeship programs.

The Department firmly rejects some commenters' characterizations of the proposal as a return to a ''bygone era'' that permitted discrimination and maintains that this final rule does not weaken the prohibition on illegal discrimination for all Registered Apprenticeship programs. It is the Department's position that this final

rule reaffirms and reinforces a prohibition on illegal discrimination by aligning the final part 30 regulation with established Federal nondiscrimination law.

General Impacts on Registered Apprenticeship Programs

Comments: Several commenters expressed concern that the proposed rule would undermine Registered Apprenticeship programs' efforts to diversify programs and extend equal opportunities for all demographic groups. One of these commenters argued that Registered Apprenticeship programs can be a powerful tool for promoting economic mobility and establishing greater equity in the workplace, and warned that removing requirements to establish affirmative action plans would undo decades of progress in remediating discrimination and improved labor market outcomes for diverse groups. One commenter expressed concern that the Department's proposal would eliminate their ability to market their program to demographic groups that are underrepresented in their program, which would shrink the available talent pool and restrict apprenticeship growth.

Other commenters expressed concern about the impact of the proposed rule on their specific programs, including one commenter who discussed the proposal's potential impact on educator apprenticeship programs. The commenter stated that all students should have access to teachers who they relate to, who affirm their identities, and who teach with an understanding of the cultural context of their lives. The commenter added that when the teaching workforce is homogenous, students may feel invisible, which harms their learning outcomes. Another commenter asserted that the proposed rule would restrict active and expansive recruitment efforts that address gaps in the educator workforce.

Department Response: The Department considered commenters' feedback on the potential impact of the proposed rule on existing Registered Apprenticeship programs and appreciates the opportunity to respond to such comments in this final rule. The Department agrees with commenters who asserted that Registered Apprenticeship is a pathway to greater economic mobility and career development for all qualified individuals. The Department does not agree that updating the part 30 regulation to remove burdensome requirements for program sponsors will undermine Registered Apprenticeship's efficacy or success as a strategy for career development and improved economic mobility. The Department emphasizes that Registered Apprenticeship opportunities will remain an attractive and comprehensive professional development solution and career path for all qualified individuals under this final rule. Further, the Department expects that reducing regulatory burdens for program sponsors will facilitate the expansion of the Registered Apprenticeship model and increased opportunities for career seekers. This final rule does not preclude Registered Apprenticeship program sponsors from engaging in recruitment efforts that fit their business needs, so long as such efforts do not constitute illegal discrimination in violation of Federal or State nondiscrimination laws and the streamlined nondiscrimination requirement for all sponsors at § 30.3 of this final rule.

The Department acknowledges the important role that educator apprenticeship programs can play in fortifying the teaching workforce. The Department's final rule does not prohibit sponsors from engaging in lawful recruitment efforts. Program sponsors, including those operating educator apprenticeship programs, should retain significant flexibility to design lawful outreach and recruitment strategies. The Department maintains that reducing prescriptive Federal mandates for all Registered Apprenticeship program sponsors, including those in the education sector, will provide program sponsors with greater flexibility in the design of their programs, including the structuring of outreach and recruitment strategies that best serve a sponsor's workforce needs.

General Comments on Economic Impacts

Comments: Some commenters cautioned that the proposed rule could undermine participation in Registered Apprenticeship programs and obstruct progress towards achieving the Trump administration's goal of reaching 1 million active apprentices. One commenter added that the proposed rule would derail innovative recruitment strategies in apprenticeship and worsen the labor shortage in the construction industry. Another commenter maintained that research shows that workforce diversity, inclusion, and emotional intelligence are essential for innovation, and warned that the proposed rule could exacerbate labor shortages, especially in the construction industry, and undermine U.S. global competitiveness. Similarly, another commenter expressed concern that the proposed changes would create a less robust pipeline to fill broadband jobs during a period of major expansion of fiber-optic infrastructure.

Department Response: The Department does not agree with commenters who asserted that updating the part 30 regulation to remove affirmative action and other requirements will reduce participation in Registered Apprenticeship programs. The Department expects that this final rule will have the opposite effect, and that significantly revising the part 30 regulation by removing burdensome requirements for program sponsors will drive expansion of the system. As such, this final rule aligns with and supports the Administration's ambitious goals to expand Registered Apprenticeship, along with other Administration directives (such as the directive to reduce regulatory burdens contained in E.O. 14192, *Unleashing Prosperity Through Deregulation*).

The Department also disagrees with the concern expressed by some commenters that the rule will exacerbate labor shortages, including in the construction industry. To the contrary, the Department expects that this final rule will support the expansion of both existing and new Registered Apprenticeship programs, including those in the construction sector, by eliminating administrative burdens that serve as a barrier to entry and an ongoing drain on administrative resources for program sponsors. As such, the Department does not agree with the commenter who suggested that the Department's proposal would undermine U.S. global competitiveness. It is the Department's position that this final rule will strengthen Registered Apprenticeship by replacing ineffective, administratively burdensome, and likely unlawful affirmative action requirements with a clearer and more concise nondiscrimination requirement. The Department expects that eliminating these requirements in favor of a system that prioritizes merit and employer needs will strengthen U.S. businesses and bolster U.S. global competitiveness.

General Comments on Recommended Alternatives

Comments: Some commenters provided alternative suggestions to the changes proposed in the NPRM, including simplifying the regulations and compliance requirements or establishing a more concise set of EEO requirements. One commenter supportive of the Department's proposal to streamline nondiscrimination requirements suggested that the

Department consider funding incentives for sponsors who hire apprentices from underrepresented groups, stating that this approach would expand access to talent pools and maintain regulatory compliance.

Department Response: The Department appreciates that commenters suggested alternative approaches to streamline the part 30 regulation, and notes that this final rule aligns with commenters who generally suggested that the Department should simplify nondiscrimination requirements in the Federal regulations governing Registered Apprenticeship. The Department further notes that establishing financial incentives for sponsors to hire apprentices from underrepresented groups is outside the scope of this final rule, fundamentally at odds with the policy priorities of the Administration and the Department, and potentially violates Federal law by incentivizing race-based selections.

D. Comments on Regulatory History and the Background of the Proposed Rule

Comments Regarding General History of Apprenticeship EEO Regulations

Comments: Several commenters provided remarks on the Department's discussion of the history of the Registered Apprenticeship regulations, including the part 30 regulation. Some commenters said that since 1937, when the NAA was passed into law, the Department's apprenticeship regulations have evolved, with a consistent focus on implementing the NAA's directive to safeguard apprentice welfare. These commenters argued that the proposed rule threatens to undermine this core objective for the Department. The commenters added that EEO efforts became a major component of the Department's role in protecting apprentices' welfare due to a long history of racial and sex discrimination. The commenters stated that the Department's oversight and enforcement of regulatory requirements was central to the Department's success in protecting apprentice welfare, citing research that the commenter described as finding that weak oversight in the 1960s led to discrimination against Black apprentices with limited consequences. The commenters added that the existing regulations provide the Department with important regulatory tools for safeguarding the welfare of apprentices, ensuring that apprentices are positioned to succeed, and supporting an apprenticeship system that reflects the breadth of workers and communities across the United States.

Another commenter added that early activism and executive actions, specifically President Kennedy's 1963 E.O. 1114, was a ''directive for the Federal government to require nondiscrimination in apprenticeships.'' The commenter asserted that affirmative action in apprenticeship programs has been key to addressing exclusion in the trades, especially for young adults and youth with disabilities. A commenter criticized the Department's goal of restoring the original focus and purpose of the 1963 version of the regulation, reasoning that the 1963 version did not prohibit discrimination based on sex, including pregnancy, childbirth, and related medical conditions, which the commenter stated was both rampant and lawful at that time. A different commenter stated that the most recent update to the part 30 regulation, finalized in 2016, expanded protected categories to align with current employment discrimination law and employed a graduated enforcement approach.

Another commenter also described the historical development of 29 CFR parts 29 and 30, agreeing with others that part 30 was initially established in 1963 in response to E.O.s 10925 and 11114. However, the commenter stated that since that time, employment law has matured with the passage of Title VII of the Act, the ADEA, and the ADA, among other laws. The commenter reasoned that, given these significant changes, it is appropriate to revisit whether the standards imposed by part 30 are necessary and whether they create unnecessary barriers to participation in Registered Apprenticeship.

Department Response: The Department agrees with commenters who noted that employment law has matured since the part 30 regulation was initially promulgated in 1963, and that subsequent developments in the legal framework for prohibiting discrimination in employment justify the Department's proposal to revisit elements of the part 30 regulation that may be duplicative or that may conflict with the existing set of such laws. The Department notes that President Kennedy's memorandum directive to the Secretary of Labor on June 4, 1963, (Statement on Equal Employment Opportunity in Federal Apprenticeship and Construction Programs) was implemented by the issuance of the first iteration of the part 30 regulation (Nondiscrimination in Employment and Training) on December 18, 1963 (28 FR 13775). However, the 1963 version of the part 30 regulation did not mandate that Registered Apprenticeship programs establish nonremedial, compulsory affirmative action plans. As described earlier in the preamble to this final rule, the Department takes the position that affirmative action programs in apprenticeship are inherently discriminatory, and therefore likely unlawful.

The Department disagrees with the commenter that characterized the Department's proposal as an effort to restore the 1963 version of the part 30 regulation, which did not protect against discrimination based on sex, pregnancy, or childbirth. Under this final rule, the part 30 regulation does prohibit discrimination on such bases because it requires compliance with all Federal nondiscrimination laws, including Title VII. Further, the Department's role in providing technical assistance, which one commenter characterized as an important tool for protecting apprentice welfare, will continue under the final rule.

General Comments on the Department's Implementation of the Part 30 Regulation

Comments: A commenter asserted that the current regulations have not been more effective because the Department adopted a prolonged, phased approach to implementing the regulation's requirements. The commenter asserted that the Department failed to fully phase in such requirements, noting that sponsors were not required to fully implement the changes finalized in the 2016 version of the part 30 regulation until their first compliance reviews, with the first compliance reviews reflecting updated part 30 requirements occurring after January 18, 2019. The commenter stated that, because those reviews occur on a 5-year cycle, some sponsors may not have had their first review until 2024 (and further noting that in some SAA States, compliance was delayed even further.)

The same commenter argued that the Department's implementation efforts were inadequate for numerous reasons, including what the commenter described as insufficient funding to implement the regulation and OA's consistent failure to request adequate funding from Congress. The commenter asserted that training for the Department's staff was limited, and updates to OA's staff manual were slow, as were the Department's efforts to make a data analysis tool available for the utilization analyses required under the regulation. The commenter asserted that OA's staff's efforts to implement the part 30 regulation were diverted due to the Department's pursuit of an alternative

apprenticeship model during the first Trump Administration. The commenter further noted that Circulars and Bulletins that conflicted with the part 30 regulation remained published for years, and that the Department failed to provide conforming templates for elements like selection procedures to clarify the regulation's requirements for program sponsors. The commenter also asserted that the Department was slow to review States' required EEO plans, remarking that even now, some States have failed to adopt conforming EEO plans.

Another commenter supportive of the existing part 30 regulation's requirements agreed that stakeholder education regarding the part 30 regulation's requirements only began recently, and suggested that increases in the number of females and African Americans in the trades, while promising, may have been more substantial had there been greater investment in oversight and enforcement of the current regulations.

A different commenter said that their Registered Apprenticeship program had diligently implemented the requirements of the part 30 regulation, and that the regulation's requirements were helpful in identifying a wider talent pool for recruitment. However, the commenter added that they understand the Department's decision to revisit the regulations due to the changing landscape in nondiscrimination law, and acknowledged the Department's efforts to reduce regulatory complexity and streamline the program registration process.

Department Response: The Department disagrees with commenters' assertions that OA had failed to fully implement the part 30 regulation in a timely or practical manner. The Department's 2016 final rule establishing the most recent version of the part 30 regulation contained different compliance timelines for distinct provisions of the final rule, and the Department clearly communicated such timelines to program sponsors in the final rule and in technical assistance provided to sponsors and SAAs. OA staff did receive extensive training on the part 30 regulation, and OA developed several resources to support sponsor awareness and compliance with the regulation's numerous and complex requirements.

Ultimately, the Department strongly disagrees with commenters' assertions that implementation failures undermined the effectiveness of the part 30 regulation. As one commenter conceded, sufficient time has passed since the rule became effective for every sponsor to have undergone at least one compliance review. The Department does agree that sponsors and SAAs have experienced significant challenges in complying with the part 30 regulation, and it attributes such challenges to the complex and burdensome nature of the regulation. Moreover, the requirement that sponsors adopt a form of affirmative action predated the 2016 version of the part 30 regulation. In the Department's view, there is no empirical evidence to suggest that the effectiveness of the affirmative action requirements contained in any version of the part 30 regulation has been adversely impacted by the Department's implementation of such regulations.

E. Comments on Legal Authority

1. General Comments on the Department's Legal Authority

Comments: A few commenters argued that the proposed rule would not satisfy the NAA's requirement that the Department promote labor standards necessary to safeguard the welfare of apprentices. These commenters asserted that the NAA charges the Department with establishing standards stricter than those applicable to the general workforce and that the proposed rule's limitations on Registration Agencies' investigative and enforcement authority would reduce apprentices' access to timely remedies. One commenter further argued that the NAA requires the Department to balance employer burden against apprentice protections, and that the proposed rule would deter sponsors from maintaining such protections. The same commenter added that the proposed rule would undermine the extensive network of labor-management programs designed to increase apprenticeship participation.

Department Response: The Department has determined that it has the authority under the NAA to promulgate this regulation. The NAA ''is written in very broad terms'' and ''contains a wide grant of authority to the Secretary of Labor.'' *Gregory Elec. Co.* v. *U.S. Dep't of Labor,* 268 F. Supp. 987, 991 (D.S.C. 1967). The NAA, in relevant part, requires that the Department formulate and promote the furtherance of labor standards necessary to safeguard the welfare of apprentices. The NAA does not dictate that the Department follow a specific approach and does not prescribe specific steps to safeguard the welfare of apprentices.

The Department maintains that requiring program sponsors to establish race-, ethnicity-, sex-, or disability-based utilization goals, engage in affirmative action based upon protected characteristics, or conduct employer-initiated inquiries into disability status does not safeguard the welfare of apprentices. Pursuing demographic balancing or proportional representation within apprenticeship programs, in fact, threatens the welfare of apprentices in that it undermines equal opportunity for all apprentices and applicants.

As discussed elsewhere in this preamble, the race- and sex-based affirmative action provisions of the prior regulation raise serious constitutional concerns. Those provisions required covered sponsors to conduct utilization analyses based on race, ethnicity, and sex, establish utilization goals when underutilization was identified, and undertake affirmative measures designed to address demographic disparities. At the very least, these provisions trigger heightened scrutiny under the Constitution's equal-protection principles. The Department declines to exercise its authority in a way that incentivizes sponsors to impermissibly consider protected characteristics when making employment decisions.

The Department exercises its authority in line with the policy choices expressed by Congress in other Federal civil rights statutes. Congress has enacted comprehensive nondiscrimination laws governing employment, including Title VII, and has expressly limited the reach of some of those statutes to employers meeting specified coverage thresholds. For example, Title VII generally applies only to employers with fifteen or more employees. The Department is reluctant to construe the NAA's vague and open-ended delegation as authorizing the Department to impose obligations on small employers that Congress expressly chose to exempt from nondiscrimination statutes. Furthermore, when Congress intends to authorize or require affirmative action based on protected characteristics, it generally does so expressly. *See, e.g.,* section 503 of the Rehabilitation Act of 1973.[30] Even assuming the NAA could be construed to authorize such requirements, the Department declines to exercise that authority and instead respects Congress's policy judgment regarding the scope and applicability of Federal employment-discrimination obligations.

The Department has also explained below in this preamble that part 30's affirmative action requirements create significant tension with Title VII's substantive protections. Such

[30] 29 U.S.C. 793.

requirements encouraged race- and sex-based employment practices that conflict with Title VII's plain text prohibiting employment decisions motivated by race, color, religion, sex, or national origin and that do not fit comfortably within the narrow, judicially created exemption for affirmative action. The Department is reluctant to exercise the NAA's general grant of authority to maintain a regulatory scheme that creates substantial tension with Title VII.

Similarly, the disability-related provisions of the prior regulation created tension with the ADA. The prior regulation required sponsors to invite applicants and apprentices to disclose disability status upon enrollment and annually thereafter and required covered sponsors to pursue a nationwide disability utilization goal established by the Department. Section 102(d) of the ADA, however, prohibits employer-initiated inquiries concerning disability status of applicants and permits such inquiries of employees only in narrow, specified circumstances.[31] The Department is reluctant to exercise the NAA's general grant of authority to broadly require employer-initiated disability inquiries that are restricted under the ADA.

At bottom, the Department should exercise its authority under the NAA to formulate and promote only labor standards that are consistent with Federal statutes. That means the Department should not impose nondiscrimination obligations on small businesses that Congress expressly exempted, require sponsors to take action to meet race- and sex-based goals that would be unlawful under Title VII, or mandate employer-initiated inquiries of disability status that would run afoul of the ADA's restrictions on such inquiries.

The Department also disagrees with commenters who claim the NAA requires that the Department prescribe a heightened standard that is different from existing laws that are applicable to the general public. Rather, the Department has a wide grant of authority to determine the approach necessary to safeguard the welfare of apprentices. As set forth in the preamble to this final rule and in the section-by-section discussion of the changes to specific provisions, the Department determined that the revisions to the current part 30 will safeguard the welfare of apprentices by aligning with existing legal authorities in Federal and State law, ensuring that apprenticeship programs remain aligned with the full scope of civil rights protections. Enforcement agencies such as the EEOC and State FEPAs possess greater expertise in discrimination law and broader authority to provide individualized relief, including make-whole relief, than Registration Agencies. Accordingly, relying on those enforcement mechanisms, rather than a duplicative apprenticeship-specific process, will better protect apprentices who experience unlawful discrimination.

The Department also disagrees with the commenter that asserted that the proposed rule contradicts the labor-management provisions of the NAA. The NAA, in relevant part, directs the Department to bring together employers and labor for the formulation of programs of apprenticeship. As set forth in the preamble of this final rule and in the section-by-section analysis of the revisions to the current part 30, the Department has determined that the elimination of redundant, and likely illegal, requirements and the reduction of administrative burden will further the expansion and growth of the National Apprenticeship System. Specifically, this final rule, contrary to the commenter's assertion, promotes, rather than inhibits, the convening of employers and labor to establish apprenticeship programs by lowering barriers and associated burdens, consistent with the NAA.

2. Administrative Procedure Act

Comments: One commenter argued that the NPRM is unlawful or violates the APA. Another commenter argued that the NPRM relies on unsubstantiated problems, such as concerns about ''reverse discrimination'' or pressures for sponsors to discriminate under the 2016 regulations. A commenter stated that, in contrast to the prior rulemaking in 2016—which they said did review apprenticeship data and analyze national labor force data to justify changes to the regulation—the Department did not include any examples, a quantitative analysis, or a factual record to support its claims under the NPRM. For example, one commenter stated they were unable to find any examples of recent EEOC charges brought against employers for discriminating against White males in apprenticeship programs, construction jobs, or trades jobs, while there are numerous examples of such cases concerning discrimination against racial minorities. Another commenter asserted that data demonstrates that discrimination against women and racial minorities is still a real concern. This commenter further stated that the Department ignored relevant available data and case law that did not align with the arguments presented under the proposed rule.

Given these perceived issues, a commenter argued that the NPRM failed to meet the APA standard that regulatory actions must examine the relevant data and articulate a satisfactory explanation for the action, including a rational connection between the facts found and the choice made. Another commenter asserted that the NPRM lacks sufficient data or a factual record, and therefore violates the APA's arbitrary and capricious standard, and does not satisfy the APA requirements for notice-and-comment rulemaking designed to ensure that the Department has made an informed decision.

Department Response: As emphasized earlier in this preamble, the Department takes the position that while program sponsors should be held accountable for findings of illegal discrimination against apprentices, the affirmative action provisions contained in the part 30 regulation do not prevent such discrimination, and, in fact, may induce such discriminatory conduct by sponsors. The Department did not refer to the concept of ''reverse discrimination'' in the preamble to the NPRM; moreover, the Department's position, consistent with that of the EEOC, is that there is no such thing as ''reverse'' discrimination; there is only discrimination and workers are protected from such discrimination under the Constitution and nondiscrimination laws regardless of their race, ethnicity, or sex.[32] As some commenters noted, when the Department issued the 2016 version of part 30, the preamble to the rule that appeared in the **Federal Register** stated that Department had ''analyzed participant demographics in apprenticeship programs . . . and the demographics of the national labor force'' and had determined that ''notable disparities exist in apprenticeship participation and completion.'' 81 FR 92028 (Dec. 19, 2016). However, those comparative analyses of the prevalence of certain demographic groups in the national apprenticeship workforce and in the broader national labor force were incapable of establishing that such demographic ''disparities'' were caused by, or were proof of, discriminatory conduct by particular program sponsors. Rather, these analyses were undertaken to support the Department's stated

[31] *See* 42 U.S.C. 12112(d).

[32] EEOC, ''What You Should Know About DEI-Related Discrimination at Work,'' Question 4, *https://www.eeoc.gov/wysk/what-you-should-know-about-dei-related-discrimination-work#_ednref7* (last visited June 26, 2026).

policy goals at the time of ''[i]ncreasing diversity'' in Registered Apprenticeship programs generally (81 FR 92027, Dec. 19, 2016) and of addressing the ''underutilization of historically disadvantaged worker groups in apprenticeship.'' 81 FR 92035 (Dec. 19, 2016).

However, in issuing this final rule, the Department has determined that the prior regulatory effort in part 30 to increase overall demographic diversity in Registered Apprenticeship programs through the establishment by certain apprenticeship programs of compulsory, group-based numerical hiring goals—while also seeking to protect individual apprentices in those programs against illegal employment discrimination on the basis of race, sex, and ethnicity—imposed distinct and fundamentally irreconcilable mandates on certain sponsors. Moreover, the Department maintains that the obligation to set such apprenticeship hiring goals in the existing and previous versions of part 30 were inherently discriminatory and legally questionable because they induced program sponsors to treat individuals differently based upon their group-based demographic identities. Therefore, the Department's prior analysis as to the prevalence of overall, global demographic disparities among certain groups enrolled in Registered Apprenticeship programs ought not be used to justify the retention of the compulsory, burdensome, and legally questionable affirmative action requirements contained in the existing part 30 regulation.

As some commenters noted, maintaining utilization goals that classify apprentices on the basis of race, ethnicity, and sex may induce sponsors to consider these protected bases as factors in their employment decisions. The Department's concern about discrimination is not unsubstantiated, as a commenter asserted. Rather, it is substantiated by the text of the regulations. The absence of formal complaints against sponsors for engaging in unlawful preferential treatment neither disproves the existence of such treatment nor undermines the Department's position that the part 30 affirmative action provisions incentivize sponsors to use improper governmental racial classifications in their selection decisions. *See Lutheran Church-Missouri Synod* v. *F.C.C.,* 154 F.3d 487, 492 (D.C. Cir. 1998) (rejecting the Federal Communications Commission (FCC)'s argument that strict scrutiny should not apply to its EEO regulations because there was no evidence that a regulated entity had engaged in racial hiring, stating that ''such an evidentiary obligation would turn equal protection analysis inside out.''). The developing case law regarding affirmative action also makes such classifications more vulnerable to challenge than they have been in the past. *See, e.g., Vitolo* v. *Guzman,* 999 F. 3d 353 (6th Cir. 2021) (invalidating a program under the American Rescue Plan Act of 2021 that disbursed funding to restaurant owners on the basis of the applicants' race and sex); *Mid-Am. Milling Co., LLC* v. *United States Dep't of Transportation,* No. 3:23–CV–00072–GFVT, 2024 WL 4267183, at *7 (E.D. Ky. Sept. 23, 2024) (citing to *SFFA* and finding that Plaintiffs were likely to succeed in their claim that the Department of Transportation's use of race and sex-based presumptions in the preferential award of Federal highway and transit funds violated the Constitution's guarantee of Equal Protection), *opinion clarified,* No. 3:23–CV–00072–GFVT, 2024 WL 4635430 (E.D. Ky. Oct. 31, 2024); *Ultima Servs. Corp.* v. *U.S. Dep't of Agric.,* 683 F. Supp. 3d 745, 764 (E.D. Tenn. 2023).

Regarding the Department's decision to rely on external enforcement agencies to investigate allegations of illegal discrimination against apprentices, the Department maintains that this will result in more thorough investigations and more tailored, individualized remedies for apprentices who experience illegal discrimination. In the nearly 10 years since part 30 was last updated, the Department has determined that OA's limited expertise in nondiscrimination law and its inability to provide individual remedies prevents it from effectively remedying unlawful discrimination. The Department's reference in the NPRM to a lack of complaints and enforcement actions under the existing part 30 was not meant to convey that there is no discrimination. Instead, in the Department's view, the scarcity of complaints and enforcement actions related to part 30 suggests that the apprentice-specific enforcement scheme administered by the Department has provided little relief to apprentices outside of what is otherwise available through FEPAs, especially since the Department's usual practice has been to refer any complaints alleging illegal discrimination to the EEOC.

Because of the lack of effective enforcement, growing legal risks, and sponsor compliance costs under the current part 30, the Department has concluded that it is inappropriate to maintain this race- and sex-based approach to nondiscrimination in apprenticeship. Instead, the Department contends that a more streamlined approach will help expand apprenticeships for all workers and return the enforcement of nondiscrimination laws to the agencies properly equipped for the task. By accounting for these considerations in its determination that the current part 30 regulation is no longer ''necessary to safeguard the welfare of apprentices,'' [33] the Department has clearly provided a ''reasoned explanation for the change,'' satisfying the APA's requirements. *Cboe Glob. Markets, Inc.* v. *Sec. & Exch. Comm'n,* 155 F.4th 704, 716 (D.C. Cir. 2025) (quoting *Encino Motorcars, LLC* v. *Navarro,* 579 U.S. 211, 221 (2016)); *see also Mozilla Corp.* v. *Fed. Commc'ns Comm'n,* 940 F.3d 1, 55–56 (D.C. Cir. 2019) (upholding the FCC's adoption of a ''light-touch'' policy for governing internet rather than maintaining a utility-style regulation where the FCC determined that the harms the prior Order ''was designed to prevent did not require the prior Order's regulatory measures but could instead be mitigated—at a lower cost—with transparency requirements, consumer protection, and antitrust enforcement measures'').

F. Comments on the Department's Goals for the Rulemaking

1. Ensuring Apprenticeship Regulations Comply With Nondiscrimination Law

Comments on the Department's Interpretation of Students for Fair Admissions v. Harvard

Comments: Some commenters stated that the Department misinterpreted the Supreme Court's decision in *SFFA* in justifying the rescission of the current part 30 regulations. These commenters reasoned that *SFFA* held only that race cannot be explicitly considered as a factor in individual higher education admissions decisions and did not address race-neutral measures or outreach efforts in employment or training contexts and, therefore, the Department's claim that the part 30 regulations ''closely resemble'' policies struck down by the Court is false.

Commenters further argued that part 30 is distinguishable from the type of affirmative action addressed in *SFFA* because part 30 expressly prohibits selection preferences and also prohibits using quotas in the context of apprenticeship programs, requiring only the establishment of aspirational goals. Some commenters asserted that, under part 30, Registered Apprenticeship program sponsors may be sanctioned for falling short of the established target. A

[33] 29 U.S.C. 50.

couple of commenters also maintained that the Department did not offer evidence that program sponsors were using protected characteristics in hiring decisions.

One commenter opined that Registered Apprenticeship program outreach is not ''zero sum,'' like the admissions processes addressed in the *SFFA* decision, in that there are frequent occasions when employer-demand outpaces the number of applicants requiring outreach, and nothing in the *SFFA* decision would prevent labor training programs from expanding selection pools by deploying targeted outreach as one strategy for growth. This commenter stated that the need for joint apprenticeship and training committees (JATCs) to engage in successful outreach, recruitment, and retention programs is underscored by the reality of acute, nationwide labor shortages for skilled labor in the construction industry. Another commenter cited to cases that it claimed upheld broad recruitment efforts like those conducted under part 30 because such measures function only to bring more candidates into consideration while remaining race-neutral in the selection of candidates.

Although the above commenters disagreed with the Department's use of *SFFA* to support this rulemaking, other commenters who favored the revision and streamlining of part 30 agreed with the Department's position that *SFFA* is relevant, noting that the Constitution prohibits actions that discriminate on the basis of race unless such measures are narrowly tailored to serve a compelling state interest. These commenters cited several Supreme Court decisions, including the *SFFA* ruling, which they said clarified that race-preferential educational programs are illegal unless they satisfy the ''twin protections'' of the Equal Protection Clause. Another commenter noted that in the *SFFA* decision the court held that race-conscious admissions policies violate the Equal Protection Clause of the Fourteenth Amendment, and that existing regulations that establish a race-conscious preference would not survive legal challenge. Yet another commenter stated that the existing part 30 regulations require ''arbitrary line drawings'' related to ''race'' and ''national origin'' designations which have been rejected by the Supreme Court.

Department Response: Commenters who suggested *SFFA*'s reasoning is cabined to the higher education context are mistaken. While *SFFA* was decided in the context of university admissions, the decision rests on longstanding and enduring equal-protection principles that predate and extend well beyond that context, and it reaffirmed that race-based governmental decision-making is presumptively invalid absent an exceedingly narrow justification. The Department cited *SFFA* in the NPRM precisely because it reaffirmed these bedrock equal-protection principles. 90 FR 28950, 28955 (July 2, 2025). Indeed, the Supreme Court recently relied upon *SFFA* outside the higher education context to reiterate that ''the general rule [is] that the Constitution almost never permits the Federal Government or a State to discriminate on the basis of race. Such discrimination triggers strict scrutiny'' under the Constitution's equal-protection guarantee. *Louisiana* v. *Callais,* 146 S. Ct. 1131, 1152 (2026) (quoting *SFFA,* 600 U.S. at 207).

Lower courts have likewise relied on equal-protection principles articulated in *SFFA* to halt or strike down race-based governmental programs in a variety of contexts. *See, e.g., Mid-Am. Milling Co., LLC* v. *United States Dep't of Transportation,* No. 3:23–CV–00072–GFVT, 2024 WL 4267183, at *7 (E.D. Ky. Sept. 23, 2024) (citing to *SFFA* and finding that Plaintiffs were likely to succeed in their claim that the Department of Transportation's use of race and sex-based presumptions in the preferential award of Federal highway and transit funds violated the Constitution's guarantee of Equal Protection), *opinion clarified,* No. 3:23–CV–00072–GFVT, 2024 WL 4635430 (E.D. Ky. Oct. 31, 2024); *Ultima Servs. Corp.* v. *U.S. Dep't of Agric.,* 683 F. Supp. 3d 745, 764 (E.D. Tenn. 2023) (citing *SFFA* and finding that the race-based presumption used by the Small Business Administration (SBA) and the Department of Agriculture in determining eligibility for preferencing in Federal contract awards failed strict scrutiny).

Contrary to some commenters' assertions, the constitutional relevance of *SFFA* does not depend upon whether apprenticeship programs are analogous to university admissions programs. The question is whether the government has employed racial classifications or induced race-based decision-making. The affirmative action provisions of the current part 30 regulation do exactly that. The regulation requires covered sponsors to conduct utilization analyses based on race and ethnicity, determine whether particular racial or ethnic groups are ''underutilized,'' establish race- and ethnicity-based utilization goals, and undertake affirmative measures designed to address such underutilization.

Although provisions in part 30 prohibit discrimination on the basis of race, sex, and ethnicity, the regulation's race-based provisions conflict with that legitimate mandate. Long before *SFFA,* courts repeatedly held that governmental policies pressuring or encouraging regulated entities to consider race in hiring, promotion, assignment, or other employment decisions constitute racial classifications attributable to the government. *See, e.g., Monterey Mechanical Co.* v. *Wilson,* 125 F.3d 702, 710–13 (9th Cir. 1997); *Lutheran Church—Missouri Synod* v. *FCC,* 141 F.3d 344, 351–54 (D.C. Cir. 1998); *MD/DC/DE Broadcasters Ass'n* v. *FCC,* 236 F.3d 13, 19–20 (D.C. Cir. 2001). A racial classification must survive strict scrutiny, meaning it must be narrowly tailored to achieve a compelling governmental interest. *SFFA,* 600 U.S. at 206. Sex-based classifications may be sustained only if they satisfy intermediate scrutiny—they must serve an important governmental objective and are substantially related to the achievement of that objective. *Vitolo,* 999 F.3d at 364 (citation modified).

As stated in the NPRM, the affirmative action provisions currently found at 29 CFR 30.5(d) require covered sponsors to establish specific numerical goals exclusively for the inclusion of women and racial and ethnic minorities in the program. Contrary to the commenters' assertion, the fact that part 30 requires setting ''utilization goals'' instead of ''quotas'' does not render these provisions race-neutral. It simply does not matter ''whether a government hiring program imposes hard quotas, soft quotas, or goals. Any one of these techniques induces an employer to hire with an eye toward meeting the numerical target. As such, they can and surely will result in individuals being granted a preference because of their race.'' *Lutheran Church,* 141 F.3d at 354. Nor does it matter that § 30.4(a)(2) suggests that the race-based regulations are needed to achieve a demographic balance that would exist ''absent discrimination.'' 29 CFR 30.4(a)(2). As Chief Justice Roberts explained nearly twenty years ago: ''The way to stop discrimination on the basis of race is to stop discriminating on the basis of race.'' *Parents Involved in Cmty. Schs.* v. *Seattle Sch. Dist. No. 1,* 551 U.S. 701, 748 (2007). That is because governmental actions that create '' '[d]istinctions between citizens solely because of their ancestry, are by their very nature odious to a free people whose institutions are founded upon the doctrine of equality.' '' *Callais,* 146 S. Ct.

1131, 1152 (quoting *SFFA,* 600 U.S. at 208).

Under the existing part 30, sponsors are also required to engage in outreach targeted to specific groups, as well as other burdensome activities when women or racial or ethnic minorities are underrepresented. Thais targeted outreach based on race, ethnicity, and sex, however, is legally vulnerable. *See MD/DC/DE Broadcasters Ass'n* v. *F.C.C.,* 236 F.3d 13, 20 (D.C. Cir. 2001) (disagreeing with the premise that ''preferential recruiting 'disadvantag[es] no one' '' and subjecting the affirmative recruiting requirement to strict scrutiny). This focus on ''utilization'' and race- or sex-based responses to such underutilization undermines the justification that these goals and targeted efforts are meant to achieve EEO for *all* apprentices. *Cf. Monterey Mech. Co.* v. *Wilson,* 125 F.3d 702, 711 (9th Cir. 1997) (system where contractors must subcontract percentages of work to minority or female owned subcontractors or show good faith effort to comply with the non-rigid ''goals'' is a racial classification under the Equal Protection Clause).

The premise underlying part 30's affirmative action provisions was that ''absent discrimination, over time a sponsor's apprenticeship program, generally, will reflect the sex, race, ethnicity, and disability profile of the labor pools from which the sponsor recruits and selects.'' 29 CFR 30.4(a)(2). This premise, however, is flawed because ''[i]t is completely unrealistic to assume that unlawful discrimination is the sole cause of people's failing to gravitate to jobs and employers in accord with the laws of chance.'' *See Watson* v. *Fort Worth Bank & Trust,* 487 U.S. 977, 992 (1988). Section 30.4(a)(2)'s ''completely unrealistic'' premise also places unconstitutional pressure on sponsors to reach these goals. ''The very term 'underrepresentation' necessarily implies that, if such a situation exists, the [employer] is behaving in a manner that falls short of the desired outcome. The regulations pressure [employers] to maintain a workforce that mirrors the racial breakdown of their 'metropolitan statistical area.' '' *Lutheran Church-Missouri Synod* v. *F.C.C.,* 141 F.3d 344, 352 (D.C. Cir. 1998). The presence of a numerical goal, combined with the threat of deregistration for failing to take ''good faith efforts'' to meet those goals, incentivizes sponsors to engage in preferential hiring to avoid a finding that they have not engaged in such efforts. *Cf. Sussman* v. *Tanoue,* 39 F. Supp. 2d 13, 26 (D.D.C. 1999) (finding that the Federal Deposit Insurance Corporation's affirmative action program need not be reviewed under strict scrutiny because the office administering the affirmative action program ''had no authority comparable to the threat of extended government audit, license denial, and forfeiture which the Court of Appeals found would inevitably convert a potential concern about under-representation on the part of the FCC and the licensee into a hiring preference'').

To survive strict scrutiny, the Department would need to show that the race-based provisions of part 30 serve a compelling state interest. The Supreme Court's ''precedents have identified only two compelling interests that can satisfy that standard.'' *Callais,* 146 S. Ct. at 1152 (quoting *SFFA,* 600 U.S. at 207). The first is ''avoiding imminent and serious risks to human safety in prisons,'' *Id.,* which plainly has no application here. The second is ''remediating specific, identified instances of past discrimination that violated the Constitution or a statute.'' *Id.; see also City of Richmond* v. *J.A. Croson Co.,* 488 U.S. 469, 497 (1989). Generalized assertions of societal or industrywide discrimination are insufficient to meet this standard, however; there must be specific instances of past intentional discrimination in which the Federal Government itself was an active or passive participant. *Id.* at 498–500; *see also Vitolo* v. *Guzman,* 999 F.3d 353, 361 (6th Cir. 2021).

For the Department to impose the requirement to adopt race- and ethnicity-based utilization goals on all sponsors, the Department would need to show specific instances of its own participation in the discrimination, rather than that it is seeking to rectify general societal inequities. *See Wygant* v. *Jackson Bd. of Educ.,* 476 U.S. 267, 275 (1986) (citing *Hazelwood School District* v. *United States,* 433 U.S. 299, 308 (1977) for the proposition that the Court focuses ''on prior discrimination as the justification for, and the limitation on, a State's adoption of race-based remedies''). The Department cannot meet this standard as the past rulemaking record for part 30 has not identified any such instances of past discrimination.

Furthermore, the utilization goals required by existing § 30.6 lack narrow tailoring, as their application has no clear end, applies regardless of occupation or industry, and the default data used to set the goal is the respective group's representation in the civilian labor force, a statistic that bears little relationship to any individual's interest in and qualifications for an apprenticeship. *See Rothe Dev. Corp.* v. *Dep't of Def.,* 545 F.3d 1023, 1036 (Fed. Cir. 2008) (identifying the ''relationship of the stated numerical goals to the relevant labor market'' as a factor in determining narrow tailoring). Similarly, the existing part 30 sex-based goals and related affirmative action requirements are likely to trigger intermediate scrutiny, which they are unlikely to survive. The government must show that the favored sex ''actually suffer[ed] a disadvantage'' caused by discrimination in a particular field or context that the policy is designed to remedy to establish an important interest. *Mississippi Univ. for Women* v. *Hogan,* 458 U.S. 718, 727–29 (1982). Statistical disparities between workforce composition and labor-market availability, standing alone, are insufficient to demonstrate an important governmental objective to remedy discrimination. *See Vitolo,* 999 F.3d at 364 (citing *Craig* v. *Boren,* 429 U.S. 190, 200–04 (1976)). Absent evidence that women suffered intentional discrimination in each of the specific trades or occupations subject to regulation, sex-based classifications in the form of goals cannot be justified as remedial measures. *Id.* at 365. For the same reasons that the race- and ethnicity-based goals are unlikely to demonstrate narrow tailoring, the sex-based goals are also unlikely to be found to be substantially related to the goal of remedying discrimination.

Given the constitutional infirmities created by the affirmative action provisions, the Department chooses to devote its resources to more supportable methods of expanding Registered Apprenticeship opportunities. If sponsors found certain elements of their affirmative action programs, such as their outreach or recruitment activities, to be helpful, they are free to continue those practices to the extent they are lawful. The Department is choosing, however, to no longer require such practices of sponsors. As discussed below, there are more effective and legally sound methods for protecting the welfare of apprentices.

Comments on Part 30's Conflict With Title VII

Comments: A couple of commenters stated that, in the NPRM, the Department incorrectly argued that the part 30 regulations violate Title VII, and critiqued the Department's citation of the *Ames* v. *Ohio Department of Youth Services* as an inaccurate basis for some of the claims made by the Department in the NPRM. The commenters argued that existing regulations do not alter terms or conditions of employment

based on race, ethnicity, or sex, and simply require organizations to set aspirational goals which courts have permitted while prohibiting programs from making discriminatory employment decisions. The commenters maintained that the *Ames* decision determined that the standard for all plaintiffs bringing suits under Title VII should be the same regardless of whether they are a member of a historically disadvantaged group, and did not address the legality of race and sex neutral measures such as those required by part 30. One of these commenters stated that DOL also claims that affirmative action requirements in existing regulations cause employers to engage in disparate treatment based on race, sex, and ethnicity, but does not provide any evidence to support this claim. One commenter stated that multiple court rulings have found that affirmative action plans similar to the regulations in part 30 are permissible under Title VII. Another commenter also argued that the Department's reliance on *Ames* is inappropriate, reasoning that the decision focused on burden-shifting standards in individual employment disputes, and adding that the Court did not rule on the legality of proactive outreach, nonbinding affirmative action plans, or utilization goals in federally administered training programs.

A different commenter maintained that the existing regulations are in tension with Title VII because they require non-exempt program sponsors to take actions that Title VII prohibits. The commenter urged DOL to incorporate these rationales in the final rule.

A couple of commenters remarked that the proposed rule would align with several Administration E.O.s. One commenter stated that the proposed rules logically follows from President Trump's January 21, 2025, E.O. 14173, ''Ending Illegal Discrimination and Restoring Merit-Based Opportunity,'' and the reasoning underlying it.

Department Response: The Department maintains that the part 30 race-, ethnicity-, and sex-based affirmative action provisions are vulnerable to challenge under both the Constitution, for the reasons discussed above, and under Title VII. As E.O. 14173 makes clear, Federal civil rights laws, including Title VII, ''serve as a bedrock supporting equality of opportunity for all Americans'' and illegal race- and sex-based preferences violate these laws. The Department agrees with the commenter that its rescission of the 2016 version's race-, ethnicity-, and sex-based utilization goals is consistent with Title VII and the principles articulated in E.O. 14173.

Commenters, however, have mischaracterized the Department's reliance on *Ames* v. *Ohio Department of Youth.* The Department does not claim that the *Ames* decision invalidates the existing part 30 affirmative action provisions as violative of Title VII. The Department cited *Ames* for the general proposition that, under both Title VII and the Equal Protection Clause, equal opportunity must extend to all apprentices, not just historically disadvantaged groups. *Ames* held that Title VII's disparate-treatment provision prohibits discrimination against *any individual,* thus ''establishing the same protections for every 'individual'—without regard to that individual's membership in a minority or majority group.'' 605 U.S. at 309–10 (2025); *see also McDonald* v. *Santa Fe Trail Transp. Co.,* 427 U.S. 273, 280 (1976) (holding that Title VII prohibits discrimination against non-minority individuals ''upon the same standards'' as minority individuals).

However, part 30's affirmative action requirements encourage preferential treatment of certain groups, specifically racial minorities and women. 29 CFR 30.4(a), 30.5(d). *Cf. Lutheran Church,* 141 F.3d at 354 (race-based employment goals induce preferential treatment based on race). The holding in *Ames* increases the likelihood that a non-minority or male plaintiff could successfully sue a sponsor claiming that the sponsor improperly took race, ethnicity, or sex into account in making employment decisions pursuant to the part 30 affirmative action provisions. *Ames* v. *Ohio Dep't of Youth Servs.,* 605 U.S. 303, 310 (2025) (''Our case law thus makes clear that the standard for proving disparate treatment under Title VII does not vary based on whether or not the plaintiff is a member of a majority group.'').

Even without the *Ames* holding, a lawsuit by a non-minority litigants alleging disparate treatment may be meritorious. Part 30's requirement for program sponsors to establish and take action to meet race- and sex-based goals conflicts with the plain text of section 703(a)(2) of the Act,[34] which makes it an unlawful employment practice to ''classify'' employees or applicants in a manner that deprives or tends to deprive individuals of employment opportunities because of race, color, sex, or national origin. The Civil Rights Act of 1991 amended Title VII (at section 703(m) [35]) to broaden this prohibition by providing that an unlawful employment practice is established when race, color, religion, sex, or national origin was even ''a motivating factor'' for an employment practice, even if other factors also motivated, or even drove, the decision. Title VII thus adopts a broad prohibition on race- and sex-based employment practices that, on its face, bars affirmative action measures to meet numeric goals based on those characteristics.

Notwithstanding the plain statutory text, the Supreme Court has construed Title VII to permit race- or sex-based affirmative action only in extremely narrow circumstances. *See United Steelworkers* v. *Weber,* 443 U.S. 193 (1979); *Johnson* v. *Transp. Agency, Santa Clara Cnty, Cal.,* 480 U.S. 616 (1987). Subsequent Supreme Court decisions call into question the continued viability of the *Weber-Johnson* framework. *See, e.g., Louisiana* v. *Callais,* 146 S. Ct. 1131 (2026); *Ames* v. *Ohio Dep't of Youth Servs.,* 605 U.S. 303 (2025); *SFFA,* 600 U.S. 181 (2023*); and Ricci* v. *DeStefano,* 557 U.S. 557, 579 (2009). While the framework is a judge-made doctrine that interprets Title VII atextually ''to permit what its language read literally would prohibit,'' *Johnson,* 480 U.S. at 647 (O'Connor., J. concurring), the Department nonetheless assumes that *Weber-Johnson* remains controlling precedent.

Under the *Weber-Johnson* framework, an employer may voluntarily adopt a race- or sex-based measure to address a manifest imbalance in traditionally segregated job categories, provided that the measure is remedial in purpose, temporary in duration, and does not employ quotas or inflexible goals or unnecessarily trammel the interests of non-beneficiaries. *Weber,* 443 U.S. at 208; *Johnson,* 480 U.S. at 638. Such programs must be designed to eliminate the effects of past discrimination or segregation, not to maintain racial or sex balance for its own sake. *Johnson,* 480 U.S. at 639–40. As the Eighth Circuit explained: ''An affirmative action policy is valid [under Title VII] if the policy is remedial and narrowly tailored to meet the goal of remedying the effects of past discrimination.'' *Humphries* v. *Pulaski Cnty. Special Sch. Dist.,* 580 F.3d 688, 695 (8th Cir. 2009). It is often difficult for an employer to establish compliance with the strict limitations of *Weber* and *Johnson;* those who attempt such a path and fail necessarily violate Title VII with the practice in question.

To comply with the current part 30's affirmative action regulations, a covered sponsor must establish race- and sex-based employment goals and undertake related affirmative measures. The

[34] 42 U.S.C. 2000e–2(a)(2).

[35] 42 U.S.C. 2000e–2(m).

Department is concerned that such practices do not fit within the *Weber–Johnson* framework—and certainly not generally across sponsors nationwide. As explained above, part 30's race- and sex-based requirements are not remedial: sponsors must undertake good faith efforts to meet, achieve, or approach proportional representation in terms of race and sex, not to specifically remedy manifest imbalances in a traditionally segregated job category. Nor are the requirements temporary: they have existed for decades, and unless rescinded, sponsors would continue to be subject to these regulations on an indefinite basis.

''[T]he existence of an affirmative action plan . . . when combined with evidence that the plan was followed in an employment decision is sufficient to constitute direct evidence of unlawful discrimination unless the plan is valid'' under *Weber-Johnson. Frank* v. *Xerox Corp.,* 347 F.3d 130, 137 (5th Cir. 2003) (quoting *Bass* v. *Bd. of Cnty. Comm'rs,* 256 F.3d 1095, 1110 (11th Cir. 2001)). Many sponsors' actions taken to comply with part 30's affirmative action regulations would not consistently satisfy the demanding *Weber–Johnson* framework and could therefore constitute direct evidence of unlawful discrimination in violation of Title VII. Part 30's utilization goals and related requirements thus compel regulated sponsors to adopt race- and sex-based employment practices that would be, in many cases, unlawful under Title VII. The Department should exercise its authority under the NAA to formulate and promote labor standards that are consistent with Federal law, rather than standards that create tension with Federal law.

Comments on the Application of Executive Order 14168

Comments: A commenter stated that the DOL fails to acknowledge that E.O. 14168 defies settled Title VII case law. The commenter asserted that in *Bostock* v. *Clayton County, Georgia,* 590 U.S. 644 (2020), the Supreme Court held that discrimination based on gender identity is a form of sex discrimination protected by Title VII, and as Executive Orders cannot override Supreme Court case law, *Bostock* remains the law of the land. A group of commenters stated that DOL inaccurately describes prevailing Title VII legal standards by claiming that the proposed elimination of sexual orientation as a category of prohibited discrimination is required to reflect ''existing legal authorities'' or ''the current statutory language and legal standards governing nondiscrimination.'' The group of commenters asserted that, in the *Bostock* ruling, the Supreme Court recognized that Title VII's prohibitions on discrimination on the basis of sex also bars discrimination on the basis of sexual orientation.

One commenter expressed different interpretations of the *Bostock* ruling and its implications. This commenter asserted that while some claim that the *Bostock* decision prohibits discrimination based on sexual orientation and gender identity, it does not. The commenter argued that in *Bostock,* the Court did not adopt a new protected basis of sexual orientation, transgender status, or gender identity in Title VII, but rather its holding and analysis was tied to what it viewed as a form of sex discrimination. The commenter further stated that the Court did not address the broad scope of conduct associated with sexual orientation or gender identify, and therefore it is inappropriate for DOL to impose nondiscrimination requirements based on these characteristics. The commenter concluded that, accordingly, the proposed rule would bring regulations into compliance with Federal nondiscrimination laws. Another commenter stated that rescinding the reference to ''gender identity'' that appears at 29 CFR 30.3(b)(5) and (c) of the current regulations comports with President Trump's E.O. 14168 ''Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government,'' which directed Federal agencies to modify regulations or policies that use the terms ''gender'' and ''gender identity.''

Department Response: The Department is removing all apprenticeship-specific nondiscrimination requirements, including references to sexual orientation and gender identity as specified protected bases under part 30, as mandated by E.O. 14168. E.O. 14168 directs agencies to ''enforce laws governing sex-based rights, protections, opportunities, and accommodations to protect men and women as biologically distinct sexes'' and to ''remove all statements, policies, regulations, forms, communications, or other internal and external messages that promote or otherwise inculcate gender ideology[.]'' The Department therefore proposed to remove references to gender identity.

The Department disagrees with commenters who contend that these revisions improperly narrow the protections afforded by Federal nondiscrimination law. Commenters' objections rest on a misunderstanding of both the purpose and effect of this rulemaking. This final rule does not amend or limit the substantive protections afforded by Title VII or any other Federal or State nondiscrimination law. Rather, it rescinds the apprenticeship-specific nondiscrimination framework previously contained in part 30 and replaces it with a straightforward requirement that program sponsors comply with all applicable Federal and State laws prohibiting illegal discrimination. Under revised § 30.3, sponsors remain fully subject to all applicable nondiscrimination requirements imposed by Federal and State law, and apprentices retain whatever protections those laws provide.

The Department acknowledges commenters' reliance on *Bostock.* Nothing in this final rule purports to alter the legal effect of *Bostock* or to resolve questions concerning the scope of Title VII. The Department is not revising Title VII, nor is it exercising authority to define the substantive reach of that statute. Those questions remain governed by applicable law and are properly resolved by the other agencies and Federal courts charged with enforcing and interpreting Federal nondiscrimination statutes.

Accordingly, the Department has determined that it is unnecessary to maintain apprenticeship-specific regulatory provisions that separately enumerate particular protected categories or otherwise establish an independent nondiscrimination regime for Registered Apprenticeship programs. Instead, the final rule adopts a uniform standard requiring compliance with all applicable Federal and State nondiscrimination laws. To the extent those laws prohibit particular forms of discrimination, program sponsors remain bound by those requirements. To the extent those laws are interpreted, amended, or otherwise modified in the future, sponsors' obligations will change accordingly without requiring further amendments to part 30.

The Department therefore disagrees that the removal of apprenticeship-specific references to particular protected categories narrows the substantive protections available to apprentices. The final rule neither expands nor contracts the protections afforded under Federal and State nondiscrimination laws. Rather, it eliminates a duplicative apprenticeship-specific regulatory framework and returns responsibility for interpreting and enforcing those laws to other agencies and courts that possess the relevant statutory authority and expertise.

2. Streamlining Enforcement, Eliminating Duplicative Frameworks, and Aligning Apprenticeship Requirements with Federal Laws

General Comments About Streamlining Requirements

Comments: Some commenters expressed support for the Department's proposal to streamline EEO requirements for Registered Apprenticeship programs. These commenters stated that the current regulations at 29 CFR part 30 impose unique EEO obligations on Registered Apprenticeship programs that have resulted in significant confusion, operational challenges, and compliance costs, potentially deterring the establishment of new apprenticeship programs and the growth of existing ones. One commenter concluded that compliance with existing nondiscrimination laws is sufficient.

Another commenter expressed support for DOL's efforts to harmonize the Department's rules for Registered Apprenticeship programs with nondiscrimination laws, arguing that the Department's proposed revisions are necessary to resolve the consequences of overlapping or unclear jurisdictional mandates.

However, one commenter asserted that the proposed rule risks increasing employer burden by shifting responsibility for EEO requirements to the ''already overburdened'' EEOC and other State agencies. The commenter maintained that employers consistently report that navigating multiple State-specific rules is more onerous than following a single Federal standard.

Department Response: The Department appreciates the various commenters' support for the rule's streamlined and uniform approach to EEO and nondiscrimination requirements. The Department agrees that the requirements imposed under the existing rule were onerous, excessive, and impeded the goal of apprenticeship expansion. Accordingly, the Department maintains that this final rule fulfills the Administration's directive in E.O. 14192 to eliminate regulations that impose costs, create confusion, hamper innovation, or otherwise restrain economic growth and opportunities for Americans.

The Department disagrees that the final rule increases compliance burdens by shifting responsibility to the EEOC or State agencies. Those agencies and the laws they administer govern sponsors regardless of whether part 30 exists. This rule does not create any new obligations under Federal or State nondiscrimination laws, nor does it create any new enforcement mechanisms. Rather, it eliminates a separate apprenticeship-specific compliance and enforcement regime that operated alongside existing Federal and State civil-rights laws. To the extent the commenter is concerned about multiple layers of regulation and bureaucracy, the final rule reduces, rather than increases, those layers by removing an additional apprenticeship-specific framework while leaving in place the generally applicable nondiscrimination laws that already govern sponsors.

3. E.O. 14192, Unleashing Prosperity Through Deregulation

Comments: A commenter supported the proposed rule changes, arguing that the changes would provide numerous benefits, including reducing regulatory burdens, decreasing stakeholder confusion, providing clarity, and encouraging more apprenticeship program participation, and aligning with President Trump's executive orders on deregulation, merit-based opportunity, and preparing Americans for skilled trade jobs. Another commenter expressed support for the proposed rule's revisions to 29 CFR parts 29 and 30, stating that these changes would remove a duplicative set of regulations on program sponsors and employers, and eliminate requirements for an unnecessarily complex array of goals, analyses, outreach, and annual reviews. A separate commenter concurred with the proposed removal of duplicative and outdated requirements.

A commenter maintained that it is essential to ensure that participating employers are not overburdened by reporting requirements and that employers can protect proprietary information, including trade secrets, program outlines, and other sensitive materials. The commenter urged the Department to consider broader improvements to the apprenticeship registration process and remove unnecessary administrative barriers and simplify the bureaucratic requirements for small and midsize employers. Specifically, the commenter recommended avoiding ''government-centric language'' that is not aligned with workplace operations, as well as delivering technical assistance through experienced practitioners, rather than static manuals and checklists.

Other commenters, however, disagreed with the Department's assertion that the part 30 regulation should be revised and streamlined to reduce undue regulatory burdens for Registered Apprenticeship stakeholders. One commenter asserted that the part 30 regulations are not burdensome on sponsors because States and other organizations have consistently created tools and templates for sponsors that have helped sponsors easily create affirmative action plans that support equal opportunity for Registered Apprenticeship program applicants. This commenter added that sponsors have been complying with these requirements for decades, and many sponsors already have policies and practices set up to effectively complete affirmative action plans, as well as internal auditing and reporting systems.

Department Response: The Department appreciates comments that acknowledged the challenges that Registered Apprenticeship program sponsors face in complying with the existing part 30 regulation and the need for a clearer and less complex regulatory framework. The Department agrees with those commenters who opined that the existing part 30 regulation's requirements were expansive, duplicative, and unclear, and that they imposed a complex regulatory framework that did not serve sponsors' business needs. The Department further agrees that such regulatory complexity may have impeded the growth of the Registered Apprenticeship model by discouraging program uptake or expansion, and that revising and simplifying the part 30 regulation will lead to expansion of the model. As such, the Department's final rule streamlining the part 30 regulation serves the shared goals of the Department and this Administration to reduce regulatory burdens and expand Registered Apprenticeship. The Department also appreciates those commenters who acknowledged the alignment between this rulemaking and the Administration's deregulatory directive to Federal agencies (as outlined in E.O. 14192 and cited in the NPRM as a motivation for this rulemaking).

The Department disagrees with commenters who asserted that the existing part 30 regulation did not impose meaningful burdens on program sponsors. Several commenters pointed to the availability of templates, technical assistance, internal auditing systems, and established compliance practices as evidence that sponsors could readily comply with the regulation. The Department does not find these observations persuasive. The existence of specialized templates, extensive technical assistance, compliance personnel, internal auditing systems, and recurring reporting processes demonstrates that sponsors and Registration Agencies devoted substantial time and resources to

satisfying the regulation's requirements. The fact that sponsors may have developed systems to facilitate compliance over time does not establish that the underlying requirements were simple, costless, or necessary.

Moreover, the Department is concerned not only with the burden imposed on existing sponsors that have already invested in compliance systems, but also with the effect of these requirements on employers considering whether to establish a Registered Apprenticeship program in the first instance. The Department concludes that reducing apprenticeship-specific compliance obligations will lower barriers to entry and facilitate broader adoption of the Registered Apprenticeship model.

The Department also received comments from employers describing the time, administrative effort, and resources devoted to compliance with affirmative action plans, utilization analyses, reporting obligations, and related requirements under part 30. After considering these comments and the record as a whole, the Department has determined that these apprenticeship-specific requirements imposed significant compliance costs while providing limited benefits beyond those already afforded by generally applicable Federal and State nondiscrimination laws. The Department therefore concludes that rescinding these requirements is an appropriate means of reducing unnecessary regulatory burden while continuing to protect apprentices through existing nondiscrimination protections.

5. Growing Registered Apprenticeship

Expansion and Growth of Registered Apprenticeship Programs

Comments: A commenter maintained that the proposed rule lacks compelling evidence that it would lead to apprenticeship growth. Instead, this commenter suggested that, to significantly increase the number of apprentices, investments in apprenticeships would need to be of an order of magnitude higher, and that adjustments to the infrastructure through legislation, such as codifying OA and SAAs as registration entities, are needed to see growth in the program. The commenter added that the Department also should adopt more ambitious growth goals, stating that 1 million apprentices only would equate to 0.6 percent of the workforce, whereas the apprentice share of the workforce in peer countries like Canada, the United Kingdom, and Australia is roughly 2 percent. Another commenter noted that the growth in public investment has led to increased apprenticeship enrollments, as Federal investment nearly doubled between 2016 and 2020 resulting in a more than 40 percent increase in the number of apprentices.

A commenter recommended that the Department pursue evidence-based regulations to speed up and simplify the registration process, including streamlined cross-State reciprocity or expedited review for programs using high-quality occupational frameworks or national standards, reasoning that these would help expand apprenticeship and result in more effective use of public resources.

Another commenter opposed the proposed rule's description that the current regulations have limited adoption or participation, particularly among small businesses, citing personal site visits over the last 15 years showing no instances in which EEO or affirmative action requirements were reported as barriers, and over the last 3 years, the commenter said they have registered 12 new apprenticeship programs with over 200 apprentices without EEO being raised as a concern.

In contrast, a commenter supported the NPRM's statement that the costs and disincentives created by the current part 30 regulations may be greater in new and emerging industries, citing personal experience in the education sector where funding is limited (or not yet apportioned as part of existing budgets) to develop or register an existing apprenticeship program.

Additionally, a commenter expressed support for simplifying 29 CFR part 30 with Federal nondiscrimination laws, stating that the changes could ease the burden for small and medium sized businesses, but added that to meet the Administration's goal of adding 1 million new apprenticeships, sponsors would need continued guidance from OA on outreach efforts for recruiting populations not traditionally served in Registered Apprenticeship programs.

Several commenters commented in support of further growing Registered Apprenticeship and modernizing the system, citing research that employers receive a positive return on investment, that apprentices receive higher wage increases than comparable workers, and that employers report apprenticeships are effective at addressing talent shortages. A commenter said that the model is underutilized, and remarked that more can be done to modernize it to build capacity and ensure long-term resilience of mutual benefit to employers and apprentices and that the NPRM is a step towards accomplishing this goal.

Department Response: The Department agrees with the commenters that Registered Apprenticeship should continue to be expanded and that it is crucial in helping address workforce shortages. The Department anticipates that the removal of onerous and burdensome requirements, such as those that are rescinded under this final rule, should facilitate increases in system participation through burden reduction and lower barriers to entry.

The Department disagrees with commenters who asserted that this final rule's rescission of provisions of the existing regulation will harm the growth of the National Apprenticeship System and that these provisions were not onerous for small businesses. As discussed throughout this preamble and in greater depth within the sections on the rescission of the existing regulation, there is no robust causal evidence that the existing regulations led to the growth of the National Apprenticeship System. Based on its delivery of technical assistance to sponsors of various sizes (including small businesses), the Department expects that the reduction of compliance burdens associated with these rescissions will facilitate program creation and expansion.

Additionally, in response to the anecdote from a commenter that the sponsors the commenter worked with did not mention part 30 and EEO requirements as burdensome, other commenters who were sponsors themselves or represented sponsors responding to the NPRM did express that part 30 is burdensome. As a result, the Department concludes, and several commenters representing industry concurred, that the existing part 30 regulations are overly burdensome and thereby suppress, not expand, potential entities' participation in the National Apprenticeship System.

Regarding comments that suggested increased funding and the codification of the National Apprenticeship System as avenues to expand the model, the Department notes that Congress, not the Department, has the authority to pursue these activities. The Department also appreciates the suggestions to further streamline registration, such as improving reciprocity, and will consider these options if there are future rulemakings on part 29.

Recommendations for Improving Apprenticeship Programs

Comments: A commenter recommended the Department identify specific strategies to facilitate

involvement of non-profit organizations and Federal contractors and expand into new and emerging industries to achieve growth in apprenticeship programs.

Another commenter suggested that, to drive meaningful adoption, apprenticeship programs should be reframed with language and structures that align with how human resources professionals operate—prioritizing upskilling, reskilling, and internal mobility. This commenter further stated that they have an extensive network of human resources professionals, nationwide chapter system, and communication channels that could partner with the Department to help educate employers about apprenticeship regulations and work to expand Registered Apprenticeship programs.

Department Response: The Department appreciates these comments and suggestions, but deems them to be outside of the scope of this rulemaking insofar as they are unrelated to the Department' focus on streamlining and simplifying the nondiscrimination requirements related to apprenticeship.

G. Comments on the Proposal's Impacts on Women, Racial and Ethnic Minorities, and Individuals With Disabilities

1. Data and Research on Demographic Representation and Economic Factors in Apprenticeship

Comments: A couple of commenters suggested that empirical evidence shows that the part 30 regulation improved diversity within the apprenticeship system. For example, some commenters stated that women's participation in apprenticeship grew threefold over the last decade or so. One commenter noted that this increase in women's participation occurred after the Department implemented intentional investments to increase the number of women in apprenticeships. Several commenters provided evidence that showed, in their view, that this growth occurred in smaller sub-groups of apprentices as well. For example, one commenter asserted that between 2014 and 2023, the growth of women of color participating in apprenticeship was particularly strong. The commenter provided data from this time period that, according to the commenter, demonstrated that the number of Latina and Asian women apprentices grew by 349 and 302 percent respectively, while the number of Black women apprentices grew by 222 percent. The commenter added that the number of women working as apprentices in construction and extraction occupations increased from 3,789 in 2015 to 10,834 in 2024, representing a 185.9 percent change. Another commenter also noted that the gains in the share of Hispanic/Latino apprentices outpace gains in the share of Hispanic/Latinos in the total labor force. One commenter reasoned that these increases in representation demonstrate the success of current Federal regulations and feared the proposed rule's rescissions would reverse increases in diversity within the National Apprenticeship System. However, one commenter acknowledged that, while the National Apprenticeship System has diversified over the last decade, there is no clear evidence of a causal relationship between the issuance of the 2016 regulation and increases in participation rates among certain demographic groups.

Some commenters also stated that demographic groups targeted by the existing part 30 regulation are still underrepresented within the apprenticeship system. A commenter said that despite progress, women remain significantly underrepresented in apprenticeship programs, making up just 14.3 percent of apprentices according to the OA data, while comprising nearly half (47.1 percent) of the labor workforce. Similarly, another commenter noted that only 9 percent of apprentices are Black despite Black workers making up 12.3 percent of the national labor force. These commenters asserted that removing the existing part 30 regulations would further exacerbate current demographic imbalances in the representation of certain demographic groups in apprenticeship. One commenter further argued that reducing these disparities could expand the talent pool available to employers, and that apprenticeship programs would need to reflect the full diversity of the U.S. population to effectively meet employer needs. Another commenter argued that if equal access were ensured for women, people of color, and other historically excluded groups, apprenticeship programs would better fulfill the goal of providing opportunity for all workers.

However, a commenter that expressed support for the Department's proposed revisions to part 30 argued that demographic disparities between apprenticeship programs and the broader workforce should not justify race-preferential programs. This commenter argued that history and culture can explain why certain groups are more common in some jobs, rather than discrimination. The commenter also observed that national and ethnic groups are not evenly distributed across most occupations, including apprenticeship programs.

Several commenters also discussed lower wages and occupational segregation among women who are apprentices and within the broader economy and, said that rescinding elements of part 30 would harm economic gains by women within apprenticeship. For example, one commenter stated that when you compare the full-time annualized salary of female versus male apprentices based on median hourly wage rates, female apprentices only earn 63.4 percent of their male counterparts earnings. The commenter added that women's median hourly earnings were significantly lower than men's across all races and ethnicities and were lowest for Native Hawaiian or Pacific Islanders and Black women who completed an apprenticeship. Another commenter stated that women comprise over 80 percent of all nursing assistant apprentices whereas the most common apprenticeship field for men in 2023 was higher paying electrician occupations. The commenter attributed this discrepancy to a lack of proactive outreach and persistent discrimination towards women in apprenticeship. Other commenters similarly noted that non-White Apprentices—and non-White workers within the economy generally—earned lower wages and are in less lucrative occupations than their White counterparts and the proposed rescissions to part 30 would not address these differences and could worsen them.

Commenters also stated that there is ongoing discrimination within the broader economy and the National Apprenticeship System, citing research, documented instances of discrimination, and surveys regarding discrimination and harassment. For example, a commenter said that, contrary to the Department's position, racial disparities in employment and positions are the result of discriminatory practices rather than lack of skills or personal preferences, citing research showing that equally qualified Black workers remain at a disadvantage compared to White workers when trying to enter certain industries, and referencing a 2023 National Bureau of Economic Research study concluding that occupational segregation in the United States today is substantially higher than what would be expected in a race-neutral environment. The commenter added that other studies show that resumes with White-sounding names were 10 percent more likely to get chosen for an interview than resumes with Black-sounding names. Another commenter suggested that the

recent charges brought by the EEOC against apprenticeship programs and construction companies for sex and race discrimination is evidence that discrimination continues to be a rampant problem.

One commenter, who identified herself as a Black woman, described her experience as a second-year apprentice; she discussed being passed over for training in favor of a White, male, first-year apprentice, despite being told by their foreman and general foreman that they would receive training on the next stage of the project. Another commenter cited their own 2021 national survey of tradeswomen, which found that one in four female apprentices reported never or rarely being treated equally when it came to lay-offs and about one out of five reported never or rarely being treated equally in work assignments, OJL, or in hiring.

Additionally, some commenters discussed how discrimination can impact apprentices after they are enrolled in the program as well. For example, one commenter reasoned that discrimination in hiring and access to hours of work means it will take longer to reach the hours required for apprenticeship progression and completion, delaying access to higher rates of hourly pay. The commenter also said that discrimination in access to work assignments, tools, and OJL means that women may have acquired fewer skills during their apprenticeship, making it harder for them to compete for skilled trades opportunities after completion.

Finally, several commenters maintained that diversity benefits more than just minority groups, citing research stating that more diverse companies have higher average profits, higher rates of innovation, and report higher revenues from launching new products, and also record higher worker satisfaction and worker longevity rates. A commenter suggested diversity could therefore help reduce turnover and help address existing skills gaps within the construction industry. Another commenter cited reports emphasizing the importance of human capital development (including critical thinking, emotional intelligence, and cross-cultural competencies) and diversity, rather than technical efficiency, in national economic and individual corporate performance. Similarly, a commenter remarked that actively encouraging individuals of color to consider jobs in teaching is important because research has consistently shown that a diverse educator workforce results in improved academic performance for all students, and especially for students of color.

Department Response: The Department acknowledges certain commenters' use of demographic and economic data purporting to show the beneficial impact of diversity initiatives pertaining to apprenticeship. However, the Department fundamentally disagrees with the underlying premise advanced by several of these commenters: namely, that a central policy goal of the part 30 regulation should be to achieve and maintain a level of representation of certain groups in Registered Apprenticeship that mirrors the demographic prevalence of such groups in the broader labor force. Instead, in this final rule, the Department maintains that the central goal of the part 30 regulation must be the prohibition of all forms of illegal discrimination in Registered Apprenticeship.

As stated earlier in the preamble of this final rule, the Department asserts that compulsory, nonremedial, group-based preferences and affirmative action schemes are inherently discriminatory because they treat individuals differently based upon their race, sex, or ethnicity. Therefore, the use of data on the existence of demographic imbalances in the overall apprenticeship workforce to justify the indefinite continuation of affirmative action requirements runs counter to the Department's paramount goal of prohibiting all forms of illegal discrimination in Registered Apprenticeship. The Department reiterates its conviction that apprenticeship programs should be free to recruit, hire, and retain apprentices solely on the basis of merit, and without reference to an applicant's group identity, ancestry, or demographic characteristics.

The Department notes that commenters failed to provide any authoritative, persuasive, or conclusive evidence to support their assertions that the part 30 regulation has been effective in improving participation rates and outcomes for apprentices in certain demographic groups, or that the removal of part 30 requirements would lead to adverse impacts on apprentices or apprenticeship programs. While some commenters asserted that there have been meaningful gains in representation of certain groups in apprenticeship, other commenters maintained that demographic imbalances and issues of underrepresentation have persisted over the past decade. Some commenters also acknowledged that increases in representation of certain demographic groups could be tied to other factors unrelated to the part 30 regulations, including investments to expand apprenticeship, or broader labor market or economic trends. One commenter opposed to the elimination of the affirmative requirements acknowledged that there was no proof of a ''robust causal link'' between the part 30 regulation and any improvements in demographic representation in apprenticeship. As noted previously, the Department disagrees with the premise that a central policy goal of the part 30 regulation should be to achieve and maintain a level of representation of certain groups in Registered Apprenticeship that mirrors the demographic prevalence of such groups in the broader labor force. However, in order to be responsive to commenters, the Department reviewed its own apprenticeship data, labor market and economic data, and other resources to ascertain the impact of its proposal, and similarly did not identify any direct causal link between the part 30 regulation's requirements and increased representation of certain demographic groups in apprenticeship.

The Department has reviewed data on active apprentices across the prior two decades to assess changes in demographic representation in the National Apprenticeship System in developing this final rule.[36] An analysis of this data fails to demonstrate a direct correlation nor causal link between the updated affirmative action and EEO requirements in the 2016 version of the part 30 regulation and significant increases in representation of demographic groups in Registered Apprenticeship programs nationwide. From FY 2006 through FY 2015, the average annual growth rate in the total number of active apprentices was 2.3%, and from FY 2016 through FY 2025, the average annual growth rate in the total number of active apprentices was 7%. The average annual growth rate for women in Registered Apprenticeship from FY 2006 through–FY 2015 was 3.1%, and the average annual growth rate for women from FY 2016–FY 2025 was 12.3%. For Hispanic and Latino apprentices, average annual growth rates were 7.1% from FY 2006 through–FY 2015, and 11.1% from FY 2016 through–FY 2026. For African Americans, average annual growth rates were 3.7% from FY 2006–FY 2015 and 7.6% from FY 2016 through FY 2025. As discussed further below, increases in the representation of certain

[36] Data discussed in the following paragraphs are available to the public on OA's website, ''Apprenticeship—Data and Statistics,'' *https://www.apprenticeship.gov/data-and-statistics.*

demographic groups in Registered Apprenticeship programs may be attributable to increases in demographic representation in certain occupations or industries outside of the Registered Apprenticeship context, increases in Federal funding to support apprenticeship expansion, or other labor markets factors and trends. The Department does not agree with commenters who posited that the part 30 regulation's requirements, such as the affirmative action program or EEO requirements established in the 2016 regulation, directly caused increases seen in representation of certain demographic groups in Registered Apprenticeship programs.

It is important to consider a comprehensive analysis of labor market trends, both within and outside Registered Apprenticeship, in assessing the impact of the part 30 regulation on representation of certain demographic groups in Registered Apprenticeship programs over the past two decades. As mentioned earlier, across this time frame, Registered Apprenticeship has expanded and evolved from a training model primarily used in the skilled trades to include more occupations, industries, and economic sectors. Two key growth areas for Registered Apprenticeship are the information technology and healthcare sectors; Registered Apprenticeship programs in the information technology sector grew from 20 programs in FY 2016 to 132 programs in 2025, while programs in healthcare grew from 533 programs in FY 2016 to 1,170 programs in 2025. Meanwhile, women's overall representation in the workforce in those two sectors has increased substantially in recent decades. The share of women in the information technology workforce has grown from a baseline of around 9% in the early 2000s to around 23% of today's information technology workforce in the United States.[37] The growth of women's participation in the healthcare workforce is even more striking. Based on data from the American Community Survey, a study from the U.S. Census Bureau reported that women have driven 80% of labor force growth in the healthcare sector since the early 2000s, with the number of full-time women in health care occupations nearly doubling from around 5 million employees in 2000 to around 9 million employees in 2019.[38]

These examples of broader demographic trends in the labor market demonstrate that it is not possible to conclusively attribute any growth in the representation of certain demographic groups in Registered Apprenticeship to the affirmative action provisions of the part 30 regulation. The slight increases in representation of certain demographic groups over the prior two decades corresponds with an overall increase in the average annual growth rate for all apprentices, and also could be attributable, in part, to the expansion of the model into new industries (outside of construction and the skilled trades), such as information technology and healthcare. In addition, overall increases in apprenticeship numbers and the slight increases in representation of certain demographic groups coincides with the introduction of increased, sustained Federal funding to support Registered Apprenticeship growth.

In summary, several of the commenters who supported the retention of the affirmative action provisions found in the 2016 version of the part 30 posited or inferred a correlation between the compulsory regime of group-based preferences contained in the regulation and increases in the demographic representation of certain groups (particularly women and Latinos) in Registered Apprenticeship programs that occurred after the issuance of that rule. In addressing such comments, the Department reiterates its firm commitment to the principle that individuals from all backgrounds—regardless of their race, ethnicity, sex, religion, or national origin—must be afforded the opportunity to compete on an equal, nondiscriminatory basis for admission into a Registered Apprenticeship program, and that apprentices must be selected and hired by program sponsors on the basis of their qualifications alone. Furthermore, as one commenter acknowledged, the available demographic data does not provide sufficient evidence of a ''robust causal link'' between the affirmative action requirements of the part 30 regulation and the subsequent increase in the representation of discrete groups in Registered Apprenticeship programs.

Some commenters offered assertions positing a direct correlation between certain economic outcomes and benefits and the increased participation of underrepresented groups in apprenticeship, such as improved profits, greater innovation, higher wages, and improved worker satisfaction and longevity. The Department maintains that not only are these supposed correlations unsubstantiated, they do not alter the Department's conviction that affirmative action requirements induce sponsors to treat individuals differently based on demographic characteristics and are therefore inherently discriminatory.

The Department acknowledges the concerns raised by commenters that, over time, illegal discrimination has persisted in both the broader labor market and in Registered Apprenticeship. As stated earlier, the Department's primary focus with this final rule is to clarify and strengthen the nondiscrimination requirement for Registered Apprenticeship in the part 30 regulation. In eliminating a duplicative, apprenticeship-specific regulatory framework for resolving issues related to discrimination, apprentices will better understand how to obtain individualized relief (which the existing part 30 regulation fails to provide). The Department maintains that establishing a stronger and more streamlined nondiscrimination framework in the revised part 30 regulation better aligns with the Department's mandate to protect apprentice welfare under the NAA.

Other Recommendations Related to Women in Apprenticeship

Comments: A commenter stated that equitable pathways into the construction trades are sorely needed, particularly given recent legislation that provides significant investment in the Nation's infrastructure and economy. The commenter mentioned the Infrastructure Investment and Jobs Act (IIJA), the CHIPS and Science Act, and the Inflation Reduction Act as bills that would create jobs, rebuild infrastructure, and increase economic competitiveness. The commenter argued that removing equal opportunity provisions from regulations that impact Registered Apprenticeship programs—a primary pathway into the construction trades—is a move in the wrong direction.

Department Response: The Department takes the position that the investments advanced in other Federal legislation, including the IIJA, the CHIPS and Science Act, or the Inflation Reduction Act, and their potential labor market impacts, have no bearing on the Department's decision to include a streamlined nondiscrimination standard for Registered Apprenticeship in this final rule.

[37] WomenTech Network, ''Women in Tech Stats 2026: Uncovering Trends and Unseen Data by WomenTech Network,'' *https://www.womentech.net/women-in-tech-stats* (last visited June 26, 2026).

[38] Jennifer Cheeseman Day and Cheridan Christnacht, ''Women Hold 76% of all Health Care Jobs, Gaining in Higher-Paying Occupations,'' U.S. Census Bureau, Aug. 14, 2019, *https://www.census.gov/library/stories/2019/08/your-health-care-in-womens-hands.html.*

The Department maintains that Registered Apprenticeship opportunities will be more accessible to all qualified individuals regardless of their demographic background under this final rule, because sponsors will no longer be subject to onerous regulatory mandates regarding the recruitment and hiring of apprentices based on demographic characteristics.

The Department disagrees with the commenter's assertion that the final rule is a step backwards and maintains that this final rule is an important step forward in making economic opportunities more accessible for all individuals. Equal opportunity does not depend on maintaining race- or sex-based affirmative-action requirements. The final rule preserves robust nondiscrimination protections while removing requirements that encourage sponsors to make decisions based on demographic characteristics. The Department believes apprenticeship opportunities are most accessible when all individuals compete under a uniform merit-based framework.

V. Section-by-Section Analysis of the Final Rule—Rescissions of Current Part 30

A. Rescission of Equal Opportunity Standards for All Sponsors

In the NPRM, the Department proposed to remove a number of requirements that the 2016 version of the part 30 regulation had applied to all program sponsors, regardless of size; these mandates included, among other things, the internal dissemination of a sponsor's equal opportunity policy, the sponsor's ongoing maintenance of a list of current recruitment sources for apprentices, the sponsor's provision of anti-harassment training to apprentices and journeyworkers who work with apprentices, and the sponsor's establishment of a procedure for handling and resolving complaints involving such harassment. After due consideration of the comments received concerning the proposed removal of these requirements, the Department has determined to rescind these previous part 30 mandates in this final rule.

Comments: A commenter said that by revising 29 CFR 30.3 to direct program sponsors to comply with all applicable Federal and State laws and regulations prohibiting illegal discrimination, the proposed rule would relieve sponsors from establishing or undertaking a complex array of goals, analyses, outreach, and annual reviews. More specifically, the commenter also expressed support for removing the requirement to establish an EEO coordinator.

A commenter supported the simplification and streamlining of the existing nondiscrimination regulations into one standard, stating that the protected bases in proposed § 30.3 mirror the bases protected by civil rights laws passed by Congress and enforced by the EEOC—Title VII of the Act, the ADEA, the Genetic Information Nondiscrimination Act of 2008, and the ADA. The commenter added that, unlike the revised version of part 30 contained in this final rule, the content of § 30.3 overreaches by imposing nondiscrimination requirements not found in the text of statutes passed by Congress, such as requiring nondiscrimination on the basis of sexual orientation and gender identity.

However, several other commenters expressed strong opposition to the rescission of the foregoing provisions of § 30.3. One commenter opposing the rescission maintained that the equal opportunity pledge, the assignment of a person responsible for EEO, and information sessions on EEO requirements remain necessary due to continued prevalence of harassment in Registered Apprenticeship programs, as well as the need to reiterate sponsors' commitment to EEO and communicate that commitment internally to all affected parties. Another commenter asserted that the proposed rule's rationale for rescinding these requirements does not consider the end goal of Registered Apprenticeship programs, which is to ensure that sponsors receive a return on investment, adding that where appropriate accommodations and support are not provided, programs see premature apprentice dropouts. A commenter remarked that Federal standards still matter because many sponsors operate in multiple States, and without a consistent Federal framework, employers may lower compliance across the board. Another commenter expressed concern that removing EEO requirements would make it difficult for programs to demonstrate compliance with civil rights laws and protect themselves from legal risk.

Department Response: The Department agrees with the commenter that characterized the requirements under existing § 30.3 as unnecessary and complex. Accordingly, the Department notes that it is maintaining a simpler and more streamlined Federal standard under this final rule through the new nondiscrimination standard contained in § 30.3 of this final rule. Additionally, and as described in greater detail below, sponsors covered by Federal nondiscrimination laws are already obligated to post a notice describing the protections afforded under Federal laws that prohibit job discrimination based on race, color, sex, national origin, religion, age (40 and older), equal pay, disability, or genetic information, and retaliation.

The Department recognizes that many sponsors may find EEO coordinators, anti-harassment training, internal complaint procedures, and similar practices useful. Nothing in this final rule prohibits sponsors from maintaining such programs. The Department has concluded, however, that these practices need not be mandated through a separate apprenticeship-specific regulatory regime because sponsors are already subject to Federal and State nondiscrimination laws and possess strong incentives to maintain workplaces free from unlawful discrimination and harassment. Sponsors remain free to adopt compliance structures they determine are appropriate for their workforce, operations, and legal obligations. To the extent commenters assert that such practices help sponsors demonstrate compliance with applicable civil-rights laws or reduce litigation risk, sponsors remain free to retain those practices under this final rule.

1. Assertions Made About Reduced EEO Protections

Comments: A commenter expressed concern that the practical effect of rolling back comprehensive EEO protections could be to limit remedies to address discrimination in apprenticeship programs. This commenter stated that the proposed rule incorrectly asserts that ''the protected characteristics contained in § 30.3(a) of the current part 30 are duplicative of the nondiscrimination requirements contained in a number of Federal civil rights statutes.'' The commenter argued that, consequently, the proposed rule fails to account for potential harms to apprentices, as well as resultant limitations to DOL's authority to remedy discrimination in apprenticeship programs because of this change. The commenter stated that ''by eliminating the longstanding prohibition on discrimination against apprentices based on certain protected characteristics . . . and instead aligning the regulation with existing civil rights laws applicable in the private sector, the Proposed Rule adopts the small employer carveouts of these civil rights laws.'' The commenter asserted this would limit the coverage of nondiscrimination requirements and

eliminate the authority of the Department to take enforcement action against small employer sponsors who engage in discrimination.

A commenter opined that, contrary to the Department's assertion in the NPRM, the current part 30 regulations do not duplicate Title VII, and instead go well beyond Title VII in providing substantive protections from discrimination and mechanisms for preventing discrimination. Specifically, unlike 29 CFR part 30, this commenter asserted that Title VII likely does not apply to all program sponsors, or to all of the apprenticeship activities of sponsors. The commenter noted that Title VII applies to employment discrimination by ''employers, labor unions, and joint labor-management committees controlling apprenticeship or other training or retraining, including on-the-job training programs,'' and makes it unlawful for such entities ''to discriminate against any individual because of his race, color, religion, sex, or national origin in admission to, or employment in, any program established to provide apprenticeship or other training.'' In contrast, the commenter said 29 CFR part 30 applies to ''sponsors of apprenticeship programs registered with either DOL or a recognized SAA.'' The commenter noted that sponsors are responsible for not only for overseeing admission to and employment in training programs, but also a wide range of other activities, and it is unclear whether Title VII would cover the full scope of activities that sponsors engage in. Another commenter expressed concern that removing these EEO requirements would make it difficult for programs to demonstrate compliance with civil rights laws and protect themselves from legal risk.

Department Response: In response to some commenters' concerns surrounding protected characteristics, the Department notes that covered apprentices are protected from discrimination on the bases of all the same protected characteristics as under existing § 30.3(a) through the following Federal statutes or precedent set by Supreme Court cases interpreting them: Title VII of the Act, the ADEA, the ADA, and the Genetic Information Nondiscrimination Act of 2008.

In response to concerns raised by certain commenters about the statutory thresholds excluding small employers from coverage under Title VII and other Federal nondiscrimination laws, the Department notes that Congress purposefully excluded small employers from these statutory nondiscrimination requirements. The application of nondiscrimination requirements to private employers is fundamentally a matter of legislative judgment. In statutes ranging from Title VII to the ADA and ADEA, Congress made explicit policy determinations regarding which employers should be subject to Federal nondiscrimination requirements and which should be exempt. Congress repeatedly chose not to extend those statutory obligations to certain smaller employers, reflecting a legislative balancing of the benefits of nondiscrimination regulation against the burdens such requirements impose on small businesses.

The Department declines to exercise its authority under the NAA in a manner that effectively subjects small employers to regulatory obligations that Congress expressly determined should not apply to them. The Department believes that the better exercise of its authority is to respect the coverage determinations embodied in Federal civil-rights statutes and to align apprenticeship requirements with the scope of those statutes rather than creating a separate apprenticeship-specific regime that expands their reach to small employers. Congress remains free to revise the coverage thresholds contained in those laws should it determine that broader coverage is warranted.

Moreover, the alignment of part 30 with the employee size-based exclusions contained in existing Federal nondiscrimination laws or relevant State nondiscrimination laws will reduce administrative burdens on certain program sponsors—particularly small- and medium-sized enterprises—that could inhibit the accelerated establishment and expansion of programs. As certain small entities that sponsor apprenticeship programs have been excluded from coverage by applicable Federal nondiscrimination laws such as Title VII, the Department should refrain from extending apprentice nondiscrimination protections on a broader basis than Congress expressly authorized under those statutes.

The Department defers to the EEOC or other relevant enforcement agencies in determining which employment practices of sponsors are covered under the various civil rights statutes. The Department notes, however, that courts have interpreted Title VII's training program provision at section 703(d) to cover more than mere ''admission to'' such programs, contrary to the commenter's assertion. *See, e.g., Langford* v. *Int'l Union of Operating Eng'rs, Loc. 30,* 765 F. Supp. 2d 486, 499 n.6 (S.D.N.Y. 2011) (acknowledging that section 703(d) of Title VII provides a valid basis for a hostile work environment claim); *Herrera* v. *Int'l Brotherhood of Electrical Workers, Local No. 68,* 228 F. Supp. 2d 1233, 1242 (D.Colo. 2002) (stating that ''[t]he plain language of [section 703(d)] prohibits sex discrimination against an individual who is 'employed in' an apprenticeship training program'' and citing to 29 CFR 30.1 as providing similar protections).

The Department maintains that, under the final rule, the Department retains the authority to deregister an apprenticeship program in instances where there has been a finding of discrimination by a governmental agency or a court made pursuant to applicable statutory standards. In response to those commenters that expressed concern about the Department losing authority to issue individual remedies under the final rule, the Department notes that the existing part 30 does not offer individualized remedies for apprentices who suffer employment discrimination based upon their race, sex, or ethnicity, but only provides for the issuance of program-level sanctions such as deregistration. Under existing part 30, individual apprentices seeking make-whole remedies are free to pursue rights of action under other statutes such as Title VII. With respect to the steps that existing part 30 prescribes to prevent discrimination, the Department acknowledges that these steps are not required under Title VII. Removing these excessive requirements is, again, in line with the goals of this Administration and with Congressional intent in enacting Title VII. Sponsors are, however, encouraged to continue adopting any lawful preventative measures that they find effective. The Department will simply not dictate the specific measures a program must take to do so.

2. Alternative Approaches and Questions About the Proposed Changes

Comments: A commenter asked if, under the proposed rule, existing programs in SAA States would be permitted to continue using their current processes and procedures, as long as they are in compliance with applicable Federal and State nondiscrimination laws. Another commenter raised a question regarding whether, in those instances where a program operating in an SAA State experiences an increase in diversity in race or sex demographics, such a program would be considered out of compliance, or presumed to be out of compliance, with the proposed rule.

A commenter recommended establishing a simplified set of

requirements in the final rule to preserve accountability while reducing compliance complexity. The commenter recommended requiring sponsors to inform apprentices of their rights in writing, and requiring sponsors to affirm, in writing, that they will follow all relevant Federal and State nondiscrimination laws. The commenter also recommended that sponsors conduct universal outreach and employ facially neutral selection procedures to the extent possible. The commenter further recommended that the Department take certain actions to clarify compliance requirements, including integrating a review of nondiscrimination compliance into a sponsor's basic program oversight, and clarifying that youth apprenticeship programs do not violate nondiscrimination laws.

Another commenter recommended that the Department continue to consider measures to lower administrative burdens and provide incentives to participate in apprenticeship, including creating a system that promotes flexible program models that contain the most essential components of apprenticeship, and incentivizing organizations, like local industry associations, to serve as intermediaries. The commenter also recommended expanding financial incentives, such as apprentice wage reimbursement, and allowing more efficient and effective delivery of programming, including by removing the apprenticeable occupations framework.

Department Response: In response to questions posed by a commenter, and as described in § 30.5 of this final rule, a Registered Apprenticeship program only will be deregistered if there is a final determination made by an enforcement entity or court that the program has violated an applicable nondiscrimination law and the Registration Agency determines that a compliance action plan is not being implemented in accordance with the remedy prescribed by the enforcement entity or court. Accordingly, programs will not be deregistered for continuing to conduct their current activities or if their program experiences increased diversity so long as the program has not violated any applicable Federal or State nondiscrimination laws.

With respect to the commenter that suggested the inclusion of a provision in this final rule that a sponsor affirm in writing that they are in compliance with all applicable Federal and State employment nondiscrimination laws and will utilize facially neutral selection procedures, the Department takes the position that such written affirmations are unnecessary and would not necessarily enhance program accountability, as such obligations are already mandated under applicable Federal nondiscrimination laws. Nothing in this final rule prohibits sponsors from voluntarily providing written notices regarding apprentice rights, obtaining written acknowledgments or certifications from program participants, or adopting other compliance measures that sponsors determine are appropriate for their operations. Although the Department declines to mandate such practices through part 30, sponsors remain free to maintain them if they believe they assist with compliance, workforce management, apprentice retention, or risk mitigation.

Similarly, this commenter's recommendation that sponsors inform apprentices of their part 30 rights in writing is redundant, as employers with 15 or more employees that sponsor Registered Apprenticeship programs are already obligated to post a notice describing the Federal laws prohibiting job discrimination based on race, color, sex, national origin, religion, age (40 and older), equal pay, disability or genetic information, and retaliation. Title VII of the Act imposes a monetary penalty for covered employers who fail to post these notices. The ''Know Your Rights: Workplace Discrimination is Illegal'' poster, prepared by the EEOC, summarizes these laws and explains how employees or applicants can file a complaint if they believe that they have experienced discrimination.

The Department also declines to adopt this commenter's suggestion that the part 30 regulation should clarify that youth apprenticeship programs do not violate nondiscrimination laws, as such a determination should be made by the EEOC. In response to the other comments summarized above, the Department notes that the thoughtful suggestions advanced by these commenters for taking non-regulatory measures to reduce administrative burdens on program sponsors and to provide financial incentives to apprenticeship stakeholders fall outside of the scope of the part 30 rulemaking initiative; accordingly, as this final rule does not constitute a suitable regulatory or policy vehicle for addressing such suggestions, the Department refrains from providing a response to these commenters.

B. Rescission of Affirmative Action Requirements

1. Affirmative Action Programs (§ 30.4)

In the NPRM, the Department explained that existing § 30.4 required non-exempt sponsors to establish affirmative action programs, document them in a written plan, and implement components specified in §§ 30.4 through 30.9 and 30.11. These compulsory, nonremedial, and ongoing sponsor requirements included conducting demographic utilization analyses, and setting numerical hiring goals and undertaking targeted outreach, recruitment, and retention activities where apprenticeship workforce underutilization based on race, sex, and ethnicity was determined to exist. These sponsor requirements also included annually reviewing personnel processes, as well as disability-related obligations, such as tracking progress toward an OA established utilization goal and inviting apprenticeship applicants to self-identify as individuals with disabilities. The NPRM articulated the Department's position that, taken together, these affirmative action program requirements across §§ 30.4 through 30.9 and 30.11 are unduly burdensome and legally questionable. In the NPRM, the Department also solicited comments from all interested parties, including Registered Apprenticeship stakeholders, on its proposal to remove the affirmative action requirements from part 30, and invited public input on how the administrative burdens associated with these regulatory mandates affected program operations or decisions to participate in Registered Apprenticeship.

After due consideration of the comments discussed below, the Department has determined, as proposed in the NPRM, to rescind the requirements set forth in §§ 30.4 through 30.9 and 30.11 in this final rule.

Comments: A commenter expressed its appreciation for the Department's observation in the NPRM that the current part 30 requirements have limited, rather than promoted, apprenticeship opportunities without corresponding gains in program effectiveness or integrity. The commenter asserted that simplifying sponsors' EEO obligations would better achieve the Secretary of Labor's obligations under the NAA and promote expansion of Registered Apprenticeship programs, which the commenter asserted would expand opportunities for women, minorities, and underrepresented groups to enter and succeed in the construction trades. The commenter specifically supported

rescinding the affirmative action program requirements, which the commenter described as burdensome. The commenter stated that currently, these plans must be updated annually, even when there are no material changes in workforce composition or recruitment practices, and that sponsors must maintain detailed records related to these affirmative action programs because they are subject to records requests and audits. Another commenter reiterated its previous objections (expressed at the time of the 2016 part 30 rulemaking) to the affirmative action program requirements that were imposed on small programs under § 30.4, and generally supported eliminating such requirements. In particular, the commenter asserted that affirmative action program requirements were difficult for nonunion program sponsors to implement.

Another commenter critiqued the existing part 30 regulation's affirmative action requirements, stating such requirements are based on the fundamentally flawed and abstract premise that any demographic disparities in a sponsor's or employer's workforce constitute *per se* discrimination. This commenter argued that there could be nondiscriminatory reasons why the demographic makeup of a given workforce may not mirror the demographic makeup of the local labor market, and that disparities alone without evidence of actual disparate treatment should not be used as a proxy for unlawful discrimination. The commenter further asserted that the part 30 regulation simultaneously prohibits discrimination while incentivizing and inducing disparate treatment of applicants through utilization analysis, utilization goals, and targeted outreach. According to the commenter, such disparate treatment is not supported by the text of neither the NAA nor Federal nondiscrimination laws, and that in *Ames,* the Supreme Court unanimously held that ''the standard for proving disparate treatment under Title VII does not vary based on whether or not the plaintiff is a member of a majority group.''

Another commenter expressed their support for the Department's proposal, stating that the affirmative action program provisions contained in part 30 and the related emphasis on achieving particular demographic results are ''in tension with the 1963 prohibition on discrimination.'' The commenter argued that the emphasis on ''numbers for their own sake'' in the development of apprenticeship affirmative action programs encourages employers to focus on tailoring their hiring practices to achieve the numerical goals mandated by the part 30 regulation, rather than on identifying and eliminating actual discrimination.

However, the Department also received some comments opposing the proposed rescission of the affirmative action provisions contained in part 30. A commenter maintained that the nondiscrimination protections contained in Title VII are not an adequate substitute for the affirmative action measures required by part 30, and supported the Department's prior analysis (contained in the preamble to the 2016 version of the part 30 final rule) that such measures are necessary because of the ''residual impact of longstanding discrimination.'' The commenter asserted that such active measures can be successful, as illustrated by another statement from the Department in the preamble to the 2016 part 30 final rule that ''women do participate and succeed in apprenticeship programs at higher levels when provided equal opportunity and support.'' The commenter discussed a survey which, according to the commenter, illustrates that diversity goals are key contributors to tradeswomen's success in their occupations. The commenter concluded that the Department could make these active requirements less burdensome without eliminating them entirely.

Similarly, another commenter cited surveys showing that only a small percentage of apprentices and females working in manufacturing trades were directed toward their career by a school counselor or an American Job Center. The commenter concluded that in the absence of systematic outreach, many women may miss out on the opportunities presented by apprenticeships in high-paying fields, and employers would lose out because they only would access a very incomplete talent pool.

A commenter criticized the Department's assertion in the NPRM that the current regulation ''has not demonstrated clear benefits in terms of improved protections against unlawful discrimination for apprentices.'' This commenter maintained that the outreach and affirmative action tools and mandates contained in part 30 have added value for program sponsors seeking new talent. The commenter said that 36.5 percent of States identify the ''challenge of recruiting qualified applicants'' as a barrier to apprenticeship expansion. The commenter added that firms have indicated that some of the best practices for meeting labor shortages include setting realistic goals for inclusion and diversity, regularly evaluating the status of those goals, and adjusting appropriately to meet them, arguing that these are all tenets of affirmative action plans. The commenter also provided examples of successful efforts to expand diversity in apprenticeships, including a program in Massachusetts where the proportion of women in construction apprenticeships grew by over 200 percent across a 5-year period thanks to partnerships among job training providers, firms, developers, community organizations, and local government. The commenter further asserted that affirmative action practices can be valuable to new apprenticeship industries, citing that 90 percent of hiring managers in information technologies consistently report difficulties in finding and hiring talent, and 83 percent report that this worker shortage is slowing company revenue growth.

Department Response: After considering these comments, the Department remains convinced that the affirmative action requirements contained in the existing part 30 regulation effectively undermined genuine equality of opportunity for apprentices and candidates for apprenticeship, imposed excessive administrative burdens on program sponsors, and may effectively induce such program sponsors to engage in discriminatory and illegal employment practices. The existing part 30 regulation requires outreach initiatives and incentivizes hiring decisions based not upon the merits or qualifications of individual candidates, but rather upon a candidate's race, sex, and ethnicity. By abandoning this divisive and pernicious framework in this final rule, the Department is seeking to maximize apprenticeship opportunities for qualified individuals from all backgrounds, irrespective of a person's race, sex, ethnicity, national origin, disability status, or religion.

The Department also asserts that this final rule will ease the administrative burden on sponsors generally, and particularly on those smaller sponsors that have five or more apprentices but that may not possess the resources or personnel needed to conduct the complex workforce demographic analyses required under the current part 30. Similarly, the Department acknowledges one commenter's assertion that these requirements posed particular implementation challenges for non-joint group programs that do not exert close control over the hiring process for employers participating in the program. (See *Associated Builders & Contractors, Inc. Baltimore Metro.*

Chapter v. *O'Connor,* 75 F. Supp. 2d 440, 441 n.3 (D. Md. 1999) (''[N]onjoint' refers to apprenticeship programs without any participation by labor interests.'')). The Department asserts that all programs will benefit from the removal of these burdensome affirmative action requirements and this final rule's emphasis on alignment with existing, congressionally enacted nondiscrimination law.

To the extent certain outreach efforts have been helpful to sponsors, sponsors may continue to engage in such efforts as part of a broad, nondiscriminatory outreach program to all qualified individuals (regardless of their race, sex, or ethnicity). Eliminating specific, inflexible targeted outreach requirements that go beyond complying with nondiscrimination law, and that focused on recruiting from only a limited, ''underutilized'' applicant pool, will reduce burdens on sponsors by enabling them to conduct outreach and recruitment in whatever lawful way they deem makes the most sense for their program. The Department is simply rescinding the one-size-fits-all approach that was imposed upon sponsors in the 2016 version of the part 30 rule. Additionally, eliminating the requirement for covered sponsors to maintain race-, sex-, and ethnicity-based affirmative action programs removes unlawful pressure on sponsors to recruit and hire apprentices from specific demographic groups, and also eliminates potential confusion and conflict with operating under various State law interpretations of nondiscrimination requirements. *See, e.g.,* Tex. Att'y Gen. Op. No. KP–0505 (2026) (re: ''Diversity, Equity, and Inclusion'' in Texas); Op. Att'y Gen. Fla.2026–02 (2026) (''Attorney General Opinion: State Laws Requiring Racial Discrimination are Unconstitutional'').

In summary, the Department encourages program sponsors to promote genuine equality of opportunity for all apprentices and applicants for apprenticeship in any lawful manner and, under this final rule, will hold accountable those programs found to have engaged in unlawful discrimination.

2. Utilization Analysis for Race, Sex, and Ethnicity (§ 30.5) and Establishment of Utilization Goals for Race, Sex, and Ethnicity (§ 30.6)

Existing § 30.5 requires those sponsors maintaining affirmative action programs to evaluate and analyze the demographic composition of their apprenticeship workforce by race, sex, and ethnicity, and to compare the representation of those groups in their workforce with the availability of those populations within the sponsor's relevant recruitment area. After conducting this analysis, if the sponsor determines that the representation of women, Hispanics or Latinos, or a specific racial minority group in their apprenticeship workforce is significantly lower than what would be reasonably anticipated, the sponsor is obligated to establish a utilization goal for the underrepresented group in accordance with § 30.6. Pursuant to § 30.6, that utilization goal must be ''at least equal to the availability'' of the underutilized group in the relevant recruitment area.

As previously discussed, the Department remains convinced that the foregoing part 30 provisions, which have required programs to analyze and to calibrate the racial, sex, and ethnic composition of their apprenticeship workforces, effectively conflict with the express Congressional prohibition on the mandatory conduct of such utilization analyses contained in section 703(j) of the Act, and also confront the sponsors of apprenticeship programs with insoluble practical and legal dilemmas. Despite the admonitory language at § 30.6(d)(2) of the part 30 regulation stipulating that the establishment of utilization goals ''may not provide a sponsor with a justification to extend a preference to any individual, select an individual, or adversely affect an individual's status as an apprentice, on the basis of that person's race, sex, or ethnicity,'' the regulation's compulsory imposition of such goal-setting upon certain sponsors may nevertheless induce those sponsors to engage in unlawful race- and sex-based apprenticeship hiring decisions in order to avoid the prospect of adverse administrative actions or sanctions by the Department (including program deregistration). As discussed earlier in the preamble, the contradictory and incoherent regulatory mandates in part 30 that simultaneously impose nondiscrimination and affirmative action requirements upon Registered Apprenticeship programs are plainly irreconcilable, contravene the fundamental policy objectives expressed in landmark Federal employment nondiscrimination statutes enacted by Congress (such as Title VII), and effectively induce sponsors to engage in impermissible group-based discrimination in the hiring and employment of apprentices based upon their race, sex, and ethnicity.

From a constitutional standpoint, the Supreme Court's recent decision in *SFFA* makes clear that race-based selection decisions would be subject to exacting scrutiny; a system of apprenticeship that codifies and incentivizes such improper preferences would likely not withstand legal scrutiny. The relevant inquiry is whether the regulatory scheme encourages, induces, or effectively requires employment decisions because of race. *See Anderson* v. *Martin,* 375 U.S. 399, 402 (1964). Where such pressure exists, courts treat the regulatory framework itself as a racial classification subject to strict scrutiny. *Lutheran Church,* 141 F.3d at 352–53; *MD/DC/DE Broadcasters Ass'n,* 236 F.3d at 19–20. And that is precisely what the regulatory framework does. Similarly, while intermediate scrutiny is less demanding than strict scrutiny, the Department also concludes that the sex-based affirmative action requirements of the existing part 30 raise serious constitutional concerns and are unlikely to survive constitutional scrutiny.

Additionally, the Supreme Court's recent decisions in *Ames* v. *Ohio,* 605 U.S. 303 (2025), and *Muldrow* v. *St. Louis,* 601 U.S. 346 (2024) increase the likelihood that such affirmative action policies could be challenged by clarifying that the standard for proving disparate treatment under Title VII does not vary based on whether or not the plaintiff is a member of a majority group and that plaintiffs need only demonstrate that they suffered ''some harm'' in relation to an allegation of unlawful discrimination in employment (such as being adversely impacted by an employer's affirmative action policy).

After due consideration of the comments received concerning these part 30 provisions, as well as the administrative burden and legal vulnerability concerns identified above, the Department has decided to rescind, in this final rule, the foregoing part 30 affirmative action-related provisions that required sponsors to conduct a utilization analysis that takes into account the race, sex, and ethnicity of the apprentices enrolled in their programs, and to set utilization goals to address and rectify any group-based demographic imbalances revealed by such an analysis.

Comments: Several commenters expressed support for the Department's proposal to rescind the requirement that sponsors with five or more apprentices conduct utilization analyses of their apprenticeship workforces. One commenter stated that their organization's members characterized these utilization analysis requirements as ''confusing,'' ''very expensive,'' and ''onerous.'' Another commenter stated that the Department's proposed revision of part 30 would appropriately

eliminate the mandate for program sponsors to adopt separate affirmative action programs in favor of aligning compliance requirements with existing Federal and State laws prohibiting discrimination. This commenter reasoned that by focusing on compliance with established nondiscrimination laws, the proposed revisions eliminate costly and duplicative requirements. The commenter added that sponsors would be able to apply existing equal employment frameworks—already in place for their broader workforce—to apprenticeship programs. The commenter concluded that this would lead to an increase in sponsorship opportunities.

However, several other commenters expressed their opposition to the Department's proposed rescission of the utilization analysis requirement. One commenter claimed that eliminating the utilization analyses would make it more difficult for sponsors to identify disparities in their workforces and determine if they are complying with nondiscrimination law. The commenter maintained that the § 30.5 analysis should be retained to help sponsors avoid litigation risks because it is a proactive version of the burden of proof required by the courts in disparate impact cases; the commenter conceded, however, that part 30's utilization analysis does not require sponsors to identify the cause of any disparity as would be required in a disparate impact case. Finally, this commenter opined that existing legal remedies under nondiscrimination law ''are merely reactionary to incidents of discrimination'' and therefore a framework of ''proactive'' affirmative action policies, such as those outlined in §§ 30.5 through 30.10 of the 2016 part 30 regulation, are necessary to sustain ''the increased diversity of the apprenticeship workforce.''

A commenter stated that, in the NPRM, the Department misconstrued the utilization analysis provision, arguing that it is only intended to establish a benchmark to determine whether barriers to equal opportunity may exist, not to establish discrimination. The commenter added that a sponsor's determination that a utilization goal is required does not constitute a finding or admission of discrimination, and that the current regulation is carefully tailored to ensure that the availability analysis excludes nondiscriminatory factors that may explain differences between the two. The commenter further noted that sponsors are only required to establish goals when there is a ''significant disparity'' in a ''Major Occupation'' and that only 25 percent of programs are large enough to be subject to the utilization goal-setting requirement.

A group of commenters similarly stated that the Department's proposal to rescind the existing utilization goals for race, sex, and ethnicity is problematic because the proposed rule rests largely on speculation that the program provisions ''may induce'' or ''incentivize'' sponsors to engage in illegal race- or sex-based decision-making in selection decisions, even though making selection decisions based on race and sex violates existing regulations.

Department Response: The Department agrees with the comment describing the utilization analyses as confusing and onerous. Indeed, in the 2016 final rule, the Department received some comments from sponsors expressing confusion over how to complete the analyses. In response, the Department committed to working ''closely with each sponsor at its regular compliance reviews to develop and conduct an availability analysis and to set or reassess utilization goals for race, sex, and ethnicity, if necessary.'' 81 FR 92057 (Dec. 19, 2016). The Department has determined that conducting these analyses has been overly time-consuming for both sponsors and Registration Agency staff and therefore it will now devote its limited resources to more effective solutions. Maintaining §§ 30.5 and 30.6 without devoting substantial staff support only would increase the burden on sponsors in completing the analyses—a burden that the Department concludes is no longer justified or supportable.

In response to the commenter expressing concern that sponsors will not have the ability to monitor their compliance with nondiscrimination laws in the absence of the current requirements of § 30.5, the Department echoes the point made by another commenter that the utilization analyses were never intended to serve as indicators of unlawful discrimination. In fact, § 30.6(b) made clear that ''[a] sponsor's determination under § 30.5 that a utilization goal is required constitutes neither a finding nor an admission of discrimination.'' The Department therefore rejects the commenter's contention that ''[i]t is exactly the means to prove such a claim of discrimination that the Proposed Rule seeks to end.''

While the goal-setting process required by current § 30.6 and a claim of disparate-impact discrimination both rely on statistical disparities, the analyses are not identical and cannot be used interchangeably. A determination as to whether discrimination exists requires an examination of personnel activity data such as hires, promotions, or terminations, and an analysis of the affected selection process, qualification requirements, positions at issue and the reasons for the sponsor's actions. Thus, the requirement that sponsors then set a race-, ethnicity-, or sex-based utilization goal is unrelated to the detection of discrimination. Furthermore, the Department never looked to the utilization analyses in assessing whether a sponsor had engaged in unlawful discrimination or harassment. Finally, such quota-like measures are illegal under section 703(a) of Title VII.[39]

However, sponsors are encouraged to continue taking any legal steps that they find helpful in assessing their programs to prevent unlawful discrimination. And, pursuant to proposed § 30.5, the Department will continue to have the authority to deregister programs for conducting illegal discrimination against apprentices, as determined by a relevant court or agency, and thereby safeguard the welfare of apprentices in Registered Apprenticeship programs. The Department maintains that, by eliminating confusing requirements regarding utilization analyses, Registered Apprenticeship will grow and create more opportunities for all workers.

In response to this commenter's concern that the remedies available to apprentices under current Federal civil rights statutes are essentially ''reactive'' and do not address workplace cultures that create ''barriers to entry'' for apprentices from certain groups, the Department again notes that these civil rights statutes provide apprentices with additional potential remedies, such as forms of individualized relief that are not available under part 30. As one commenter noted, only about 25 percent of sponsors are currently required to comply with the current affirmative action program provisions, thereby limiting any utility claimed by the commenters. Furthermore, sponsors may choose to employ lawful, race-neutral proactive means to remove barriers to entry in their programs, rather a compulsory, nonremedial regulatory regime of hiring preferences.

Comments on the Impact on Women and Underrepresented Groups in Apprenticeships

Comments: A commenter expressed concern that the proposed removal of utilization goals for race, sex, and

[39] 42 U.S.C. 2000e–2(a).

ethnicity in certain apprenticeship programs would have devastating consequences on women's participation in apprenticeships, particularly in higher paying fields where women are a small minority of apprentices. Another commenter asserted that eliminating these regulatory provisions could hinder individuals from certain underrepresented groups from gaining access to apprenticeship opportunities on an equal basis.

A commenter expressed opposition to the Department's proposed removal of utilization goals for race, sex, and ethnicity in apprenticeship programs. This commenter asserted that, because such goals are not quotas but rather benchmarks for measuring representation, they help sponsors to identify existing workforce gaps and disparities, and also help sponsors assess next steps to correct them. The commenter further asserted that eliminating these goals would undermine data-driven equity efforts and hinder progress for underrepresented groups in apprenticeship.

Department Response: The Department completely rejects the notion advanced by these commenters that the rescission of the provisions of the 2016 version of the part 30 regulation that mandated that certain program sponsors adopt preferential utilization goals based upon the race, sex, and ethnicity of apprentices will hinder individuals from these groups ''from accessing opportunities on an equal basis.'' The Department reiterates that this final rule's removal of the pernicious, group-based demographic analyses and affirmative action mandates that were contained in the previous version of part 30 is intended to reaffirm that *all* employment discrimination against apprentices based upon their race, color, religion, sex, or national origin is illegal, and that the use of group-based preferences to promote ''equity efforts'' for select populations is legally questionable and completely contrary to the policy thrust of Title VII. The Department also challenges the assertion made by one of these commenters that the rescission of these utilization goals would result in ''devastating consequences on women's participation in apprenticeships, particularly in higher paying fields where women are a small minority of apprentices.'' The Department fundamentally rejects the abstract and invidious notion that group-based outcomes, rather than demonstrated individual merit, should influence or determine whether a person should be admitted to a Registered Apprenticeship program.

Costs Associated With Rescinding Utilization Analysis and Goals for Race, Sex, and Ethnicity

Comments: A commenter opined that rescinding the utilization analysis requirements under § 30.5 would render the Department incapable of reviewing the rule's efficacy with respect to claims of harassment and discrimination. The commenter questioned how the Department would know if its claims of more effective relief for victims would come to fruition without tracking demographic data. The commenter stated that by failing to offer any solution to collect relevant demographic data or enforcement outcomes, the Department is skirting its responsibility to ensure the welfare of apprentices as mandated by Congress.

Department Response: The Department disagrees with this commenter's assertion that the final rule's removal of the demographic data collection requirements contained in the 2016 version of the part 30 regulation will harm the welfare of apprentices. If an individual apprentice believes that they have been harmed by an employer's or program sponsor's discriminatory or harassing conduct, that person may still have recourse under Title VII and other Federal and State nondiscrimination laws to file a complaint with the EEOC or a State's FEPA. As noted earlier in this preamble, 29 CFR part 30 has never provided individualized, make-whole remedies to apprentices or applicants who have been injured by such illegal conduct, while Title VII and other employment nondiscrimination laws do provide such potential individual relief. Contrary to the commenter's assertion, the Department maintains that the removal of these burdensome and cumbersome demographic data collection requirements—requirements that were imposed on sponsors primarily to support the onerous group-based preferences and affirmative action mandates contained in the 2016 version of part 30—will serve to accelerate apprenticeship growth and will enhance the welfare of apprentices by promoting the hiring of apprentices solely on the basis of individual merit. The Department also wishes to note that, pursuant to a technical amendment to 29 CFR 29.7(l) made by this final rule with respect to the required content of apprenticeship agreements, the Department will nevertheless retain the right to request demographic data regarding individual apprentices.

Alternative Approaches

Comments: A commenter stated that while the revision and elimination of numerical goals and requirements may simplify the registration process for new and existing program sponsors, the Department should replace these eliminated regulations with a focus on and investment in activities that support veterans, individuals with disabilities, and discouraged workers in accessing Registered Apprenticeship programs.

This commenter argued these requirements help programs reach diverse candidates, especially as apprenticeships expand beyond traditionally White and male-dominated trades. The commenter suggested an alternative approach that would maintain workforce analysis requirements without specific targets, which would help modernize the apprenticeship system while ensuring diverse representation.

Department Response: The Department notes that nothing in §§ 30.5 and 30.6 specifically addressed the employment of veterans or discouraged workers. Sponsors will remain free to engage in any lawful recruitment and retention efforts focused on these groups, particularly as targeted outreach to veterans and workers with disabilities does not raise the same legal concerns as doing so on the basis of race, ethnicity, or sex. And, as stated above, removing only the goals themselves, while still requiring a race-, ethnicity-, and sex-based utilization analysis would not fully address the Equal Protection concerns identified by the Department.

No alternative option would satisfy the Department's goals of aligning the regulations with recent court decisions regarding affirmative action if the regulation continued to improperly require that sponsors take race, sex, and ethnicity into account in evaluating their program's employment processes. Additionally, removing only the requirement to set goals themselves, while still requiring the collection of demographic data, the review of personnel processes, targeted outreach, and the invitation to identify as an individual with a disability would do very little to address the associated burden identified by several commenters.

3. Utilization Goals for Individuals With Disabilities (§ 30.7) and Invitation To Self-Identify as an Individual With a Disability (§ 30.11)

As emphasized throughout this final rule preamble, the Department contends that the central goal of a program

sponsor's hiring process should be to attract, admit, and retain those individuals—regardless of their group identity—who possess the right mix of the relevant skills and capabilities that are required for the successful completion of an apprenticeship program. Accordingly, ensuring that all qualified candidates, including people with disabilities, are eligible for consideration in the hiring and promotion process on an equal, nondiscriminatory basis is critically important to realizing this goal. Similarly, in keeping with the workplace protections for individuals with disabilities that were enacted by Congress in the ADA, the Department is committed to facilitating the hiring and retention of skilled and capable workers through the provision of effective job accommodation for apprentices and other employees with disabilities. While this final rule rescinds the burdensome and problematic regulatory mandates imposed on program sponsors by §§ 30.7 and 30.11 of existing part 30, the Department nevertheless continues to encourage program sponsors to establish supportive workplace policies and practices for individuals with disabilities. The voluntary implementation of such initiatives on behalf of these workers can be instrumental in advancing the broader goal of ensuring genuine equality of opportunity for all qualified individuals who seek to participate in the American workforce.

In the NPRM, the Department noted that the current regulation, at § 30.7, requires sponsors to conduct a utilization analysis of the participation of individuals with disabilities in their program, and establishes a specific utilization goal of 7% that sponsors must aim to achieve. Under the current regulation, if the share of apprentices with disabilities in a program are found to be below this threshold, sponsors are required to identify barriers to equal opportunity and to implement targeted measures to mitigate such barriers. The Department proposed eliminating this requirement in the NPRM, as well as the requirement that sponsors invite apprentices (or applicants for apprenticeship) to self-identify as having a disability. The Department maintained that these obligations were burdensome, and that sponsors faced practical and legal challenges in meeting these requirements.

The Department also noted in the NPRM that sponsors with 15 or more employees are already subject to title I of ADA, which affords important protections against discrimination to individuals with disabilities. The apprenticeship-specific nondiscrimination requirements in part 30, including the 7% utilization goal for sponsors, do not afford apprentices with meaningful access to remedies for alleged workplace discrimination. Instead, this goal requires sponsors to consider factors other than merit and qualifications in making decisions about outreach, recruitment, and hiring for their program. Therefore, the Department proposed eliminating the requirement to conduct a disability-focused utilization analysis and the regulation's specific 7% utilization goal, in line with the Department's broader objectives to emphasize merit-based hiring and expand employment and training opportunities for all American workers, including individuals with disabilities.

The Department also proposed rescinding § 30.11, which requires sponsors maintaining an affirmative action program to invite applicants and current apprentices to self-identify as an individual with a disability. In the NPRM, the Department asserted that this requirement creates confusion among sponsors and other apprenticeship stakeholders, and that the requirement has resulted in a high level of administrative burden for program sponsors. Additionally, the Department maintained that compliance with this requirement presents practical and legal challenges for program sponsors, who must protect apprentice confidentiality and privacy while simultaneously taking actions to meet a specific 7 percent utilization goal for individuals with disabilities. Sponsors' invitations to applicants and apprentices to disclose disabilities under § 30.11 constitute ''inquiries'' prohibited by section 102(d)(2)(A) and (d)(4)(A) of the ADA.[40]

Accordingly, for the reasons discussed in the NPRM and in response to the comments summarized below, the Department is finalizing the rescission of these disability-related provisions in this final rule.

Comments Regarding the Proposals To Remove the 7-Percent Utilization Goal for People With Disabilities and the Disability Self-Identification Requirement

Comments: A commenter supported the rescission of the 7 percent utilization goal for individuals with disabilities. One commenter opined that they supported the removal of the 7 percent utilization goal for qualified individuals with disabilities and the ''voluntary self-identification'' as it was an onerous and arbitrary requirement. Another commenter stated that utilization goals require knowledge of a protected disability, which is presumably why there is an invitation to self-identify as an individual with a disability. However, the commenter asserted that the ADA prohibits disability-related inquiries prior to employment and after employment if not job-related and consistent with business necessity. The commenter argued that the ADA does not give the Department authority to create exceptions to the ADA's statutory requirements via regulations.

However, several commenters expressed opposition to the Department's proposed rescission of both the 7 percent disability goal and the requirement that all current apprentices (as well as individuals who have been approved for admission to a Registered Apprenticeship program) be provided with an opportunity to confidentially disclose to the program that they have a disability. One commenter said that individuals with disabilities are an underrepresented population that are underemployed and represent an underutilized talent pool. Another commenter cited Registered Apprenticeship Partners Information Data System (RAPIDS) data to justify that these current regulatory requirements are still necessary, noting that only 1.1 percent of participants in Registered Apprenticeship programs reported having a disability, and these participants were more likely to be in nonunion apprenticeships. This commenter added that individuals with disabilities are less likely to have work experience, a college degree, or the means to afford postsecondary career training.

Several commenters opposed removing the disability utilization analysis, stating that these requirements help sponsors identify, assess, and eliminate existing workforce gaps and encourage businesses to look at all types of talent for apprenticeships. Specifically, one commenter maintained that the existing rule has been effective at increasing apprentices with disabilities, as the number of apprentices self-identifying as having disabilities has tripled in the last 5 years (2019–2024).

A commenter also asserted that eliminating these utilization goals for individuals with disabilities would undermine data-driven equity efforts and hinder progress for underrepresented groups. One commenter expressed concern that rescinding this requirement would undermine decades of established

[40] 42 U.S.C. 12112(d)(2)(A) and (d)(4)(A).

practice and deprive Registered Apprenticeship programs of critical information necessary to assess the inclusivity of their recruitment and hiring efforts. Several commenters worried removing these requirements could result in heightened inequality, making it more difficult for affected individuals to access the same employment opportunities and exacerbating existing disparities.

Some commenters also asserted that there was no legal or factual basis for eliminating these regulatory provisions. Regarding the 7 percent utilization goal for individuals with disabilities, a commenter noted that the current regulation explicitly prohibits quotas, and asserted that the Department did not provide evidence that program sponsors were imposing quotas to meet this benchmark. One commenter asserted that the utilization goal instead functions as a neutral benchmark allowing sponsors to evaluate whether their recruitment and outreach strategies effectively create equitable opportunities for people with disabilities. A group of commenters asserted that the Supreme Court's decision in *SFFA* has no bearing whatsoever on disability-related affirmative action efforts, which are subject only to rational basis review, citing *Cleburne* v. *Cleburne Living Center, Inc.*

Similarly, several commenters disagreed with the proposition that the disability self-identification requirement in the existing part 30 is burdensome, and asserted that the Department did not provide evidence in support of this claim. For example, one commenter referenced research that the commenter described as showing that employers of apprentices do not perceive the collection of demographic apprenticeship data as a major cost or inhibitor to the growth of apprenticeship programs. Another commenter asserted that if the requirement was onerous there would be limited voluntary compliance for sponsors with fewer than five apprentices—which the commenter said is not true. Specifically, the commenter said that sponsor behavior above and below the threshold is similar, citing RAPIDS data that programs with four apprentices had a 64.7 percent disability status reporting rate compared to 67.8 percent for programs with five apprentices. This commenter concluded that sponsors must view the benefits to their program and apprentices as outweighing any administrative burden, contradicting the Department's characterization of the provision as burdensome.

Additionally, one commenter expressed concern with the proposed rescission of the utilization goal as the requirement implements section 503 of the Rehabilitation Act of 1973, which requires Federal contractors and subcontractors to ''take affirmative action to employ and advance in employment qualified individuals with disabilities.'' [41] The commenter added that in 2014, the Office of Federal Contract Compliance Programs (OFCCP) issued regulations setting a nationwide benchmark for employers to aim for 7 percent employees with disabilities and annual tracking for data collection.

Finally, a commenter expressed opposition to the elimination of requirements that sponsors invite applicants to self-identify as individuals with disabilities, asserting that this allows sponsors to access certain funding streams to grow apprenticeships depending on the population they serve. The commenter suggested that the Department could achieve its goals of reducing unnecessary paperwork while still collecting information on disability by including a self-declaration on apprenticeship intake forms.

Department Response: The Department agrees with the commenters expressing concerns over the administrative burden imposed on programs by the disability utilization analysis, as well as concerns with potential ADA conflicts resulting from the requirement to invite applicants and apprentices to identify as individuals with disabilities.

In response to commenters who discussed the benefits and value of collecting information on individuals with disabilities participation in workforce training programs and pursuing increased representation of such individuals in the workforce, the Department notes that nothing in this final rule prohibits sponsors from exercising their own judgment in making inquiries or proactive efforts to employ qualified individuals with disabilities, so long as any such actions are consistent with the ADA and its implementing regulations. With this final rule, sponsors will no longer be subject to the current part 30 regulation's mandates concerning the collection of information on individuals with disabilities, nor its requirements concerning the employment of individuals with disabilities.

In response to the commenter who suggested changing the nature of the inquiry to a ''declaration,'' the Department is not persuaded that such a recharacterization would eliminate the Department's concerns with improperly requesting disability information under the ADA, which were echoed by other commenters in response to the NPRM. In addition, the Department takes the position that such an adjustment would neither eliminate, nor meaningfully reduce, the administrative burden associated with storing responses to disability inquires in a secure and confidential manner. The Department also agrees with the commenter who suggested that the existing part 30 regulation specifies that the utilization goals should not be construed as rigid quotas.[42] However, the Department has determined that these utilization goal requirements, along with other affirmative program requirements in the existing regulation, have had the practical effect of inducing sponsors to make preferential hiring decisions based on demographic characteristics. Accordingly, the Department has decided to remove the legally questionable affirmative action requirements from the revised part 30 regulation.

The rescission of the disability utilization analysis within part 30 is consistent with the Department's decision to rescind the similar utilization analysis and goal as a form of required affirmative action under the implementing regulations for section 503 of the Rehabilitation Act of 1973. 90 FR 28494 (July 1, 2025). While the utilization goal required by existing § 30.7 was not issued pursuant to section 503, the part 30 disability utilization goal was designed to mirror the one issued by OFCCP under section 503 and the reasons for removing both goals are related. In both cases, the Department contends that the analyses and goals are unnecessarily burdensome, rely on ambiguous statutory authority, create the possibility of conflicts with the ADA, and put pressure on sponsors to use hiring quotas despite regulatory prohibitions on doing so.

The Department recognizes that the disability goal and utilization analysis would not be subject to strict scrutiny review under equal protection principles in the same way that the race- and ethnicity-based utilization goals and Canalyses would be pursuant to *SFFA.* The Department did not rely on *SFFA* in proposing to rescind existing § 30.7. However, the regulatory mandate

[41] 29 U.S.C. 793(a).

[42] The existing part 30 regulation, at § 30.6(d)(1), states that ''Utilization goals may not be rigid and inflexible quotas, which must be met, nor are they to be considered either a ceiling or a floor for the selection of particular groups as apprentices. Quotas are expressly forbidden.''

that sponsors not treat the disability goal as a quota is inherently at odds with the expectation that sponsors undertake good faith efforts to attain a workforce that meets the 7 percent utilization goal. This tension creates confusion among sponsors regarding their obligations with respect to ensuring equal opportunity for individuals with disabilities.

The Department emphasizes that, while it is no longer requiring covered sponsors to conduct these utilization analyses, sponsors remain free to assess their programs and encourage the participation of qualified apprentices with disabilities in any lawful way. As is the case for Federal contractors under section 503, the Department encourages sponsors to continue supporting the employment and advancement of qualified apprentices with disabilities in ways that do not involve the setting of a numerical goal or that depend on the sponsor's knowledge of a particular applicant's or apprentice's disability status.[43]

Legal Interpretation of ADA and Self-Identification

Comments: A commenter stated that asking applicants to voluntarily disclose a disability is not a violation of the ADA's prohibition on disability-related pre-employment inquiries. This commenter opined that the affirmative action requirements in section 503 were in place when the ADA was passed in 1990, although the utilization goal would come later in regulations. The commenter added that implementing an affirmative action plan and reporting on its success required employers to know whether they are hiring individuals with disabilities but did not end either the prohibition on pre-employment inquiries or affirmative action for people with disabilities. The commenter also cited a 2018 EEOC declaration which stated that for more than 20 years it had been recognized that ''the ADA permits affirmative action on behalf of individuals with disabilities, whether legally required or voluntarily undertaken,'' and also reaffirmed enforcement guidance from 1995 on ''Preemployment Disability-Related Questions and Medical Examinations Under the ADA,'' which explained that employers may ask job applicants to voluntarily self-identify as individuals with disabilities for affirmative action purposes under certain conditions. Similarly, another commenter stated that the EEOC has consistently upheld voluntary self-disclosure of disability at the applicant stage as permissible under the ADA.

Another commenter noted that a 2013 letter from the EEOC legal counsel indicated that such inquiries are permissible under the ADA but argued that this letter should not be relied on by DOL. The commenter said that the letter is from a single attorney at the EEOC and does not represent the Commission, does not make a statutory argument, and its conclusion contradicts the best reading of the ADA. The commenter added that, even assuming the ADA is ambiguous, whatever deference the EEOC had to interpret ambiguous provisions of the ADA is gone following *Loper Bright Enterprises* v. *Raimondo,* which directs agencies and courts to determine the best reading of a statute.

Department Response: The Department maintains that requiring covered sponsors to invite applicants and apprentices to self-identify as individuals with disabilities is in tension with the best reading of the ADA's text. With respect to job applicants, section 102(d)(2)(A) of the ADA states that an employer ''shall not . . . make inquiries of a job applicant as to whether such applicant is an individual with a disability.'' [44] But this inquiry is what § 30.11(a)(1) currently requires. (''A sponsor adopting an affirmative action program pursuant to § 30.4 must invite applicants for apprenticeship to inform the sponsor whether the applicant believes that he or she is an individual with a disability as defined in § 30.2.'') Although the disability inquiry requirement is framed as an ''invitation'' for applicants to ''self-identify'' disability status, this is a requirement imposed on the sponsor. And while congressional committee reports may have suggested that the ADA's ban on preemployment inquiries would not apply to data collected for certain affirmative action purposes, *see, e.g., Associated Builders & Contractors* v. *Shiu,* 30 F.Supp.3d 25, 37–38 (D.D.C. 2014), legislative history cannot overcome the statute's plain meaning because ''legislative history is not the law.'' *Epic Sys. Corp.* v. *Lewis,* 584 U.S. 497, 523 (2018). DOL must interpret the statute based on ''what the statute means,'' not ''what the legislature meant.'' *Id.* (quoting *Schwegmann Bros.* v. *Calvert Distillers Corp.,* 341 U.S. 384, 397 (1951) (Jackson, J., concurring)). Therefore, legislative history cannot change what section 102(d)(2)(A) and (B) of the ADA commands: a covered entity ''shall not'' make preemployment ''inquiries'' as to an applicant's disability status, except in only a few situations expressly enumerated in the ADA.[45] *See Milner* v. *Dep't of Navy,* 562 U.S. 562, 574 (2011). (''Legislative history, for those who take it into account, is meant to clear up ambiguity, not create it.'').

With respect to current apprentices/employees, section 102(d)(4)(A) of the ADA states that an employer ''shall not make inquiries of an employee as to whether such employee is an individual with a disability . . . unless such . . . inquiry is shown to be job-related and consistent with business necessity.'' [46] Current § 30.11(c), which requires all covered sponsors to annually remind apprentices that they may voluntarily update their disability status, does not limit this requirement to situations where the sponsor determines that such an inquiry is job-related and consistent with business necessity. Current § 30.11 therefore requires sponsors to make disability inquiries that likely run afoul of the ADA and the rescission of this requirement ensures that part 30 does not compel conduct that the ADA either prohibits or permits only in limited circumstances not reflected in current § 30.11.

As some commenters noted, the EEOC has issued subregulatory guidance indicating that otherwise-prohibited disability-related inquiries are lawful when made in order to benefit individuals with disabilities. Most notably, this guidance has been captured in the 1995 Enforcement Guidance and in the 2013 letter from the EEOC's Office of Legal Counsel. *See* 78 FR 58682, 58691 (Sept. 24, 2013). Upon consideration, DOL concludes that this guidance is inconsistent with the best reading of the statute and will not defer to it.

The Department first notes that it agrees with the commenter regarding the reliability and authority of the 2013 EEOC Office of Legal Counsel Letter in that it does not reflect the views of the entire Commission but only those of single attorney. Second, the substance of the letter is not clearly in line with the statutory text of the ADA. Recent Supreme Court precedent reinforces the need to adhere to the statute's best

[43] In this connection, the Department's Office of Disability Employment Programs (ODEP) offers several resources to help sponsors at *https://www.dol.gov/agencies/odep/program-areas/employers/recruitment-retention*—including the Job Accommodation Network (which is available to provide free, expert and confidential guidance on work placement accommodations and other disability employment matters) at *https://askjan.org/*and other resources on the ODEP website at: *https://www.dol.gov/agencies/odep.*

[44] 42 U.S.C. 12112(d)(2)(A); see also 29 CFR 1630.13(a).

[45] 42 U.S.C. 12112(d)(2)(A) and (B).

[46] 42 U.S.C. 12112(d)(4)(A); see also 29 CFR 1630.13(b).

reading. In *Loper Bright Enterprises* v. *Raimondo,* 603 U.S. 369 (2023), the Court emphasized that '''statutes . . . have a single, best meaning''' that is '''fixed at the time of enactment.''' 603 U.S. at 400 (quoting *Wisconsin Central Ltd.* v. *United States,* 585 U.S. 274, 284 (2018)). Applying that principle here, the Department concludes that the best reading of section 102(d)(2)(A) of the ADA [47] is that employers may not make disability-related inquiries of job applicants prior to an offer of employment, regardless of the employer's intent or the framing of the question.

Although sponsors are required to keep disability disclosures confidential and not use them in employment decisions, confidentiality requirements do not eliminate the practical pressures or risk of distress that individuals may experience when presented with an employer-initiated request to disclose disability status. Additionally, sponsors have indicated confusion over how best to keep such data confidential while integrating their program data with RAPIDS. This practical confusion, along with the questionable legality of the invitation itself, places sponsors in a challenging position. Through this final rule, the Department aims to ease any confusion sponsors may have experienced resulting from the requirement to invite disability self-identification.

Alternative Approaches and Recommendations

Comments: A commenter recommended that, while the revision and elimination of numerical goals and requirements may simplify the registration process for new and existing Registered Apprenticeship program sponsors, DOL should replace these eliminated regulations with a focus on and investment in activities that, among other groups, assist individuals with disabilities in accessing Registered Apprenticeship programs.

Department Response: The Department is committed to the expansion of Registered Apprenticeship programs for all qualified workers and encourages the full participation of individuals with disabilities in those programs. At the same time, the Department contends that mandating the use of burdensome and prescriptive analyses that fail to respect the privacy of individuals with disabilities is not the best means of accomplishing these objectives. As discussed previously, the Department maintains various resources that can assist sponsors in making their Registered Apprenticeship programs more accessible to individuals with disabilities. For example, the Department's Office of Disability Employment Policy has created an Apprenticeship Toolkit, which is designed to provide information on a series of topical areas focused on Registered Apprenticeship and how it can be used to provide employment opportunities for people with disabilities. The Department encourages sponsors to take advantage of these, and other resources, to support apprentices with disabilities.

4. Targeted Outreach, Recruitment, and Retention (§ 30.8)

Existing § 30.8 mandates that sponsors who identify instances of underutilization engage in focused outreach, recruitment, and retention strategies designed to enhance the number of applications from, and improve the retention of, apprentices belonging to the targeted group(s) or individuals with disabilities, as applicable. However, given that these requirements involve race- and sex-based data that could impact final recruitment decisions, the Department has determined that they carry similar legal risks as those associated with the utilization goals based on race, sex, and ethnicity.

These regulatory requirements may exert pressure on sponsors to prioritize recruiting candidates from specific racial, sex-based, or ethnic backgrounds, potentially resulting in unequal treatment of individuals in different demographic categories. This pressure could lead sponsors to allocate their limited recruitment resources disproportionately to benefit certain minority groups. *MD/DC/DE Broadcasters Ass'n* v. *FCC,* 236 F.3d 13, 15, 20–21 (D.C. Cir. 2001), *cert. denied,* 534 U.S. 1113 (2002). Thus, for the same reasons discussed in § 30.5, the Department is rescinding these requirements.

Additionally, the Department's rescission of existing §§ 30.5 and 30.7 removes the circumstances under which findings to engage in such activities might occur. Accordingly, the ''targeted'' activities in current § 30.8 are no longer required and the Department will proceed with rescission.

Support and Concern Regarding Reducing Outreach Requirements

Comments: A commenter stated that current rules prescribe targeted outreach strategies that may be ill-suited for certain industries or regions, and that smaller sponsors in particular often lack the staff and systems to efficiently manage the requirements of the current EEO regulations. A different commenter stated that they opposed burdens related to the outreach, recruitment, and selection processes for apprentices, particularly with regard to merit-based programs that the association does not control.

In contrast, several commenters opposed rescinding outreach requirements. One commenter asserted that current outreach, recruitment, and retention requirements do not require preferences, do not put employers at legal risk, and maintaining target outreach requirements supports pathways for opportunity for youth and other underrepresented groups in apprenticeship programs. Another commenter asserted that removing the regulatory basis for sponsors' existing outreach, recruitment and retention programs would limit the pool of apprentices available for selection. Another commenter agreed and stated growth is needed in the construction industry (which has faced an ever-increasing shortage since the mid-2000s) and that part 30's approach aligns with the measures in President Trump's plan for ''engaging and supporting the disconnected workforce.'' Several commenters stated that requiring program sponsors to consider the diversity of their apprentices in their recruitment process positively impacts Registered Apprenticeship expansion to underrepresented groups in their industry, and described successful programs that have implemented recruitment and outreach goals, especially within the construction industry. For example, one commenter said there has been a notable uptick in Registered Apprenticeship programs conducting affirmative outreach to populations underrepresented in the construction trades, and cited that in the last 4 years, there have been two new direct-entry pathways formally created in the Chicago area between local trade union apprenticeship programs and local pre-apprenticeship programs. The commenter also described a July 2024 roundtable hosted by Chicago Women in Trades with the EEOC Vice Chair where industry leaders shared the efforts they were making through the framework of 29 CFR parts 29 and 30 regulations that were improving their recruitment and retention of apprentices from diverse sex, racial, and ethnic backgrounds.

Similarly, a commenter expressed that several Registered Apprenticeship programs have identified recruitment strategies targeting certain protected classes which have proved fruitful in building and maintaining robust

[47] 42 U.S.C. 12112(d)(2)(A).

apprenticeship registrations, and shared concerns about their ability to continue to employ those strategies after the proposed rule is adopted. The commenter requested guidance regarding the extent to which such recruitment strategies are not compliant and specific examples of types of recruitment strategies that would not be deemed compliant under the proposed rule. Another commenter asserted that the part 30 regulation gives non-White and nonmale individuals a chance to enroll in apprenticeship without them having to ''know someone on the inside,'' or other historical practices that have resulted in denied equal opportunities for women and people of color.

A commenter stated that removing outreach requirements risks employers misinterpreting this as a reason to reduce deliberate recruitment of veterans, who often face barriers transitioning to civilian careers, and recommended that DOL explicitly clarify that nothing in the rule prevents or discourages sponsors from prioritizing veteran recruitment through engagement with veteran-serving organizations and workforce partners.

Department Response: The Department appreciates the comments discussing the recruitment challenges faced by sponsors. The Department maintains that this final rule gives sponsors more flexibility to lawfully recruit apprentices. By rescinding the overly prescriptive provisions in existing § 30.8, sponsors will no longer be required to expend resources on recruitment and retention activities that may not have benefited their programs. To the extent sponsors have found any partnerships or recruitment strategies to be useful, sponsors remain free to continue using those methods on a nondiscriminatory basis. The Department defers to the respective EEO enforcement agencies in determining whether specific recruitment methods are consistent with applicable nondiscrimination laws. Ultimately, the Department is confident that the removal of the onerous requirements under the existing part 30 regulation will spur expansion of the National Apprenticeship System generally, creating more opportunities for women, Americans of color, and all Americans across all demographic groups to access the training model.

In response to those commenters raising concerns about recruitment targeted towards veterans, the Department notes that targeted outreach on this basis does not raise the same constitutional concerns as outreach targeted to members of a specific race or sex. Sponsors are encouraged to continue engaging in efforts to recruit veterans. Existing § 30.8 did not contain any requirements specific to the recruitment of veterans; the rescission of this section, therefore, will not impact the ability of sponsors to continue engaging in such efforts. The same is true of other recruitment strategies relying on non-protected bases, such as geography and income status. The Department supports programs that seek to reach all potential applicants, and the rescission of existing § 30.8 enables sponsors to conduct outreach and recruitment in line with their business needs and in a lawful manner.

Impact on the Construction Industry

Comments: One commenter who opposed the proposed changes to outreach and recruitment requirements described difficulties in recruiting potential employees to the construction industry due to the nature of the work, and asserted that growing the apprenticeship pool in the industry involves successfully recruiting from every part of the population. The commenter described how apprenticeship programs conduct outreach to veterans, community groups, and institutions within relevant geographic areas; support all candidates to maximize success; and eliminate completion barriers based on factors such as language, learning deficits, addiction, and childcare responsibilities. The commenter opined that these practices are not discriminatory, but instead advance the legitimate objectives of sponsors to grow the workforce.

Another commenter stated that in the construction industry, there are legitimate business reasons for Registered Apprenticeship programs to develop geographically focused outreach and recruitment plans, including proximity to training centers and job sites to which apprentices would be dispatched for OJL. The commenter stated that recruitment in the construction industry typically involves outreach to community colleges, high schools, county or State fairs, unemployment offices, veterans groups, parks and recreation, and other entities that have historically been viable sources of candidates for admission to JATCs. The commenter added the 2016 final rule offered sponsors flexibility in defining pertinent geographic areas so long as they justify the scope of the recruitment area and do not exclude individuals based on race, sex, or ethnicity. The commenter also maintained that due to the fluctuating nature of business demands in the construction industry, development of geographic lines for recruitment based on volume of work at anticipated job sites is a legitimate business interest.

Impact on the Education Sector

Comments: A national labor union stated that teaching apprenticeships are new in the last four years and have been transformative for non-traditional students and adults who show an interest in teaching. The commenter described traditional sex-based imbalances in the teaching profession, saying that apprenticeship programs under existing regulations are making efforts to recruit more male teachers from varying backgrounds, and labeling this approach as ''illegal discrimination'' may negate recruitment efforts. The commenter cited research showing that diversifying the teacher workforce is beneficial for students. A professional association similarly expressed concern about the proposed restriction on recruitment activities under the proposed rule and the impact this change would have on the expansion of apprenticeship programs in education.

Impact on Women and Other Groups

Comments: A commenter stated that the Department's proposed changes to targeted outreach requirements would threaten participation for women in apprenticeships, particularly in high-paying fields where women are a small minority of apprentices. The commenter described research they said shows apprentices are often provided with limited information on career opportunities, particularly among women. The commenter cited additional research indicating that women who do pursue higher paying apprenticeship fields often do not have the benefit of merit-based recruitment and must be more qualified and persistent.

Another commenter stated that as apprenticeships continue to grow into new sectors, the analysis, recruitment, and reporting parameters as currently written in part 30 would serve as guidelines to allow program sponsors to strategically build apprenticeships in new job categories. The commenter stated that many types of careers benefit from intentional promotion and recruitment, and the proposed rule not only eliminates requirements for this analysis and effort but would likely chill programs from acting on their recruitment efforts to engage diverse candidates. Another commenter stated that requirements for outreach and recruitment grew out of the insular nature of the construction trade which

uses informal networks and referrals to recruit for apprenticeships, and which perpetuates issues of underrepresentation particularly for women.

Department Response: As stated elsewhere in this preamble, a fundamental purpose of this final rule is to rescind all provisions of the part 30 regulation that aimed to impose legally problematic ''equitable'' outcomes on the demographic composition of apprenticeship programs through a systematic regime of group-based preferences that are tied to an individual's race, sex, or ethnicity. Accordingly, any arguments advanced by commenters to justify retaining the targeted recruitment provisions found at existing § 30.8 and that are grounded upon the general notion of achieving or maintaining greater demographic ''balance'' or ''diversity'' in a sponsor's apprenticeship workforce through targeted recruitment efforts are contrary to the fundamental principle of hiring individuals solely on the basis of merit and without considering demographic characteristics. Additionally, nothing in the final rule precludes individual sponsors from voluntarily conducting lawful outreach or recruitment activities to attract qualified apprenticeship candidates from all backgrounds or from engaging in hiring practices they believe to be in their business interest, provided that such activities and practices conform with applicable nondiscrimination laws.

Reliance Interests and Existing Investments in Outreach Programs

Comments: A commenter stated that the rescission of outreach and recruitment requirements would strongly impact the reliance interest of their training network. The commenter stated that existing § 30.8 currently requires programs that identify underutilization to engage in neutral outreach activities (that are not race- or sex-based) but that are designed to reach underrepresented communities. The commenter stated that, relying upon these part 30 regulatory provisions, sponsors affiliated with the commenter's organization have invested significant funds and human resources to build a variety of strategies and programs that support growth. The commenter stated that the rescission of these regulations would seriously undermine these programs and imperil the years of investments which have gone into their creation, particularly by the labor-management organizations that are responsible for JATCs. The commenter also asserted that outreach and recruitment activities under § 30.8 are legal under Federal and State nondiscrimination laws.

Another commenter stated that the Department's proposed rescission of § 30.8 would adversely impact the significant reliance interests of Registered Apprenticeship programs that have adapted outreach and recruitment to comply with the part 30 regulation. The commenter stated that, under the regulation, sponsors have been required to develop a list of recruitment sources that generate referrals of women, minorities, and persons with disabilities, with contact information for each source, and to notify these sources in advance of any apprenticeship opportunities. The commenter continued that the broad rescission of this provision would disrupt past success by JATCs in developing recruitment sources and partnerships particularly in blue collar professions due to vocational training and careers becoming less popular. The commenter asserted that its recruitment efforts in schools, community colleges, and community-based organizations have been successful, but expressed concern that, under the Department's proposal, such efforts would cause a Registered Apprenticeship program to risk deregistration.

Department Response: The part 30 regulation mandated that sponsors subject to utilization goals under § 30.8 of that regulation conduct ''targeted outreach, recruitment, and retention activities that are likely to generate an increase in applications for apprenticeship and improve retention of apprentices'' from ''underutilized groups'' based upon race, sex, and ethnicity. The Department has determined that preferential treatment in the recruitment of apprentices is inherently discriminatory in nature, and thus legally suspect. The Department takes the position that the deliberate targeting of individuals from ''underutilized'' groups in apprenticeship outreach and recruitment based upon shared characteristics of race, sex, or ethnicity necessarily disadvantages the recruitment of individuals who do not belong to such groups.

In rescinding this preferential and discriminatory recruitment provision, the Department reaffirms the view that individuals from all backgrounds—regardless of their race, ethnicity, sex, religion, or national origin—must be afforded the opportunity to compete on an equal, nondiscriminatory basis for admission into a Registered Apprenticeship program. The Department takes the position that every apprentice should be recruited without regard to their race, sex, or ethnicity, and that every apprentice should be hired or retained by a program sponsor on the basis of their qualifications and performance alone.

While the Department acknowledges that certain program sponsors have made significant investments to satisfy the requirements that were contained in § 30.8 of the 2016 regulation, the Department nevertheless takes the position that a sponsor's recruitment activities must be nondiscriminatory in their operation. Accordingly, in accordance with this final rule and governing nondiscrimination law, program sponsors that have made significant investments in apprenticeship recruitment and outreach activities are free to continue such initiatives, provided that these efforts are designed to attract and retain qualified candidates from all backgrounds, and do not constitute preferential, discriminatory conduct based upon an individual's race, sex, and ethnicity.

Some commenters implicitly acknowledged the burden associated with the part 30 regulation's outreach and recruitment requirements in stating they have invested significant resources into complying with the existing § 30.8. By rescinding these provisions, the Department is reducing the administrative and regulatory burden placed on sponsors to comply with part 30 requirements. Finally, because the Department is not infringing on sponsors' ability to voluntarily maintain legally compliant outreach activities, the Department maintains that removing part 30 requirements will not adversely impact sponsors' reliance interests associated with part 30 regulatory requirements that are being rescinded with this final rule.

5. Review of Personnel Processes (§ 30.9)

As noted in the NPRM, the Department explained that existing § 30.9 required sponsors maintaining an affirmative action program to perform an annual assessment of their personnel processes concerning the administration of the apprenticeship program to ensure that the program is not operating in a discriminatory manner. The Department has concluded that this requirement is both confusing and burdensome, as sponsors are already subject to Federal and State nondiscrimination laws and have established procedures to maintain compliance, rendering this additional regulatory obligation unnecessary.

Moreover, the Department expressed the view in the preamble to the NPRM that eliminating this requirement would

enable sponsors to explore innovative strategies, reduce redundancy in compliance efforts, and align with the Administration's commitment to promoting efficiency and effectiveness in apprenticeship programs. The Department also opined that rescinding this mandate would allow sponsors to pursue innovative approaches, reduce duplication, and align with the Administration's stated policy to ''significantly reduce the private expenditures required to comply with Federal regulations to secure America's economic prosperity . . .'' as established by E.O. 14192, Unleashing Prosperity Through Deregulation.

The Department did not receive public comments specifically related to its proposed rescission of § 30.9. Therefore, for the reasons discussed in the NPRM and reiterated in this final rule, the Department is finalizing the rescission of this provision.

C. Rescission of the Anti-Harassment Training Requirement and the Provision Relating to Retaliation Against Apprentices

In the NPRM, the Department proposed rescinding the existing regulatory mandate contained in § 30.3(b)(4), which requires all Registered Apprenticeship program sponsors to conduct anti-harassment training. The Department also proposed rescinding existing § 30.17, which prohibits intimidation, retaliation, discrimination, and coercion against apprentices for filing a complaint, opposing a prohibited practice, assisting investigations, or exercising rights or privileges provided under part 30. The Department proposed eliminating these provisions in the NPRM to remove unnecessary administrative burdens or duplicative regulatory requirements on program sponsors, and to align the content of part 30 with governing Federal nondiscrimination laws prohibiting harassment in the workplace. After consideration of the comments received concerning the proposed rescission of these regulatory provisions, which are summarized and addressed below, the Department has determined to finalize these proposed changes in this final rule.

As a general matter, the Department has consistently maintained that harassing conduct in the workplace is plainly unacceptable. Depending on the facts, the harassment of an apprentice on the basis of their race, sex, or other protected characteristics may give rise to a hostile work environment allegation under Title VII of the Act or other applicable employment nondiscrimination laws, a claim which may be appropriate for further investigation by the EEOC or a State FEPA. From a labor standards perspective, the Department recognizes that the prevalence of such conduct in the workplace, including in Registered Apprenticeship programs, could undermine the dignity of individual employees and diminish worker productivity and morale.

Accordingly, while this final rule removes the overbroad and administratively burdensome requirement that all Registered Apprenticeship programs, regardless of their size, must conduct comprehensive anti-harassment training for those individuals connected with the program, the Department does not seek to discourage sponsors from voluntarily adopting lawful strategies and measures that are carefully tailored to minimize the occurrence or mitigate the impact of such impermissible conduct in their respective programs. However, the Department cautions sponsors that, to avoid giving rise to potential hostile work environment claims under Title VII or other nondiscrimination laws, any anti-harassment strategies or measures that are voluntarily instituted by a program must avoid unlawfully stereotyping or demeaning any group of employees or apprentices based upon their sex, race, or other protected characteristics.

Comments: One commenter expressed support for rescinding the part 30 anti-harassment training requirements because it would provide regulatory relief to employers while preserving nondiscrimination protections. However, another commenter opposed these rescissions, asserting that the removal of the anti-harassment training requirements would remove essential apprentice safeguards, would undermine the standard and value of Registered Apprenticeship, and would likely worsen the work environment for many apprentices, particularly those who are in occupations where they are the minority of workers. Several commenters also cited data purporting to demonstrate that the compulsory provision of anti-harassment training by sponsors has resulted in tangible benefits that have outweighed the costs of these trainings, such as higher apprenticeship completion rates, reduced levels of harassment in the workplace, and a lower risk of potential sponsor liability.

Several commenters also maintained that the anti-harassment training requirement contained in the existing part 30 remains necessary because of the ongoing prevalence of sex- and race-based harassment, intimidation, bullying, and retaliation, both generally and within the construction trades, and particularly against women. For example, one commenter cited a report stating that the majority of apprentices who failed to complete their programs identified harassment and discrimination as the reason they resigned from their apprenticeship or as one of the biggest challenges they faced during their apprenticeship, and that more than half of the apprentices who left or seriously considered leaving the trades cited harassment or lack of respect as the reason. Another commenter stated that 57.9 percent of tradeswomen who made the decision to speak up about discrimination or harassment to someone in authority felt their concerns were not addressed satisfactorily. Other commenters cited other surveys, research, and apprentice testimony as well to illustrate the prevalence of harassment.

Several commenters asserted that, in contrast to the data and research they provided purporting to show the need for retaining the compulsory anti-harassment training provisions of part 30, the Department did not offer any compelling rationales in the NPRM to support its proposed removal of the anti-harassment training requirement. One commenter asserted that, in the preamble to the proposed rule, the Department had argued that the anti-sexual harassment training regulations in part 30 conflicted with merit principles, and that the only legal standard cited for this proposition was the *SFFA* decision, which did not address the issue. The commenter stated that the proposed rule's suggestion that anti-harassment training is potentially unlawful is unfounded and likely to have a chilling effect on Registered Apprenticeship program sponsors. This commenter stated that they were not aware of an instance in which a court held that a training aimed at preventing sexual harassment was unlawful, and that numerous courts have upheld the lawfulness of trainings to encourage diversity and respect. Lastly, the commenter suggested there are other ways to reduce the burdens related to the mandatory provision of anti-harassment training without eliminating the requirement.

One commenter stated that pointing to Title VII as adequate protection for apprentices from discrimination and harassment is not accurate, considering the special contexts of the apprenticeship model and the limitations of an enforcement mechanism almost solely dependent on worker complaints. Similarly, another commenter urged the Department to

retain all provisions expressly stipulating that harassment will not be tolerated, such as the anti-intimidation and anti-retaliation provisions; this commenter maintained that removing these regulatory provisions would deprive apprentices of a viable means of redress for intimidation and retaliation.

A commenter recommended that, rather than eliminating the anti-harassment training requirement, the Department should instead require stronger diversity training for employers and mentors, covering topics including but not limited to cultural competency, inclusivity, bias awareness, and nondiscrimination law. Another commenter added that the Department should continue to provide free online trainings.

Several commenters also expressed opposition to the proposed rescission of the regulatory prohibition on intimidation and retaliation found at § 30.17, contending that the removal of this provision would reduce awareness of such protections, create delays in the resolution of complaints, and create barriers for apprentices to assert their rights if they are experiencing intimidation or retaliation. One commenter urged the Department not to rescind this provision because it would burden youth apprentices with navigating complex Federal court systems. Some commenters also stated that the elimination of this provision could discourage apprentices from speaking up about discrimination, unsafe, or unfair practices and may result in higher attrition and lower completion rates among the most vulnerable apprentices. A commenter expressed particular concern about the proposed change in combination with the other changes that require Registration Agencies to await final determinations of discrimination, reasoning that apprentices who are retaliated against for having witnessed discrimination would have to undergo lengthy processes before receiving any remedy.

Department Response: The Department agrees with those commenters who asserted that the rescission of these regulatory provisions would remove burdensome or duplicative mandates from part 30, thereby providing meaningful regulatory relief to program sponsors. Importantly, the Department notes that, by dispensing with such mandates, the final rule will enable sponsors to align their compliance obligations with the requirements of applicable nondiscrimination laws and protections with which they may be most familiar.

While the Department acknowledges the existence of reports that illustrate the harmful effects of workplace harassment on apprentice retention, the Department also notes the absence of data demonstrating the efficacy of compulsory anti-harassment training in counteracting such outcomes. As such, it disagrees with the conclusion reached by some commenters that the rescission of the existing part 30 training requirement removes an integral tool for protecting apprentices from harassing conduct. Rather, the Department maintains that existing legal protections against harassment or retaliation that are afforded under existing Federal and State nondiscrimination laws are sufficiently robust.

Title VII prohibits workplace harassment, which may occur when an employee is subjected to unwelcome remarks or conduct based on protected characteristics. As noted earlier, harassment based on a protected characteristic is illegal when it results in an adverse change to a term, condition, or privilege of employment, *Muldrow* v. *City of St. Louis,* 144 S. Ct. 967 (2024), or it is so frequent or severe that a reasonable person would consider it intimidating, hostile, or abusive. *See* Title VII of the Act, section 703(a)(1).[48] Title VII also prohibits retaliation by an employer because an individual has engaged in protected activity under the statute. *Id.* at section 704.[49]

Because of the foregoing Title VII prohibitions against harassment and retaliation, which are grounded in the language of the statute and elaborated under subsequent case law, the Department considers the existing regulatory provision at § 30.3(b)(4) mandating the provision of anti-harassment training by all Registered Apprenticeship programs to be unduly burdensome, and the existing regulatory provision at § 30.17 prohibiting retaliation for engaging in a protected activity to be largely redundant of existing Federal protections and therefore unnecessary. Moreover, under the foregoing Title VII provisions, individual apprentices who allege that they have been subjected to such impermissible employer conduct or work environments may file a complaint with, and request relief from, the EEOC or a State FEPA—and a final agency or court determination that a program sponsor has engaged in such behavior could potentially result in the Department's deregistration of that program. Given these existing protections under nondiscrimination law, the removal of these burdensome or duplicative requirements from part 30 aligns with E.O. 14278's mandate that the Department seek to expand Registered Apprenticeship and improve efficiency.

The Department does not dispute that anti-harassment training may be beneficial in some workplaces. Rather, the Department has concluded that the decision whether, how, and how often to provide such training should be left to sponsors rather than prescribed through a uniform Federal apprenticeship-specific mandate. The Department's decision to rescind the mandatory anti-harassment training requirement should not be construed as prohibiting such training. Sponsors remain free to provide anti-harassment training, establish workplace-conduct policies, and undertake other measures they determine are appropriate for their workplaces and apprenticeship programs. The final rule merely eliminates the Federal regulatory mandate that all program sponsors conduct such training regardless of their size, circumstances, and need for such training. Some sponsors may find anti-harassment training beneficial and may voluntarily choose to provide such training. The Department's conclusion is simply that Federal law does not require a separate apprenticeship-specific mandate in light of existing statutory protections against harassment and retaliation.

D. Rescission of Apprenticeship Selection Procedure Requirements

Under the NPRM, the Department suggested rescinding § 30.10, which outlined the permissible methods for sponsors to select apprentices. This provision allowed sponsors to utilize any selection method or combination of methods, so long as those methods adhered to the criteria established in the regulation. The Department concluded that these provisions were unnecessary, as they either duplicated the prohibitions against discrimination in selection and related employment practices already established under Title VII or imposed additional regulatory burdens on sponsors beyond those mandated by Title VII.

For the reasons discussed in the NPRM and in response to comments discussed below, the Department has determined to finalize the rescission of this regulatory provision as originally proposed.

Comments: Several commenters opposed rescinding the apprenticeship selection procedure requirement. For example, one commenter opposed the rescission because it enables

[48] 42 U.S.C. 2000e–2(a)(1).

[49] 42 U.S.C. 2000e–3.

Registration Agencies to know the minimum requirements for entry into a Registered Apprenticeship program, thus helping to ensure nondiscrimination in such a program. Several commenters also said that the apprenticeship selection procedure recruitment was intended to expand access and representation in apprenticeship programs. These commenter suggested retaining this requirement is important for building pipelines for individuals into the system and to ensure the apprenticeship system is accessible to all workers. One commenter stated that this apprenticeship selection requirement helps support the success of quality pre-apprenticeship and apprenticeship readiness programs in their State, as sponsors may specify in their selection procedures that completers of these preparatory programs can receive advanced standing, direct interviews, or direct entry into their Registered Apprenticeship program.

However, another commenter disagreed and supported the rescission because they said that the current apprentice selection procedure requirement is burdensome and complicates the process to recruit apprentices, particularly for industries facing shortages like construction.

Department Response: In response to these comments, the Department takes the position that the inclusion of a sponsor's procedures for the selection of apprentices in the program's standards of apprenticeship (as was required in § 30.10(b)(1) of the 2016 part 30 regulation and in § 29.5(b)(21) of the 2008 part 29 regulation) was unnecessary and unduly burdensome, and that the rescission of this requirement in this final rule is therefore appropriate.

Requiring sponsors to include selection procedures in their apprenticeship standards is not necessary to ensure compliance with applicable nondiscrimination laws or to safeguard apprentice welfare. Questions concerning the legality of selection practices are appropriately addressed under generally applicable Federal and State nondiscrimination laws and by the agencies charged with enforcing those laws. Accordingly, the Department concludes that mandatory inclusion of selection procedures in apprenticeship standards is not necessary to ensure equal opportunity within Registered Apprenticeship programs. Sponsors remain free to include selection procedures in their standards or other program materials if they determine that doing so promotes transparency, consistency, or effective program administration.

The Department also reiterates that § 30.10(b)(1) of the part 30 regulation imposed obligations on program sponsors beyond those mandated under Title VII by requiring compliance with the Uniform Guidelines on Employee Selection Procedures (UGESP), which provides discretionary guidance to the EEOC and employers regarding validation of selection procedures rather than binding substantive standards. *See* 29 CFR 1607.1. Accordingly, the rescission of that regulatory provision was appropriate in order to align part 30 with the scope of Title VII's requirements and to reduce regulatory burden upon program sponsors. Furthermore, the Department has proposed in a separate rulemaking to rescind its codification of UGESP at 41 CFR part 60–3 as applied to covered contractors because of the revocation of E.O. 11246, which provided the underlying authority for that rule. Finally, the Department of Justice's Office of Legal Counsel recently issued an opinion concluding that the EEOC's existing interpretations of the disparate impact provisions in Title VII, including as reflected in UGESP, ''embrace an unconstitutional reading of Title VII.'' *See Constitutionality of Disparate-Impact Liability Under Title VII,* 50 Op. O.L.C. __, at *2 (June 9, 2026) (''Disparate-Impact Liability'').

Similarly, the requirements contained in § 30.10(b)(3) of the part 30 regulation were redundant of the obligations already imposed upon certain program sponsors by the ADA and the EEOC's implementing regulations at 29 CFR part 1630. However, the Department notes that nothing in this final rule precludes program sponsors from voluntarily including selection procedures in their standards. This rescission simply removes a description of the program's selection procedures as a mandatory requirement. Overall, the Department maintains that the rescission of § 30.10 of the existing part 30 regulation in this final rule will significantly reduce compliance burdens on program sponsors, thereby facilitating the accelerated establishment and expansion of Registered Apprenticeship programs, particularly in those sectors and occupations that are currently facing acute labor shortages.

In response to one commenter, the Department is clarifying that nothing in this final rule prohibits sponsors from providing advanced standing, direct interviews or direct entry into their Registered Apprenticeship program for individuals that complete a pre-apprenticeship or other preparatory program. Sponsors should record their policy for granting advanced standing to preparatory program completers and must ensure this policy allows all applicants to be equally granted such standing as required by 29 CFR 29.5(b)(12).

E. Rescission of Sponsor Recordkeeping Requirements

The Department proposed to rescind § 30.12, which imposed certain recordkeeping requirements on program sponsors.

Comments: A commenter expressed concern that by eliminating recordkeeping requirements, data from sponsors about the availability of apprenticeship opportunities across demographic categories would become inconsistent and impossible to assess, significantly weakening the effectiveness of 29 CFR part 30. However, another commenter stated that it would rescind burdensome recordkeeping requirements including the obligation of retaining detailed demographic information about each apprentice and applicant for multiple years.

Department Response: The Department disagrees with commenters who suggest that the rescission of § 30.12 will prevent meaningful oversight. As discussed elsewhere in this preamble, the Department does not view the assessment of demographic proportionality as an appropriate purpose of part 30. Rather, the purpose of part 30 is to prohibit unlawful discrimination and ensure that apprenticeship opportunities are made available on an equal basis to all individuals. Therefore, the continued maintenance of extensive sponsor-level demographic records is not necessary to safeguard apprentice welfare or enforce applicable nondiscrimination laws. In the NPRM, the Department clarified that apprenticeship agreements must still include ''a request for demographic data about the apprentice.'' The elimination of sponsors' recordkeeping obligations for part 30 requirements does not eliminate part 29's requirements to collect and maintain demographic data on apprentices through the apprenticeship agreement requirements at 29 CFR 29.7(l) and recordkeeping requirements at 29 CFR 29.5(b)(23).

VI. Section-by-Section Analysis—Revised Part 30 Under the Final Rule

A. Section 30.1—Purpose and Applicability

The proposed introductory ''Purpose and Applicability'' section would have significantly updated and condensed

the previous ''Purpose, applicability, and relationship to other laws'' provision in part 30. In alignment with the policy approach described above, proposed § 30.1 eliminated references to affirmative action and removed redundant language concerning protected bases and complaint processes, which are addressed elsewhere in the regulation.

Proposed § 30.1 of this final rule explicitly stated that the part 30 regulation establishes a uniform Federal standard that prohibits unlawful discrimination against apprentices and applicants in Registered Apprenticeship programs. It also reaffirmed that these nondiscrimination requirements apply to program sponsors and must be enforced by SAAs. Furthermore, it clarified the scope of compliance reviews, compliance assistance, and enforcement actions to be conducted by the Registration Agency. For the reasons discussed in the NPRM and in response to comments discussed below, the Department is finalizing this provision as proposed.

Comments: A commenter asked if the Department considered applying the proposed changes only to employers greater than a certain size (*e.g.,* 500 or more employees).

Department Response: As stated in the final regulatory language at § 30.1, this final rule creates a uniform, non-burdensome Federal standard for all Registered Apprenticeship program sponsors to follow applicable Federal and State nondiscrimination laws. The Department considered applying the changes to the part 30 regulation only to employers greater than a certain size, but it determined that doing so would not serve the interest of establishing a uniform rule. The Department has determined that uniformity promotes greater clarity for Registered Apprenticeship program sponsors on their obligation to prevent and address illegal discrimination against apprentices, as well as part 30's applicability to all programs.

B. Section 30.2—Definitions

Under the NPRM, the Department proposed to eliminate all definitions in the current part 30 regulation and to adopt by reference the applicable existing definitions from the labor standards of apprenticeship regulation at 29 CFR part 29. In the NPRM, the Department maintained that the definitions found in existing § 30.2 are either duplicative of those in 29 CFR 29.2 or would no longer be relevant due to the significant revisions proposed to the substantive provisions of part 30.

The Department asserts that consolidating all apprenticeship-related definitions within the existing regulatory framework of 29 CFR part 29 will reduce administrative burdens on sponsors of Registered Apprenticeship programs and other stakeholders by providing a single point of reference for definitions within the Federal apprenticeship regulations. For the reasons discussed in the NPRM and in response to comments discussed below, the Department is finalizing the provision as proposed.

Comments: A commenter agreed with the proposed revision to remove definitions in 29 CFR 30.2 and adopt by reference the existing definitions found in 29 CFR 29.2, stating that the definitions in both parts should be aligned and that doing so would ''reduce confusion for the regulated community'' and simplify compliance for sponsors and employers.

This commenter recommended retaining certain definitions proposed for removal, such as ''pre-apprenticeship program,'' which is not currently defined in 29 CFR 29.2. The commenter opposed removing this as a defined term in the apprenticeship regulations, asserting that defining key terms provides clarity for apprenticeship stakeholders. Alternatively, if the Department does not retain the definition in regulation, the commenter recommended that the Department update Training and Employment Notice No. 23–23 to align with recent E.O.s, or with the definition of ''pre-apprenticeship program'' under the Workforce Innovation and Opportunity Act (WIOA) regulations at 20 CFR 681.480. The commenter also urged the Department to preserve the definition of ''selection procedure'' in a revised 29 CFR 29.2 to ensure Registration Agencies understand program entry requirements and to help prevent discrimination. Lastly, the commenter recommended preserving definitions for ''race,'' ''ethnicity,'' and ''disability,'' either in revised § 29.2 or by citing other Federal definitions, to facilitate effective data collection.

Department Response: The Department appreciates the comments regarding the consolidation of definitions within part 29 as proposed by the NPRM. Regarding a commenter's concerns about eliminating the definition for ''pre-apprenticeship,'' the Department notes that pre-apprenticeship programs are not registered by the Department pursuant to the NAA. As such, the Department does not regulate such programs. The Department maintains that this rulemaking updating part 30 requirements is not an appropriate vehicle for establishing any regulatory definitions or other regulations for pre-apprenticeship programs. The Department agrees with the commenter's suggestion to align any future guidance on pre-apprenticeship with the Administration's E.O.'s, as well as the definition for pre-apprenticeship from the WIOA regulation at 20 CFR 681.480, to support alignment among workforce development programs overseen by the Department.

In response to comments on the removal of the definition of ''selection procedures,'' the Department asserts that a definition of this term is not necessary in this final rule due to the substantial revisions to part 30 and the conforming edits to 29 CFR 29.5(b)(21), which remove all references to the term ''selection procedure'' from parts 29 and 30. Furthermore, the Department notes that the definition of ''selection procedure'' was drawn from the UGESP. As noted earlier in the preamble, the Department has proposed in a separate rulemaking to rescind its codification of UGESP at 41 CFR part 60–3.

Regarding maintaining definitions for race, ethnicity, and disability, the final rule's conforming edits to existing § 29.7(l) eliminate the requirement that a sponsor must specifically request information from apprentices on their race, sex, ethnicity, and disability status. Instead, under this final rule, sponsors only are required to include ''a request for demographic data about the apprentice'' within apprenticeship agreements. Accordingly, the Department has determined it is not necessary to include a regulatory definition for these terms to assist with data collection.

C. Section 30.3—Nondiscrimination Standards Applicable to All Sponsors

Under the NPRM, the Department proposed obligating all sponsors of a Registered Apprenticeship program to comply with all applicable Federal and State laws and regulations prohibiting illegal discrimination on the basis of race, color, religion, national origin, sex, age (40 or older), genetic information, or disability. The Department explained in the NPRM that this list of protected bases is fully consistent with the content and scope of currently applicable Federal civil rights statutes, including Title VII of the Act and its subsequent amendments, the ADEA, as amended, the ADA, as amended, and the Genetic Information Nondiscrimination Act of 2008.

The proposed regulatory provision additionally specified that non-compliance by a Registered

Apprenticeship program sponsor with relevant Federal and State nondiscrimination laws may lead to enforcement actions or deregistration proceedings by a Registration Agency, in accordance with § 30.5 of the proposed rule, if the non-compliance pertains to illegal discrimination against an apprentice or an apprenticeship applicant regarding any aspect of employment benefits, terms, or conditions related to the apprenticeship. The Department's intent is to confer the benefits of registration upon those sponsors that conduct their programs in a manner consistent with applicable Federal and State nondiscrimination laws. Further, the Department has an interest in carrying out the Administration's directive to undertake deregulatory actions where existing regulations impose unnecessary and burdensome requirements on businesses.

Accordingly, for the reasons discussed in the NPRM and in response to comments discussed below, the Department is finalizing the provision as proposed.

1. General Comments on the Proposed Nondiscrimination Standards Provision

Comments: A couple of commenters expressed support for revising § 30.3 to direct Registered Apprenticeship program sponsors to comply with all applicable Federal and State laws and regulations prohibiting illegal discrimination to eliminate unnecessarily complex requirements.

However, other commenters opposing the change stated that the proposed rule would replace § 30.3's robust protections with a generic requirement to comply with ''applicable Federal and State laws'' governing discrimination, which would weaken safeguards, reduce accountability, and would leave certain apprentices unprotected. One of these commenters concluded that, under the proposed rule, sponsors that are not joint labor-management committees or do not have at least 15 employees or members would not be covered by any nondiscrimination law. Other commenters noted that, while Title VII of the Act provides that it is unlawful for employers, labor organizations, or joint labor-management committees controlling apprenticeship to discriminate, there are apprenticeship programs run by other entities (such as non-profit trade associations) that do not fall under any of these categories. These commenters asserted that current § 30.3 helps bridge this gap and provide protections to apprentices in programs not covered by Title VII. Some of these commenters cited the case of *Salas* v. *Independent Electrical Contractors Inc.* (W.D. Wash. May 6, 2013), where an apprentice sued his non-joint apprenticeship program alleging discrimination, but the Federal district court held that because the apprentice was not an employee of the apprenticeship program and the program had only five employees, the program did not constitute an ''employer'' under Title VII. Moreover, the court noted that because the program was not associated with a union, it did not constitute a ''joint labor-management committee,'' thus leaving the apprentice without legal recourse. One of these commenters further remarked that several States' nondiscrimination laws do not seem to cover non-joint apprenticeship programs, including Kentucky, New York, Louisiana, Utah, Virginia, and Montana, and provided language from those States' nondiscrimination laws to support their position.

Department Response: The final rule adopts this provision as proposed. The Department agrees with the commenters that the revisions to § 30.3 will eliminate unnecessarily complex requirements, focusing instead on compliance with laws with which employers are already familiar.

The Department disagrees with the commenters that the proposed protections are not sufficiently robust and reiterates that apprentices retain safeguards available under Federal and State nondiscrimination laws. To the extent that certain apprentices are not covered by those existing laws, Congress and State legislatures have chosen the relevant jurisdictional thresholds, and they could seek to amend them in the future. For example, Congress specifically contemplated coverage of apprentices in Title VII, including in sections 703(d) and 704(a) and (b),[50] while also setting in section 701(b) a statutory minimum of 15 employees for covered employers.[51] In response to comments citing the *Salas* case—which dealt with the definition of ''employee'' under Title VII, the ADEA, and Washington State law—the Department recognizes that there are some entities with apprentices that are not covered by Federal or State nondiscrimination laws, including those that have fewer employees than statutory minimums. Congress and some State legislatures likewise determined that nondiscrimination laws apply to employers, labor organizations, and joint labor-management committees.

As indicated earlier in this preamble, the Department is convinced that it would be manifestly improper to retain any of the regulatory provisions contained in part 30 (such as the regulatory language delineating the scope of coverage of the nondiscrimination provision available under existing § 30.3) that may have operated to either circumvent or contravene the foregoing coverage provisions of Title VII or of other applicable Federal or State employment nondiscrimination statutes. Were the Department to retain such broadly encompassing regulatory coverage language in this final rule—as it was urged to do by several commenters—the Department would be essentially subverting the legislative intent of Congress and of State legislatures via an agency regulation, which is a plainly inadmissible course of action. The Department does not wish to exercise its authority under the NAA in a manner that contravenes clear Congressional instruction. Accordingly, as Congress did not include non-joint committees as entities falling under Title VII's definition of ''employer'' or ''labor organization,'' the Department defers to the apparent legislative intent of the Nation's elected representatives and declines to adopt these commenters' recommendations.

In this connection, the Department has consistently maintained that the sponsor of a Registered Apprenticeship program is the entity that bears responsibility for ensuring that the program is conducted and operated in a manner consistent with all governing apprenticeship-related statutes and regulations, including compliance with the nondiscrimination requirements contained in this final rule. This broad compliance obligation applies to all models of program sponsorship, regardless of whether the sponsor directly employs each of the apprentices enrolled in their program, or instead operates a ''group'' program (administered on either a joint or a non-joint basis) in which one or more participating employers have agreed, in writing, to adopt the sponsor's apprenticeship standards for the training of their respective apprenticeship cohorts. There may be instances where the sponsor of a group program receives information—either through their own monitoring or as a result of a program review by the Registration Agency—that a participating employer has not met their contractual obligation to follow the program's standards of apprenticeship, or has failed to comply with governing

[50] 42 U.S.C. 2000e–2(d) and 2000e–3(a) and (b).

[51] 42 U.S.C. 2000e(b).

apprenticeship-related laws (such as applicable Federal employment nondiscrimination statutes or the part 30 requirements contained in this final rule). In such cases, the group sponsor should promptly implement effective corrective measures to ensure participating employers' ongoing compliance with their program standards, which includes the requirement to comply with part 30.

Further, the Department notes that the current part 30 enforcement structure was largely duplicative of other Federal and State law protections, and that these revisions will remove this duplication, thereby reducing burden and confusion among sponsors, who should already be familiar with Federal and State nondiscrimination laws. This aligns with E.O. 14278's mandate that the Department seek to expand Registered Apprenticeship and improve efficiency.

2. State Law Requirements

Comments: A commenter expressed concern about the proposed regulatory provision at § 30.3, which would require compliance with ''all applicable'' Federal and State laws and regulations prohibiting discrimination. The commenter interpreted this as requiring compliance with all nondiscrimination laws that apply to a program sponsor but reasoned that ''applicable'' State laws and regulations could be read more narrowly to refer only to those that pertain exclusively to nondiscrimination in apprenticeship, as in proposed § 30.7(b)(1)(i). Therefore, the commenter asked the Department to clarify its intent and the scope of laws covered by § 30.3. Regardless, the commenter urged DOL to drop the requirement to comply with State nondiscrimination laws and regulations, expressing concern that requiring compliance with State laws would undermine the Trump administration's goals and executive orders on ''restoring biological truth, protecting women and girls, and eradicating gender ideology.'' Furthermore, the commenter cautioned that State nondiscrimination laws and regulations may not be as solicitous as Federal laws and regulations, citing *Union Gospel Mission* v. *Ferguson,* No. 23–2606, 2024 WL 3755954 (9th Cir. Aug. 12, 2024), regarding protections for religious organizations to run their organizations in accordance with their religious beliefs. Citing *World Vision* v. *McMahon,* the commenter argued, that while the First Amendment applies to State nondiscrimination laws, Federal statutory protections for religious liberty do not. The commenter proposed specific alternative regulatory text for § 30.3 to address these concerns.

Similarly, another commenter supported retaining the prohibition on religious discrimination but remarked that religious employers should have the ability to apply religious criteria when making workforce decisions. However, the commenter expressed concern that removing the language referring to legal standards and defenses applied under Title VII could prevent religious employers from invoking Title VII's exemptions in the apprenticeship context.

A commenter expressed concern that removing the detailed language currently in § 30.3 would leave SAAs with fewer tools to train sponsors and employers on compliance and to prevent discriminatory practices before they escalate to legal action. The commenter recommended that if finalized, the Department should offer guidance, training, and tools to address this concern.

A commenter recommended that the Department issue subregulatory guidance outlining when OA would exercise its authority to register apprenticeship programs in SAA States, as permitted under § 29.13(j)(2), in the context of SAAs found to be out of compliance with the proposed rule because of nondiscrimination policies that do not ''conform only'' to the rule. Refer to section V.F.7.a for additional commentary on State nondiscrimination laws and their conformity to the requirements of part 30.

Department Response: The Department agrees with the commenters' interpretation that § 30.3 requires program sponsors to comply with all applicable State laws that prohibit illegal discrimination on the delineated bases. The Department notes that there is a distinction between the language set out in § 30.3 and § 30.7. Under the final rule's revised language, § 30.7 clarifies that its provisions cover State laws, regulations, policies, and operational procedures specific to nondiscrimination or equal opportunity in apprenticeship. In this way, the Department intends for the scope of laws subject to § 30.7 to be narrower than § 30.3, as § 30.3 requires compliance with all applicable Federal and State laws prohibiting illegal discrimination on the listed bases. In response to the commenter's concern about undermining the Administration's goals if State law compliance is required, the Department notes that, absent the language in § 30.3, entities that serve as program sponsors will still be required to comply with applicable State laws as long as such laws have not been held to conflict with Federal law, regardless of whether the entity chose to become a program sponsor. Additionally, the language in § 30.5 directs Registration Agencies to assess compliance based on any final determinations of a sponsor's violation of an applicable nondiscrimination law made by an enforcement entity or court—a determination that would have been made regardless of the language in § 30.3. Thus, the final rule does not place any additional regulatory burdens or coverage requirements onto sponsors.

The Department appreciates commenters' concerns surrounding religious liberty and the availability of religious exemptions for program sponsors. The Department acknowledges that, under the United States' system of federalism, religious liberty protections are dependent on whether State or Federal law applies. The Department points out that, federally, Title VII of the Act and the ADA, provide exemptions for religious organizations, which would apply to all employers covered by those laws, including in the apprenticeship context. While Federal statutory protections for religious liberty do not apply to State nondiscrimination laws, many States have chosen to enact their own statutory and regulatory schemes to protect religious liberty and provide religious exemptions. For example, several States have enacted their own religious freedom laws that are modeled after the Religious Freedom Restoration Act.[52] The Department asserts that agencies including the EEOC and State FEPAs are better positioned to further address the applicability of religious exemptions as they enforce the applicable statutes.

Additionally, the Department notes that the provisions of part 30 have no bearing on the availability of religious exemptions under Title VII (or other nondiscrimination statutes), and that the Department will respect a court's determination that a sponsor has properly invoked an exemption when considering the sponsor's compliance with the standard in § 30.3. As such, in response to commenters requesting that the Department change the proposed text at § 30.3 to remove the requirement that sponsors must comply with State nondiscrimination laws, the Department declines to adopt the suggestion, but notes that the existing part 30 exemption provision is being retained in this final rule. This provision allows sponsors to request exemptions from part 30 requirements in writing, supported by an explanation of the

[52] 42 U.S.C. ch. 21B. *See, e.g.,* DOL, ''Workforce Discrimination Resources by State,'' *https://www.dol.gov/agencies/faith/workforce-discrimination-resources-by-state* (last visited June 26, 2026).

reasons for the request. Where a sponsor has been found to be in violation of a State law that the sponsor views as infringing on its religious liberties, the sponsor may request an exemption pursuant to § 30.8 from the Registration Agency and the Registration Agency will consider whether the sponsor has presented good cause sufficient to avoid deregistration on the grounds of such violation.

In response to the comment expressing concern that SAAs will have less compliance assistance and resources to help prevent illegal discrimination, the Department provides that it will engage in technical assistance as requested. Additionally, the Department notes that the relevant Federal and State enforcement agencies can engage in compliance assistance and may have guidance, training, and other resources available that covered entities can utilize in their compliance efforts.

3. Youth Apprenticeship

Comments: A commenter requested clarification or subregulatory guidance from the Department on how the proposed § 30.3's prohibition of discrimination based on age (40 or older) can be navigated when developing youth apprenticeship programs. The commenter said that while they are supportive of this provision to ensure no age discrimination is allowed, dedicated youth apprenticeship programs with upper age requirements at 24 may be considered discriminatory based on age. The commenter remarked that this is further challenging for instances where high school Career and Technical Education programs may seek to be sponsors of Registered Apprenticeship programs, but in most instances, a student cannot be in high school after age 21. The commenter elaborated that this tension is compounded by the fact that on April 2, 1996, the EEOC adopted a rule that ended the longstanding policy exemption for apprenticeship programs from coverage under the ADEA. The commenter noted that OA issued a policy in Circular 96–01 on May 30, 1996, which communicated that upper age limits on programs were no longer allowed, but this circular was rescinded on June 4, 2020, by Circular 2020–01.

Department Response: The Department appreciates the commenter's interest in expanding Registered Apprenticeship opportunities for youth. Under the final rule, what activity constitutes illegal discrimination on the basis of age is a matter for the EEOC to determine in their enforcement of the ADEA. Furthermore, the Department maintains that this part 30 rulemaking is not a suitable regulatory vehicle for addressing the topic of Federal registration of youth apprenticeship programs.

D. Section 30.4—Complaints

In the NPRM, the Department proposed to remove the complaint provision in the current part 30 regulation and to replace it with a substantially simplified complaint process set forth at proposed § 30.4. Under that proposal, the Registration Agency would direct individuals alleging unlawful discrimination to an enforcement authority with the appropriate jurisdiction and expertise to investigate compliance with Federal or State nondiscrimination statutes or regulations. Examples of such authorities include the EEOC, the U.S. Attorney General or a State Attorney General, and relevant State enforcement agencies (such as FEPAs). The Department proposed this change after determining that the existing part 30 complaint procedures are burdensome, difficult to navigate, and ineffective, and that Registration Agencies are less well-suited to investigating or resolving apprentice discrimination complaints than the enforcement entities identified in proposed § 30.4.

As explained in the NPRM, replacing a duplicative, apprenticeship-specific complaint mechanism with a straightforward referral process advances the Administration's deregulatory objective to eliminate unnecessary regulatory burdens, ensures that complaints are handled by agencies with the requisite expertise, and serves apprentices' interests by providing a single, clear avenue for filing complaints. Accordingly, for the reasons discussed in the NPRM and in response to comments discussed below, the Department is finalizing the provision with minimal edits. In response to comments discussed below, the Department is revising the proposed language to eliminates language in § 30.4(c) that could have been interpreted as only allowing SAAs to refer complaints to State FEPAs. The Department is also adding that a Registration Agency may refer complaints to any Federal or State enforcement entity with jurisdiction over discrimination issues. Under the revised language as adopted by this final rule, the Department is clarifying that complaints can be referred by any Registration Agency to the EEOC, the U.S. Attorney General, a State FEPA, or another Federal or State enforcement agency with jurisdiction over discrimination issues as appropriate. Furthermore, a complaint may be referred to several of these entities as appropriate.

1. Support for the Proposed Provision

Comments: A commenter expressed support for proposed § 30.4 and shifting enforcement of nondiscrimination laws and regulations to the EEOC, the U.S. Attorney General, and for an SAA, to its FEPA. The commenter stated that this change would eliminate duplicative oversight and enforcement by DOL without sacrificing necessary oversight and enforcement and still retaining the possibility of deregistration by DOL after a final determination of unlawful discrimination. The commenter also stated that nothing in the proposal would prohibit an apprentice from filing a charge of discrimination with the EEOC or State agencies directly.

Department Response: The Department appreciates the commenter's support for the proposed changes and agrees with the commenter that these changes would eliminate duplicative oversight and enforcement measures.

2. Concerns About Removing Registration Agency Authority

Comments: Several commenters expressed opposition to the proposal to eliminate the authority of Registration Agencies to investigate discrimination complaints. These commenters expressed concern that the proposal would eliminate the existing compliance review framework and restrict enforcement actions to cases where a final determination of discrimination had already been made by a court or enforcement entity, which would limit the ability of Registration Agencies to address discrimination effectively.

Several commenters further reasoned that referral-only enforcement would delay remedies, reduce the deterrent effect on noncompliant sponsors, leave apprentices unprotected during lengthy Federal investigations, severely restrict Registration Agencies' options for timely interventions, and erode the cooperative Federal-State framework that has long underpinned the success of the National Apprenticeship System. For example, one commenter said that requiring complaints to be referred to other agencies would mean that sponsors that discriminate would virtually never face deregistration because of how long final determinations will take to reach Registration Agencies. The commenter remarked that under Title VII, a party

alleging illegal discrimination can file a lawsuit in Federal court after completing the prerequisite administrative requirements, but the percentage of Federal EEOC or State FEPA investigations that result in a Federal court lawsuit is very small. Of these, only a small proportion become final through a court decision where an appeal is not filed, because most cases are settled. The commenter also said that the EEOC itself does not issue final determinations, but complainants must pursue their complaints in court after the EEOC makes a preliminary determination.

A commenter expressed concern that the proposal would render Registration Agencies as passive intermediaries and said that research suggests OA and SAAs are often able to resolve discrimination complaints with technical advice and by intervening informally. The commenter warned that such interventions, which the commenter described as timely and cost effective, may be lost under the proposed changes. The commenter further stated that under the proposed rule, if implemented, apprenticeship agencies may be less likely to become aware of potential misconduct because they would no longer be the primary recipient of complaints, thus they may be less likely to help resolve and address complaints. Another commenter stated that eliminating program complaint investigation authority without analysis of its impact on apprentices' ability to seek relief is inconsistent with the NAA's mandate, particularly in terms of how its impact on the timeline for relief for apprentices would affect the welfare of apprentices.

As a result of these concerns, several comments recommended that Registration Agencies should retain their authority to investigate and pursue remediation of discrimination complaints under the existing regulation. One commenter said the retention of this authority is particularly important for issues that implicate both nondiscrimination and broader part 29 compliance. Similarly, another commenter recommended that to align with the NAA's directive to safeguard apprentice welfare, the final rule should consider: (1) retaining investigative and enforcement authority for Registration Agencies to address complaints of discrimination, harassment, or intimidation; (2) enhancing agencies' capability to provide technical assistance in resolving issues with employers collaboratively before they escalate; and (3) clarifying referral protocols to ensure coordination with EEOC or State FEPAs.

Department Response: The Department disagrees with the concerns raised by these commenters. The Department has determined that investigation of discrimination complaints and related tasks are better left with the EEOC or State-level FEPAs because such agencies have the appropriate subject matter expertise and jurisdiction over such matters. For example, the EEOC is the most appropriate enforcement agency for making a determination that a program sponsor violated an applicable Federal nondiscrimination law. Registration Agencies, by contrast, are apprenticeship administrators whose primary responsibility is the registration, oversight, and promotion of Registered Apprenticeship programs. The Department therefore concludes that the investigation and adjudication of discrimination complaints should be conducted by entities specifically established for that purpose rather than by Registration Agencies operating under the NAA.

Under this final rule, once the Registration Agency is made aware of such a determination concerning a Registered Apprenticeship program sponsor, it may initiate appropriate administrative actions, including establishing a compliance action plan or initiating deregistration proceedings, as described in the section-by-section discussion of the nondiscrimination compliance and enforcement section at § 30.5 of this final rule.

The Department is unpersuaded that a referral-based framework will undermine apprentice welfare. To the contrary, the Department maintains that apprentice welfare is best served when allegations of unlawful discrimination are investigated by agencies with the expertise, procedural safeguards, and remedial authority necessary to resolve such claims. The EEOC, State FEPAs, the Department of Justice, and similar entities possess the expertise, jurisdiction, procedural safeguards, and remedial authority necessary to investigate discrimination claims and adjudicate alleged violations of Federal and State civil-rights laws. Registration Agencies, by contrast, lack these key capabilities. The Department is convinced that directing complainants to the appropriate enforcement authority better aligns discrimination enforcement responsibilities with the institutions specifically established to carry out those functions, rather than maintaining a parallel apprenticeship-specific process.

The Department also disagrees with some commenters' suggestion that the ability of Registration Agencies to provide informal technical assistance or facilitate voluntary resolutions justifies retaining investigative authority over discrimination complaints. While the Department recognizes that Registration Agencies have occasionally assisted sponsors and apprentices in resolving workplace disputes, the commenters' observations merely demonstrate that Registration Agencies have historically referred many discrimination complaints to appropriate Federal or State enforcement agencies while providing ancillary assistance where appropriate. Indeed, the report cited by one commenter noted that SAAs frequently refer discrimination complaints to State or Federal FEPAs, particularly where the SAA lacks the means or expertise to investigate the allegations independently.[53] This report thus confirms that the referral-based approach proposed in the NPRM is already common practice for both OA and SAAs. The final rule formalizes and clarifies this practice by directing discrimination complaints to the agencies specifically charged with enforcing nondiscrimination laws.

The Department further maintains that significant administrative consequences, including the development of compliance action plans, suspension of the right to register new apprentices, or deregistration, should be predicated upon findings made by entities possessing legal authority to investigate and adjudicate claims of unlawful discrimination. Registration Agencies should not independently make de facto determinations regarding violations of Federal or State nondiscrimination laws, which risks inconsistent enforcement and conflicting interpretations of nondiscrimination requirements.

Similarly, the Department disagrees with some commenters' assertions that a referral-based approach undermines the NAA's directive to safeguard the welfare of apprentices. The Department has determined that referring complaints alleging illegal discrimination to appropriate enforcement agencies will better safeguard the welfare of apprentices by ensuring that the substance of the complaint will be investigated by entities with the appropriate expertise

[53] Zach Boren and Shruti Nayak, ''State-Level Policies Develop Skilled Workforces through Registered Apprenticeship Programs Lessons from the Office of Apprenticeship and Four State Apprenticeship Agencies,'' Urban Institute, Apr. 2025, *https://www.urban.org/sites/default/files/2025-04/State-Level%20Policies%20Develop%20Skilled%20Workforces%20through%20Registered%20Apprenticeship%20Programs.pdf.*

and providing apprentices with a legitimate opportunity to receive individualized relief in response to the alleged illegal conduct. The Department notes that such individualized forms of relief are available under Title VII and other Federal statutes, but have never been included in the part 30 regulation.

Separately, in response to one commenter who asserted that the EEOC does not issue final determinations and that complainants must pursue complaints in court after a preliminary determination by the EEOC, the Department maintains that this and other similar enforcement agencies are the most appropriate venues for apprentices to raise allegations of discriminatory conduct by an apprenticeship program. In response to the commenter raising concerns about delayed enforcement, while the Department acknowledges that it is possible that the referral of complaints to other agencies may take additional time, such referrals nevertheless ensure that such complaints are investigated and handled appropriately, and that determinations are made accurately by entities with the relevant expertise.

3. Concerns About Reliance on Complaints

Comments: Some commenters expressed concern about the proposal's reliance on complaints to address discrimination. These commenters stated that most individuals who experience discrimination do not file formal complaints due to, among other reasons, fear of retaliation, a lack of resources, or concerns that final determinations are rare and often take years to resolve. One commenter cited research which it found that only between 6 and 13 percent of harassment incidents are formally reported in the construction trades, in part due to fears of retaliation or that their compliant will not be acted upon. Some commenters also asserted that relying on a complaints-driven civil rights compliance system would place the burden of preventing discrimination on apprentices, and maintained that such a system would be ineffective and unfair.[54] Another commenter added that the EEOC recommends that multiple people in an organization should be authorized to receive complaints, so that complainants have more reporting options.

Department Response: The Department understands commenters' concerns that some apprentices who experience discrimination may choose not to file formal complaints. The Department is not persuaded, however, that retaining apprenticeship-specific compliance reviews would meaningfully uncover instances of unlawful discrimination.

The compliance reviews conducted under the prior regulation were principally designed to assess compliance with the affirmative action requirements contained in part 30, including utilization analyses, utilization goals, action taken to meet such goals, and related recordkeeping requirements. As discussed elsewhere in this preamble, the Department has determined that these requirements were burdensome and, in many cases, likely unlawful. While there is no longer a need to conduct compliance reviews that assess compliance with the rescinded provisions of part 30, the final rule at § 30.5 does preserve a mechanism for monitoring compliance with the revised part 30 requirements pursuant to the program review provision under 29 CFR 29.6.

While affirmative action requirements can be assessed through the review of records and other objective indicators, individual allegations of intentional discrimination frequently involve fact-specific disputes concerning motive, intent, harassment, or other conduct directed at particular individuals. Such matters are frequently identified only through complaints, witness testimony, and investigative procedures conducted by agencies and courts with expertise in enforcing nondiscrimination laws. It is unsurprising that Congress and State legislatures have generally relied on complaint-driven processes to enforce nondiscrimination laws. Therefore, allegations of unlawful discrimination are more appropriately addressed through the established Federal and State nondiscrimination enforcement framework than through apprenticeship-specific compliance reviews.

Commenters' concern over the chilling effect on employees who file complaints is addressed by Federal and State nondiscrimination laws that prohibit retaliation against individuals who file complaints or otherwise participate in protected activities. If a sponsor is found to have engaged in unlawful retaliation under one of these laws or any other applicable nondiscrimination law, the EEO agency and the Department can hold the sponsor accountable pursuant to revised § 30.5. Finally, in response to one commenter's concern, the Department also clarifies that nothing in the rule prohibits sponsors from designating multiple people within their organizations as being responsible for receiving complaints related to nondiscrimination law.

4. Comments Alleging Certain Harmful Impacts That Would Result From the Department's Proposed Streamlining of Enforcement and Oversight Activities

Comments: A commenter asserted that the proposed rule would reduce Registration Agency oversight and intervention in cases of discrimination and harassment and would therefore likely increase non-completion of apprenticeship programs, preventing employers and labor markets overall from the benefits of investments in apprenticeship. The commenter also cited research finding that the lifetime costs of workplace sexual harassment and retaliation were particularly high for those pushed out of well-paid occupations, reaching $1.3 million for an apprentice in the construction trades.

Another commenter also raised questions on how Registration Agencies would become aware of final determinations. One commenter recommended that the Department consider data sharing practices or subregulatory guidance on how it will receive final judgments and pursue enforcement actions for consistency.

Department Response: While these commenters raised concerns regarding the proposed rule's adverse impacts upon apprenticeship completion rates and the lifelong costs of discrimination and harassment, they did not provide persuasive evidence that the compliance review provisions in the existing part 30 regulation have been effective in mitigating the prevalence of discrimination and other forms of egregious conduct in the apprenticeship workplace. As with discrimination, it is unclear how, for instance, compliance review can detect unreported harassment allegations. Since apprentices will retain the opportunity to file complaints in response to such conduct, and will have a more streamlined and clear approach to filing such complaints, the Department does not agree that the proposed regulatory revisions will harm completion rates or will result in an increase in the prevalence of discrimination or harassment in apprenticeship programs.

The Department received comments requesting clarity regarding how Registration Agencies will be made aware when a final determination from an enforcement entity or court regarding a violation of applicable nondiscrimination against a program's apprentice or applicant for apprenticeship. The Department appreciates these comments and has included a provision in the ''Nondiscrimination Compliance and Enforcement'' section of this final rule,

at § 30.5(b)(1) and (2), that requires sponsors to report any final determinations that an applicable nondiscrimination law has been violated with respect to an apprentice or applicant for apprenticeship to the Registration Agency within 60 days. The Department asserts that this requirement will strengthen transparency and accountability regarding sponsors' compliance with applicable nondiscrimination laws.

Further, the Department maintains that there are several ways Registration Agencies can work with the EEOC or State FEPAs and the court system to be informed of final determinations of illegal discrimination against apprentices or applicants to an apprenticeship program. For example, Registration Agencies could review court filings or could send inquiry letters to the relevant Federal and State FEPAs as part of the program review process. To the extent possible and appropriate, Registration Agencies are also encouraged to develop MOUs and other partnerships with Federal and State FEPAs to receive notifications of final determinations concerning nondiscrimination violations against apprentices or applicants to an apprenticeship program by Registered Apprenticeship program sponsors from such governmental entities or establish a mechanism by which Registration Agencies can make inquiries. The Department maintains that the addition of a self-disclosure requirement for sponsors whose program is the subject of a final determination will facilitate Registration Agencies' awareness of any relevant nondiscrimination law violations among the Registered Apprenticeship programs they oversee and declines to add any specific requirements for Registration Agencies to establish information-sharing agreements to verify such violations. Given that different options may be suitable based on different administrative structures across States, the Department maintains that imposing a uniform approach for Registration Agencies to conduct any additional verification of such information through regulatory text is not appropriate.

5. Other Administrative Concerns Related to Complaints

Comments: A commenter remarked that, among other issues, one concern with requiring complaints to be referred to State FEPAs is that in two SAA States, Alabama and Arkansas, there is no such State agency, and that in some other SAA States, there may be multiple applicable agencies, but the proposed rule does not provide clarity on identifying the correct agency. The commenter also expressed concern about the lack of discretion for Registration Agencies allowed under the proposed rule, specifically posing a hypothetical where the EEOC's budget were to shrink to the point where it could not accept additional complaints from OA. Additionally, another commenter expressed concern that the proposed changes would place investigative and resource strains on already under-resourced agencies.

A commenter warned that the proposed rule's reliance on complaints would largely inhibit Registration Agencies' ability to perform compliance reviews. The commenter stated that while the rule nominally retains the compliance review provision, the Registration Agency would not be able to initiate any enforcement action against a sponsor unless there was a final determination of wrongdoing, which would rely on the filing of complaints by apprentices. As a result, the commenter warned that the proposed reliance on complaints would mean that Registration Agencies would have no authority to take any action if they observe blatant discrimination that violates part 30 while they are conducting a part 29 review unless and until there is a final determination.

Department Response: Regarding the concern that some States do not have a State FEPA, as the preamble above clarifies, this final rule does not limit SAA States to referring complaints to their State FEPA. Under the final rule, SAA states may refer the complaint to any Federal or State agency with appropriate subject matter expertise and jurisdiction over matters concerning illegal discrimination. In response to this concern, and as noted above, the Department has changed the regulatory text at § 30.4 in this final rule to clarify that the list of enforcement entities is not limited to the EEOC, U.S. Attorney General, or State FEP, and that Registration Agencies may refer the complaint to any other appropriate enforcement entities with appropriate subject matter expertise and jurisdiction. In addition, the Department changed the regulatory text at § 30.4 to clarify that Registration Agencies are not limited to referring complaints to one enforcement entity, and may refer complaints to multiple entities as appropriate.

In response to commenters' concerns that the EEOC is facing restraints on its resources that could impact its capacity to handle complaints effectively, the Department notes that the budgetary resources and staffing capacity of the EEOC are determined by Congress and not the Department. Additionally, the Department has received only a small number of discrimination complaints from apprentices under the existing regulation, and notes that its longstanding practice has been to refer such complaints to the EEOC as the appropriate Federal agency for determining whether an allegation of discriminatory conduct has merit. EEOC data indicates that the agency received over 88,000 charges of workplace discrimination in FY 2024 alone, whereas the Department has received fewer than 60 complaints of discrimination under part 30 from apprentices since the beginning of FY 2021.[55]

Finally, the Department does not share commenters' concerns that the proposed rule would limit the ability of Registration Agencies to initiate any enforcement actions against a sponsor unless there was a final determination of illegal discrimination. The Department maintains that it is appropriate to defer adverse administrative actions under part 30 against a program sponsor until the Department has received confirmation that a violation of an applicable nondiscrimination law has occurred from an enforcement agency with the appropriate subject matter expertise and jurisdiction to make such determinations.

E. Section 30.5—Nondiscrimination Compliance Reviews and Enforcement

In the NPRM, the Department proposed eliminating the extensive EEO and affirmative action requirements in the current part 30 regulation and revising the existing compliance and enforcement framework in §§ 30.13 and 30.15 by consolidating and simplifying those provisions into a new § 30.5. Under the current rule, the Department conducts routine ''EEO compliance reviews'' to evaluate sponsors' adherence to the comprehensive set of requirements across part 30, with particular attention to the development and implementation of an affirmative action program required for programs with five or more apprentices under current § 30.4, the contents of which are detailed in §§ 30.5 through 30.9 and 30.11. Accordingly, the Department proposed to merge the compliance review and enforcement components of the regulation into a single section—''Nondiscrimination compliance reviews and enforcement''—at proposed § 30.5.

[55] EEOC, ''Enforcement and Litigation Statistics'' *https://www.eeoc.gov/data/enforcement-and-litigation-statistics-0* (last visited June 26, 2026).

This proposal was designed to focus Departmental resources—principally OA staff's expertise in apprenticeship program quality—on labor standards rather than on making legal determinations regarding compliance with the extensive EEO and affirmative action obligations in the existing part 30 regulation. Consistent with this approach, the Department proposed to rely solely on final determinations issued by an enforcement entity or court with jurisdiction over the matter. The Department anticipated that deferring to the authority and expertise of these entities to decide whether sponsors or other apprenticeship stakeholders (such as employers participating in Registered Apprenticeship programs) have engaged in unlawful discrimination under applicable Federal or State statutes or regulations would yield a more efficient oversight system, strengthen accountability, provide clearer expectations for stakeholders, and result in more appropriate and effective remedies for individuals subjected to discrimination, harassment, or other unlawful treatment in Registered Apprenticeship.

The Department also proposed that compliance reviews related to the streamlined part 30 nondiscrimination requirement occur alongside the program's routine review for compliance with part 29, and that Registration Agencies initiate enforcement actions for violations of the part 30 nondiscrimination requirement only after a court with jurisdiction over employment discrimination (including alleged discrimination involving apprentices or applicants to apprenticeship programs) issues a final, non-appealable determination finding a violation of applicable nondiscrimination laws or regulations. This sequencing was intended to ensure that Registration Agencies do not act while related matters are pending adjudication, consistent with due process principles. Proposed § 30.5(c) outlined the enforcement initiation process, including collaborating with the sponsor to develop a compliance action plan that aligns with the remedy prescribed by the enforcement entity or court. Under proposed § 30.5(c), if a Registration Agency determines that a sponsor is not carrying out the compliance action plan in accordance with the enforcement entity's or court's remedy, the Agency may take additional enforcement steps, including suspending the sponsor's authority to register new apprentices or commencing formal deregistration proceedings under 29 CFR 29.8.

The Department concluded that this streamlined compliance and enforcement framework preserves Registration Agencies' essential role in conferring the benefits of registration and, when necessary, rescinding registration. The Department received several comments requesting clarity on how the proposed compliance framework would work in practice; specifically, how Registration Agencies would be made aware when an enforcement entity or court makes a final determination that an applicable nondiscrimination law was violated with respect to an apprentice or an applicant for apprenticeship. The Department appreciates these comments and agrees that additional clarity on the enforcement framework will benefit stakeholders and support transparency and accountability regarding Registered Apprenticeship program sponsors' compliance with applicable nondiscrimination laws. Accordingly, in this final rule, the Department has added a requirement that sponsors notify the Registration Agency of any final determinations regarding a violation of an applicable nondiscrimination law with respect to an apprentice or applicant for apprenticeship made by a relevant enforcement entity or court within 60 days at § 30.5(b)(1). In addition, at § 30.5(b)(2) of this final rule, the Department has added a requirement for sponsors to disclose the details of any remedies prescribed by the enforcement entity or court to the Registration Agency. The Department has determined that this additional disclosure requirement will facilitate the requirement that the Registration Agency work with the sponsor to develop a compliance action plan that aligns with any such remedy set forth in § 30.5(c) of this final rule. Aside from these additions to the final rule, the Department is adopting § 30.5 as proposed.

Support for the Proposed Compliance Review and Enforcement Provision

Comments: A commenter expressed support for the proposed review and enforcement provision. This commenter reasoned that empowering sponsors to tailor compliance plans to their unique operations, rather than imposing a rigid, one-size-fits-all model, would more effectively promote adherence to Title VII and other nondiscrimination laws in apprenticeship programs. This commenter expressed further support for the proposed enforcement regime, stating that the proposed rule appropriately recognizes that Congress established particular enforcement regimes for nondiscrimination laws and established specific remedies, and that it does not seek to add new enforcement regimes or sanctions on top of those established by Congress. However, the commenter expressed concern about the discretion that would be granted to Registration Agencies to assess whether a compliance plan is being followed and when a violation is resolved, stating that these determinations should remain the purview of the court or agency that issued the original order.

While expressing general support for the provision, a commenter recommended that the Department consider establishing a new regulatory provision that creates a ''rebuttable presumption of compliance'' for programs that demonstrate adherence to key voluntary practices in nondiscrimination and equal opportunity. This commenter remarked that this approach is used successfully by other agencies, and suggested that this approach could assist in addressing reliance interests of existing sponsors who are already complying with the 2016 final rule and reduce the overall regulatory burden while still providing regulatory incentives for programs to exceed the minimum nondiscrimination requirements with good practices and behaviors. The commenter provided alternative regulatory text to effect this suggestion.

Department Response: The Department appreciates these supportive comments. The Department understands the concern regarding the wide degree of discretion available to Registration Agencies under the proposed rule. The Department agrees that it is crucial that there be consistency across Registration Agencies in determining if compliance plans are being followed and that Registration Agencies defer to the remedial actions that enforcement agencies direct sponsors who have been found to have engaged in discriminatory conduct to undertake. In response to comments discussing the need for compliance action plans to adhere to the remedies to nondiscrimination violations provided by enforcement entities or courts, the Department has added a disclosure requirement for sponsors whose programs are the subject of such final determinations. This disclosure requirement will ensure that Registration Agencies are aware of the remedy provided by the enforcement entity or court, and that any compliance action plans established to address violations of nondiscrimination laws are suitably aligned with any such remedies. The Department confirms that the

enforcement framework established in this final rule does not add any new enforcement mechanisms beyond those established by Congress.

In response to a commenter's suggestion to create a ''rebuttable presumption of compliance,'' the Department maintains that the proposed enforcement framework would effectively establish such a presumption of compliance, as a program only would be found noncompliant if there is a final determination that the program violated an applicable nondiscrimination law.

1. Comments on the Status Quo and the Department's Reasoning

Comments: One commenter stated that compliance reviews serve important functions in an enforcement scheme that are not and cannot be served by relying solely on complaints. The commenter remarked that apprentices and applicants are not always aware of discriminatory practices, especially with regard to recruitment and hiring decisions, and that compliance reviews can uncover such practices. The commenter further argued that the Department's reasoning for the proposed change, that Registration Agency staff do not have the required expertise to enforce nondiscrimination requirements, does not stand up to scrutiny. The commenter said that the Department underestimates staff abilities and knowledge; that the Department has substantial resources it can provide to Registration Agency staff to train and support them in their enforcement of nondiscrimination requirements; and that while other enforcement authorities may have more expertise in nondiscrimination law, they are unlikely to have expertise in apprenticeship, which may be necessary to understand forms of discrimination unique to the apprenticeship setting. The commenter also stated that the Department has extensive resources in other departments, mainly the Solicitor's Office, that could provide training, back-up, assistance, and legal analysis to Registration Agency staff and that the Department did not evaluate utilizing the Solicitor's or other existing resources as an alternative to the proposed rule.

Another commenter stated that the proposed rule is correct in arguing that OA lacks the capacity to properly enforce the EEO regulations under 29 CFR part 30, and there are not enough career staff to perform compliance reviews, as required under § 30.13. However, the commenter did not agree that Registration Agency staff lack the knowledge and experience to ensure compliance with the affirmative action requirements. The commenter concluded that any challenges with enforcing the existing framework could be solved by hiring additional staff to perform compliance reviews of affirmative action requirements or utilizing SAAs to perform compliance reviews.

Department Response: In response to these comments, the Department reiterates that, as a general matter, FEPAs are better suited than Registration Agencies to make authoritative administrative determinations regarding whether a program sponsor's hiring practices or other workplace practices constitute illegal discrimination against apprentices or applicants. One commenter acknowledged this reality, agreeing with the Department that FEPAs possess more subject-matter expertise in assessing and identifying discriminatory conduct by employers. Accordingly, the Department has determined that it is wasteful and duplicative for a Registration Agency to conduct investigations into allegations of illegal discrimination, to attempt to resolve issues locally, or to make determinations with respect to discriminatory workplace practices when a referral to the EEOC or other FEPA with subject-matter expertise may be the most appropriate course of action. The Department maintains that providing additional training on nondiscrimination law for Registration Agency staff would be an inefficient use of limited agency resources, particularly since there are other enforcement agencies, such as the EEOC and State FEPAs, that have been directed by Federal and State laws to evaluate allegations of illegal discrimination.

In response to the commenter who suggested Registration Agencies' expertise in apprenticeship matters is useful in determining whether discrimination has occurred in a Registered Apprenticeship program, the Department notes that nothing in this final rule prevents Registration Agency staff from responding to inquiries from enforcement agencies during their investigation. The commenter did not provide any concrete examples of how the expertise of Registration Agencies regarding apprenticeship matters is specifically beneficial in investigating discrimination complaints. The Department maintains that investigating complaints alleging discrimination against apprentices should not differ from the investigation of complaints in other employment settings.

F. Section 30.6—Reinstatement of Program Registration

The Department proposed to retain the ''Reinstatement of program registration'' provision at current § 30.16. As part of the streamlined part 30 framework under the NPRM, sponsors would retain the right to request reinstatement of registration by demonstrating—to the Registration Agency and to the court that issued the final determination of a violation of applicable nondiscrimination law or regulation—that the program was being operated in compliance with nondiscrimination law and this part. The proposal preserved the existing requirement that sponsors present ''adequate evidence'' of compliance with part 30. Because violations under part 30 would have been confirmed by a court of competent jurisdiction, sponsors would have been required to provide evidence satisfactory to that court that they had addressed the issues underlying the nondiscrimination complaint, including implementing any ordered remedies. Retaining a reinstatement provision was consistent with the proposed compliance approach and supported the Department's objective, in streamlining the regulation, to enhance regulatory flexibility for Registered Apprenticeship stakeholders.

The Department did not receive public comments related to proposed § 30.6. Accordingly, for the reasons discussed in the NPRM, the Department finalizes the provision as proposed.

G. Section 30.7—State Apprenticeship Agencies

In the NPRM, the Department proposed to rescind parts of current § 30.18, the provision covering SAAs, in the existing part 30 regulation. The Department explained that the current part 30 regulation, and the existing regulatory requirements for SAAs under part 30, have not been fully successful in achieving a uniform national standard for nondiscrimination and equality of opportunity in Registered Apprenticeship, as evidenced by the variations in content and requirements in the State EEO plans required by existing § 30.18. Given the inconsistencies the existing part 30 regulation has created across SAAs, the Department proposed a new section for SAA requirements related to the part 30 regulation, at proposed § 30.7, that reflects the Department's determination that sponsors operating Registered Apprenticeship programs should not be required to comply with excessive and legally suspect requirements that only apply to Registered Apprenticeship and

not their general workforce. In the NPRM, the Department argued that proposed § 30.7 would facilitate the establishment of a uniform Federal standard governing nondiscrimination in Registered Apprenticeship and reduce administrative burdens for SAAs by stipulating that compliance with applicable Federal and State nondiscrimination laws is sufficient to conform with the requirements of an updated part 30 regulation.

As proposed, § 30.7(a) would have required that, within 1 year of the effective date of the final rule, all SAAs seeking to obtain or maintain recognition under current § 29.13 must ensure that their State's apprenticeship laws, regulations, policies, and procedures specifically pertaining to nondiscrimination for apprentices ''conform only to the requirements of this part [30].'' This provision was proposed to relieve SAA States from having to impose the complex, burdensome, and legally suspect set of regulatory obligations that are found in current version of part 30 and would substitute a straightforward requirement that such states conform to the nondiscrimination requirements found in applicable Federal and State laws. The Department explained that the purpose of this proposed provision was to establish a nationally uniform standard for nondiscrimination protections across all States participating in the National Apprenticeship System.

In proposing to establish a uniform Federal standard at proposed § 30.7(a), the Department sought to ensure that State laws and regulations concerning nondiscrimination or equality of opportunity in Registered Apprenticeship were coextensive in their substance and scope with the requirements of the proposed revision to part 30 and consistent with Federal and State nondiscrimination laws. The Department explained that attaining a uniform standard across all States would be particularly helpful for sponsors that register and operate their programs in multiple States, and would foster an environment that is conducive to accelerating the expansion of Registered Apprenticeship programs. In addition, proposed § 30.7(a) would have allowed States to seek an extension for ''good cause'' to provide needed flexibility for States with differing legislative or regulatory processes to enact and implement laws that conform only to the requirements stipulated at proposed § 30.7.

Proposed § 30.7(b) and its subordinate paragraphs set forth the elements of State plans for nondiscrimination in apprenticeship for States seeking new or continued SAA recognition. Proposed § 30.7(b)(1)(i) stipulated that State plans include all of a State's statutes, regulations, and policies pertaining specifically to nondiscrimination in apprenticeship, and that such statutes, regulations, and policies conform only to the requirements of the proposed part 30. The Department explained that this language would help to prevent operational fragmentation among State-registered programs and would ensure consistent application of nondiscrimination standards. Proposed § 30.7(b)(1)(ii) further stipulated that all State-registered programs comply with a State's Department-approved State plan within 180 days from the date that the Department approved the State plan submitted under proposed § 30.7(a). The Department determined that a 180-day compliance window would allow for an orderly and timely transition to full implementation at the program level, particularly since sponsors must already be operating their apprenticeship program in compliance with the applicable Federal and State nondiscrimination laws.

Proposed § 30.7(b)(2) mirrored the purpose of existing § 30.18(a)(2)(i-iii) in outlining the review process that OA will undertake upon receipt of the State plan, including providing technical assistance to support conformity with Federal regulations. Similarly, proposed § 30.7(b)(3) stipulated that if an SAA State did not submit a revised State plan that adequately responded to OA's provision of technical assistance on nonconformity issues within 90 days, OA may initiate derecognition proceedings set forth in § 29.14 and proposed § 30.7(e) to formally derecognize the SAA. The Department explained that this provision was intended to provide both due process and accountability for the State. Proposed § 30.7(b)(4) reaffirmed the requirement at existing § 30.18(a)(4) that any subsequent amendments to the State plan for nondiscrimination in apprenticeship must be submitted to the OA Administrator for review and approval prior to implementation to promote alignment between State plans and the Federal nondiscrimination framework described herein.

The recordkeeping requirements stipulated by proposed § 30.7(c) largely replicated the SAA recordkeeping obligations currently found in § 30.18(b), which require a recognized SAA to keep records pertaining to program compliance reviews, complaint investigations, and any other records pertinent to a determination of compliance with the part 30 regulation. These records must be maintained for five years from the date of their creation. The proposed recordkeeping provision was intended to reinforce OA's ability to continue overseeing and auditing compliance over time, including by requiring SAAs to maintain adequate documentation to enable OA to make informed decisions about SAAs' recognition status.

Proposed § 30.7(d)(1) stated that OA would retain full authority to conduct compliance reviews of all registered programs for Federal purposes, even programs registered by an SAA. Similarly, proposed § 30.7(d)(2) reiterated that any SAA that fails to comply with the requirements of this proposed rulemaking would be subject to deregistration proceedings as provided in the part 29 regulation at §§ 29.8(b) and 29.10. The Department explained that the rescission of existing § 30.18(c)(2) and (4)(i) through (iii) was intended to align with proposed § 30.4, which proposed a significantly streamlined complaints framework for complaints alleging illegal discrimination against apprentices. The Department determined that these revisions would more efficiently deploy agency resources and would prevent duplication of investigatory efforts with those civil rights enforcement agencies that possess the statutory authority and expertise to conduct such inquiries. Under this approach, the Department would no longer independently investigate or resolve complaints of discrimination in Registered Apprenticeship. However, OA would retain the authority to refer complaints to appropriate civil rights enforcement agencies (under proposed § 30.4), and to take appropriate enforcement action (under proposed § 30.5) based on another agency's findings regarding discriminatory conduct by program sponsors.

Proposed § 30.7(e) replicated the content of current § 30.18(d). This derecognition provision may be utilized by the Department in appropriate circumstances to assure full conformity by SAA states with Federal nondiscrimination obligations contained in this part.

The Department received some public comments on proposed § 30.7, with some focused on the proposed standard that State laws, regulations, and policies on nondiscrimination in apprenticeship conform only to the revised part 30 regulation. The Department considered all public comments, including comments discussing the proposed ''conform only to'' standard for SAAs, in developing this final rule. In response to concerns raised by public commenters,

the Department has made adjustments to the final regulatory text at § 30.7, including changing the standard to require that SAAs' State laws and regulations ''conform to'' the revised part 30 regulation, and specifying in the regulatory text throughout § 30.7 that such standard applies to State laws and regulations that pertain specifically to nondiscrimination or equal opportunity in apprenticeship. The Department also clarified its requirements for the content of State plans for nondiscrimination in apprenticeship necessary for recognition or continued recognition. These changes to the final rule regulatory text are described below in the Department's responses to public comments on this proposed provision, as are instances where the Department is adopting the regulatory text proposed in the NPRM.

1. Comments on the Proposed Requirement That State Laws Relating to Nondiscrimination in Apprenticeship Must ''Conform Only to the Requirements of [Part 30]'' (§ 30.7(a))

Clarification of the ''Conform Only to'' Requirement

Comments: A commenter expressed concern that the proposed rule did not describe how SAAs' autonomy would be maintained or clarify the extent to which it would supersede SAAs' prerogatives for addressing specific needs within their jurisdictions. Another commenter criticized the proposed provision as contradicting the cooperative federalist model of the NAA. These commenters recommended allowing SAAs to continue exercising their current level of apprenticeship system oversight to preserve innovation and local regulatory responsiveness. A group of commenters opined that the NPRM contains contradictory statements about States' ability to establish their own nondiscrimination laws (*e.g.,* that States have the ability to establish nondiscrimination laws but that States must ''conform only'' to part 30) and expressed concern that, as written, the proposed rule would create confusion about the interaction of State and Federal laws, thereby undercutting States' rights. One commenter requested that the Department clarify whether SAAs are prohibited from retaining or enforcing additional EEO-related provisions, how the Department would treat enforcement of requirements that are ''in addition to'' but not inconsistent with part 30, and what options would be available to sponsors in SAA States where such additional EEO-related provisions are being enforced.

One commenter requested that the Department provide guidance on situations where apprenticeship programs may be subject to conflicting State and Federal requirements, such as if a State maintains nondiscrimination provisions that go beyond the streamlined Federal requirements. This commenter recommended that the Department establish clear procedures for resolving such conflicts, adding that failure to do so could burden sponsors and deter prospective sponsors from registering their programs. This commenter also requested that the Department clarify that the requirement for regulatory uniformity would be confined to part 30 nondiscrimination requirements, and not expand to apprenticeship registration requirements under part 29. The commenter reasoned that the flexibility of the existing OA–SAA system is important for allowing programs to reflect local- and State-level labor market conditions, trade-specific considerations, and collective bargaining agreements, such as setting wages appropriate to local cost of living and journeyworker-to-apprentice ratios and training curricula appropriate for an occupation's safety and training requirements. The commenter also requested that the Department affirm that the proposed rule would not override State laws or policies governing apprenticeship program standards outside the scope of EEO requirements.

One commenter expressed support for the Department taking steps to ensure that SAAs conform to Federal standards and do not discriminate against merit-based apprenticeship programs. Another commenter, which expressed support for this provision and recommended removing the State law requirement from the § 30.3 nondiscrimination standard, opined that the Department may need to modify the provision to clarify that sponsors are not obligated to comply with State nondiscrimination requirements where they go beyond or conflict with Federal requirements.

Some commenters opposed the provision at proposed § 30.7(a), arguing that it would improperly impede States' constitutional authority to implement their own State laws and programs that meet local needs. Some commenters asserted that this change would set a ''concerning'' precedent for undermining States' rights. One commenter expressed opposition to what it characterized as the Department's effort to reduce proactive and innovative policymaking at the State level. This commenter opined that women's participation rate in apprenticeships varies widely across States, but that women have made significant strides in high-paying fields in SAA States due to proactive policies, such as data analysis and reporting, research, funding, and cooperation among industry stakeholders; the commenter concluded that limiting States' ability to innovate and take initiative would stifle these gains.

A commenter expressed opposition to limiting States' authority to promote EEO and advance civil rights beyond Federal requirements. The commenter reasoned that the NAA contemplates shared authority between the Federal Government and the States. This commenter asserted that the NAA's language on shared authority means that States can meet or exceed the minimum requirements set by OA, adding that States have implemented additional protections, such as for marital status and gender identity. The commenter characterized the proposed conformity requirement as improper overreach.

Another commenter expanded on these sentiments, arguing that the NPRM exceeds the Department's authority under the NAA by restricting the ability of States to go above and beyond the Federal rules for preventing discrimination, and reasoning that, while Congress may preempt State laws, it declined to do so with respect to apprenticeship standards. This commenter opined that the plain meaning of the statute is that States have their own authority to effectuate standards of apprenticeship, and that Federal requirements are a floor that States must meet, not a ceiling they cannot exceed. The commenter further asserted that the rule would force many SAAs to abandon their unique protective nondiscrimination and affirmative action requirements.

While similarly arguing that the Congress did not intend for the NAA to have a preemptory effect, a group of commenters asserted that Title VII expressly disavows preemption of State nondiscrimination laws, adding that a State law exceeding the proposed rule's narrow standards does not mean that there is a conflict with Federal law warranting preemption.

Department Response: The Department appreciates commenters' concerns and requests for clarity as to the scope of this rule's nondiscrimination standard and SAA conformity. Upon review and analysis of the comments, the Department views it as necessary to clarify its intent regarding the applicability of the conformity analysis to State laws, regulations, or policies that specifically pertain to nondiscrimination in Registered Apprenticeship. The Department intends to focus solely on

any additional nondiscrimination or equal opportunity requirements imposed upon sponsors that are specific to Registered Apprenticeship. Because SAAs are recognized by the Department to register apprenticeship programs for Federal purposes, the Department is exercising its authority under the NAA to review State requirements that are specific to Registered Apprenticeship to determine conformity with Federal requirements. In other words, the Department is not purporting to regulate generally applicable State nondiscrimination laws and requirements but rather to ensure that, in exercising the Department's delegation of authority to register apprenticeship programs for Federal purposes to SAAs, such delegated authority is not provided to States with nondiscrimination or equal opportunity laws and requirements that apply specifically to Registered Apprenticeship that conflict with Federal nondiscrimination law or the overall purpose of the NAA. This is in furtherance of the Department's interest in uniformity within the Registered Apprenticeship system, reduced burden on sponsors, and facilitation of the growth of Registered Apprenticeship. Thus, the Department only will consider State laws and requirements specifically pertaining to nondiscrimination or equal opportunity in apprenticeship when determining whether to confer initial or continued recognition to an SAA under the revised part 30 regulation.

To that end, and to address commenters' concerns about the interaction of Federal and State nondiscrimination requirements, the final rule modifies § 30.7(a) to clarify that § 30.7 of this final rule only applies to State statutes, regulations, policies, and operational procedures that specifically pertain to nondiscrimination or equal opportunity in apprenticeship. This refers to those nondiscrimination or equal employment requirements that apply to sponsors by virtue of their participation in the Registered Apprenticeship system; it does not refer to laws that specifically include program sponsors among the covered entities but that do not impose obligations that are unique to such sponsors. This modification is responsive to commenters' concerns that the Department's proposed language sought to infringe upon States' authority to regulate nondiscrimination requirements in their States, which may exceed Federal nondiscrimination laws, and clarifies the Department's intent to analyze any additional nondiscrimination or equal opportunity requirements that are specific to Registered Apprenticeship. As stated throughout the preamble, with this final rule, the Department intends to remove burdensome, duplicative, and legally questionable requirements for Registered Apprenticeship program sponsors that discourage or disincentivize sponsors from participating in Registered Apprenticeship.

This change to the final rule at § 30.7 clarifies that the Department will review State-level laws, regulations, and policies specific to nondiscrimination or equal opportunity in apprenticeship when assessing a State's request to obtain or retain recognition as an SAA. SAAs must include any State laws, regulations, or policies that contain nondiscrimination or equal opportunity requirements specific to Registered Apprenticeship in their State plans for nondiscrimination in apprenticeship so that the Department can assess whether any apprenticeship-specific requirements are unduly burdensome, unlawful, or detrimental to the expansion of Registered Apprenticeship opportunities for all qualified individuals. The Department does not intend to preempt State nondiscrimination laws; however, it does intend to create a uniform Federal standard for nondiscrimination and equal opportunity in Registered Apprenticeship that applies to SAAs seeking to register apprenticeships for Federal purposes.

In conjunction with this modified language in the final rule, the Department has also modified the conformity language from ''conform only to'' to ''conform to'' in § 30.7(a) and (b). The Department acknowledges the concerns raised by the commenters regarding federalism, States' authority to regulate nondiscrimination laws in their states, and the various questions raised about the impact of a ''conform only to'' analysis on the recognition of SAAs. The Department has determined that using the ''conform to'' language in part 30 provides consistency across the apprenticeship regulations, meets the Department's goals of streamlining nondiscrimination requirements, and provides sufficient basis for review, technical assistance, and SAA derecognition, if necessary. The Department has also determined that this change addresses concerns about Federalism and the balance between State and Federal authority in regulating nondiscrimination within each State. As described below, the Department views this change from ''conform only to'' to ''conform to'' as addressing commenters' concerns by: (1) providing consistency in the review of SAAs across parts 29 and 30; (2) mitigating concerns about preemption of State nondiscrimination laws; and (3) allowing the Department to review SAA recognition under the revised part 30 with an individualized analysis of whether each SAA conforms to the revised regulations.

In addition, in this final rule, the Department has added ''equal opportunity'' to the regulatory text at § 30.7(a), and at § 30.7(b)(1)(i) and (ii), to clarify that the Department intends to review any State-level laws, regulations, and policies on equal opportunity that are specific to Registered Apprenticeship in determining whether a State's laws, regulations, and policies conform to the requirements of this part. The Department's decision to add ''equal opportunity'' to the apprenticeship-specific State laws, regulations, and policies that it will review in determining whether a State's laws, regulations, and policies conform to the requirements of this part provides clarity to Registered Apprenticeship stakeholders on the scope of the Department's part 30 analysis for SAA recognition. The Department recognizes that States have established apprenticeship-specific equal opportunity requirements based on the existing part 30 requirements that are being revised, including the requirements for the State EEO plan contained in § 30.18 of the existing regulation. The Department is concerned that such requirements may have restricted growth of the Registered Apprenticeship system by discouraging employers from becoming sponsors, and that some of those requirements may induce disparate treatment of applicants for apprenticeship programs based on their race or sex. Both of these impacts run counter to the Department's goals with this rulemaking, which include removing barriers to participation in Registered Apprenticeship, aligning the Department's apprenticeship regulations with applicable Federal and State nondiscrimination laws, and safeguarding apprentice welfare by removing requirements for sponsors to consider factors other than an applicant's merit in recruiting and hiring apprentices.

Consistency in the Review of SAAs

The Department has long applied the ''conform to'' analysis when recognizing SAAs. This is the standard articulated in part 29 under which the Department reviews State applications for recognition as SAAs and under which the Department has successfully

derecognized an SAA due to its failure to conform to part 29 regulations. The ''conform to'' analysis is familiar to SAAs and ensures consistency in SAA review across both parts 29 and the revised part 30. This more uniform approach across the regulations allows for consistency in review and recognition of SAAs and avoids differing approaches to monitoring conformity with both parts 29 and 30. This approach is also responsive to commenters' concerns that SAAs continue exercising their current level of apprenticeship system oversight, innovation, and responsiveness to local conditions—indeed, this uniformity across both parts 29 and 30 will allow for a continuation of this same level of SAA autonomy within the requirements of the revised part 30. This change relaxes the rigidity of the ''conform only'' language, allows flexibility to the States to consider their own unique circumstances so long as they conform to the revised part 30, and ensures that the Department maintains the ability to recognize or derecognize SAAs based on their conformity to the revised part 30 regulations.

Federalism and State Nondiscrimination and Equal Opportunity Laws

The Department intends to review State plans for nondiscrimination in apprenticeship to ensure that State laws, regulations, policies, or operational procedures specific to nondiscrimination or equal opportunity in apprenticeship conform to the nondiscrimination standard in § 30.3. This does not mean that State laws must mirror exactly the language of the regulations, nor does it mean that any deviation will result in a finding of nonconformity. The Department does, however, expect that the part 30 revisions will create greater uniformity in the application of nondiscrimination in Registered Apprenticeship across the Registered Apprenticeship system as a whole and expects SAAs to adopt their laws, regulations, policies, or operational procedures in accordance with the revised part 30 requirements in order to obtain or maintain recognition as SAAs. With respect to commenters' concerns about State nondiscrimination laws that may be in addition to those in part 30, the Department views its clarification regarding the scope of its review of SAAs and the adjustment of the conformity language to be responsive to these concerns. Indeed, the Department envisions review of SAAs to largely follow the review process in part 29, whereby the Department reviews for conformity, provides technical assistance as needed, and works cooperatively with the State to ensure conformity with the revised part 30 regulations. The Department does not view its interest in uniformity and clarity in nondiscrimination requirements specific to Registered Apprenticeship across the National Apprenticeship System to be a barrier to State innovation as the nondiscrimination standard is firmly rooted in Federal nondiscrimination law that is applicable across the National Apprenticeship System. Further, the nondiscrimination standard in § 30.3 does not serve to supplant State nondiscrimination law (instead, the standard incorporates such laws), and States laws regarding nondiscrimination are not preempted by this rule; rather, States must conform to the revised part 30 regulations should they include or wish to include additional nondiscrimination or equal opportunity requirements, beyond any broadly applicable State nondiscrimination requirements, that are specific to registering apprenticeship programs for Federal purposes. In this vein, the Department is acting well within its authority to promote standards of apprenticeship applicable across the National Apprenticeship System as a whole; ease the regulatory burden upon sponsors, employers, and SAAs alike; and further its goal of expanding Registered Apprenticeship.

Additionally, with respect to concerns about the Department's review of affirmative action requirements, as discussed more fully below, it is indeed the Department's intent to eliminate illegal consideration of protected characteristics in Registered Apprenticeship, and it will consider any SAA affirmative action provisions—in addition to other nondiscrimination requirements—that require consideration of protected characteristics that may induce race-based decision-making in Registered Apprenticeship, as determined by an enforcement authority or court with jurisdiction over such claims. Furthermore, the Department will review an SAA's additional nondiscrimination requirements, affirmative action or otherwise, to assess whether they infringe upon the Department's authority under the NAA and its core duties of overseeing and expanding the Registered Apprenticeship system.

Individualized Assessments of Conformity

The Department intends to analyze SAA plans to ensure that they do not interfere with the Department's goals of expanding the National Apprenticeship System and establishing a more uniform set of requirements for Registered Apprenticeship programs across all States. The Department's review for conformity under the well-established ''conform to'' standard will allow for the flexibility necessary to make an individualized determination as to each SAA's conformity to revised part 30 requirements. The Department also intends to take any such action that it deems necessary under the authority of the NAA and the regulations at parts 29 and 30 to deny recognition to SAAs that fail to conform to the revised part 30 requirements. In reviewing for conformance, the Department will analyze whether a State's statutes, regulations, policies, and operational procedures specific to nondiscrimination or equal opportunity in apprenticeship comply with this part and with the Department's responsibilities under the NAA, including whether they limit the expansion of apprenticeship opportunities.

With respect to the concerns and requests for clarity about sponsors' rights if there are additional EEO protections within a State with a recognized SAA, the Department expects sponsors to follow State laws regarding nondiscrimination so long as the SAA continues to be recognized by the Department. Should sponsors have concerns about an SAA's compliance with the revised part 30 regulations, they may submit complaints to the Department through the established complaint process in part 29. Further, should sponsors encounter barriers to registration with an SAA for any reason, they may seek to register directly with OA. The Department emphasizes that sponsors must continue to follow State nondiscrimination laws that are applicable to them as sponsors of Registered Apprenticeship programs or employers of apprentices and that the Department's recognition of an SAA should provide the necessary assurance to the sponsors of their obligations under nondiscrimination laws as applicable to Registered Apprenticeship. Conversely, with respect to concerns about the Department's impeding of progress made in increasing women's participation rate in Registered Apprenticeship, the Department's analysis of SAA nondiscrimination requirements will not prohibit SAAs from taking merit-based actions to increase participation in Registered Apprenticeship; rather, the Department will consider whether SAAs have requirements that limit or inhibit the

growth of Registered Apprenticeship or that permit unlawful discrimination, such as affirmative action requirements that may induce Registered Apprenticeship program sponsors to treat applicants for apprenticeship programs differently based on their race or sex.

2. State Plan for Nondiscrimination in Apprenticeship (§ 30.7(b))

Comments: A commenter requested that the Department clarify the meaning and scope of its reference to the ''policies and operational procedures related to nondiscrimination'' that would be required to conform only to the revised part 30 and to provide examples of what is meant by those terms. Another commenter requested that SAAs be permitted to continue to impose requirements contained in the existing part 30 regulation, such as its universal outreach, anti-harassment, and selection procedure requirements. The commenter described these requirements as important elements of a comprehensive approach to increasing participation in Registered Apprenticeship.

Department Response: As discussed above, the Department has adjusted the ''conform only to'' requirement to ''conform to'' and has also specified that the State laws, regulations, or policies affected by this rule are those that specifically pertain to nondiscrimination or equal opportunity in apprenticeship. For example, if a State has a law that extends certain protections specifically for apprentices in Registered Apprenticeship programs, then it would be required to include that law in its State plan. Similarly, if the State has requirements for outreach policies and procedures that involve outreach to certain demographic groups for the purpose of increasing Registered Apprenticeship participation, the SAA would be required to include such policies in its State plan.

With respect to the suggestions to include additional requirements for SAAs and their State plans, including universal outreach or other requirements from the part 30 regulation that the Department is rescinding with this final rule, the Department appreciates these suggestions but declines to add additional requirements in the State plan beyond those discussed below. This final rule streamlines nondiscrimination requirements in the part 30 regulation, and the Department's requirements for State plans follow a similar streamlining. As such, the Department declines to impose additional affirmative requirements in State plans that would include policies and procedures not required by the final rule.

Based on the Department's review and analysis of the NPRM and the public comments submitted in response to the NPRM, however, the Department has added additional provisions to the State plan requirements to clarify the contents of the State plan necessary for the Department's review of conformity. These additions further clarify the final part 30 regulatory text to explain how the Department will conduct analyses of State plans to determine whether they conform to the regulation, as requested by public commenters. The Department expects that these additions will provide additional clarity for States on what to include in State plans such that they include all relevant information regarding State nondiscrimination requirements specific to Registered Apprenticeship. The Department's review for conformity will include an assessment of whether any additional requirements frustrate or impede the Department's authority under the NAA to expand Registered Apprenticeship, including whether they impose additional unnecessary burden or cost upon sponsors, disincentivize the establishment of new Registered Apprenticeship programs or growth of existing programs, or create unnecessary bifurcation within the National Apprenticeship System. The Department additionally expects SAAs to adhere to their responsibility to prohibit illegal discrimination in Registered Apprenticeship by removing requirements that promote illegal discrimination, such as requirements that may induce sponsors to make apprentice employment decisions based on their race or sex rather than their merit and qualifications, as determined by enforcement entities or courts with jurisdiction over such claims. As the Department discussed at length above regarding affirmative action programs, whether a particular law or policy constitutes illegal discrimination is a final determination made by an enforcement entity or court. The Department emphasizes that its focus is on eliminating unnecessary barriers for the growth of Registered Apprenticeship and removing legally questionable requirements imposed upon sponsors of Registered Apprenticeship programs. SAAs are recognized by the Department to carry out the responsibilities of a Registration Agency. As such, in order to obtain or maintain recognition as an SAA, States have the responsibility to change any State laws or regulations specific to nondiscrimination or equal opportunity in apprenticeship that create such unnecessary barriers. In developing State plans for nondiscrimination in apprenticeship, the Department expects States seeking to obtain or maintain recognition as an SAA to adjust any such laws or regulations.

The Department modified § 30.7(b)(1)(i) in this final rule to remove the word ''only'' so that the provision adheres to the ''conform to'' standard that the Department has adopted in the final rule. This is consistent with the change in § 30.7(a) of this final rule and the rationale described above for using a ''conform to'' standard rather than ''conform only to'' when evaluating State plans. The Department also included a provision at § 30.7(b)(1)(ii) in this final rule to clarify that State plans must ''[i]nclude a description of any State statutes, regulations, policies, and operational procedures pertaining specifically to nondiscrimination or equal opportunity in apprenticeship which impose requirements in addition to those prescribed in this part'' to provide increased clarity for on what laws, regulations, and policies the Department will review when evaluating State plans. This is necessary to confirm that the SAA is submitting all State statutes, regulations, policies, and operational procedures relevant to the analysis of the State plan. This provision complements § 30.7(b)(1)(i) in the final rule because it serves to ensure that any State-level requirements specific to nondiscrimination in Registered Apprenticeship that go beyond the requirements of this final rule are assessed and evaluated by the Department for conformity. The Department will assess any additional requirements to determine whether they conflict with, contradict, or undermine the Department's authority under the NAA and its goal of expanding Registered Apprenticeship.

The Department also added a new § 30.7(b)(1)(iii) to this section outlining requirements for State plans for nondiscrimination in apprenticeship, which provides that States must ''Not require any sponsor seeking to register a program with the State for Federal purposes, through any State statutes, regulations, policies, or operational procedures, to engage in any activity that is unlawful under Federal or State nondiscrimination law.'' This directly addresses the Department's concerns articulated throughout this rulemaking about illegal discrimination in Registered Apprenticeship and explicitly prohibits States seeking to obtain or maintain recognition as an SAA from retaining laws or regulations

specific to nondiscrimination or equal opportunity in apprenticeship that incorporate such illegal preferences. The provision also provides clarity, as requested by commenters, on legal or regulatory requirements specific to apprenticeship that do not conform to this part. The Department is particularly concerned about legally questionable affirmative action plans that may run afoul of nondiscrimination law and will be paying particular attention to this issue as it evaluates State plans for conformity. SAAs are expected to update their statutes, regulations, policies, and operational procedures pertaining to nondiscrimination or equal opportunity in apprenticeship to remove any requirements for Registered Apprenticeship programs to engage in practices that would constitute illegal discrimination under Federal and State law.

As discussed in sections pertaining to the revised procedures for complaints and compliance reviews above, the Department will not make an independent determination about the legality of any preferential program but will rely on decisions by agencies or courts with competent jurisdiction. The Department did not receive any comments on proposed § 30.7(b)(2) through (4) regarding OA's review of the State plan for nondiscrimination in apprenticeship and adopts the provision as proposed. Similarly, because the Department did not receive any comments on proposed § 30.7(c) (Recordkeeping requirements) nor on proposed § 30.7(d) (Retention of authority), the Department adopts the provisions as proposed.

3. Program Compliance Timelines for Programs and SAAs

Comments: A commenter expressed concern about the proposed 1-year compliance timeline for States to update their laws and regulations to conform with the proposed rule, reasoning that in their State, the legislature would likely only have one session in which to complete the revisions, and that the SAA only can request that the legislature make the necessary changes, not demand it. Another commenter expressed a similar concern about the length of time necessary for the administrative rulemaking process and legislative process. A commenter criticized the proposed rule for not acknowledging the burden that States would face in updating their laws and policies. These commenters therefore recommended extending the compliance timeline to at least 2 years. Similarly, a commenter disagreed with the Department's estimate of the burden on SAAs, State legislatures, and OA staff, and commented that the time and effort involved would detract from other work necessary to support and expand Registered Apprenticeship.

Department Response: The Department appreciates commenters' concerns regarding the timeline for SAA compliance to conform with the proposed rule. The Department is well aware that State legislative timelines and processes dictate the speed with which a State can update its laws to conform with the revised part 30. The Department anticipates that its adjustments to § 30.7(a) and (b) in the final rule provide additional clarity of the Department's review of SAA State plans for nondiscrimination in apprenticeship that conform to the requirements of this part and anticipates that this will ease the burden on SAAs.

The Department has also accounted for delays and internal processes by allowing an extension for good cause to be sought by the SAA and granted by the Administrator. This balances the Department's goals of effectuating this rule in a timely manner with the understanding that States may need to seek an extension of time from the Administrator should there be barriers to achieving compliance within 1 year of the effective date of this rule. The Department has determined that the SAAs' ability to seek and be granted an extension sufficiently addresses these concerns.

Finally, the Department appreciates that this change will require effort by SAAs and the Department alike. SAAs will be required to update their laws and policies to conform to this part, and OA will be required to devote time and effort to review SAA plans. The Department disagrees, however, that this will detract from its goal of expanding Registered Apprenticeship. On the contrary, the Department has determined the revised part 30 will result in efficiencies and reduced requirements that are well worth any time and effort spent on effectuating this rule and are fully consistent with the goal of expanding Registered Apprenticeship.

Comments: A commenter expressed concern that it would be challenging for SAAs to ensure program compliance with the proposed rule within 180 days of a State plan being approved, based on their past experiences with seeking statewide changes to apprenticeship programs. The commenter recommended extending the program compliance timeline to 1 year.

Department Response: The Department appreciates commenters' concern about the ability of sponsors to comply with the new requirements of the State plan within 180 days. Nonetheless, given that the State plan requirements in this final rule are fewer and less burdensome on sponsors than the existing part 30 requirements and that entities are already subject to and required to comply with applicable State and Federal nondiscrimination laws, the Department does not anticipate that there will be a need for additional time. This rule requires that sponsors comply with the nondiscrimination standard in § 30.3. To the extent that the State plan includes any additional requirements specific to nondiscrimination or equal opportunity in apprenticeship, such requirements must conform to the requirements of the revised part 30; therefore, the Department anticipates that requirements on sponsors will decrease, and compliance with the State plan will not result in additional burden on sponsors. As such, the Department is finalizing the compliance timeline for programs registered in SAA States at 180 days in this final rule at § 30.7(b)(iv).

4. Comments on Changes to SAA Compliance and Review Requirements in Part 30

Comments: A commenter expressed concern about changes to provisions related to reviews of SAAs, warning that they would result in regulatory uncertainty for SAAs and adversely impact Registered Apprenticeship programs and apprentices. The commenter recommended DOL establish clear guidelines and process descriptions that would ensure system stability and program continuity, including a description of review metrics, how reviews would be conducted, and available remedies for improvement. The commenter also recommended a description of enforcement mechanisms that include whether penalties would extend beyond loss of recognition and include other impacts such as funding. The commenter further recommended regulatory guidance framing how existing programs and apprentices would be impacted if a State were found to be noncompliant, whether options would be available to programs and apprentices, and the role of OA in that process.

A commenter recommended that the Department clarify a compliance review schedule for SAAs, including frequent program reviews or audits and the provision of actionable technical assistance. The commenter further recommended that the Department include other requirements for SAAs,

including requiring that SAAs measure program success through equity indices that show the representation of apprentices from underserved demographic groups, publish disaggregated data and center data in determining priorities, making investment decisions, and developing staff trainings and technical assistance programs. The commenter further recommended that the Department require SAAs to conduct regular, anonymized surveys of apprentices to gauge their experiences in Registered Apprenticeship programs, and to address issues that interfere with apprentices' entry into and completion of Registered Apprenticeship programs (citing aptitude tests that, according to the commenter, tend to screen out applicants from underserved groups).

Another commenter expressed support for the potential to ease the burden for small and medium size business sponsors but anticipated an added burden on SAAs to comply with the regulatory changes and a need for technical assistance regarding outreach to populations not traditionally served by Registered Apprenticeship in order to meet the Administration's goal of one million new apprentices.

Department Response: The Department appreciates that there may be a need for subregulatory guidance, technical assistance, and other cooperation with SAAs to ensure successful implementation of this final rule. The Department notes that OA already conducts SAA reviews for compliance with parts 29 and 30, and such compliance reviews will continue under the revised part 30 requirements. The Department further notes that mechanisms for accountability, review, the processing of complaints, SAA derecognition and associated impacts are addressed by part 29's conforming edits that incorporate an SAA's State plan for nondiscrimination in apprenticeship and other sections of part 30. These mechanisms are reinforced in proposed § 30.7(d) (Retention of authority), which cites to OA's authority in § 29.13 to conduct compliance reviews of all Registered Apprenticeship programs and in §§ 29.8(b) and 29.10 to deregister for Federal purposes an apprenticeship program registered with an SAA, and § 30.7(e) (Derecognition), which cites to § 29.14's derecognition proceedings for SAAs that fail to comply with the requirements of § 30.7. Given the integration into part 29 of the review of SAAs and their State plans for nondiscrimination in apprenticeship, the Department declines to create additional unnecessary and duplicative processes and procedures for review of SAA compliance with part 30 and adopts § 30.7(d) and (e) as proposed.

Finally, with respect to concerns about SAA outreach to populations less familiar with Registered Apprenticeship, the Department is eager to work with States on recruitment of apprentices and remains committed to working with SAAs to reach the goal of 1 million active apprentices in a manner that is merit-based and consistent with Federal law.

H. Section 30.8—Exemptions

The Department proposed to maintain the ''Exemptions'' provision from the current part 30 at § 30.19. The proposed revisions were intended to reduce burdens on Registered Apprenticeship stakeholders, and the Department determined that preserving the part 30 exemptions supports this objective and maintains the regulatory flexibility embedded in the existing rule. Under the existing provision, which the Department proposed to keep, sponsors were required to submit written requests for exemptions from part 30 requirements to the Registration Agency, which could grant exemptions for good cause. The Department also proposed to retain the requirement that SAAs receiving exemption requests from sponsors in their State obtain OA approval before issuing an exemption. Therefore, proposed § 30.8 reflected the same regulatory text as § 30.19.

Accordingly, for the reasons discussed in the NPRM and in response to comments discussed below, the Department is finalizing the provision as proposed.

1. Religious Exemptions

Comments: A commenter expressed support for adding a specific religious exemption to the regulations, arguing that religious organizations have protections under the First Amendment, the Religious Freedom Restoration Act, and Title VII, proposing specific regulatory text stating that regulations ''do not apply to a religious organization to the extent that application of these regulations would be inconsistent with the religious tenets of the organization,'' similar to title IX exemption language.

Another commenter expressed support for religious employer exemptions on the basis of ''sex,'' ''disability,'' and ''religion'' as protected characteristics, and stated that religious employers should be able to invoke the ADA's religious exemption in the apprenticeship context. The commenter maintained that some courts have held that ''gender dysphoria'' is a disability, despite the exclusion in the ADA and section 7(20)(F) of the Rehabilitation Act of 1973 [56] of ''gender identity disorders'' from the definition of ''disability,'' and that religious program sponsors would not be able to invoke the ADA's religious exemption, and that program sponsors would be required to accommodate the ''disability'' of gender dysphoria. Additionally, because of the proposal to remove the language at § 30.3 referring to legal standards and defenses applied under Title VII, the commenter recommended that the Department include an explicit exemption for religious employers from applications of the nondiscrimination rule that conflict with their religious tenets and suggested incorporating language, with necessary revisions, from the religious exemption in title IX of the Education Amendments of 1972 and its implementing regulations.

This commenter and another also objected to particular terminology used in the NPRM. A commenter said that in several instances, the NPRM used the term ''gender-based,'' which is inappropriate because it is not as clear as ''sex-based,'' because ''sex'' mirrors the text of the statutes from which the Department derives its authority to issue the rule, and because the use of ''gender'' is inconsistent with the directives of E.O. 14168. Another commenter echoed this concern, reasoning that ''sex'' is commonly understood to refer to genetic and biological, attributes of human beings, but ''gender'' is a less precise term.

Department Response: The Department appreciates the comments raising concerns about the need for religious exemptions. The Department will take seriously any request for an exemption from this regulation under proposed § 30.8, including those citing religious freedom as the reason supporting the request. Because the Department will, pursuant to this final rule, defer to other enforcement agencies in determining compliance with applicable nondiscrimination laws, it no longer needs to incorporate into part 30 the standards and exemptions from external statutes, such as Title VII and the ADA. As noted earlier in the preamble, the Department will respect the application of religious exemptions as determined by the relevant enforcement agency in determining a sponsor's compliance with proposed § 30.3. As such, the Department does not think a specific exemption for religious sponsors is necessary, particularly as such an exemption would not relieve the sponsor from complying with the applicable

[56] 29 U.S.C. 705(20)(F).

nondiscrimination law in general, and would instead only apply as it pertains to the sponsor's standing as a program sponsor. Accordingly, the Department declines to incorporate the suggestion to establish a specific religious exemption provision in this final rule.

In response to some commenters' preference for different terminology, including using ''sex'' instead of ''gender,'' the Department agrees that the terminology the Department uses should align with the terminology used in relevant Federal nondiscrimination statutes, such as Title VII. The Department concurs that aligning its language with existing nondiscrimination laws promotes clarity for the regulated community.

2. Other Exemption Comments

Comments: A commenter urged the Department to clarify the exemption process by providing examples and guidance on when exemptions may be granted, expressing concern that exemptions in industries with prevailing wage projects could create unfair competitive advantages, particularly in high-hazard industries like construction and energy. The commenter recommended developing guidance detailing the exemption process and evaluation criteria.

Department Response: Under the text of proposed § 30.8, which mirrors the existing exemption provision at § 30.19, exemption requests must be in writing and must identify the provision(s) of part 30 from which the applicant is seeking exemptive relief. The provision further clarifies that all exemption requests to the Registration Agency must demonstrate ''good cause'' to support the applicant's exemption request.

The Department declines to provide specific examples of permissible exemptions in this final rule, as the exemption provision is meant to provide flexibility to sponsors on a case-by-case basis. The Department notes, however, that an exemption issued pursuant to § 30.8 of this final rule only would extend to requirements covered by part 30 (as has been the case under existing § 30.19). This final rule's exemption provision does not authorize a Registration Agency to grant an exemption from the part 29 requirements, or any other applicable law, including those related to prevailing wages.

I. Section 30.9—Severability

As a prudential measure, the Department has decided to add (at § 30.9) a severability provision to the text of this revised and streamlined part 30. This new provision states that, to the extent that any provision of part 30 is declared invalid by a court of competent jurisdiction, the Department intends for all other provisions of part 30 that are capable of operating in the absence of the specific provision that has been invalidated to remain in effect. The Supreme Court has previously held that a statute or regulation is severable if its separate provisions are ''wholly independent of each other'' and can operate independently. *Brockett* v. *Spokane Arcades, Inc.,* 472 U.S. 491, 502 (1985). In the case of this final rule, the Department takes the position that no other provisions of the revised part 30 would be affected if a particular provision of the regulation is found to be unlawful or invalid. Moreover, the Department expects that courts and regulated parties would be able to apply the remaining provisions of this final rule if one of its provisions was held to be invalid. See *Department of Education et al* v. *Louisiana,* 603 U.S. 866, 868 (2024) (*per curiam*) (denying the government's request to stay a preliminary injunction against an entire rule where only parts of the rule were found to be invalid).

J. Technical and Conforming Edits to Part 29

The Department proposed limited technical and conforming amendments to 29 CFR part 29 to align that part with the proposed revisions to 29 CFR part 30. The Department proposed updating cross-references and terminology in part 29 to reflect the revised nondiscrimination framework in part 30. For example, the Department proposed to amend part 29 at §§ 29.3(b)(2) and 29.5(b)(21) to align with the streamlined nondiscrimination requirements in revised part 30, including referencing the proposed ''State plan for nondiscrimination in apprenticeship'' in § 29.5(b)(21) and removing other references to requirements from the existing part 30 regulation (such as the equal opportunity pledge and affirmative action requirements) in the part 29 section covering standards of apprenticeship.

The Department proposed revising part 29 at § 29.12 (Complaints) to clarify that allegations of unlawful discrimination—based on race, color, religion, national origin, sex, age, disability, genetic information, or other protected characteristics—would be referred by the Registration Agency to the appropriate enforcement authority, consistent with proposed § 30.4. This revision conformed to the proposed structure under which enforcement for discrimination would be handled by agencies with jurisdiction to administer applicable nondiscrimination laws, such as the EEOC, the U.S. Department of Justice, State FEPAs, or other enforcement agencies as appropriate.

The Department proposed amendments to § 29.7 (Apprenticeship Agreement) to reflect the protected characteristics specifically covered by applicable Federal nondiscrimination statutes. As proposed, § 29.7(j) would prohibit discrimination in apprenticeship on the bases of race, color, religion, national origin, sex, age (40 or older), genetic information, and disability, thereby ensuring consistency with the statutory text of Title VII of the Act, the ADEA, the ADA, and the Genetic Information Nondiscrimination Act.

The Department also proposed modifying § 29.7(l) by removing explicit references to an apprentice's race, sex, ethnicity, and disability status and replacing them with a general request for demographic information. The Department determined that a broad authorization to request ''demographic information'' would provide greater flexibility for apprenticeship stakeholders and Registration Agencies regarding the collection of demographic information in Registered Apprenticeship.

In addition, the Department proposed edits to the provisions governing SAA recognition and operation. The Department proposed revising §§ 29.13 and 29.14 to require State apprenticeship statutes, nondiscrimination plans, and enforcement procedures to conform to the streamlined Federal requirements in revised part 30. These changes were intended to reduce divergence between OA and SAA jurisdictions, eliminate inconsistent nondiscrimination standards across States, and promote uniform application and enforcement nationwide.

Finally, the Department proposed conforming updates throughout part 29 to replace outdated references and to clarify that nondiscrimination enforcement responsibilities rest with the appropriate governmental entities with jurisdiction to administer Federal or State nondiscrimination laws. These included proposed revisions to § 29.11 (Limitations) to reflect applicable law and Executive Orders, and updates to recordkeeping provisions in §§ 29.13 and 29.14 to align with the proposed updates to the part 30 regulation and the recordkeeping requirements for SAAs that would be necessary under the revised part 30 regulation and its updated requirements for SAAs.

The Department received public comments on several of these proposed technical and conforming edits to the part 29 regulation, which are discussed below.

1. Section 29.7—Apprenticeship Agreements

Proposed Changes Would Reduce Quality and Quantity of Data

Comments: Some commenters expressed concern that the proposed revisions to 29 CFR 29.7 would reduce the quality and quantity of data collected and published about apprenticeships, and that a lack of uniformity in the collected demographic data for apprenticeship agreements would generate significant challenges. Some commenters suggested that the proposed changes would reduce accountability and transparency. One commenter echoed this argument, indicating that without consistent definitions and demographic reporting, employers and apprenticeship stakeholders would face significant challenges in integrating data across systems and operationalizing the data to evaluate progress.

Commenters also expressed concern that poor quality data would complicate the understanding of current participation rates and eliminates the ability to measure progress towards serving the intended populations. One commenter said that the change would undermine efforts to understand who is participating in apprenticeships, in which fields, and with what outcomes, as well as progress or innovative best processes for outreach and inclusive practices. The commenter concluded that rather than providing greater flexibility or minimizing confusion, as DOL claims, such changes would instead hinder individual apprentices, apprentice stakeholders, and Registered Apprenticeship programs from gaining valuable insights for strategic ventures—including efforts to build a workforce development system that can meet the challenges of the 21st-century labor market through apprenticeship. Several commenters therefore urged the Department to continue demographic data collection in a uniform manner and to retain demographic specificity in its data collection activities. Alternatively, a group of commenters urged the Department to allow States to use their own discretion in what demographic data they collect to ensure Registered Apprenticeship is reaching as many people as possible and ensure compliance with State programs and law.

A commenter also raised concerns that a lack of uniform data would complicate aggregation and assessment of data. One commenter argued that at the Federal level, standardized demographic data are used to demonstrate adherence to regulations and policies. The commenter suggested that States have invested in systems to aggregate cross-agency data and, the commenter argued, without standardized demographic fields these States would face challenges in aggregating data. The commenters suggested that educational institutions also use these demographic data to demonstrate the value of apprenticeships across the community and population and researchers rely on these demographic data to understand how different groups respond to different program designs or policy interventions. The commenter also mentioned that apprenticeship stakeholders have repeatedly called for higher data quality and validation processes to inform return on investment calculations, inform outreach, and improve program design and outcomes.

A commenter argued that evidence shows that employers do not perceive the collection of apprenticeship demographic data as a major cost or inhibitor to growth of Registered Apprenticeship. Another commenter stated that the Department made it voluntary for apprentices to provide their demographic data to avoid undue burden and protect privacy, and with a response rate of over 80 percent for apprentices' race, the commenter suggested that the data submission and collection is not overly burdensome.

Another commenter requested additional guidance on the bounds of the collected data including whether the proposed rule would give autonomy to State agencies to mandate a set of demographic data requests in all apprenticeship agreements or whether the proposed rule would allow program sponsors to request whatever demographic data they wish. One commenter asked the Department to clarify what demographic information it intends to collect, and recommended collecting information pertaining to veteran status, as it applies to the Post 9–11 Veterans Educational Assistance Act of 2008 (title V of Pub. L. 110–252), the Veterans Apprenticeship and Labor Opportunity Reform Act (VALOR Act) (Pub. L. 115–89), and the Support for Veterans in Effective Apprenticeships Act (Pub. L. 116–134). Another commenter recommended that the Department utilize tools, such as artificial intelligence, to minimize reporting burden, create public dashboards to track this data, and use that data to evaluate the impact of the final rule within 3 years of its implementation and every 5 years thereafter.

Department Response: The Department understands the comments raised by commenters but disagrees that the conforming edits raise concern for data collection. The Department maintains that a general request for demographic information is consistent with existing practice, and that removing reference to specific categories of demographic information would not adversely affect data quality nor stakeholders' ability to aggregate, analyze, and identify trends, outcomes, and other data-drive insights related to Registered Apprenticeship. The Department expects a general request for apprentices' demographic information will still yield valuable data on apprentices' race, sex, and ethnicity, along with other demographic characteristics that apprentices may report about themselves. In response to one commenter specifically, the Department confirms that it intends to continue to collect information on veteran status. Veteran status is not listed in the description of demographic characteristics at existing § 29.7(l), and as such, the Department's conforming edit to that provision does not alter the section of ETA Form 671, Section II (the apprenticeship agreement form), that provides for the collection of information on apprentices' veteran status, which supports compliance with the VALOR Act and the other laws cited by the commenter.

The Department notes that the collection of additional demographic data at the SAA level is not necessarily precluded under this final rule. However, the Department encourages SAAs to align demographic data collections with the Department's approach and afford stakeholders with flexibility in the collection of demographic data to reduce burdens and challenges associated with requiring that sponsors solicit particular demographic information in apprenticeship agreements.

In response to one commenter's request that the Department review and make accessible data to evaluate the impacts of the rule in the years following publication, the Department notes it will continue to monitor and evaluate the impacts of this rule (and other policies implemented throughout the National Apprenticeship System) using relevant apprenticeship data.

K. Final Rule Implementation

Under the NPRM, the Department proposed requiring SAAs to submit a State plan for nondiscrimination in apprenticeship that demonstrates that the State's apprenticeship laws, regulations, policies, and operational procedures related to the nondiscrimination obligation conform only to the requirements of this part. The NPRM required the plan's submission within 1 year of the effective date of the final rule and provided that extensions may be granted for good cause by the OA Administrator. The proposed rule further stipulated that SAAs must require all apprenticeship programs registered with the State for Federal purposes to comply with the requirements of the State's plan within 180 days from the date that OA provides written approval of the State plan for nondiscrimination in apprenticeship.

The NPRM did not include a specific transition date for sponsors registered with OA directly to comply with the new rule. In this final rule, the Department clarifies that these sponsors are expected to comply with the final rule when it becomes effective 60 days after its publication in the **Federal Register**. In addition, the Department reiterates that it has changed the provision at § 30.7 of this final rule to require that SAAs' laws, regulations, and policies specific to nondiscrimination or equal opportunity in apprenticeship conform to the requirements of this part.

To provide clarity regarding implementation of the final rule, the following tables summarize the applicable compliance timeframes for Registration Agencies and sponsors.

Compliance Timeframes Under the Final Rule

For Sponsors

Entity	Registration agency	Requirement	Compliance timeframe
Sponsors with a Registered Apprenticeship Program.	DOL Office of Apprenticeship	Comply with the applicable requirements of this final rule.	Beginning on the effective date of the final rule, 60 days after publication in the **Federal Register**.
Sponsors with a Registered Apprenticeship Program.	State Apprenticeship Agency	Comply with the applicable requirements of the State's OA-approved plan for nondiscrimination in apprenticeship.	Within 180 days after OA provides written approval of the State plan.

State Plans for Non-Discrimination

Entity	Requirement	Compliance timeframe
State Apprenticeship Agency	Submit to OA a State plan for nondiscrimination in apprenticeship that satisfies the requirements of § 30.7.	Within 1 year after the effective date of the final rule, unless OA grants an extension for good cause.

Based on this clarification and the response to comments below, the Department is adopting the final rule implementation timeline as proposed.

1. Effective Date and Timeline for Implementation

Comments: A few commenters expressed concern that the 1-year implementation timeline for SAAs to submit State plans for nondiscrimination in apprenticeship that reflect the proposed rule's requirements would not be sufficient. The commenters remarked that State processes that would be required for full implementation of the final rule include public comment and public hearings by legislative bodies and enacting legislation to revise statutory provisions that conflict with the rule, a process that can vary by State and may require longer than 1 year. The commenters provided several suggestions for extending the implementation timeline, including extending to 2 years or allowing for two legislative sessions.

Department Response: The Department maintains that 1 year is sufficient for SAAs to comply with the final regulation, especially given the final rule adopts a ''conform to'' instead of a ''conform only to'' standard for State plans for nondiscrimination in apprenticeship. Additionally, through a review of relevant State laws, regulations, and policies, the Department determined that many SAAs are presently complying with the requirements of current part 30 because they incorporate the Federal part 30 regulation by reference in their State laws, regulations, or policies. Therefore, these States will not need to undertake State legislative or administrative rulemaking, or other processes, to comply with and implement the final rule.

For States that will require updates to State laws, regulations, or other policies to implement this final rule, the Department has determined that the 1-year implementation timeline is sufficient for States to make any such changes. Because of the nature of the revisions to part 30, any updates to State laws, regulations, or policies would primarily involve the removal of elements that are no longer required by part 30. The Department acknowledges that changes to State laws or regulations may require additional time, and the final rule accounts for this possibility by providing the OA Administrator with the authority to grant extensions of the implementation timeline for good cause. The Department intends to provide extensions for good cause to any State that needs an extension of the implementation timeline to make updates to State laws, regulations, and policies if the State is making good faith efforts to comply with this final rule.

2. Other Comments on Sponsor and SAA Compliance

Comments: A commenter recommended establishing a clear process for Registered Apprenticeship programs to maintain their Federal registration status if an SAA is derecognized as a result of failing to comply with the final rule by the implementation deadline. The commenter suggested that the Department could adopt a similar process to the approach used when California's SAA was derecognized in 2007, where apprenticeship programs had 30 days to register with DOL if they wished to retain authority. The commenter recommended allowing programs 60 days (rather than 30) to register with OA to ensure continuity and minimize disruption, particularly since multiple States could be faced

with the need to register programs in multiple jurisdictions.

A commenter asked for clarification on the consequences for SAAs and Registered Apprenticeship programs that fail to comply with the rule, and whether DOL would seek immediate derecognition or deregistration of non-compliant entities, or whether those entities be given opportunity to come into compliance via a corrective action plan or similar means of achieving compliance. The commenter further asked whether there would be any attempt to seek penalties or other types of punitive enforcement actions not currently contemplated by the Federal apprenticeship statutes or rules. The commenter also suggested that more than 180 days are needed for apprenticeship programs to comply with proposed rule, given the need to update all apprenticeship agreements and policies related to nondiscrimination in apprenticeship.

A commenter expressed concern that once the rule is implemented, all existing apprenticeship standards would be out of compliance and require updates, creating significant burden for sponsors, employers, State agencies, and OA. The commenter recommended that the Department issue guidance for transition arrangements, allowing programs to operate under existing standards for a specified period, or creating a process for programs to opt into a blanket modification of program standards.

A commenter requested that the Department provide clear technical assistance and guidance to existing sponsors regarding any required activities or updates to their standards of apprenticeship, and that the Department establish a reasonable implementation timeframe. The commenter suggested such technical assistance could include updating the Department's Boilerplate Standards of Apprenticeship through a bulletin or other public method and should identify the Department's process for updating existing apprenticeship program standards.

Department Response: The Department appreciates these comments requesting clarification on compliance expectations under the final rule for program sponsors. As noted above, the Department will require sponsors registered with OA to comply with the final rule beginning on its effective date, which is 60 days after publication. Programs registered with SAAs must comply within 180 days from the date that OA provides written approval of the SAA's State plan for nondiscrimination in apprenticeship submitted pursuant to the final rule. The Department maintains that this approximately 6-month period provides sufficient time to update program standards, especially given that sponsors will mainly be required to remove elements from their standards instead of drafting new components from scratch. As such, the Department is finalizing the compliance timelines for programs registered with OA and with SAAs as proposed.

The Department agrees with commenters who suggested that technical assistance and subregulatory guidance would support systemwide compliance. The Department further agrees that updating technical assistance tools such as the Boilerplate Standards of Apprenticeship will be an important aspect of the Department's implementation of this final rule. OA's Apprenticeship Training Representatives and other staff whose roles include providing technical assistance to sponsors will play a key role in supporting sponsors' transition under the final rule, including answering questions, identifying elements of program standards that are no longer required under the revised part 30 regulation, and otherwise providing technical assistance to Registered Apprenticeship stakeholders. The Department will also consider providing an extension for sponsors to comply with the final rule, if needed, and is available to review and approve case-by-case exemption requests, as needed.

In response to one commenter's question regarding whether the Department intends to immediately pursue derecognition or deregistration of SAAs or program sponsors that have not come into compliance with the revised part 30 regulation within the specific compliance timeline, the Department confirms that this final rule includes provisions on providing technical assistance to SAAs and a process for establishing a compliance action plan for program sponsors as proposed in the NPRM. At § 30.5(c) of this final rule, the Department specifies that when Registration Agencies learn of a final determination regarding a sponsor's violation of a relevant nondiscrimination law, it may work with the sponsor to establish a compliance action plan aligned with any remedies prescribed by the enforcement entity that issued the determination, and will monitor the sponsor's adherence to the established compliance action plan to ultimately bring the program into compliance with the part 30 regulation. Similarly, at § 30.7(2)(ii) of this final rule, the Department specifies that OA will provide any necessary technical assistance to SAAs regarding State plans for nondiscrimination in apprenticeship to facilitate SAA conformity with the revised part 30 regulation. In addition, at § 30.7(a) of this final rule, the Department included language allowing States to request extensions on the 1-year timeline for submitting a conforming State plan for nondiscrimination in apprenticeship for good cause.

In response to a commenter's request that the Department establish a clear process for sponsors to maintain their program registration should the SAA that registered their program be derecognized, the Department notes that 29 CFR 29.14(e) provides such a process and is appropriate to address this potential scenario. The Department maintains that the 30 days provided under § 29.14(e) is sufficient for sponsors to request registration with OA. Finally, the Department confirms that it will not pursue any enforcement or punitive actions not currently contemplated under the existing apprenticeship regulations against program sponsors or SAAs.

VII. Procedural Issues and Regulatory Review

A. Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 14192 (Unleashing Prosperity Through Deregulation) and Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996

Under E.O. 12866, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) determines whether regulatory action is significant and, therefore, subject to the requirements of the executive order and review by OMB. *See* 58 FR 51735 (Oct. 4, 1993). This final rule is an economically significant regulatory action under section 3(f)(1) of E.O. 12866, and OIRA has reviewed it.

E.O. 13563 directs agencies to propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; the regulation is tailored to impose the least burden on society, consistent with achieving the regulatory objectives; and in choosing among alternative regulatory approaches, the agency has selected those approaches that maximize net benefits. E.O. 13563 recognizes that some benefits are difficult to quantify and provides that, where appropriate and permitted by law, agencies may consider and discuss

qualitatively values that are difficult or impossible to quantify.

The Department derived costs and cost savings for this final rule by comparing the baseline (the costs and benefits of the current part 30 regulation) with the costs and benefits of implementing the provisions in the final rule. Only the additional impacts that are expected to be incurred due to the changes in this regulation are included in the analysis.

The Department sought to quantify and monetize the costs and cost savings of the final rule where feasible. Where we were unable to quantify impacts—for example, due to data limitations—we describe them qualitatively. This analysis covers a 10-year period (2026 through 2035) to ensure it captures major impacts that accrue over time. In this analysis, we have sought to present impacts both undiscounted and discounted at 7 and 3 percent, respectively.[57]

This rule is considered a deregulatory action under E.O. 14192, ''Unleashing Prosperity Through Deregulation.''

Using a perpetual time horizon to allow for cost comparisons under that order, the Department estimates that the annualized cost savings amount to $93 million in 2024 dollars, using a 7 percent discount rate. For the purpose of this analysis, the Department assumed the cost savings from the rule remain constant after the last year of the analysis period, resulting in a perpetual cost savings estimate that may have a tendency toward understatement.

Pursuant to subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA),[58] also known as the Congressional Review Act,[59] OIRA has found that this rule meets the criteria at 5 U.S.C. 804(2).

1. Relevant Federal Rules Duplicating, Overlapping, or Conflicting With the Proposed

The Department has not identified any Federal rules that may duplicate, overlap, or conflict with this final rule. Instead, this final rule is removing duplication that currently exists because sponsors will no longer be required to refer complaints to SAAs. Requiring sponsors to refer complaints to the SAAs is duplicative because, in practice, SAAs referred complaints to the appropriate nondiscrimination enforcement agencies and employers are already required to refer such complaints to the relevant nondiscrimination enforcement agency.

2. Summary of the Analysis

The Department estimates that the rule will result in costs and cost savings. As shown in Exhibit 1, the rule is expected to have an annualized quantifiable cost of $1.31 million and a 10-year quantifiable cost of $9.23 million, each at a discount rate of 7 percent. All costs from the final rule are incurred in the first year. The rule is estimated to result in annualized quantifiable cost savings of $100.18 million and a total 10-year quantifiable cost savings of $703.64 million at a discount rate of 7 percent. Additional benefits of the final rule were not monetized.

EXHIBIT 1—ESTIMATED MONETIZED COSTS AND COST SAVINGS OF THE FINAL RULE

[2025 $millions]

	Costs	Cost savings
Undiscounted 10-Year Total	$9.87	$1,016.11
10-Year Total with a Discount Rate of 3%	9.58	861.39
10-Year Total with a Discount Rate of 7%	9.23	703.64
Annualized Undiscounted	0.99	101.61
Annualized at a Discount Rate of 3%	1.12	100.98
Annualized at a Discount Rate of 7%	1.31	100.18

After considering both the quantified and non-quantified impacts of the final rule, the Department has concluded that the estimated cost savings would justify the costs of the final rule. Below, we present an analysis of the costs and cost savings of the final rule in the year and over the 10-year analysis period.

3. Significant Issues Raised in Public Comments

Several commenters submitted feedback in response to the NPRM's RIA or otherwise addressing the potential impact of this rulemaking on affected entities. This section describes how the Department adjusted the regulatory analysis in response to public comment.

Comments: A commenter submitted feedback that the RIA was incomplete because it should consider: (1) whether eliminating certain part 30 requirements could cause some individuals to miss apprenticeship opportunities and therefore experience lower career earnings; and (2) whether apprentices may incur costs from lengthier investigative processes at Federal or State agencies due to the requirement that sponsors refer all complaints to relevant civil rights agencies.

Department Response: In response to these comments, the Department examined available data sources, including a Government Accountability Office report and EEOC case load data to determine whether such impacts could be quantified or monetized.[60] With respect to potential missed opportunities or reduced lifetime earnings, the Department found no reliable data sources that would allow for assessing case-specific impacts, and such considerations are beyond the scope of this rulemaking. Furthermore, the Department does not anticipate, and commenters did not provide evidence that, the final rule will cause individuals to miss apprenticeship opportunities.

Additionally, the Department concluded that there is no evidence indicating investigative processes would lengthen as a result of the rule, or sufficient data to determine that any hypothetical impacts might not occur within existing investigation timeframes (and thereby not lengthen the response time).

Comments: Several commenters expressed skepticism about the NPRM's estimated cost savings associated with removing affirmative action

[57] OMB, Circular A–4, ''Regulatory Analysis,'' Sept. 17, 2003, *https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.* As noted in E.O. 14192, ''Unleashing Prosperity Through Deregulation,'' on January 31, 2025, regulations should be consistent with the 2003 version of Circular A–4.

[58] Title II of Public Law 104–121 (Mar. 29, 1996).

[59] 5 U.S.C. 801–808.

[60] The Government Accountability Office report provides estimate charge processing times, and can be found at *https://www.gao.gov/assets/gao-23-106245.pdf;* the U.S. Equal Opportunity Commission case load data can be found at *https://www.eeoc.gov/data/enforcement-and-litigation-statistics-0.*

requirements. The commenters cited a study finding that compliance with existing 29 CFR part 30 accounts for only 0.13 percent of total sponsor costs and noted that sponsors generally do not identify regulatory compliance as a major barrier to program operation. Some of the commenters further stated that, based on their estimate of an average annual total cost of program delivery of $80,768 per apprentice, compliance with part 30 amounts to approximately $102 per apprentice annually. The commenters also referenced an analysis indicating that the NPRM's estimate of regulatory compliance at registration is 1.88 times the total median registration costs reported by employers and more than 37 percent of total mean registration costs, concluding that the NPRM's characterization of part 30 as a ''substantial barrier to employer entry and program sustainability'' is incorrect.

Department Response: In response to these comments, the Department acknowledges the data and comparisons submitted but disagrees with the conclusion that existing part 30 requirements are not burdensome. In the Department's view, the 2016 final rule imposed excessive administrative requirements, as well as affirmative action obligations that are legally vulnerable, and that impede the goal of apprenticeship expansion. Revisions to part 30 are necessary to eliminate a duplicative EEO framework that applies only to Registered Apprenticeship. This final rule therefore adopts a streamlined approach consistent with the Administration's directive to reduce regulatory burdens. Recent U.S. Supreme Court decisions have clarified the legal limitations on race- and sex-based measures under the Equal Protection Clause and Federal nondiscrimination laws. These developments raise serious questions about the validity of certain affirmative-action-related provisions in part 30, particularly those that incentivize or induce sponsors to make decisions based on protected characteristics. In light of recent court decisions, the Department has determined that revising part 30 is necessary to ensure the regulatory framework for Registered Apprenticeship is fully aligned with nondiscrimination standards and legal precedent.

The Department also notes that comparisons expressing part 30 compliance costs as a share of total apprenticeship program costs are of limited value. The majority of program costs identified in the analyses cited by commenters consist of apprentice wages, which are associated with well-documented benefits to sponsors. These wages lead to increased productivity and improve long-term workforce development, which are the benefit returns that are under study in the source provided by the commentor. By contrast, the administrative and affirmative action obligations imposed by part 30 represent non-productive overhead costs that do not generate operational benefits. Accordingly, even when expressed as a relatively small share of total program expenditures, compliance costs may nonetheless constitute a meaningful barrier to employer entry and program sustainability, particularly for small or first-time sponsors, because these costs are not an investment with meaningful returns to the sponsor. The Department therefore does not agree that a per-apprentice compliance cost of approximately $102 annually is inconsequential, or that such figures undermine the NPRM's conclusion that existing part 30 requirements impose a substantial and disproportionate administrative burden. The Department maintains that the NPRM's estimates reflect the best available data on the administrative activities required of sponsors under part 30 and that the projected cost savings from removing these requirements remain appropriate.

Comments: A commenter said that the analysis conflates the one-time cost of developing anti-discrimination training materials from scratch with the smaller, ongoing cost of periodically updating those materials. The commenter also suggested that routine updates to anti-discrimination training, under the current regulation, do not require extensive time or the senior-level involvement assumed in the Department's calculations.

Department Response: The Department disputes the notion that this is a one-time cost, and disagrees that the cost estimates for developing and maintaining anti-discrimination training materials are inflated. The Department finds it reasonable to assume that human resources personnel conduct periodic orientation and informational sessions that include anti-harassment and anti-discrimination content, and that a fee for updating materials as needed is assessed by the sponsor. Additionally, the Department acknowledges the cyclical administrative burden related to the preparation, review, and implementation of updated materials. Accordingly, the Department has not adjusted the cost estimates in response to this comment.

Comments: Some commenters commented that the six requirements in 29 CFR part 30 do not impose a substantial burden, comparing the cost estimates in the 2016 final rule with the cost-savings estimates in the NPRM. The commenters stated that the assumptions underlying the 2016 final rule and the NPRM were similar and noted that the 2016 final rule estimated $63.9 million in costs for the selected provisions, whereas the NPRM estimated $75.1 million in savings for those same provisions, contributing to a total estimated savings of $77.4 million when all provisions are considered. The commenters further asserted that the NPRM's estimate of regulatory compliance costs at registration is unrealistically high, stating that their analysis shows the NPRM estimate is 1.88 times the total median registration costs reported by employers and more than 37 percent of the total mean registration costs. They also cited a return-on-investment study in which only one of six manufacturing sponsors listed administrative costs, suggesting minimal burden under existing 29 CFR part 30 requirements.

Department Response: In response to these comments, the Department acknowledges the comparison submitted. The Department notes that the commenters' comparison relies on the median registration cost reported in the cited study rather than the mean. The study itself reflects a highly skewed distribution of costs, with a median of approximately $240 but a mean exceeding $1,200, indicating that some sponsors incur substantially higher registration-related costs. The presence of this long right tail is likely driven by variations in sponsor size and structure, particularly for those establishing new programs. The Department also notes that the return-on-investment study cited by the commenters does not assess the ongoing compliance obligations imposed by current 29 CFR part 30. Rather, the study is limited to a small sample of six program sponsors and focuses primarily on initial program establishment costs and sponsor perceptions relevant to return-on-investment calculations. The study does not attempt to measure the ongoing administrative, recordkeeping, reporting, or affirmative action activities required under the current 29 CFR part 30. Accordingly, the Department does not consider the study an appropriate basis for evaluating the regulatory burden of the existing rule, and the Department disagrees with the conclusion that the requirements of current 29 CFR part 30 are not burdensome. The Department maintains that the NPRM's burden estimates

reflect the best available data and appropriately account for the administrative activities required of sponsors under the regulation.

Comments: A commenter commented that the Department's regulatory analysis should include the expenses that employers and SAAs would incur to familiarize themselves with the new regulations, asserting that these costs were omitted due to difficulties in quantification and that including them would temporarily reduce projected savings.

Department Response: The Department agrees in part with this comment and has updated the analysis to include familiarization costs for SAAs, including time required by human resources managers and attorneys. The Department, however, did not separately value familiarization costs for employers who are not sponsors, as sponsors are the entities required to review and comply with the rule, while non-sponsor employers will not need to do so.

Comments: A commenter submitted feedback that the Department relied on inaccurate data and underestimated the time and effort required for sponsors to update compliance standards in response to the regulatory changes proposed in the NPRM. The commenter disagreed with the Department's estimate that these updates only would require 20 minutes of administrative assistant time, arguing instead that meaningful revisions demand substantial involvement from management and key stakeholders and would exceed the Department's estimated labor costs.

Department Response: In response to these comments, the Department reviewed its assumptions and determined that the RIA's time estimates appropriately reflect the typical tasks required for these updates. Accordingly, the Department has made no changes to the RIA.

Comments: Several commenters submitted feedback that the proposed rule would impose a greater burden on SAAs and State legislatures than estimated, particularly regarding the work required to update State apprenticeship plans and related State laws. These commenters stated that the Department's 1-year estimate for a full-time staff member to complete plan updates understates the complexity and duration of the multi-stage approval processes, including legal review, legislative cycles, and regulatory revisions, and urged the Department to significantly simplify the approval process for State plans for nondiscrimination in apprenticeship in the final rule to reduce burden on OA and SAA staff.

Department Response: In response to these comments, the Department reviewed these assumptions and acknowledges that State plan revisions can involve multi-stage processes and varying legislative timelines. The Department added explanatory text accompanying the RIA calculations to note that State apprenticeship plans may proceed on different schedules; however, the best available data support the Department's existing estimates, and the RIA was not adjusted in response to this comment.

Although the original estimates in the RIA were found to be reasonable, several methodological adjustments were made to the analysis and assumptions, in addition to adding rule familiarization costs for SAAs, to better align with the approach used in the 2016 final rule and to respond to public comments. These revisions included updating the annualization formula for cost savings to reflect methodologies applied in prior rulemakings, adjusting the assumed average annual sponsor growth rate to be consistent with historical trends, and revising wage and fringe benefit rates based on 2025 historical data and published 2026 wage rates. Detailed descriptions of the assumptions and methodologies and assumptions used in the analysis are presented in the sections below.

Comments: Commenters expressed concern that the proposed requirement that SAA nondiscrimination laws ''conform only to'' part 30 could undermine State autonomy, conflict with the cooperative federalism framework, and create uncertainty regarding the interaction between Federal and State requirements, including whether States could maintain or enforce additional EEO provisions and how potential conflicts would be resolved. Several commenters requested clarification on the scope of the requirement and its application to State policies and procedures, while others emphasized the importance of preserving flexibility for States to address local labor market conditions and maintain broader apprenticeship program authorities.

Department Response: As discussed earlier in the preamble, the Department revised the regulatory text to require that State laws ''conform to'' part 30. Retaining a ''conform to'' standard preserves State flexibility by allowing SAAs to maintain or adopt requirements that are compatible with, but not limited to, Federal rules. This approach avoids Federal preemption of State policies while maintaining Departmental oversight to ensure consistency with baseline Federal standards. Because the existing CFR framework already requires State plans and programs to ''conform to'' Federal requirements, this provision does not introduce new compliance obligations. As a result, the final rule is not expected to impose incremental costs or generate additional regulatory impacts relative to the current baseline.

4. Estimates of Sponsors Impacted by the Rule Across the 10-Year Period

The Department's analysis considered the expected costs, cost savings, and benefits of the changes to part 30. This analysis measured the costs, cost savings, and benefits as they accrue to sponsors and State agencies. It is estimated that the number of sponsors will grow over time and our annual cost calculations reflect this growth. The Department based its estimate of the number of sponsors in each year using data from RAPIDS regarding the number of Registered Apprenticeship programs and based its estimate of the annual growth in Registered Apprenticeship programs on the average annual growth rate from FY 2021 to 2025. Because 2025 program data became available between publication of the NPRM and issuance of the final rule, the Department updated growth rates to reflect changes observed between FY 2021 and FY 2025, where data permitted. In addition, the average annual sponsor growth rate used to project future program participation was revised to align more closely with historical patterns. The final RIA presents updated sponsor data incorporating these revisions. The Department also used the same RAPIDS data to develop an estimate of the number of Registered Apprenticeship programs that have five or more apprentices in each year of the analysis.[61] While the Department expects that the number of apprentices will increase after part 30 is streamlined, we used prior data to estimate future growth because it is common practice in cost-benefit analysis and because it is difficult to quantify how much the streamlining of

[61] The Department identified 26,466 total programs and 7,429 programs with five or more apprentices in RAPIDS as the starting point. The annual average growth rate for all programs was 1.30 percent and 5.17 percent for programs with five or more apprentices between FY 2021 and FY 2025. For the purpose of this analysis, we assume that each program is supported by a single sponsor. Therefore, these data are used to estimate the projected number of total programs and total sponsors as well as those with five or more apprentices for each year in the analysis.

part 30 will increase the growth of apprenticeship programs.[62]

This analysis primarily discusses how the first-year costs were calculated and indicates that the analysis repeats that calculation across the 10-year time frame using the appropriate number of sponsors in any given year. Exhibit 2 presents the estimated number of total active and new active program sponsors, and the estimated number total and new active sponsors with five or more apprentices projected for each year in the analysis.

EXHIBIT 2

A	B	C	D	E
Year	Total active sponsors	New sponsors [a]	Total active sponsors with five or more apprentices	New sponsors with five or more apprentices
2026	26,810	344	7,813	384
2027	27,158	348	8,217	404
2028	27,511	353	8,642	425
2029	27,869	358	9,089	447
2030	28,231	362	9,559	470
2031	28,598	367	10,053	494
2032	28,970	372	10,573	520
2033	29,346	377	11,119	547
2034	29,728	381	11,694	575
2035	30,114	386	12,299	605

[a] New sponsors (column C) includes only sponsors that newly register in a given year. In contrast, new sponsors with five or more apprentices (column E) includes both (1) newly registered sponsors that have hired five or more apprentices, and (2) existing sponsors that expand their programs to reach the five-apprentice threshold for the first time. As a result, the annual growth rate and count of new sponsors with five or more apprentices exceeds that of the total number of newly registered sponsors.

5. Cost Savings

The Department first presents the cost savings that will accrue under the final rule. Most of these cost savings accrue to the sponsors of Registered Apprenticeship programs because the final rule eliminates several requirements for sponsors under the current part 30 regulations. The savings from eliminating these requirements are discussed in greater detail below.

Eliminating One-Time Costs for Sponsors of New Registered Apprenticeship Programs

Under the current part 30 regulation, sponsors must post their equal opportunity pledge on bulletin boards and through electronic media, such that it is accessible to all apprentices and applicants to apprenticeship programs. This requirement imposes costs on sponsors operating a Registered Apprenticeship program for the first time, as they are required to take staff time to post this pledge. Under Title VII[63] and the ADA,[64] employers are already required to post a notice summarizing Federal laws prohibiting discrimination in employment. Removing this comparable requirement from part 30 would therefore lead to savings for new sponsors of Registered Apprenticeship programs without depriving apprentices of crucial information about their employment rights.

The Department assumed that new sponsors would choose to put up a physical copy of the pledge and also post it on their website. The Department assumed it takes a sponsor 5 minutes (0.08 hours) to post the pledge and that this task is performed by an administrative assistant. To calculate the hourly compensation rate, the Department used the median hourly wage rate for Secretaries and Administrative Assistants, Except Legal, Medical, and Executive (Standard Occupational Classification code 43–6014) of $22.70,[65] and assumed a 17% overhead cost[66] and a 42-percent benefit cost.[67] The total hourly compensation rate is [$22.70 + ($22.70 × 42%) + ($22.70 × 17%)], or $36.10. We multiplied the time estimate for this provision by the hourly compensation rate to obtain a total labor cost per sponsor of $2.89 ($36.10 × 0.08). To estimate the materials cost, the Department assumed that the pledge is one page, and that the cost per page for photocopying is $0.10, resulting in a materials cost of $0.10 ($0.10 × 1) per sponsor. The total cost of putting up a physical copy of the pledge per sponsor is therefore $2.99 ($2.89+$0.10). Additionally, the Department also assumed it takes a sponsor 10 minutes (0.17 hours) to post the pledge on its website and that this task is performed by a web developer at an hourly compensation rate of $72.57.[68] The cost of posting the pledge on the sponsor's website is $12.34 ($72.57×0.17). In total, the Department estimated the cost of the current provision requiring the posting of physical copy of the pledge and the posting of the pledge on the sponsor's website of $15.32 ($2.99+$12.34) per new sponsor.

The Department estimated that there are 344 new sponsors in the first year (see Exhibit 2) that would incur these costs. Multiplying this sum ($15.32) by the estimate of new sponsors (344) in the first year (2026) resulted in a cost

[62] The Department's cost-benefit analysis finds that the majority of the benefits from streamlining part 30 accrue to sponsors of Registered Apprenticeship programs. If the Department estimated a higher growth rate to Registered Apprenticeship, the estimated benefits of the final rule would be higher.

[63] 42 U.S.C. 2000e–10.

[64] 42 U.S.C. 12115.

[65] Bureau of Labor Statistics (BLS), ''2024 National Occupation Employment and Wage Estimates for Secretaries and Administrative Assistants, Except Legal, Medical, and Executive (43–6014), Hourly median wage,'' last modified May 15, 2026, *https://www.bls.gov/oes/tables.htm.*

[66] Cody Rice, EPA, ''Wage Rates for Economic Analyses of the Toxics Release Inventory Program,'' June 10, 2002, *https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0005.*

[67] Benefit cost is derived from the ''Employer Costs for Employee Compensation Summary'' for June 2025 release from BLS, can be found at *https://www.bls.gov/news.release/ecec.t04.htm.* The total benefits value was compared to the wages and salary amount at the 50th wage percentile for private industry workers. This calculation, $13.58 ÷ $32.07, produced a benefits cost of 42 percent of wages.

[68] Median wage for Web Developer (Occupation code: 15–1134) is $45.64. BLS, ''National Occupation Employment and Wage Estimates by Ownership,'' accessed January 15, 2026, *https://www.bls.gov/oes/current/000001.htm#11-0000.* The fully adjusted wage rate for a web developer accounting for overhead and benefits is 45.64 + (45.64 × 0.17) + (45.64 × 0.42), which equals $72.57.

savings of $5,271 from eliminating this provision. Looking over the full ten-year period, we estimated the annualized cost savings from eliminating the cost of posting the EEO pledge of $5,573 with 3 percent discounting and $5,551 with 7 percent discounting.

Eliminating Ongoing Costs for All Sponsors

The current part 30 regulations also require that each sponsor conduct orientation and periodic information sessions for apprentices, journeyworkers who directly supervise apprentices, and other individuals connected with the administration or operation of the sponsor's apprenticeship program to inform and remind such individuals of the sponsor's EEO policy with regard to apprenticeship (current § 30.3(b)(2)(iii)). Under current § 30.3(b)(4)(i), sponsors are also required to provide anti-harassment training, which we assume is incorporated into periodic orientation and information sessions. This training must include active participation by trainees, such as attending a training session in person or completing an interactive training online and includes, at a minimum, communications to apprentices and journeyworkers who directly supervise apprentices that harassing conduct will not be tolerated, the definition of harassment and types of conduct that constitute harassment, and the right to file a harassment complaint.

Using data from RAPIDS, the Department calculated that there are on average 25.4 apprentices per sponsor, rounded down to 25 apprentices per program.[69] The Department further assumed a one-to-one ratio between apprentices and journeyworkers in estimating the cost of orientations and periodic information sessions. The Department first estimated that the 26,810 program sponsors in the first year (2026) will hold one 45-minute regular orientation and information session with an average of 25 apprentices ($37.07 per hour)[70] and 25 journeyworkers ($57.18 per hour)[71] per sponsor. The Department estimated that a human resources manager ($113.78)[72] will need to spend 2 hours to develop and prepare written materials for the session in the first year, and 2 hours to maintain and update the training materials in subsequent years.

Using this calculation, we estimated a total cost savings for removing this provision of approximately $53.48 million in the first year (2026). The Department assumed that all sponsors would hold one 45-minute regular orientation and information session annually if this requirement was not eliminated by the rule. We therefore repeated this calculation in subsequent years. We estimated the annualized savings from the elimination of this cost at $56.54 million with 3 percent discounting and $56.31 million with 7 percent discounting.

Additionally, under the current part 30, all sponsors are required to reach out to a variety of recruitment sources, including organizations that serve individuals with disabilities, to ensure universal recruitment (current § 30.3(b)(3)). Sponsors are required to develop a list of recruitment sources that generate referrals of women, minorities, and persons with disabilities with contact information for each source. Further, sponsors are required to notify these sources in advance of any apprenticeship opportunities and while a firm deadline is not set, the part 30 regulations suggest 30 days' notice if possible. This current outreach protocol may lead employers to incur costs due to the additional delay it introduces into the hiring process. The Department, however, does not have enough information to estimate the potential costs sponsors currently incur from these delays.

The kinds of activities sponsors engage in to satisfy this outreach requirement include distributing announcements and flyers detailing job prospects, holding seminars, and visiting some of the sources who are likely able to provide access to designated groups. The Department assumed that the cost to sponsors to distribute information to designated groups will be the labor cost to comply with this provision. We also assumed that the activity to satisfy this provision will be performed by a human resources manager and an administrative assistant with hourly compensation rates of $113.78 and $36.10, respectively. We assumed this task takes 30 minutes (0.5 hour) of a human resources manager's time and 30 minutes (0.5 hour) of an administrative assistant's time per targeted source. We calculated the cost of this provision per affected sponsor by multiplying the time each staff member devotes to this task by their associated hourly compensation rates. We then multiplied the total labor cost by the assumed number of outreach sources (5) and by the total number of sponsors. All sponsors are assumed to conduct this outreach in all years. We estimated the cost savings from eliminating this outreach provision at $10.05 million in the first year, with an annualized savings from the elimination of this cost for sponsors at $10.62 million with 3 percent discounting and $10.58 million with 7 percent discounting.

Savings From Eliminating Costs of Performing Utilization and Workforce Analysis Costs for Sponsors With Five or More Apprentices

The current part 30 regulations require sponsors with five or more apprentices to establish utilization goals for women and minorities (current §§ 30.5 through 30.7). First, sponsors conduct a workforce analysis to identify the racial, sex, and ethnic composition of their apprentices. Second, an availability analysis will establish a benchmark against which the existing composition of apprentices will be compared. Sponsors establish utilization goals and engage in targeted outreach, recruitment, and retention efforts when the sponsor's utilization of women, Hispanics or Latinos, or individuals in racial minority groups are ''significantly less than would be reasonably expected given the availability of such individuals for apprenticeship.'' Registration Agencies work closely with sponsors during compliance reviews to assist in the development of an availability analysis and setting or reassessing utilization goals for race, sex, and ethnicity. The Department also provides a data tool to assist in the collection and analysis of relevant demographic data for the purposes of goal setting.

The Department determined that eliminating the utilization goal requirement will create three types of cost savings: Savings from the elimination of costs associated with the familiarization with the data tool for new sponsors, savings from the elimination of costs associated with the workforce analysis, and savings from

[69] This estimate is from RAPIDS data at the end of FY2024.

[70] We calculated the hourly compensation rate for an apprentice by multiplying the average hourly wage of $23.32 (inflation adjusted annual average hourly rate published by ZipRecruiter, last updated Mar. 4, 2026), *https://www.ziprecruiter.com/Salaries/Apprenticeship-Salary*) by 1.59 to account for private-sector employee benefits and overhead. Thus, the hourly compensation rate for an apprentice is $37.07 ($23.32 × 1.59).

[71] We calculated the hourly compensation rate for a journeyworker by multiplying the average hourly wage of $35.96 (inflation adjusted annual average hourly rate published by ZipRecruiter, last updated Mar. 4, 2026, *https://www.ziprecruiter.com/Salaries/Journeyman-Salary*) by 1.59 to account for private-sector employee benefits and overhead. Thus, the hourly compensation rate for a journeyworker is $57.18 ($35.96 × 1.59).

[72] We calculated the hourly compensation rate for a human resources manager (Occupation code 11–3121) by multiplying the median hourly wage of $71.56 by 1.59 to account for private-sector employee benefits and overhead. Thus, the hourly compensation rate for a human resources manager is $113.78 (71.56 × 1.59).

the elimination of costs associated with the utilization analysis.

To quantify the savings from the elimination of costs associated with new sponsors' familiarization with the data tool, the Department assumed that new sponsors with five or more apprentices (384 in 2026) will incur one hour of human resources manager labor ($113.78 per hour) to familiarize the organization with the tool. We estimated this will create $43,700 in cost savings from the elimination of these tool familiarization costs in the first year of 2026. We repeated this calculation for the following years. We estimated that removing the utilization goal requirement from part 30 therefore creates an annualized savings of $54,729 with 3 percent discounting and $53,872 with 7 percent discounting from the elimination of new sponsors' tool familiarization costs.

To calculate the savings from removing the workforce analysis requirements from part 30, the Department determined that the methodology for conducting workforce analyses under the current part 30 results in 2 hours of human resources manager labor ($113.78 per hour) for all sponsors with five or more apprentices (7,813 in 2026). Under the current part 30 regulations, all sponsors with five or more apprentices must conduct workforce analysis every 2.5 years. In calculating the savings for each year, the Department divided the number of applicable sponsors in each year by 2.5 to reflect the assumption that sponsors would have conducted the analysis once per the 2.5-year timeline. This means that in any given year 40 percent of sponsors with five or more apprentices would have conducted the workforce analysis, or that it would have taken 2.5 years to have these sponsors conduct new workforce analyses. We estimated the cost savings from eliminating the requirement to conduct workforce analyses in the first year at $711,149 ($7{,}813 \times 0.4 \times \$113.78 \times 2$ hours). We repeated this calculation for the following years using the appropriate number of sponsors in any given year, resulting in an annualized savings from the removal of the workforce analysis requirement of $890,620 with 3 percent discounting and $876,680 with 7 percent discounting for sponsors.

To calculate the savings from the removal of the utilization analysis requirement, the Department determined that the utilization analysis resulted in 0.5 hour of human resources manager time ($113.78 per hour) for all sponsors with five or more apprentices (7,813 in 2026) every 5 years (because the utilization analysis is completed in support of the compliance review process, which has typically been performed at 5-year intervals for programs in OA States). The cost savings from removing the requirement to conduct utilization analyses in the first year is $88,894 (0.5 hour $\times$ $113.78 $\times$ (7,813/5 years)). We repeated this calculation for the following years, and the savings to sponsors from not having to conduct utilization analyses results in an annualized cost savings of $111,327 with 3 percent discounting and $109,585 with 7 percent discounting for sponsors.

In addition to the normal outreach, recruitment, and retention activities required of all sponsors under current part § 30.3(b), current § 30.8 requires a sponsor of an apprenticeship program to engage in targeted outreach, recruitment, and retention, if: (1) the sponsor's utilization analyses revealed underutilization of a particular designated group or groups of individuals pursuant to current § 30.6; or (2) the sponsor has determined pursuant to current § 30.7(e) that there are impediments to EEO for individuals with disabilities. We assumed that this additional outreach happens in the same manner as the universal outreach discussed above.

We assumed that the current cost to sponsors to distribute information about apprenticeship opportunities to organizations serving individuals with disabilities is the labor cost. We also assumed that the labor for this provision will be performed by a human resources manager and an administrative assistant with hourly compensation rates of $113.78 and $36.10, respectively. The Department estimated that this dissemination task takes 30 minutes (0.5 hour) of a human resources manager's time and 30 minutes (0.5 hour) of an administrative assistant's time per targeted source. We estimated the cost of the current provision per affected sponsor is the time each staff member devotes to this task multiplied by their associated hourly compensation rates. Based on this calculation we estimated a labor cost of $74.94 (($113.78 $\times$ 0.5) + ($36.10 $\times$ 0.5)) per source.

We estimated that the number of sponsors who need to engage in targeted outreach and recruitment for at least one relevant demographic group is 95 percent of the total sponsors with five or more apprentices. We understand this is likely an over-estimate of the number of sponsors that must conduct this outreach, as more than 5 percent of sponsors may meet their utilization goal for all demographic groups and may not have to conduct outreach; however, the Department does not have complete or reliable data to produce an alternative estimate. We then multiplied this total labor cost by the number of sponsors with five or more apprentices (7,813 in 2026), the share of sponsors that undertake a utilization analysis in any given year (20 percent), and the share of sponsors that are estimated to identify underutilization or problem areas in one or more of the relevant demographic groups (95 percent).[73] This calculation ($\$74.94 \times 7{,}813 \times 0.20 \times 0.95$) results in a total cost of the current outreach provision of approximately $111,242 in 2026. The cost savings from eliminating this requirement is equal to these estimated costs since sponsors will no longer need to conduct this outreach. We repeated this calculation for the following years using the appropriate number of sponsors in any given year. We estimated the annualized cost savings to sponsors from not having to conduct this additional outreach at $139,316 with 3 percent discounting and $137,135 with 7 percent discounting.

Savings From Eliminating Affirmative Action Program Review Costs for Sponsors With Five or More Apprentices

EEO compliance reviews in the current part 30 regulations result in three additional costs for sponsors: personnel process reviews, written affirmative action plan updates during compliance reviews, and written affirmative action plan updates within 3 years of compliance reviews. The current part 30 requires sponsors with five or more apprentices to review personnel processes annually (§ 30.9). The Department estimated the current costs of each of these components and summed them to estimate the cost savings to sponsors from eliminating EEO compliance reviews.

To calculate the current costs imposed on sponsors from personnel process reviews, the Department estimated that each review takes 8 hours for a human resources manager ($113.78 per hour). Therefore, we estimated this provision to result in an undiscounted cost, for all sponsors in 2026 with five or more apprentices (7,813), of $7.11 million ($7{,}813 \times 8$ hours $\times$ $113.78).

To determine the current cost of the written affirmative action plan update at the time of the compliance review, the Department calculated the cost for all sponsors in 2026 with five or more apprentices (7,813) to spend 12 hours of

[73] This is the percentage of sponsors that undergo compliance review each year, as determined by the 5-year schedule on which sponsors undergo compliance reviews.

human resources manager labor every 5 years at the time of the compliance review.[74] With the existing compliance review rate at 20 percent, this means that approximately one in five of these sponsors undergoes a compliance review every year. We estimated this provision to currently result in an undiscounted cost of approximately $2.13 million in 2026 (7,813 × 12 hours × 0.20 × $113.78).

To determine the cost of the written affirmative action plan update within 3 years of the compliance review, the Department calculated the cost for all sponsors in 2026 with five or more apprentices (7,813) to spend 6 hours (estimated to be less because of the lesser workload from not overlapping with the compliance review) of human resources manager time every 5 years.[75] We estimated this provision to result in an undiscounted cost of $1.07 million in 2026 (7,813 × 6 hours × 0.20 × $113.78). We repeated this calculation for the following years using the appropriate number of sponsors in any given year.

Based on the assumptions above, we estimated the total cost of the current affirmative action plan program provision, and therefore the cost savings from it being eliminated, to be $10.31 million in 2026 ($7.11 million + $2.13 million + $1.07 million). We estimated the annualized savings from eliminating EEO compliance reviews to be $12.91 million and $12.71 million at 3 percent and 7 percent discounting, respectively.

Invitation To Self-Identify as an Individual With a Disability

Current § 30.11 requires sponsors with five or more apprentices to invite applicants for apprenticeship to voluntarily self-identify as an individual with a disability protected by this part at two stages: (1) at the time they apply or are considered for apprenticeship; and (2) after they are accepted into the apprenticeship program but before they begin their apprenticeship. Additionally, all sponsors with five or more apprentices are required to administer the invitation to self-identify to existing apprentices annually.

The Department estimated that sponsors will post 42 positions in 2026 and receive 15 applicants per posting.[76] Of those positions, the Department estimated that 42 offers of enrollment are made and 42 apprentices choose to enroll in 2026. The Department estimated that it would take an apprentice ($37.07 per hour) 5 minutes (0.08 hours) to complete the form. Furthermore, an administrative assistant ($36.10 per hour) would need to spend 0.5 hour annually to record and keep the forms. For the final RIA, the Department reevaluated and revised the calculation of this cost to more accurately account for labor costs associated with inviting applicants and hired apprentices to self-identify as an individual with a disability. As a result, we estimated this requirement to have an undiscounted cost in 2026 of $15.71 million (7,813 sponsors × ((15 applications × 42 job listings × 0.08 hours) + (42 offers of apprenticeship × 0.08 hours)) × $37.07 + 7,813 programs × 0.5 hour × $36.10). For the 10-year analysis period, we estimated this provision's annualized cost as $19.68 million and $19.37 million (at 3 percent and 7 percent discounting, respectively).[77]

In addition, sponsors with five or more apprentices are required to remind apprentices yearly that they can update their invitation to self-identify. The Department assumed that these sponsors send out an annual reminder email at the cost of $22,563 (7,813 × 0.08 hour × $36.10). We repeated this calculation for each remaining year in the analysis period using the estimated number of sponsors for each year. We therefore estimated that eliminating this provision will result in an annualized cost savings of $28,257 and $27,814 (at 3 percent and 7 percent discounting, respectively).

Non-Quantified Cost Savings

In addition to the cost savings discussed above, there are several other cost savings from streamlining the nondiscrimination requirements under part 30 that are not included in the Department's quantitative analysis. Under the final rule, sponsors will benefit from a more streamlined and less complex part 30 regulation, reducing confusion and the time required to answer questions or address confusion regarding compliance requirements. The final rule will also benefit sponsors by removing the legally questionable components of the current part 30 regulations, thereby eliminating legal risk that sponsors could be sued or legally challenged for actions taken to comply with part 30, such as setting utilization goals regarding the race or sex of program participants. Additionally, the final rule will eliminate the costs associated with discrimination complaint investigations involving obtaining full complaint information, gathering relevant materials (*e.g.,* interview statements, transcripts, pertinent documents), and developing a narrative report of the allegations and investigation findings.[78]

Since the final rule reduces the barriers for sponsors to create and operate Registered Apprenticeship programs, it may also lead to the registration of additional apprenticeship programs. The enhanced growth of Registered Apprenticeship programs could improve access for individuals to enroll in apprenticeships and receive high-quality job training—boosting their long-term earnings and having spill-over effects in the local economy. The proliferation of Registered Apprenticeship programs also could benefit local employers, as the training of additional skilled apprentices could expand local talent pools and allow employers to more easily fill positions for in-demand occupations.

[74] A compliance review includes: (1) a workforce analysis; (2) a utilization analysis; (3) goal-setting (if necessary); and (4) a full update of the written affirmative action plan. Because we have already costed out items (1), (2), and (3), the sponsor would need additional 12 hours to fully update the written affirmative action plan.

[75] An EEO compliance review within three years of compliance reviews contains (1) workforce analysis and (2) updating the written affirmative action plan to include the updated workforce analysis and a description of the review of personnel practices and any changes made as a result of that review (see § 30.9(b)). Because we have already costed out (1), the 6 hours are for including updated the workforce analysis and a description of the review of personnel practices and any changes made as a result of that review (see current § 30.9(b)).

[76] The Department determined the number of positions posted from conversations with programs of various sizes. We determined that the largest, statewide programs post more than 15 jobs, but the Department used this as an average for all apprentices to avoid under-estimating the costs.

[77] It is assumed that there will be 100 percent participation in the invitation to self-identify and therefore, the cost of this provision is likely overestimated.

[78] The Department did not quantitatively estimate the cost savings from the elimination of discrimination complaint investigations due to the lack of data and the lack of understanding of the frequency with which investigations occurred.

Finally, chief among these cost savings is the elimination of regulatory provisions that have the effect of encouraging the use of race- and sex-based preferences in apprenticeship selection and advancement decisions. By removing these requirements, the final rule promotes a return to individual, merit-based evaluation, consistent with the principle that all Americans should be treated as individuals rather than as members of demographic groups. This shift will strengthen public confidence in the fairness of the apprenticeship system, reduce legal uncertainty, and encourage broader participation by sponsors who may have been deterred by the prior rule's prescriptive and group-based mandates.

While these cost savings could be substantial, the Department did not estimate these cost savings because of data limitations that impede our ability to accurately quantify these cost savings. Collectively, however, these cost savings reinforce the Department's conclusion that the advantages of this proposal outweigh any potential costs.

6. Costs

Below, the Department presents the costs estimated to be incurred by relevant stakeholders, mainly program sponsors and SAAs, from this final rule. These costs are broken into three major categories: costs to sponsors and SAAs of familiarizing themselves with the regulatory change, costs to sponsors and Registration Agencies of updating standards for compliance, and costs to SAAs of updating State plans for nondiscrimination in apprenticeship. The following sections present estimates for each of these cost categories imposed by the final rule.

Familiarization With Regulatory Change

To estimate the cost of rule familiarization for sponsors, we multiplied the number of program sponsors in 2026 (26,810), the first year in which the change will be in effect, by the amount of time required to read the new rule (which we estimate to be 1 hour) and by the average hourly compensation of a private-sector human resources manager with fringe benefits included ($113.78). This cost is only incurred in the first year of the change, so the total cost to sponsors for time spent on familiarization is approximately $3.05 million in labor costs.

In response to public comments, the Department also estimated the cost of rule familiarization for SAAs. The Department assumed that for SAAs, both a human resources manager and a lawyer would review the regulatory change in the first year. The Department estimated the cost of rule familiarization by SAAs by multiplying the number of SAA states (33) by the amount of time required to read the new rule (1 hour) and by the sum of the average hourly compensation of a public-sector human resources manager ($92.04) and a State-level lawyer ($98.84). The total cost to SAAs for time spent on familiarization is approximately $6,299 in labor costs.[79]

There are no familiarization costs for future years because sponsors and SAAs will already be familiar with the rule and new sponsors would have had to familiarize themselves with the prior part 30 regulations. Therefore, we estimated the total cost of initial rule familiarization of $3.06 million in labor costs, realized entirely in the first year.

Updating Standards for Compliance

Pre-existing sponsors of Registered Apprenticeship programs will also need to develop language or make adjustments and updates to existing standards to comply with the changes to part 30. The Department estimated that this will be a one-time cost only imposed on pre-existing sponsors that already had standards prior to the publication of the final rule. The Department estimated that updating standards to comply with part 30 will mainly involve removing items currently required by part 30 and therefore estimated the burden will be minimal. Accordingly, the Department estimated the average response time for the projected 26,466 pre-existing apprenticeship programs in 2026 to ensure standards comply with part 30 is 20 minutes (0.33 hours).[80] We estimated an annual burden of 8,734 hours (26,466 × 0.33). The Department assumed the standards will be updated by an administrative assistant. Therefore, the Department estimated a one-time cost of $315,266 (8,734 × $36.10).

Registration Agency staff are responsible for reviewing and providing input on a sponsor's apprenticeship program standards to ensure compliance with the requirements in part 30. Registration Agencies will therefore incur a one-time cost to review updated standards for pre-existing programs. The Department estimated that the review and input provided by Registration Agency staff for program sponsors will take 10 minutes, which resulted in 4,499 annual burden hours (26,466 × 0.17 hours). Using the State employee wage calculated above, we estimated a total cost to Registration Agencies of this one-time review of $399,891 (4,499 hours × $88.88).

Revision of State Plan

The process of updating a State plan (under current part 30, a ''State EEO plan,'' and in the final rule, a ''State plan for nondiscrimination in apprenticeship'') may potentially involve various people at different stages of implementation. Updating the plan will include drafting the new plan, ensuring conformity and that State laws and practices do not exceed the final rule, and completing all administrative procedures that may apply, such as revisions to a State's apprenticeship law or policy that may require a public notice-and- comment period, training for SAA staff on the revised State plan, and outreach to program sponsors to inform them of the relevant aspects of the revised State plan once it has been approved by the Department. The

[79] The Department notes that there are 32 officially recognized SAA. Additionally, one State, California, also operates a SAA that is not recognized by the Department but registers apprenticeship programs for State purposes. Many of the programs registered by the Department's OA for Federal purposes in California are also recognized by California's SAA for State purposes. The Department therefore anticipates that the California SAA will review the final rule, despite not being recognized by the Department to register programs for Federal purposes under the NAA and its regulations. To ensure the most accurate estimate of burden, the Department is choosing to include costs related to the California SAA's review of this final rule within the RIA.

[80] There are 26,466 pre-exiting sponsors in FY 2026 because there are 26,810 projected sponsors in FY 2026 and 344 of these sponsors are new. (26,810 − 344 = 26,466).

updates to State plans include changing language and existing requirements such that they align with the regulatory changes herein. To calculate the costs, the Department assumed that the process to revise the State plan will take a full year of effort (2,080 hours) to complete.[81] The Department acknowledges that State plan revisions can involve multi-stage processes and varying legislative timelines, but these assumptions used in the analysis represent the best data available and the Department's best estimate for updating the existing State plan. As noted above, many State apprenticeship laws incorporate part 30 requirements through referencing the Federal regulations and will not need to be updated, likely leading to lower costs for some SAA States than others. However, the Department assumes that all SAA States will experience the same cost. As a result, the Department is likely overstating the true cost of revising State plans. For simplicity, we assumed that an SAA human resources manager will complete the task at an hourly compensation rate of $88.88.[82] Based on this calculation we estimated a one-time cost of $6.10 million in the first year (2,080 hours × $88.88 × 33 SAA States).[83]

Complaint Referral Procedures

Section 30.4, Complaint referral procedures, directs the Registration Agencies to refer complainants alleging illegal discrimination against apprentices to the appropriate enforcement agency. Since the complaint process is not a new process, the Department does not expect that these provisions will result in any incremental change in the burden on Registration Agencies as these agencies are already required to refer complaints to other EEO agencies under current § 30.14(c)(3). Therefore, the Department does not estimate any additional costs associated with complaint referrals under the final rule.

Nondiscrimination Compliance Reviews and Enforcement

In response to public comment, the section on nondiscrimination compliance reviews and enforcement (§ 30.5) within the final rule adds a requirement that sponsors disclose to the Registration Agency any final determinations by an enforcement entity or court with jurisdiction over an applicable nondiscrimination law that the sponsor violated such law with respect to an apprentice or applicant for apprenticeship. Sponsors must provide this written disclosure within 60 days of the final determination and must include, at a minimum, copies of relevant final determinations, judgments, decisions, and orders. Sponsors must also include, as part of this disclosure, a description of any remedies prescribed by the enforcement entity or court to address the violation.

The Department expects that this requirement may impose some administrative burden on sponsors in the limited circumstances in which a final, non-appealable determination of a violation of a nondiscrimination law has been made. In such cases, a sponsor may need to review the final determination and related orders, prepare a written disclosure to the Registration Agency, and describe any prescribed remedies. The Department expects these activities will involve legal, managerial, or administrative staff time, depending on the sponsor's size, organizational structure, and the complexity of the final determination or ordered remedy.

The Department is not aware of prior instances in which sponsors have been subject to final, non-appealable determinations of nondiscrimination violations that would trigger this requirement, and it expects such events to occur infrequently. The Department does not have data that would allow it to estimate how often enforcement entities or courts will issue such determinations involving apprentices or applicants, nor how often those determinations will result in prescribed remedies that sponsors must describe to the Registration Agency or the extent to which any such disclosures will vary in complexity. Because the requirement is triggered only when an external enforcement entity or court has issued a final determination of a nondiscrimination violation relating to an apprentice or applicant, the Department cannot estimate whether this requirement will be triggered frequently, infrequently, or at all for many sponsors. For these reasons, the Department discusses the potential administrative costs of this disclosure requirement qualitatively but does not include a quantified estimate in the RIA.

7. Analysis Summary

Exhibit 3 presents a summary of the first-year cost savings and costs of the final rule, as described above. As shown in the exhibit, the total first-year cost savings of the final rule are $90.53 million and the total first-year costs are $9.87 million.

EXHIBIT 3

Provision	Entity affected	Monetized costs ($ million)
No longer posting equal opportunity pledge	Sponsor	−$0.01
No longer conducting equal opportunity training	Sponsor/Apprentice	−53.48
No longer conducting universal outreach	Sponsor	−10.05
No longer conducting utilization and workforce analysis	Sponsor	−0.95
No longer conducting EEO compliance reviews	Sponsor	−10.31
No longer providing an invitation to self-identify as an individual with a disability	Sponsor/Apprentice	−15.73
Familiarization with regulatory change	Sponsor	3.05
Familiarization with regulatory change	SAA	0.01

[81] Note that this calculation is only the administrative costs of updating the State plan, as opposed to the costs of implementing the new plan, or any new burdens on State Agencies. Since the updated State plan for nondiscrimination in apprenticeship should reflect the Federal regulations, these costs should be accounted for and addressed elsewhere in the analysis under discussions of costs.

[82] We calculated the hourly compensation rate for a human resources manager at a State agency by multiplying the hourly wage of $48.07 (GS–13 step 5) by 1.63 for public sector employee benefits. BLS, ''National Compensation Survey, Employer Costs for Employee Compensation,'' last modified June 12, 2026, *https://www.bls.gov/news.release/ecec.t03.htm*. For State and local government workers, wages and salaries averaged $49.38 per hour worked in 2025, while benefit costs averaged $24.63, which is a benefits rate of 63 percent) and 1.17 to account for overhead costs. Cody Rice, EPA, ''Wage Rates for Economic Analyses of the Toxics Release Inventory Program,'' June 10, 2002, *https://www.regulations.gov/document/EPA-HQ-OPPT-2014-0650-0005* to account for State and local employee benefits. The hourly compensation rate for a human resources manager at a State agency is thus $88.88 (($49.38 × 1.17) + ($49.38 × 1.63)).

[83] The estimated time to complete the revisions is 12 months (2,080 hours). The calculation used the hourly compensation rate for a State human resources manager ($88.88) multiplied by 2,080 (the assumed number of work hours in a year) and by the total number of State Apprenticeship Agencies (33) to obtain the total cost. This cost only accrues in the first year of the ten-year analysis period.

EXHIBIT 3—Continued

Provision	Entity affected	Monetized costs ($ million)
Updating standards to align with revised part 30 regulation	Sponsor/Registration Agencies	0.72
Revision of State plan for nondiscrimination in apprenticeship	SAA	6.10
Total First-Year Costs		−80.66

Exhibit 4 presents a summary of the monetized costs and cost savings associated with the final rule over the 10-year analysis period. The monetized costs and cost savings displayed are the yearly summations of the calculations described above. Costs and cost savings are presented as undiscounted 10-year totals, and as present values with 7 and 3 percent discount rates.

EXHIBIT 4

Year	Monetized cost savings ($Million)	Monetized cost ($million)
2026	$90.53	$9.87
2027	92.75	
2028	95.06	
2029	97.45	
2030	99.93	
2031	102.51	
2032	105.19	
2033	107.97	
2034	110.86	
2035	113.86	
Undiscounted	1,016.11	9.87
7% Discounted	703.64	9.23
3% Discounted	861.39	9.58
Annualized Undiscounted	101.61	0.99
Annualized 7%	100.18	1.31
Annualized 3%	100.98	1.12

As mentioned above, due to data limitations, the Department did not quantify several important benefits to society provided by the final rule. The final rule is expected to result in several overarching benefits to apprenticeship programs and specific benefits resulting from a less legally ambiguous and more streamlined part 30. The final rule will reduce barriers to register and operate an apprenticeship program, allowing the creation of additional programs that allow more individuals to receive training and benefiting businesses in meeting their skills needs.

8. Regulatory Alternatives

In addition to the final rule, the Department considered three regulatory alternatives: (a) repeal part 30 entirely; (b) only eliminate the additional affirmative action requirements pertaining to sponsors with five or more apprentices while retaining the reminder of the 2016 final rule; and (c) take no action (*i.e.,* leave the 2016 final rule intact).

The Department conducted economic analyses of the three alternatives to better understand their costs and cost savings and the implied tradeoffs (in terms of the costs and cost savings that would be realized) relative to the final rule. Below is a discussion of each alternative along with an estimation of their costs and cost savings. All costs and cost savings use the 2016 final rule as the baseline for the analysis.

Repeal Part 30 Entirely

This alternative yields many of the same cost savings as the final rule but also would remove the cost to Registration Agencies (OA or SAAs) related to the referral of complaints, leading to additional cost savings.

The Department assumed that, when a Registration Agency receives a complaint, it takes 15 minutes (0.25 hours) for a public-sector human resources manager ($88.88 per hour) to refer the complaint to the correct entity. The Department estimated that 421 apprentices will file a complaint in the first year and that the number of complaints rises by 9 percent each year.[84] Based on this assumption, the Department estimated that the savings to Registration Agencies from not having to refer complaints would be $37,507 in the first year. The Department estimated that this would have an annualized savings of $56,428 and $54,889 (at 3 percent and 7 percent discounting, respectively).

Additionally, removing part 30 would remove the costs associated with deregistering programs and derecognizing SAAs that are violating part 30. However, instance in which a program or an SAA has been deregistered or derecognized because of failure to comply with part 30 (current §§ 30.15, 30.16, and 30.18(d)) are rare. The Department therefore assumed that removing the deregistration or

[84] The EEOC reports that there were 88,531 charges in FY2024 and that the number of complaints between FY 2023 to FY 2024 rose by 9.22%. EEOC, ''Enforcement and Litigation Statistics,'' *https://www.eeoc.gov/data/enforcement-and-litigation-statistics-0* (last visited June 26, 2026). Based on this growth rate, we estimate there will be 105,616 complaints in 2026. We assume apprentices file the same percentage of complaints as their share of the workforce. We understand this may be an over or underestimate as apprentices may be less or more likely to fill complaints than the broader workforce. Since apprentices make up 0.4% of the workforce, we assumed that they file 422 complaints a year (105,616 × 0.4%). We repeat this calculation each year to account for the growth in complaints each year.

derecognition components of the current part 30 rule would create minimal to no cost savings. The Department estimated that the cost savings of this alternative would therefore be the same in each year as the final rule, with additional cost savings from the elimination of referral requirements.

In estimating costs, the Department expects that the elimination of part 30 entirely would remove conformity across the Registered Apprenticeship system by creating an inconsistent regulatory framework across states. If some States left their current apprenticeship affirmative action laws in place, it may be harder for sponsors to navigate and comply with this system and these sponsors may not receive the same amount of regulatory relief. This lack of conformity would therefore create confusion and hinder the deregulatory goals of the rulemaking from being achieved on a nationwide basis. Additionally, if some states retained the use of race- and sex-based preferences in apprenticeship selection and advancement decisions, the apprenticeship system in these states would continue to conflict with the merit-based principles that the apprenticeship system, and overall American workforce, should represent.

Eliminating part 30 entirely also would remove an important standard of apprenticeship that was designed to safeguard the welfare of apprentices. As mentioned previously, a Registration Agency's grant of registration to an apprenticeship program serves as an official recognition of that program's overall quality and represents the conferral of a valuable governmental benefit upon the program sponsor. Accordingly, the Department takes the position that there should be appropriate sanctions available (such as program deregistration) if it is determined that a sponsor has engaged in illegal discriminatory conduct against the apprentices enrolled in its program. Rescinding part 30 entirely would remove this important quality safeguard protecting the welfare of apprentices and the mechanism for holding sponsors accountable for illegal discrimination.

While the Department expects that the costs associated with a lack of conformity and conflicts with merit principles could be substantial, these costs are largely intangible and would be difficult to estimate. As a result, the Department estimated that the only monetized costs would be the one-time cost of removing references to part 30 in apprenticeship program standards, which we estimated to be $715,157, and due to data and other limitations referenced above, there would be no quantifiable costs to repealing part 30 entirely because States would not have to submit updated State plans and sponsors would not need to familiarize themselves with the rule change. Exhibit 5 presents a summary of the monetized costs of this alternative over the 10-year analysis period. Costs are presented as undiscounted 10-year totals, and as present values, using 7 percent and 3 percent discount rates.

EXHIBIT 5

Year	Monetized cost savings ($million/year)	Monetized cost ($million/year)
2026	$90.57	$0.72
2027	92.79	.....
2028	95.10	.....
2029	97.50	.....
2030	99.99	.....
2031	102.57	.....
2032	105.25	.....
2033	108.04	.....
2034	110.93	.....
2035	113.95	.....
Undiscounted	1,016.68	0.72
7% Discounted	704.03	0.67
3% Discounted	861.88	0.69
Annualized Undiscounted	101.67	0.07
Annualized 7%	100.24	0.10
Annualized 3%	101.04	0.08

Only Remove Additional Requirements Pertaining to Programs With Five or More Apprentices

This alternative yields only the cost savings that come from eliminating the provisions under the current part 30 regulations that require sponsors with five or more apprentices to take additional affirmative action steps. This more limited change would therefore eliminate the following costs: new sponsors' familiarization with the apprenticeship utilization data tool, the cost of the workforce analysis, the cost of the utilization analysis, the additional dissemination of resources for designated demographic groups if a sponsor is found to be underutilizing said group, costs related to EEO compliance reviews, and the cost of inviting apprentices to self-identify as an individual with a disability (as well as sending email reminders about this self-identification). Sponsors would still incur the costs of orientation and information sessions and universal outreach. New sponsors also would continue to incur the cost of posting EEO pledges.

Under this alternative, the Department assumed that sponsors and SAAs would still incur the same rule familiarization costs and SAAs would still have to submit revised State plans under current § 30.18. Only pre-existing programs with five or more apprentices would incur costs from updating standards. The Department estimated that there will be 7,429 pre-existing programs with more than 5 apprentices in 2026.[85] Based on the methodology described above, we estimated sponsors with five or more apprentices would incur $88,495 from the cost of updating standards and Registration Agencies would incur $112,249 in costs from

[85] There were estimated to be 7,813 sponsors with five or more apprentices in total in FY 2026, 401 of which would be new sponsors. Subtracting new programs, it is estimated that there will be 7,501 pre-existing sponsors with five or more apprentices in FY 2026.

reviewing updated standards, for a total cost of $200,372 for updating standards for programs with five or more apprentices. This cost is lower because fewer sponsors (*i.e.,* only those with five or more apprentices) would need to update standards. We estimated the total cost of this option at $9.36 million.

Exhibit 6 presents a summary of the monetized costs of this alternative over the 10-year analysis period. Costs are presented as undiscounted 10-year totals, and as present values, using 7 percent and 3 percent discount rates. As shown in the table, this alternative option of only removing additional requirements pertaining to programs with five or more apprentices fails to provide the same cost-savings as the final rule because, as outlined above, sponsors would still need to conduct several additional activities to comply with part 30.

EXHIBIT 6

Year	Monetized cost savings ($million/year)	Monetized cost ($million/year)
2026	$27.00	$9.36
2027	28.40	.....
2028	29.87	.....
2029	31.41	.....
2030	33.03	.....
2031	34.74	.....
2032	36.54	.....
2033	38.43	.....
2034	40.41	.....
2035	42.50	.....
Undiscounted	342.33	9.36
7% Discounted	233.79	8.75
3% Discounted	288.45	9.09
Annualized Undiscounted	34.23	0.94
Annualized 7%	33.29	1.25
Annualized 3%	33.82	1.07

Take No Action

This alternative yielded no additional costs or cost savings to society because it does not deviate from the baseline, that is, the 2016 final rule. However, the Department notes that taking no action would prevent the cost savings that would accrue from this final rule. In addition to decreasing the burden on sponsors and Registration Agencies, chief among the cost savings from the final rule is the elimination of regulatory provisions that have the effect of encouraging the use of race- and sex-based preferences in apprenticeship selection and advancement decisions. By removing these requirements, the final rule promotes a return to individual, merit-based evaluation, consistent with the principle that all Americans should be treated as individuals rather than as members of demographic groups. Without this change, the Department is concerned that the public's confidence in the fairness of the apprenticeship system could be undermined, that legal uncertainty would remain for current sponsors, and that prospective sponsors may be deterred by the 2016 final rule's prescriptive and group-based mandates.

Additionally, as noted throughout the preamble, the Department anticipates that the removal of these burdensome requirements from part 30 will spur further growth of the National Apprenticeship System, providing more opportunities for American workers to up-skill and for employers to fill their workforce shortages. While the Department has not monetized these benefits due to data limitations, they are likely to be significant. However, if the Department took no action and did not streamline the part 30 regulation, these benefits would not occur.

B. Regulatory Flexibility Act, Small Business Regulatory Enforcement Fairness Act of 1996, and Executive Order 13272 (Proper Consideration of Small Entities in Agency Rulemaking)

The Regulatory Flexibility Act of 1980,[86] as amended by subtitle D of SBREFA, requires agencies to prepare an initial regulatory flexibility analysis when proposing, and a final regulatory flexibility analysis when issuing, regulations that will have a significant economic impact on a substantial number of small entities.

The Department conducted the analysis below of the burden on small entities from the proposed rule, and based on that analysis, certifies that the costs of this rule will not have a significant economic impact on a substantial number of small entities.

1. Why Action Is Being Taken

The Department has determined that this deregulatory action is necessary to remove administrative barriers to participation in Registered Apprenticeship. As described throughout the preamble for this final rule, in the Department's view, this final rule's changes to the regulation at 29 CFR part 30 will significantly reduce administrative burdens for existing program sponsors, and will alleviate concerns expressed by employers (including small businesses) regarding the amount of administrative burden they would have to take on to participate in Registered Apprenticeship. The Department is finalizing these changes to the regulation at 29 CFR part 30 because these outcomes will help accelerate the expansion of Registered Apprenticeship, in line with the Administration's and the Department's ambitious goals to grow the system, including in industries and sectors where Registered Apprenticeship is not currently widespread. In addition, the Department is finalizing this deregulatory action in light of the Administration's call for Federal agencies to review their regulations and remove regulations that impose undue or unnecessary burdens on stakeholders. Finally, as discussed throughout the preamble in depth, the Departments finds that the existing part 30 regulations impose mandates that may induce the utilization of race and sex-based preferences in a manner that

[86] 5 U.S.C. 601 *et seq.*

is unlawful and in direct conflict with controlling Supreme Court precedent. Accordingly, the Department is removing these requirements.

2. Objectives of, and Legal Basis for, the Final Rule

A primary objective of the final rule is to alleviate administrative burden for Registered Apprenticeship stakeholders and promote a more straightforward framework for the regulated community to participate in the system and maintain compliance with the governing regulations (at 29 CFR parts 29 and 30). In addition, this final rule seeks to eliminate a duplicative and ineffective (and, in light of recent case law, legally questionable) regulatory framework for nondiscrimination protections in Registered Apprenticeship. These objectives align with the broader goals of the Administration and the Department to identify and modify burdensome regulations, preserve limited enforcement resources, and keep pace with evolving issues in nondiscrimination law. The NAA stands as the Department's statutory basis for promulgating regulations on apprenticeship.

3. Classes of Small Entities

A small entity is one that is independently owned and operated and that is not dominant in its field of operation.[87] The definition of small entity varies from industry to industry to properly reflect industry size differences. 13 CFR 121.201. An agency must either use the SBA definition for a small entity or establish an alternative definition for the industry. Using SBA size standards, the Department has conducted a small entity impact analysis on small entities in the five industry categories with the most Registered Apprenticeship programs and for which data were available: Construction, Educational Services, Manufacturing, Other Services, and Healthcare.[88]

One industry, Public Administration, made the initial top-five list but is not included in this analysis because no data on the revenue of small local jurisdictions were available. Local jurisdictions are classified as small when their population is less than 50,000.[89]

Registered Apprenticeship program sponsors may be employers, employer associations, industry associations, or labor management organizations and, thus, may represent businesses, multiple businesses, and not-for-profit organizations. The requirements of the final rule, however, fall on the sponsor, and therefore we used sponsor data to create industry breakdowns.

4. Impact on Small Entities

The Department estimated the incremental costs for small entities from the baseline of the 2016 final rule.[90] This analysis reflects the incremental cost of the final rule, as it adds to the requirements of the 2016 final rule. Using available data, we estimated the costs to sponsors of familiarizing themselves with the rule change. A significant economic burden results when the total incremental annual cost as a percentage of total average annual revenue is equal to or exceeds 3 percent.[91] Because the estimated annual burden of the final rule is less than 1 percent of the average annual revenue of each industry category, the final rule is not expected to cause a significant economic impact to small entities. These entities include individual employers, groups of employers, labor management organizations, or industry associations that sponsor apprenticeships. As explained in detail below, the total impact amounts to approximately $125.69 per affected small entity in the first year. All costs are incurred in the first year. Because all the final rule provisions will have a similar impact on entities across economic sectors, we calculated impacts to a representative single entity.[92]

Costs

Familiarization With Regulatory Change

During the first year after implementation of the final rule, sponsors will need to learn about the new regulatory requirements. We estimated this cost for a hypothetical small entity by multiplying the time required to read the new rule (1 hour) by the average hourly compensation rate of a human resources manager ($113.78, as calculated above). Thus, the resulting cost per small entity is $113.78 ($113.78 × 1). This cost occurs only in the year after the final rule is published.

Updating Standards for Compliance

Sponsors of Registered Apprenticeship programs will also need to develop language or make adjustments and updates to existing standards to comply with the proposed changes to part 30. The Department assumed that updating standards to comply with part 30 will mainly entail removing items currently required by part 30 and therefore estimated the burden will be minimal. The Department assumed new sponsors will take a similar amount of time to ensure the standards they develop do not conflict with part 30. Accordingly, the Department estimated the average response time for sponsors to ensure standards comply with part 30 is 20 minutes (0.33 hours). Thus, the Department estimated a cost per small entity of $11.91 (0.33 × $36.10).

Total Cost Burden for Small Entities

Based on the cost estimates above, for a hypothetical small entity in the top five industry categories, the estimated first-year cost of this rule is $125.69 ($113.78 + $11.91). There are no costs in subsequent years. The total cost impacts, as a percentage of revenue, are all well below the 3 percent threshold for determining a significant economic impact.

The Department used the following steps to estimate the cost of the final rule per Registered Apprenticeship program sponsor as a percentage of annual receipts. First, the Department used the SBA's Table of Small Business Size Standards to determine the size thresholds for small entities within each major industry.[93] Next the Department obtained data on the number of firms, number of employees, and annual revenue by industry and firm size category from the Census Bureau's Statistics of U.S. Businesses.[94] Then, the Department divided the estimated first-year cost per sponsor by the average annual receipts per firm to determine whether the final rule will have a significant economic impact on sponsors in each size category.[95] Finally, the Department divided the number of firms in each size category by

[87] 5 U.S.C. 601(3); 15 U.S.C. 632.

[88] According to RAPIDS, the percent of programs (of all sizes) in the selected sectors in 2024 were as follows: Construction, 33.5 percent; Educational Services, 24.1 percent; Manufacturing, 4.3 percent; Other Services, 3.7 percent; Health Care and Social Assistance, 3.6 percent. Public Administration was 24.1 percent, and 11.6 percent of programs did not have an industry available.

[89] 5 U.S.C. 601(5).

[90] 81 FR 92102 (Dec. 19, 2026).

[91] See SBA, ''A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act,'' pp.17–19, (Aug. 2017), *https://advocacy.sba.gov/wp-content/uploads/2019/07/How-to-Comply-with-the-RFA-WEB.pdf.* The Department has used the 3 percent threshold in previous regulations.

[92] A large entity could have a single apprentice or a small entity could have multiple apprentices.

[93] SBA, ''Table of Small Business Size Standards,'' Mar. 17, 2023, *https://www.sba.gov/document/support-table-size-standards.* The size standards, which are expressed in either average annual receipts or number of employees, indicate the maximum allowed for a business in each subsector to be considered small.

[94] U.S. Census Bureau, ''Statistics of U.S. Businesses,'' last revised March 11, 2025, *https://www.census.gov/programs-surveys/susb.html.*

[95] For purposes of this analysis, the Department used a 3-percent threshold for ''significant economic impact.'' The Department has used a 3-percent threshold in prior rulemakings.

the total number of small firms in the industry to determine whether the final rule will have a significant economic impact on a substantial number of small entities.[96]

[96] For purposes of this analysis, the Department used a 15-percent threshold for ''substantial number of small entities.'' The Department has used a 15-percent threshold in prior rulemakings.

The results are presented in the following five tables, one for each major industry sector with the most Registered Apprenticeship programs and for which data are available: Construction, Educational Services, Manufacturing, Other Services, and Healthcare. As shown in the five tables below, the first-year costs for sponsors in these five industries are not expected to have a significant economic impact (3 percent or more) on small entities of any size. Therefore, the Department certifies that the final rule is not expected to have a significant economic impact on a substantial number of small entities.

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Construction Industry

Small Business Size Standard: $19.0 million - $45.0 million

Enterprise Category	Number of Firms[1]	Number of Firms as Percent of Small Firms in Industry[2]	Total Number of Employees[1]	Annual Receipts[1]	Average Receipts per Firm[3]	First Year Cost per Firm[4]	First Year Cost per Firm as Percent of Receipts[5]
Enterprises with receipts below $100,000	167,522	24.0%	156,090	$ 8,725,609,000	$ 52,086	$126	0.2%
Enterprises with receipts of $100,000 to $499,999	247,074	35.5%	544,141	$ 59,292,938,000	$ 239,980	$126	0.1%
Enterprises with receipts of $500,000 to $999,999	89,351	12.8%	444,318	$ 64,312,630,000	$ 719,775	$126	0.0%
Enterprises with receipts of $1,000,000 to $2,499,999	95,739	13.7%	828,261	$ 151,543,429,000	$ 1,582,881	$126	0.0%
Enterprises with receipts of $2,500,000 to $4,999,999	45,814	6.6%	707,745	$ 106,596,928,000	$ 3,505,412	$126	0.0%
Enterprises with receipts of $5,000,000 to $7,499,999	17,860	2.6%	416,512	$ 108,352,122,000	$ 6,066,748	$126	0.0%
Enterprises with receipts of $7,500,000 to $9,999,999	9,233	1.3%	283,971	$ 79,262,068,000	$ 8,584,649	$126	0.0%
Enterprises with receipts of $10,000,000 to $14,999,999	9,925	1.4%	401,418	$ 119,793,304,000	$ 12,069,854	$126	0.0%
Enterprises with receipts of $15,000,000 to $19,999,999	5,029	0.7%	270,176	$ 85,738,468,000	$ 17,048,810	$126	0.0%
Enterprises with receipts of $20,000,000 to $24,999,999	3,089	0.4%	200,568	$ 67,308,726,000	$ 21,789,811	$126	0.0%
Enterprises with receipts of $25,000,000 to $29,999,999	2,011	0.3%	150,472	$ 53,427,466,000	$ 26,567,561	$126	0.0%
Enterprises with receipts of $30,000,000 to $34,999,999	1,396	0.2%	119,403	$ 43,667,793,000	$ 31,280,654	$126	0.0%
Enterprises with receipts of $35,000,000 to $39,999,999	1,056	0.2%	99,968	$ 37,941,329,000	$ 35,929,289	$126	0.0%
Enterprises with receipts of $40,000,000 to $49,999,999	1,466	0.2%	166,727	$ 63,454,897,000	$ 43,284,377	$126	0.0%

[1] Source: U.S. Census Bureau, Statistics of U.S. Businesses

[2] Number of Firms ÷ Small firms in the industry

[3] Annual receipts ÷ Number of firms

[4] First year cost per firm with 7% discounting ÷ Average receipts per firm

[5] Annualized cost per firm with 7% discounting ÷ Average receipts per firm

Manufacturing Industry

Small Business Size Standard: 500 - 1,500 employees

Enterprise Category	Number of Firms	Number of Firms as Percent of Small Firms in Industry	Total Number of Employees	Annual Receipts	Average Receipts per Firm	First Year Cost per Firm	First Year Cost per Firm as Percent of Receipts
Enterprises with 0–4 employees	102,242	41.5%	188,002	$ 41,641,473,000	$ 407,283	$126	0.0%
Enterprises with 5–9 employees	45,821	18.6%	306,025	$ 54,272,680,000	$ 1,184,450	$126	0.0%
Enterprises with 10–19 employees	37,549	15.2%	511,380	$ 97,477,689,000	$ 2,596,013	$126	0.0%
Enterprises with 20–99 employees	46,089	18.7%	1,872,005	$ 434,974,512,000	$ 9,437,708	$126	0.0%
Enterprises with 100–499 employees	12,397	5.0%	2,162,360	$ 684,189,119,000	$ 55,189,894	$126	0.0%
Enterprises with 500–749 employees	1,127	0.5%	526,397	$ 212,921,994,000	$ 188,928,122	$126	0.0%
Enterprises with 750–999 employees	608	0.2%	370,263	$ 145,396,128,000	$ 239,138,368	$126	0.0%
Enterprises with 1,000–1,499 employees	578	0.2%	487,897	$ 230,429,698,000	$ 398,667,298	$126	0.0%

Educational Services Industry

Small Business Size Standard: $9.0 million - $47.0 million

Enterprise Category	Number of Firms	Number of Firms as Percent of Small Firms in Industry	Total Number of Employees	Annual Receipts	Average Receipts per Firm	First Year Cost per Firm	First Year Cost per Firm as Percent of Receipts
Enterprises with receipts below $100,000	22,439	24.3%	42,944	$ 1,072,093,000	$ 47,815	$126	0.3%
Enterprises with receipts of $100,000 to $499,999	37,156	40.3%	197,950	$ 9,253,888,000	$ 249,055	$126	0.1%
Enterprises with receipts of $500,000 to $999,999	11,425	12.4%	139,745	$ 8,015,282,000	$ 701,556	$126	0.0%
Enterprises with receipts of $1,000,000 to $2,499,999	9,837	10.7%	237,256	$ 15,395,145,000	$ 1,565,024	$126	0.0%
Enterprises with receipts of $2,500,000 to $4,999,999	4,483	5.4%	227,231	$ 17,812,220,000	$ 3,472,559	$126	0.0%
Enterprises with receipts of $5,000,000 to $7,499,999	2,051	2.2%	142,147	$ 12,111,348,000	$ 5,905,094	$126	0.0%
Enterprises with receipts of $7,500,000 to $9,999,999	1,085	1.2%	99,135	$ 8,953,268,000	$ 8,251,860	$126	0.0%
Enterprises with receipts of $10,000,000 to $14,999,999	1,217	1.3%	149,025	$ 13,862,557,000	$ 11,390,762	$126	0.0%
Enterprises with receipts of $15,000,000 to $19,999,999	788	0.9%	130,304	$ 12,669,721,000	$ 16,078,326	$126	0.0%
Enterprises with receipts of $20,000,000 to $24,999,999	405	0.4%	83,052	$ 8,138,742,000	$ 20,095,659	$126	0.0%
Enterprises with receipts of $25,000,000 to $29,999,999	266	0.3%	72,713	$ 6,484,352,000	$ 24,377,263	$126	0.0%
Enterprises with receipts of $30,000,000 to $34,999,999	193	0.2%	53,118	$ 5,395,885,000	$ 27,957,953	$126	0.0%
Enterprises with receipts of $35,000,000 to $39,999,999	157	0.2%	49,519	$ 4,946,014,000	$ 31,503,274	$126	0.0%
Enterprises with receipts of $40,000,000 to $49,999,999	230	0.2%	84,073	$ 8,636,464,000	$ 37,549,843	$126	0.0%

Other Services Industry

Small Business Size Standard: $8.0 million - $47.0 million

Enterprise Category	Number of Firms	Number of Firms as Percent of Small Firms in Industry	Total Number of Employees	Annual Receipts	Average Receipts per Firm	First Year Cost per Firm	First Year Cost per Firm as Percent of Receipts
Enterprises with receipts below $100,000	170,346	24.6%	255,297	$ 8,652,069,000	$ 50,675	$126	0.2%
Enterprises with receipts of $100,000 to $499,999	317,048	45.7%	1,077,568	$ 78,960,123,000	$ 249,048	$126	0.1%
Enterprises with receipts of $500,000 to $999,999	102,517	14.8%	754,571	$ 71,799,849,000	$ 700,370	$126	0.0%
Enterprises with receipts of $1,000,000 to $2,499,999	68,210	9.8%	955,461	$ 103,187,937,000	$ 1,512,798	$126	0.0%
Enterprises with receipts of $2,500,000 to $4,999,999	20,419	2.9%	564,101	$ 69,277,561,000	$ 3,392,790	$126	0.0%
Enterprises with receipts of $5,000,000 to $7,499,999	6,414	0.9%	280,574	$ 37,605,902,000	$ 5,863,097	$126	0.0%
Enterprises with receipts of $7,500,000 to $9,999,999	2,783	0.4%	161,164	$ 22,887,699,000	$ 9,825,110	$126	0.0%
Enterprises with receipts of $10,000,000 to $14,999,999	2,571	0.4%	195,893	$ 28,880,096,000	$ 11,233,024	$126	0.0%
Enterprises with receipts of $15,000,000 to $19,999,999	1,264	0.2%	119,626	$ 19,348,930,000	$ 15,307,689	$126	0.0%
Enterprises with receipts of $20,000,000 to $24,999,999	692	0.1%	72,568	$ 13,156,352,000	$ 19,012,026	$126	0.0%
Enterprises with receipts of $25,000,000 to $29,999,999	506	0.1%	63,522	$ 11,408,983,000	$ 18,312,836	$126	0.0%
Enterprises with receipts of $30,000,000 to $34,999,999	325	0.0%	42,921	$ 8,458,331,000	$ 26,035,634	$126	0.0%
Enterprises with receipts of $35,000,000 to $39,999,999	292	0.0%	37,383	$ 6,844,270,000	$ 24,609,003	$126	0.0%
Enterprises with receipts of $40,000,000 to $49,999,999	326	0.0%	49,042	$ 10,596,957,000	$ 32,506,003	$126	0.0%

Health Care and Social Assistance Industry							
Small Business Size Standard: $9.0 million - $47.0 million							
Enterprise Category	Number of Firms	Number of Firms as Percent of Small Firms in Industry	Total Number of Employees	Annual Receipts	Average Receipts per Firm	First Year Cost per Firm	First Year Cost per Firm as Percent of Receipts
Enterprises with receipts below $100,000	105,782	16.3%	144,258	$ 5,157,367,000	$ 48,755	$126	0.3%
Enterprises with receipts of $100,000 to $499,999	247,723	38.0%	919,768	$ 66,746,907,000	$ 269,932	$126	0.0%
Enterprises with receipts of $500,000 to $999,999	130,435	20.0%	1,066,795	$ 92,688,993,000	$ 710,614	$126	0.0%
Enterprises with receipts of $1,000,000 to $2,499,999	102,005	15.7%	1,733,292	$ 155,576,671,000	$ 1,525,187	$126	0.0%
Enterprises with receipts of $2,500,000 to $4,999,999	32,793	5.0%	1,269,403	$ 112,848,383,000	$ 3,441,234	$126	0.0%
Enterprises with receipts of $5,000,000 to $7,499,999	11,292	1.7%	768,478	$ 67,880,384,000	$ 6,011,369	$126	0.0%
Enterprises with receipts of $7,500,000 to $9,999,999	6,073	0.9%	587,923	$ 51,322,879,000	$ 8,450,993	$126	0.0%
Enterprises with receipts of $10,000,000 to $14,999,999	6,282	1.0%	843,098	$ 74,388,140,000	$ 11,841,474	$126	0.0%
Enterprises with receipts of $15,000,000 to $19,999,999	3,193	0.5%	582,465	$ 52,937,196,000	$ 16,579,141	$126	0.0%
Enterprises with receipts of $20,000,000 to $24,999,999	1,945	0.3%	432,978	$ 41,376,894,000	$ 21,273,467	$126	0.0%
Enterprises with receipts of $25,000,000 to $29,999,999	1,297	0.2%	333,840	$ 33,402,569,000	$ 25,753,715	$126	0.0%
Enterprises with receipts of $30,000,000 to $34,999,999	939	0.1%	287,523	$ 28,762,117,000	$ 30,630,583	$126	0.0%
Enterprises with receipts of $35,000,000 to $39,999,999	672	0.1%	251,011	$ 23,637,148,000	$ 35,174,327	$126	0.0%
Enterprises with receipts of $40,000,000 to $49,999,999	903	0.1%	357,594	$ 37,602,128,000	$ 41,641,338	$126	0.0%

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5. Alternatives to the Final Rule

Regarding significant alternatives to the final rule that accomplish the objectives of applicable statutes and minimize any significant economic impact of the final rule on small entities, there are limited options. Repealing part 30 entirely would still require sponsors that are small entities to update their standards to remove reference to part 30, costing $11.91 per sponsor. There could be lower to no rule familiarization costs for small entities if part 30 was removed entirely, since there would be no rule that entities would have to be familiarized with, but sponsors would still need to be informed of the change and may review the **Federal Register** notice. However, the Department is concerned that removing part 30 entirely would prevent conformity across the National Apprenticeship System, as some states may choose to impose additional requirements for sponsors to conduct legally questionable affirmative action or other EEO activities that expand beyond the scope of the Department's proposed part 30 rule. If part 30 was repealed entirely and states were to impose additional EEO requirements, these new requirements and the resulting confusion from a patchwork of different requirements across jurisdictions could ultimately lead to greater costs for small entities.[97]

Alternatively, the Department considered publishing a direct final rule or an interim final rule to make changes to the part 30 regulation. However, the Department determined that these approaches to rulemaking would have given smaller entities no advanced notice of changes to the part 30 regulation, given that the changes would take effect immediately upon (or soon after) publication, and would have denied small entities the opportunity to provide robust feedback on the changes. Accordingly, the Department determined notice-and-comment rulemaking to be more appropriate, in part because it would allow the Department to better account for small businesses' viewpoint and needs.

C. Paperwork Reduction Act

The purpose of the Paperwork Reduction Act (PRA) [98] includes minimizing the paperwork burden on affected entities. The PRA requires certain actions before an agency can adopt or revise a collection of information, including publishing for public comment a summary of the collection of information and a brief description of the need for and proposed use of the information.

As part of its continuing effort to reduce paperwork and respondent burden, the Department conducts a preclearance consultation program to provide the public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the PRA.[99] Furthermore, the PRA requires all Federal agencies to analyze proposed and final regulations for potential time burdens on the regulated community created by provisions in the regulations that require any party to obtain, maintain, retain, report, or disclose information. The information collection requests (ICRs) also must be submitted to OMB for approval. Such submissions often accompany a proposed and final rulemaking that seeks to modify an existing information collection (IC), introduce new ICs, or both.

A Federal agency may not conduct or sponsor a collection of information unless it is approved by OMB under the PRA and displays a currently valid OMB control number. The public also is not required to respond to a collection of information unless it displays a currently valid OMB control number. In addition, notwithstanding any other provisions of law, no person will be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number.[100]

This rulemaking affects specific ICRs (OMB Control Number 1205–0223, which includes OMB-approved forms ETA–671, ETA–9186, and ETA–9039). Changes to these collections will be communicated through an upcoming 60-day **Federal Register** Notice.

1. Labor Standards and Equal Employment Opportunity for Registered Apprenticeship Programs—Registration and Reporting Requirements

Agency: DOL–ETA.

Title of Collection: Labor Standards and Equal Employment Opportunity for Registered Apprenticeship Programs—Registration and Reporting Requirements.

Type of Review: Revision.

OMB Control Number: 1205–0223.

Description:

Affected Public: State, Local, and Tribal Governments; Private Sector; Individuals or Households.

Obligation to Respond: Required to Obtain or Retain Benefits.

Estimated Total Annual Respondents: placeholder.

Estimated Total Annual Responses: placeholder.

Estimated Total Annual Burden Hours: placeholder.

Estimated Total Annual Burden Costs: placeholder.

Estimated Total Annual Other Burden Costs: placeholder.

Regulations Sections: placeholder.

[97] The Department is not able to estimate or monetize the cost of the additional potential EEO requirements states may pursue if part 30 is repealed, because it is unknown what requirements states would impose on small entities.

[98] 44 U.S.C. 3501 *et seq.*

[99] *See* 44 U.S.C. 3506(c)(2)(A).

[100] See 44 U.S.C. 3512.

Comments: A commenter expressed confusion about whether the Department will continue to collect apprentice data, through ETA Form 671, related to race, sex, ethnicity, and disability. The commenter recommended that, given the Department's proposed removal of the definitions for those terms, and because the Department proposed to revise § 29.7 to only require ''demographic data,'' rather than specific types of demographic data, that the Department clarify what data would be collected under a revised Form 671.

Department Response: As noted in the ICR referenced in an August 25, 2025, **Federal Register** Notice (90 FR 41414) following the NPRM's publication, there is no change to the collection of demographic data under ETA Form 671, Section II. Accordingly, race, sex, and ethnicity will still be collected through this form on a voluntary basis. As noted in the ICR, Form 671, Section IIA, which allows an apprentice to voluntarily self-report their disability status, is discontinued and therefore the Department will cease collecting disability information on apprentices.

D. Congressional Notification

As required by 5 U.S.C. 801, once finalized, DOL will report to Congress on the promulgation of this rule at least 60 days before its effective date. The report will state that it has been determined that the rule meets the criteria set forth in 5 U.S.C. 804(2).

Comments: The Department did not receive any comments on its congressional notification analysis.

E. Executive Order 13132 (Federalism)

The Department has reviewed this final rule in accordance with E.O. 13132 and found that it will have Federalism implications because it will have substantial direct effects on States. As stated in the Federalism analysis that accompanied the Department's NPRM, matters of Federalism in the National Apprenticeship System are primarily related to the regulatory requirements established in part 29, Labor Standards for Registration of Apprenticeship Programs, which establishes the requirements for the recognition of SAAs as Registration Agencies. However, this final rule's revisions to the part 30 regulation also have direct effect on a State's method of administering Registered Apprenticeship for Federal purposes. In particular, the final rule requires a State that seeks to obtain or maintain recognition as a Registration Agency to submit State apprenticeship legislation, regulations, policies, and operational procedures that pertain specifically to nondiscrimination or equal opportunity in apprenticeship to the Department so that the Department may assess whether any such laws, regulations, policies, and operational procedures conform to the revised part 30 regulation.

The Department has determined that requiring States to submit State laws, policies, regulations, and procedures that pertain specifically to nondiscrimination or equal opportunity in apprenticeship to the Department is essential to ensure that SAAs conform to the new requirements of part 30. OA regularly consults and collaborates with State partners and organizations, including on matters pertaining to the Federal regulations governing Registered Apprenticeship at 29 CFR parts 29 and 30. More specifically, such engagement with State partners often relates to States' conformity with these regulations, in particular those States with State agencies that have been recognized (or are seeking recognition) as SAAs that serve as the Registration Agency responsible for registering apprenticeship programs for Federal purposes in the State. These engagements are critical for determining whether the Department should confer the distinct responsibility of acting as a Registration Agency to a State agency. The Department and OA will continue consulting and collaborating with State partners, which the Department views as central to OA's role in promoting and maintaining quality Registered Apprenticeship programs.

Comments: The Department did not receive any comments on its Federalism analysis required under E.O. 13132. The Department did receive several comments raising Federalism concerns in the context of the Department's proposal to require SAAs to ''conform only to'' the part 30 requirements in proposed § 30.7. As discussed above in addressing SAA requirements in § 30.7, the Department has considered this issue and has determined to change the language in § 30.7 of this final rule to require that States' laws, regulations, policies, and procedures specific to nondiscrimination or equal opportunity in apprenticeship ''conform to'' to the part 30 regulation. In addition, in this final rule, the Department has made additional clarifications regarding the scope of the Department's analysis of State laws, regulations, policies, and procedures, specifically clarifying that the Department only will assess those laws, regulations, policies, and procedures specific to nondiscrimination in Registered Apprenticeship in determining whether the Department will confer recognition to a State agency as a Registration Agency for Federal purposes.

F. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) [101] requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a final rule that may result in $100 million or more in expenditures (adjusted annually for inflation) in any 1 year by State, local, and Tribal governments, in the aggregate, or by the private sector. The current threshold after adjustment for inflation is $177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product.

This final rule does not meet or exceed the expenditure threshold in any 1 year when adjusted for inflation. The requirements of title II of UMRA, therefore, do not apply, and the Department has not prepared a statement under UMRA.

Comments: The Department did not receive any comments on its UMRA analysis.

G. Executive Order 13175 (Indian Tribal Governments)

The Department has reviewed this final rule in accordance with E.O. 13175 and has determined that it does not have Tribal implications. The final rule does not 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.

Comments: The Department did not receive any comments on its Indian Tribal Governments analysis.

List of Subjects

29 CFR Part 29

Administrative practice and procedure, Employment, Intergovernmental relations, Labor, Licensing and registration, Manpower training programs, Reporting and recordkeeping requirements, State and local governments.

29 CFR Part 30

Administrative practice and procedure, Employment, Equal employment opportunity, Manpower training programs, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Department amends 29 CFR parts 29 and 30 as follows:

[101] 2 U.S.C. 1532.

PART 29—LABOR STANDARDS FOR THE REGISTRATION OF APPRENTICESHIP PROGRAMS

■ 1. The authority citation for part 29 continues to read as follows:

Authority: 29 U.S.C. 50; 40 U.S.C. 3145; 5 U.S.C. 301; 5 U.S.C. App. P. 534.

■ 2. Amend § 29.3 by revising paragraph (b)(2) to read as follows:

§ 29.3 Eligibility and procedure for registration of an apprenticeship program.

* * * * *

(b) * * *

(2) It is in conformity with the requirements of the Department's nondiscrimination in apprenticeship regulation at 29 CFR part 30, as amended.

* * * * *

■ 3. Amend § 29.5 by revising paragraph (b)(21) to read as follows:

§ 29.5 Standards of apprenticeship.

* * * * *

(b) * * *

(21) Compliance with 29 CFR part 30, including a statement that the program will be conducted, operated, and administered in conformity with applicable provisions of 29 CFR part 30, as amended, or if applicable, an approved State plan for nondiscrimination in apprenticeship.

* * * * *

■ 4. Amend § 29.6 by revising paragraph (b)(1)(ii) to read as follows:

§ 29.6 Program performance standards.

* * * * *

(b) * * *

(1) * * *

(ii) Compliance Reviews; and

* * * * *

■ 5. Amend § 29.7 by revising paragraphs (j) and (l) to read as follows:

§ 29.7 Apprenticeship agreement.

* * * * *

(j) A statement that the apprentice will not be illegally discriminated against on the basis of race, color, religion, national origin, sex, age (40 or older), genetic information, or disability in any phase of apprenticeship employment and training.

* * * * *

(l) A request for demographic data about the apprentice.

■ 6. Amend § 29.11 by revising paragraph (b) to read as follows:

§ 29.11 Limitations.

* * * * *

(b) Any special provision for veterans in the standards, apprentice qualifications or operation of the program, or in the apprenticeship agreement, which is not prohibited by law, Executive order, or authorized regulation.

■ 7. Amend § 29.12 by revising paragraph (a) to read as follows:

§ 29.12 Complaints.

(a) This section is not applicable to any complaint concerning illegal discrimination; all such complaints received by a Registration Agency must be submitted to the relevant enforcement authority, as set forth in 29 CFR 30.4, or according to applicable provisions of the State plan for nondiscrimination in apprenticeship.

* * * * *

■ 8. Amend § 29.13 by revising paragraphs (a)(3), (b)(4), (h)(2), and (j) to read as follows:

§ 29.13 Recognition of State Apprenticeship Agencies.

(a) * * *

(3) The State Apprenticeship Agency must submit a State plan for nondiscrimination in apprenticeship that conforms to the requirements published in 29 CFR part 30;

* * * * *

(b) * * *

(4) Establish policies and procedures to prohibit illegal discrimination in registered apprenticeship programs in conformity with the requirements set forth in 29 CFR part 30;

* * * * *

(h) * * *

(2) Provide all apprenticeship program standards, apprenticeship agreements, completion records, cancellation and suspension records, Compliance Review files, and any other documents relating to the State's apprenticeship programs, to the Department; and

* * * * *

(j) *State apprenticeship programs.* (1) An apprenticeship program submitted to a State Registration Agency for registration must, for Federal purposes, be in conformity with the State apprenticeship law, regulations, and with the State plan for nondiscrimination in apprenticeship as submitted to, and approved by, the Office of Apprenticeship pursuant to 29 CFR part 30.

(2) In the event that a State Apprenticeship Agency is not recognized by the Office of Apprenticeship for Federal purposes or that such recognition has been withdrawn, or if no State Apprenticeship Agency exists, registration with the Office of Apprenticeship may be requested. Such registration must be granted if the program is conducted, administered, and operated in accordance with the requirements of this part and the nondiscrimination in apprenticeship regulation in 29 CFR part 30, as amended.

■ 9. Amend § 29.14 by revising paragraphs (a) and (h)(1) to read as follows:

§ 29.14 Derecognition of State Apprenticeship Agencies.

* * * * *

(a) Derecognition proceedings for failure to adopt or properly enforce a State plan for nondiscrimination in apprenticeship must be processed in accordance with the procedures prescribed in this part.

* * * * *

(h) * * *

(1) Provide all apprenticeship program standards, apprenticeship agreements, completion records, cancellation and suspension records, Compliance Review files, and any other documents relating to the State's apprenticeship programs, to the Department.

* * * * *

■ 10. Revise part 30 to read as follows:

PART 30—PROHIBITING ILLEGAL DISCRIMINATION IN REGISTERED APPRENTICESHIP PROGRAMS

Sec.

30.1 Purpose and applicability.
30.2 Definitions.
30.3 Nondiscrimination standards applicable to all sponsors.
30.4 Complaints.
30.5 Nondiscrimination compliance reviews and enforcement.
30.6 Reinstatement of program registration.
30.7 State apprenticeship agencies.
30.8 Exemptions.
30.9 Severability.

Authority: Sec. 1, 50 Stat. 664, as amended (29 U.S.C. 50; 40 U.S.C. 276c; 5 U.S.C. 301); Reorganization Plan No. 14 of 1950, 64 Stat. 1267, 3 CFR, 1949–53 Comp., p. 1007.

§ 30.1 Purpose and applicability.

(a) *Purpose.* The purpose of this part is to establish a uniform Federal standard prohibiting illegal discrimination against apprentices (including applicants for apprenticeship) in registered apprenticeship programs. To achieve this purpose, this part sets forth nondiscrimination requirements for program sponsors and State Apprenticeship Agencies (SAAs), and clarifies the scope and content of compliance reviews, compliance assistance, and enforcement actions by Registration Agencies.

(b) *Applicability.* This part applies to all sponsors of apprenticeship programs registered with either the U.S. Department of Labor or a recognized SAA.

§ 30.2 Definitions.

The definitions in § 29.2 of this title also apply to this part.

§ 30.3 Nondiscrimination standards applicable to all sponsors.

Registered apprenticeship program sponsors must comply with all applicable Federal and State laws and regulations prohibiting illegal discrimination on the basis of race, color, religion, national origin, sex, age (40 or older), genetic information, or disability. Failure to comply with such nondiscrimination laws is grounds for deregistration or the imposition of other enforcement actions in accordance with § 30.5(c), if such non-compliance is related to illegal discrimination against apprentices or an applicant to an apprenticeship program with respect to any benefit, term, or condition of employment associated with an apprenticeship.

§ 30.4 Complaints.

If the Registration Agency receives any complaints from apprentices (including applicants for apprenticeship) alleging illegal discrimination, it will immediately refer the individual to any of the following:

(a) The Equal Employment Opportunity Commission;

(b) The U.S. Attorney General;

(c) A State Fair Employment Practices Agency; or

(d) Another Federal or State enforcement entity with jurisdiction over discrimination issues, as appropriate.

§ 30.5 Nondiscrimination compliance reviews and enforcement.

(a) *Conduct of compliance reviews.* Concurrently with a Registration Agency's review of a registered apprenticeship program for conformity with the requirements of part 29 of this title, a Registration Agency will assess a program's compliance with the nondiscrimination requirement of § 30.3.

(b) *Determining compliance.* For the purpose of determining compliance under this part, the Registration Agency may initiate enforcement actions against a sponsor for failure to comply with the nondiscrimination requirement at § 30.3 in instances where a final determination of a violation of an applicable nondiscrimination law, without any remaining right to appeal, has been made by an enforcement entity or court with jurisdiction over a matter, and authority to issue a final determination, relating to an apprentice or an applicant to an apprenticeship program.

(1) Sponsors must disclose in writing to the Registration Agency any instances when an enforcement entity or court with jurisdiction over an applicable nondiscrimination law has rendered a final determination, without any remaining right to appeal, that the sponsor has violated such laws relating to an apprentice or an applicant to an apprenticeship program within 60 days of the final determination. The disclosure must include, at a minimum, a copy of all relevant final determinations, judgments, decisions and orders.

(2) As a part of the self-disclosure requirement under paragraph (b)(1) of this section, sponsors must include a description of any prescribed remedies mandated by the enforcement entity or court to address the violation of applicable nondiscrimination law.

(c) *Compliance and enforcement actions.* Upon learning of a final determination made by an enforcement entity or court with respect to a sponsor's violation of an applicable nondiscrimination law (as described in paragraph (b) of this section), the Registration Agency may work with the sponsor to develop a compliance action plan that aligns with the remedy prescribed by the enforcement entity or court and brings the program into compliance with this part. If the Registration Agency determines that a compliance action plan is not being implemented in accordance with the remedy prescribed by the enforcement entity or court, the Registration Agency may initiate enforcement actions that will remain in place until the violation is resolved to the satisfaction of the Registration Agency. Enforcement actions by the Registration Agency include:

(1) Suspension of the sponsor's right to register new apprentices; or

(2) The initiation of deregistration proceedings set forth in part 29 of this title.

§ 30.6 Reinstatement of program registration.

An apprenticeship program that has been deregistered pursuant to this part may be reinstated by the Registration Agency upon presentation of adequate evidence that the apprenticeship program is operating in accordance with this part.

§ 30.7 State apprenticeship agencies.

(a) *State laws specific to nondiscrimination in apprenticeship.* Within 1 year of January 5, 2027, unless an extension for good cause is sought and granted by the Administrator, an SAA that seeks to obtain or maintain recognition under § 29.13 of this title must submit a State plan for nondiscrimination in apprenticeship, as described in paragraph (b) of this section, that demonstrates that the State's laws, regulations, policies, and operational procedures specific to nondiscrimination or equal opportunity in apprenticeship conform to the requirements of this part and part 29 of this title.

(b) *Elements of the State plan for nondiscrimination in apprenticeship.* (1) The State plan for nondiscrimination in apprenticeship must—

(i) Include all State statutes, regulations, policies, and operational procedures pertaining specifically to nondiscrimination or equal opportunity in apprenticeship that conform to the requirements of this part;

(ii) Include a description of any State statutes, regulations, policies, and operational procedures pertaining specifically to nondiscrimination or equal opportunity in apprenticeship which impose requirements in addition to those prescribed in this part;

(iii) Not require any sponsor seeking to register an apprenticeship program with the State for Federal purposes, through any State statutes, regulations, policies, or operational procedures, to engage in any activity that is unlawful under Federal or State nondiscrimination law; and

(iv) Require all apprenticeship programs registered with the State for Federal purposes to comply with the requirements of the State's plan within 180 days from the date that the Office of Apprenticeship (OA) provides written approval of the State plan submitted under paragraph (a) of this section.

(2) Upon receipt of the State plan, OA will review the plan to determine if the plan conforms to this part. OA will:

(i) Grant the SAA continued recognition during this review period;

(ii) Provide technical assistance, if necessary, to facilitate conformity, and provide written notification of the areas of nonconformity, if any; and

(iii) Upon successful completion of the review process, notify the SAA of OA's determination that the State plan conforms to this part.

(3) If the State does not submit a revised State plan that adequately responds to OA's technical assistance within 90 days from the date that OA provides the SAA with written notification of the areas of nonconformity, OA is authorized to

initiate the process set forth in § 29.14 of this title to rescind recognition of the SAA.

(4) An SAA that seeks to obtain or maintain recognition must obtain the Administrator's written concurrence in any proposed State plan, as well as any subsequent modification to that plan, as provided in § 29.13(b)(9) of this title.

(c) *Recordkeeping requirements.* A recognized SAA must keep all records pertaining to program compliance reviews and any other records pertinent to a determination of compliance with this part. These records must be maintained for 5 years from the date of their creation.

(d) *Retention of authority.* As provided in § 29.13 of this title, OA retains the full authority to:

(1) Conduct compliance reviews of all registered apprenticeship programs; and

(2) Deregister for Federal purposes an apprenticeship program registered with a recognized SAA as provided in §§ 29.8(b) and 29.10 of this title.

(e) *Derecognition.* A recognized SAA that fails to comply with the requirements of this section will be subject to derecognition proceedings, as provided in § 29.14 of this title.

§ 30.8 Exemptions.

Requests for exemption from this part, or any part thereof, must be made in writing to the Registration Agency and must contain a statement of reasons supporting the request. Exemptions may be granted for good cause by the Registration Agency. SAAs must receive approval to grant an exemption from the Administrator, prior to granting an exemption from this part.

§ 30.9 Severability.

Should a court of competent jurisdiction hold any provision(s) of this part to be invalid, such action will not affect any other provision of this part.

Marek Laco,

Acting Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2026–22680 Filed 11–5–26; 8:45 am]

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FEDERAL REGISTER

Vol. 91 Friday,
No. 214 November 6, 2026

Part IV

Department of Agriculture

Food and Nutrition Administration

7 CFR Part 246

Special Supplemental Nutrition Program for Women, Infants, and Children (WIC): Online Ordering and Transactions and Food Delivery Revisions To Meet the Needs of a Modern, Data-Driven Program; Final Rule

DEPARTMENT OF AGRICULTURE

Food and Nutrition Administration

7 CFR Part 246

[FNA–2026–0595]

RIN 0584–AE85

Special Supplemental Nutrition Program for Women, Infants, and Children (WIC): Online Ordering and Transactions and Food Delivery Revisions To Meet the Needs of a Modern, Data-Driven Program

AGENCY: Food and Nutrition Administration (FNA), Department of Agriculture (USDA).

ACTION: Final rule with request for comment.

SUMMARY: This final rule considers public comments submitted in response to the proposed rule to remove barriers to online ordering and internet-based transactions in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) published on February 23, 2023. USDA FNA is issuing this regulatory action to support State innovation and develop and implement modernized systems, while underscoring program integrity. It allows for the use of new technologies to improve the WIC shopping experience while increasing access to healthy foods for WIC participants. This final rule also complements the Program's complete transition to electronic benefit transfer (EBT) by streamlining and modernizing certain WIC food delivery regulations to support current technology and future innovation, and introduces measures to support a modern, data-driven program that uses new technologies for food delivery.

DATES:

Effective Date: This rule is effective December 7, 2026. Online comments submitted through the Federal eRulemaking Portal must be received on or before January 5, 2027 to be assured of consideration.

Implementation Dates: See section VI of the **SUPPLEMENTARY INFORMATION**.

Compliance Dates: This rulemaking consists of multiple provisions. Compliance for each provision is referenced in section VI of the **SUPPLEMENTARY INFORMATION** section of this final rule and detailed in the section-by-section analysis.

• Severability. If any provision of such section promulgated through this final rule, ''Special Supplemental Nutrition Program for Women, Infants, and Children (WIC): Online Ordering and Transactions and Food Delivery Revisions to Meet the Needs of a Modern, Data-Driven Program'' (FNA–2026–0595; RIN 0854–AE85) is held to be invalid or unenforceable by its terms, or as applied to any person or circumstances, it shall be severable and not affect the remainder thereof.

ADDRESSES: The Food and Nutrition Administration, USDA, invites interested persons to submit written comments on this final rule. USDA seeks comment on the impacts to stakeholders, specifically State agencies and their Management Information Systems (MIS), Electronic Benefit Transfer (EBT), and vendor system partners. Comments may be submitted to the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments. All comments submitted in response to this final rule will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identity of the individuals or entities submitting the comments will be subject to public disclosure. FNA will make the comments publicly available on the internet via *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Allison Post, Supplemental Nutrition and Safety Programs, Food and Nutrition Administration, USDA, 201 14th Street SW, Washington, DC 20227, 703–457–7708 or *sm.fn.WICPolicy@usda.gov.*

SUPPLEMENTARY INFORMATION:

I. Overview

This rule sets forth regulatory flexibilities, encourages innovation, and modernizes WIC food delivery regulations. The rule ensures WIC participants have the same shopping options as non-WIC shoppers to transact their WIC benefits as the retail marketplace innovates and evolves. This rule also clarifies requirements so that State agencies can effectively carry out a modern, data-driven program that uses current technologies for food delivery. This final rule considers public comments on the proposed rule ''Special Supplemental Nutrition Program for Women, Infants, and Children (WIC): Online Ordering and Transactions and Food Delivery Revisions to Meet the Needs of a Modern, Data-Driven Program'' (88 FR 11516) published on February 23, 2023, referred to as ''the proposed rule.'' The changes finalized in this rule better serve families across the country by improving the WIC shopping experience and ensuring that WIC participants have access to healthy foods, while maintaining security and oversight measures at the federal and State agency levels. This rule:

(1) Removes barriers to online shopping and internet-based transactions in WIC, including a current prohibition of the authorization of internet-based vendors. This provides State agencies the flexibility to determine how to offer online shopping to participants in a way that maintains program integrity. The revisions support oversight measures and policies appropriate for current technologies, and adaptable for future ones (*e.g.,* Europay, Mastercard, and Visa (''EMV'') chip cards, mobile apps), as well as security requirements to support program integrity as the retail marketplace innovates.

(2) Streamlines and modernizes WIC food delivery requirements to reflect the Program's complete transition to electronic benefit transfer (EBT), supports current technology and future innovation, and expands opportunities for WIC participants to utilize innovations in the retail grocery industry. The revisions allow State agencies to use new types of food instruments (*e.g.,* mobile payments) and provide State agencies with more flexibility in the issuance of WIC benefits.

(3) Updates reporting requirements to reflect a modern, data-driven program.

II. Background

This part provides an overview of the WIC Program and key terms used throughout this preamble.

A. Overview of the WIC Program

The WIC Program is administered by 88 WIC State agencies, including the 50 States, 32 Indian Tribal Organizations, the District of Columbia, and 5 U.S. Territories (American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands).[1] WIC is an evidence-based public health program, with a long history of improving health outcomes for nutritionally at risk and income-eligible pregnant, breastfeeding, and non-breastfeeding postpartum women, and infants and children up to age five. In fiscal year (FY) 2025, WIC served an average of 6.9 million participants per month.[2] As of the most recent published estimates (2023), WIC

[1] The number of WIC State agencies operating as of September 2026.

[2] U.S. Department of Agriculture Food and Nutrition Administration, ''WIC Data Tables,'' 2026. *https://www.fna.usda.gov/pd/wic-program.*

participants included around 40 percent of all infants in the United States.[3]

The USDA provides grants to WIC State agencies to provide supplemental foods, referrals to health care and other social services, and nutrition education, including breastfeeding promotion and support, to WIC participants. WIC participation is associated with purchasing healthier foods and improved diets for pregnant women and children and has been shown to reduce prevalence of childhood obesity.[4] [5] According to their participant category and nutritional needs, WIC participants receive supplemental foods on a monthly basis from one of seven evidence-based food packages. The amounts and categories of foods provided in each package are intended to supplement participants' diets and provide specific nutrients known to be lacking in the diets of WIC's target population.

WIC participants typically access supplemental foods through a retail food delivery system. In such systems, a WIC shopper goes to a WIC-authorized vendor (*i.e.,* a retail grocery store authorized by the State agency), selects foods available in their benefit balance, and uses an electronic benefit transfer (EBT) card to purchase the items. In FY 2023, there were approximately 37,368 WIC-authorized vendors nationwide and, as of August 2024, all WIC State agencies completed the transition from paper vouchers to EBT. This rule does not fully remove references to paper food instruments because when the proposed rule was published in early 2023, there were still State agencies in the midst of implementing EBT. The Department intends to use a future rulemaking to update WIC regulations to reflect that EBT is now the sole benefit delivery method in the retail food delivery system.

[3] U.S. Department of Agriculture, Food and Nutrition Service, ''National- and State-Level Estimates of WIC Eligibility and WIC Program Reach in 2023: Final Report, Volume I,'' pp. 65, by Courtenay Kessler et al. Project Officer Grant Lovellette, Alexandria, VA: December 2025. *https://www.fna.usda.gov/research/wic/eer-2023.*

[4] Caulfield LE, Bennett WL, Gross SM, Hurley KM, Ogunwole SM, Venkataramani M, Lerman JL, Zhang A, Sharma R, Bass EB. Maternal and Child Outcomes Associated With the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). Comparative Effectiveness Review No. 253. (Prepared by the Johns Hopkins University Evidence-based Practice Center under Contract No. 75Q80120D00003.) AHRQ Publication No. 22–EHC019. Rockville, MD: Agency for Healthcare Research and Quality; April 2022. DOI: *https://doi.org/10.23970/AHRQEPCCER253.*

[5] Kenney EL, Lee MM, Barrett JL, Ward ZJ, Long MW, Cradock AL, Williams DR, Gortmaker SL. Cost-effectiveness of Improved WIC Food Package for Preventing Childhood Obesity. Pediatrics. 2024 Jan; 153. *https://doi.org/10.1542/peds.2023-063182.*

WIC State agencies are responsible for making sure the distribution of WIC-authorized vendors in their geographic area provides sufficient access to WIC foods for participants, and vendors stock an adequate amount and variety of WIC foods. The regulatory changes in this final rule aim to reduce some of the burden associated with shopping for WIC foods, and support State agency vendor management operations in maintaining strong program integrity efforts. The Department recognizes that the development and expansion of online shopping is a novel and developing component in WIC. In order to protect both participants and taxpayer funds, the Department is committed to ensuring all available resources are deployed toward increased oversight and prevention of potential vendor fraud and abuse.

B. Introduction of Key Terms

The following are key terms used throughout this final rule preamble:

- ''WIC shopper'' means a person shopping using WIC benefits (*i.e.,* a WIC participant, proxy, or a parent or caretaker of an infant or child participant).
- ''Online shopping'' means the general use of an online, internet-based ordering system, platform, or site. It can encompass online ordering with or without internet-based transactions (*i.e.,* the transaction can occur via the internet, in store, curbside, or at the point of delivery).
- ''Online ordering'' means the process a customer (including a WIC shopper) uses to select food items for purchase via an internet-based ordering system, platform, or site.
- ''Transaction'' means the process by which a WIC shopper exchanges their WIC benefits for supplemental foods.
- ''Internet-based transaction'' means a transaction where the WIC payment is completed through the payment section of the online ordering system, platform, or site. This terminology is being used in lieu of ''online transaction'' to avoid confusion with transactions that occur using online EBT technology.
- ''Redemption'' means the process in which a vendor submits records of electronic benefit transactions for redemption and the State agency (or its financial agent) makes payment to the vendor.

III. Approach To Rulemaking and Status of WIC Online Shopping

This rulemaking finalizes regulatory changes in consideration of public comments received on the proposed rule published February 23, 2023. In developing the proposed rule, the Department considered technical materials developed by a wide variety of WIC stakeholders, lessons learned from the Supplemental Nutrition Assistance Program (SNAP) online shopping projects that began in 2019, as well as feedback from WIC State agencies, Indian Tribal Organizations, and participants. The following technical resources informed the Department's identification of regulatory barriers to online shopping and provisions in this rulemaking:

- Blueprint for WIC Online Ordering: Through a cooperative agreement with FNA, The Center for Nutrition and Health Impact (CNHI), an independent non-profit research institute, developed a comprehensive plan for implementing online shopping in WIC. This Blueprint, which initially identified waivers to federal regulations necessary to begin online shopping projects and provided guidance to begin implementing, has since been revised and republished in May 2026, with up-to-date information to support WIC State agencies as they develop their WIC online shopping projects.[6]
- The Task Force on Supplemental Foods Delivery: This task force convened WIC providers, retailers, manufacturers, EBT processors, advocacy organizations, and WIC participants to develop an online shopping Recommendation Report for the Department.[7]

The Department initially supported WIC State agencies in pursuing online shopping projects by issuing waivers under the American Rescue Plan Act (ARPA, Pub. L. 117–2) authority, which allowed FNA to waive regulatory barriers to support outreach, innovation and modernization in WIC and the WIC Farmers' Market Nutrition Program (FMNP). Online shopping waivers were issued through September 2024 and remain in effect to support ongoing projects. With these waivers, the Department provided State agencies with the necessary regulatory flexibility and technical assistance to pursue online shopping projects, regardless of whether or not they received a subgrant from CNHI. The Department recognizes and appreciates the WIC State agencies and authorized retailers that have developed different ways to provide online ordering to WIC participants. Through the cooperative agreement with CNHI, 22 WIC State agencies have received subgrants to pursue online shopping including the necessary

[6] *https://www.wicshopplus.org/the-blueprint.*

[7] *https://www.fna.usda.gov/wic/food-delivery-task-force-recommendations-report.*

development of internet-based transactions.

This final rulemaking permanently removes regulatory barriers to allow State agencies to implement online shopping in WIC and eliminates the need for waiver flexibility; therefore, the online shopping waivers will be superseded by regulation once this rulemaking is effective. Additional waivers supporting mobile pay and remote issuance will also be superseded by this rulemaking once effective.

IV. Proposed Rule Comment Summary

The proposed rule published in the **Federal Register** on February 23, 2023, with a 90-day comment period closing on May 24, 2023. During this time, USDA received 1,664 comments. Five form letter campaigns comprised 881 submissions. There were 752 unique comments of which 216 were substantive, providing specific input on the topics included in this final rule. A total of 31 comments were either duplicates or out of the scope of this rule, as they did not provide feedback related to topics in this final rule. The comments came from a variety of sources, including WIC State and local agencies, state representatives, professional organizations and associations, advocacy groups, health care professionals, universities, the food industry, WIC participants, and private citizens. USDA worked in collaboration with a data analysis company to code and analyze the public comments using a commercial web-based software product. This analysis provided data showing support for or opposition to each proposed change. Over 1,070 commenters provided broad support for revisions to the regulations while approximately 10 commenters provided general comments in opposition to the proposed rule. The Final Summary of Public Comments is available online at *www.regulations.gov* in docket FNS-2022-0015. The Final Summary of Public Comments includes the specific number of comments in support or opposition to each provision in the proposed rule, with a detailed narrative describing the key points made by commenters. USDA used the Final Summary of Public Comments and a supplementary review of individual comments to finalize provisions within this final rule. USDA refers to the Final Summary of Public Comments for numbers of comments received on each provision, with general summaries of comments provided in the preamble of this final rule.

As required under the Administrative Procedure Act, FNA considered all relevant, timely-submitted comments received on the proposed rule. Some comments addressed topics out of scope for the revisions and therefore are not addressed in this final rule.

V. Discussion of Final Rule

The following is a discussion of the provisions set forth in the proposed rule, a summary of the comments received that addressed these provisions, and the Department's rationale for either retaining or modifying the proposed provisions in the final rule. Provisions not discussed in this preamble did not receive significant or substantial public comments and are retained in this final rule as proposed.

This preamble communicates the rationale for modifications to the proposed rule codified in this final rulemaking. The Department re-examined the goals of this rulemaking while reviewing the comments to determine the continued applicability of each proposed change. Unless otherwise stated in the preamble of this final rule, the rationales included in the preamble of the proposed rule are regarded as a basis for the final regulations. Therefore, an understanding of the rationales for the final regulations may require reference to the preamble of the proposed rule.

USDA appreciates the many comments expressing support for the proposed revisions and urging USDA to implement the changes included in the proposed rule. USDA agrees the changes improve access to healthy foods and the efficiency of the WIC shopping experience while ensuring State agencies have the flexibility to oversee new types of vendors and to maintain program integrity and security. Before addressing each provision specifically, the following is a summary of overarching themes related to online shopping that the Department is acknowledging broadly.

(i) Technical assistance to support online shopping: the Department received numerous comments requesting guidance and technical assistance to support the implementation of online shopping in WIC.

The Department is committed to providing ongoing technical assistance and guidance to State agencies to ensure they have the support and resources necessary to implement online shopping and can do so while preserving program integrity. The Department is developing best practices, lessons learned, and technical resources to support State agencies in the implementation of online shopping using the many recommendations and ideas stakeholders provided during the public comment period for the proposed rule.

(ii) Internet vendor authorization: Many commenters expressed concern the State agency-by-State agency approach to internet vendor authorization would be lengthy and cumbersome, and instead recommended the Department adopt a national authorization process for online shopping, including national monitoring and management, similar to that of SNAP.

The Department notes there is a significant difference in how SNAP and WIC are authorized in legislation. The Child Nutrition Act expressly delegates responsibility for vendor authorization, monitoring, and oversight to WIC State agencies. Therefore, the Department did not propose a national process related to the authorization of WIC internet vendors.

(iii) Costs of technology innovations and online shopping: Many comments discussed concerns around the cost of adopting new technologies and stated the need for more federal funding to implement the various changes included in this rulemaking.

The Department notes the majority of the changes in this rulemaking either, (1) increase options and flexibilities for State agencies in vendor management activities without increased costs, or (2) provide the opportunity for State agencies to pursue new technologies at their discretion. The Department recognizes funding is a consideration for State agencies and therefore is not requiring implementation of any new technologies at this time. This rulemaking allows State agencies the opportunity to determine an appropriate and feasible timeline to implement new technologies. The Department recognizes the costs associated with authorizing internet vendors, largely due to the EBT and MIS changes necessary to allow new types of transactions and is therefore prioritizing flexibility and has recently supported State agencies through various funding opportunities, including subgrant opportunities from CNHI.

(iv) Modernizing offline EBT systems: Some commenters questioned how State agencies with offline EBT systems (*i.e.,* chipped EBT cards in which benefits cannot be used or issued online) would be able to implement some of the provisions in this rule, such as those related to online shopping or issuing benefits remotely. Commenters asked for technical assistance and funding to help transition to online EBT systems.

The Department recognizes that offline EBT systems will not be able to operate WIC online shopping or issue

benefits remotely. The Department is actively working with all offline State agencies to transition to online EBT systems so that they can also take part in these opportunities. The Department also highlights that neither online shopping nor remote benefit issuance are requirements for State agencies under this rulemaking. This rule creates the necessary flexibilities for the State agencies that are interested and able to develop online shopping and encourages the flexible issuance of benefits where possible.

(v) Impact to small vendors and accessibility: Some commenters expressed concerns that implementing online shopping would be especially challenging for small vendors.

To support small vendors, CNHI conducted a survey and hosted listening sessions to hear directly from small, Tribal, and rural vendors, and farmers and farmers' markets, to understand the perceptions, experiences, and potential barriers vendors face in implementing online shopping.[8] The Department recognizes different types of support and guidance may be needed to initiate WIC online shopping. USDA is committed to gathering feedback and learning from implementation projects to develop technical resources and assistance.

Commenters also noted that access to online shopping through the inclusion of alternative languages to English, as well as alternative online formats for persons with disabilities are key to ensuring all participants can access online shopping opportunities. The Department will explore opportunities to provide ongoing technical assistance to ensure that State agencies are encouraging vendors to equip their online platforms to meet the needs of their participants.

Following this summary of overarching themes, the Department presents a summary comparison of the proposed and final provisions of this rule with detailed discussion on each following.

Section	Summary of proposed revision	Summary of final revisions based on public comment
1. Remove Barriers to Allow for Online Ordering and Internet Based Transactions.	Clarify which vendor agreement provisions apply only to paper food instruments and modernize the purchase price provision to be inclusive of EBT transactions. (section 1.a.i).	Finalize as proposed.
	Remove the requirement that WIC shoppers must sign printed food instruments in the presence of a cashier. (section 1.a.ii).	Finalize as proposed.
	Remove the requirement to use a personal identification number (PIN) in lieu of a signature. (section 1.a.iii).	Finalize as proposed.
	Create new provisions to allow WIC State agencies to explore and identify options to authenticate EBT transactions and require vendors, farmers, and farmers' markets to authenticate EBT transactions in accordance with State agency policy. (section 1.a.iv).	Modify to remove reference to Department standards that are not yet published and require FNA approval to use an authentication method other than PIN.
	Create a new definition for ''brick-and-mortar vendor.'' (section 1.b.i).	Finalize as proposed.
	Create a new definition for ''internet vendor.'' (section 1.b.ii).	Modify to clarify the transactions at each internet vendor must be assigned to that internet vendor.
	Create a new definition for ''mobile vendor.'' (section 1.b.iii).	Modify to clarify the transactions at mobile vendors must be assigned to that specific vendor.
	Update the definition of ''above-50-percent vendor'' to be applicable to all vendor types. (section 1.b.iv).	Finalize as proposed.
	Modernize the current definition of ''vendor'' by removing the requirement that vendors must have a single, fixed location, simplifying the definition of vendor, and clarifying that all vendors must be authorized separately. (section 1.c.i).	Modify to remove the reference to SNAP and clarify each entity must be separately authorized.
	Remove a clause in the definition of ''vendor'' requiring a special needs justification for mobile vendors and remove associated language from the State Plan requirements. (section 1.c.ii).	Finalize as proposed.
	Clarify that cash refunds are still prohibited and update the exchange policy to accommodate recalls, ensuring that WIC shoppers are treated the same as other customers in the event of a recall. (section 1.d.i).	Modify the refunds provision to clarify the different types of cash refunds that are prohibited and modify the exchange provision to reflect changes from the Implementation of the Access to Baby Formula Act of 2022 and Related Provisions Final Rule[9] by clearly defining a supplemental food recall in 7 CFR § 246.2.
	Allow for the return of electronic benefits to a participant's balance when items in an online order are not fulfilled and for the use of returned electronic benefits. (section 1.d.ii).	Modify to allow returns for purchases that took place at any vendor type, not just online orders.

[8] Akers, L, Anderson-Steeves ET, Crespo-Bellido M, Ángel-López M, Vest D, Nitto AM, Hill JL. WIC Online Shopping Brief Report: Small, Tribal, and Rural Vendors and Farmers and Farmers Market (STRFM) Study. Prepared for: USDA Food and Nutrition Service. December 2024. *https://www.wicshopplus.org/resource-library/wic-online-shopping-strfm-brief-report.*

[9] Special Supplemental Nutrition Program for Women, Infants, and Children (WIC): Implementation of the Access to Baby Formula Act of 2022 and Related Provisions (88 FR 86545). *https://www.federalregister.gov/d/2023-26641.*

Section	Summary of proposed revision	Summary of final revisions based on public comment
	Require State agencies to provide participants with no less than seven (7) days to transact returned electronic benefits, which could go beyond the last date of use (LDTU). (section 1.d.iii).	Modify to clarify that State agencies must allow participants to use returned electronic benefits through the end of the benefit issuance month. Make the use of returned electronic benefits after the last date of use (LDTU) a State agency option and set a maximum of seven (7) days for benefit use beyond the LDTU. The Department is requesting comment on the impacts this would have on stakeholders and their systems if this flexibility were to be a requirement.
	Update the definitions of ''routine monitoring'' and ''compliance buy'' to remove the on-site requirement. (section 1.e.i).	Finalize as proposed.
	Introduce virtual visits as an allowable type of preauthorization visit. (section 1.e.ii).	Finalize as proposed.
	Prohibit vendors, farmers or farmers' markets from charging State agencies fees associated with WIC purchases and permit WIC shoppers to pay such fees. (section 1.f.i).	Modify to apply the prohibition to all fees associated with a WIC purchase (*e.g.,* delivery, service, convenience, bag fees) for any vendor type, not just online shopping fees, to ensure consistent treatment of all vendor types.
	Clarify costs associated with home food delivery and direct distribution to ensure State agencies still pay for the cost of transporting food under these two food delivery systems. (section 1.f.ii).	Modify to further clarify that food funds can be used to pay for the cost of transporting foods in home food delivery and direct distribution but cannot be used in retail food delivery systems.
2. Streamline and Modernize WIC Food Delivery.	Allow the remote issuance of electronic benefits by separating the benefit issuance provisions for paper food instruments and cash-value vouchers from electronic benefit issuance and updating signature requirements. (section 2.a.i).	Modify to ensure State agencies have procedures for recipient proof of receipt to ensure program integrity measures, and to clarify that signatures are required only when benefits are received in person.
	Create new definitions of ''electronic benefits,'' ''cash-value benefit,'' and ''cash-value voucher'' to reflect a modern WIC Program. (section 2.a.ii).	Finalize as proposed.
	Expand the definition of ''food instrument.'' (section 2.b).	Finalize as proposed.
	Allow State agencies to develop and test new WIC food instrument types. Clarify uniform food delivery systems and system combinations. (section 2.c.i).	Modify to clarify that State agencies can have more than one food instrument type within a food delivery system at a time.
	Remove the requirement for State agencies to collect shelf price data, as EBT data are a sufficient replacement. (section 2.d).	Modify to clarify that State agencies can use existing EBT data for vendors applying for re-authorization.
	Allow State agencies using a non-retail, home food delivery system to ship supplemental foods to a location designated by participants and approved by the State agency. (section 2.e).	Modify to allow State agencies to confirm delivery location of supplemental foods as an additional measure of program integrity.
	Extend vendor application and agreement periods from three to five years.	FNA will not finalize as proposed; no change to current provision.
3. Meet the Needs of a Modern, Data Driven Program.	Update the reporting requirements for WIC food delivery systems, including the timing of reporting and information required. (section 3.a).	Modify to remove the proposed requirement for quarterly submissions, maintaining the current annual minimum.
	Increase the staffing standards for the position of the WIC Food Delivery Coordinator.	FNA will not finalize as proposed; no change to current provision. State agencies may optionally implement more stringent standards at the State level.
	Add staffing standards to create a WIC Quality Improvement Coordinator.	FNA will not finalize as proposed; no change to current provision. State agencies may optionally implement more stringent standards at the State level.
4. Request for Public Comment on Key Topic Areas.	The Department requested comment on whether there is a need to authorize vendors that sell a specific subset of supplemental foods (*e.g.,* dairies, bakeries, produce sellers) but would not meet the minimum variety and quantity of supplemental foods, as required by WIC regulations. (section 4.a).	Due to feedback received discussing concerns related to cost containment, program integrity, and the impact on small vendors, the Department will not allow exceptions to minimum stocking requirements for authorizing specialty vendors in this rulemaking.

1. Remove Barriers To Allow for Online Ordering and Internet-Based Transactions

This final rule allows vendors and WIC shoppers to complete internet-based transactions, creates new definitions for internet and mobile vendors, modernizes the definition of brick-and-mortar and above-50-percent vendors, allows vendors to return benefits to a participant's benefit balance, allows State agencies to develop virtual methods of oversight, permits WIC shoppers to pay fees associated with WIC purchases, and clarifies that State agencies may use non-WIC funds to pay fees associated with WIC purchases.

a. Allow vendors and WIC shoppers to complete internet-based transactions [§§ 246.12(h)(3)(v), (vi), and (xxxii), 246.12(v)(1)(iv), and 246.12(bb)(2)]. The changes to provisions in this section that clarify which vendor agreement provisions apply only to paper food instruments and modernize the purchase price provision, § 246.12(h)(3)(v) and (vi), are finalized as proposed. The provisions that allow vendors, farmers and farmers' markets, and WIC shoppers to complete internet-based transactions by removing requirements that WIC shoppers must sign food instruments, or enter a personal identification number (PIN), in the presence of a cashier, § 246.12(h)(3)(v) and (vi), and § 246.12(v)(1)(iv), are also finalized as proposed. The provisions requiring vendors, farmers and farmers' markets to authenticate transactions in accordance with State agency policies, § 246.12(h)(3)(xxxii) and § 246.12(v)(1)(iv), are finalized as proposed, and the provision requiring State agencies to develop policies on transaction authentication methods, § 246.12(bb)(2), is finalized with modifications.

i. Clarify which vendor agreement provisions apply only to paper food instruments and modernize the purchase price provision to be inclusive of EBT transactions. (§ 246.12(h)(3)(v) and (vi))

This final rule codifies the change from ''printed'' to ''paper'' at § 246.12(h)(3)(vi) as proposed to clarify which vendor agreement provisions apply only to paper food instruments. This final rule also codifies proposed revisions to the purchase price provision at § 246.12(h)(3)(v) to ensure the requirement that WIC shoppers are made aware of the total purchase price before transactions are completed continues to be applicable to EBT transactions.

Commenters expressed general support for the changes that clarify which provisions apply to paper food instruments versus EBT transactions, especially the requirement that participants be made aware of the purchase price before the transaction is completed, affirming these requirements enable WIC participants to make informed choices and ensure program integrity. No comments were opposed.

Some commenters requested flexibility on how State agencies meet the requirement that participants be made aware of the total purchase price, and recommended the Department require vendors ensure the price of produce for online purchases does not increase during fulfillment so that the amount of cash-value benefits transacted is not higher than what the participant agreed to during the shopping process.

The Department does not define in regulation how vendors must ensure participants are made aware of the total purchase price. Vendors should make WIC participants aware of prices in the same ways they show all other customers prior to the completion of the transaction, while still meeting the WIC receipt requirements outlined in the WIC EBT Operating Rules.[10] The Department will incorporate feedback on best practices on handling produce during the fulfillment process into future policy guidance.

ii. Remove the requirement that WIC shoppers must sign in the presence of a cashier. (§ 246.12(h)(3)(vi))

This final rule codifies revisions as proposed at § 246.12(h)(3)(vi) to remove the requirement that WIC shoppers must sign printed food instruments in the presence of a cashier.

This change received overwhelming support, with commenters stating this change will enhance convenience for participants and reduce burdens associated with the current WIC shopping experience. The Department agrees this change supports modernization of the WIC Program and the changing retail landscape, and makes WIC shopping less burdensome, which also supports greater benefit utilization. No comments were opposed.

iii. Remove the requirement to use a personal identification number (PIN) in lieu of a signature. (§ 246.12(h)(3)(vi))

This final rule codifies revisions as proposed at § 246.12(h)(3)(vi) to remove the requirement to use a PIN in lieu of a signature.

Many comments supported removing the requirement to use a PIN in lieu of a signature, stating it would allow State agencies to modernize alongside the grocery industry as PIN authentication is just one of many authentication models employed in the commercial marketplace. The Department agrees that allowing for new types of authentication methods facilitates security innovation in the WIC Program.

An opposed commenter expressed concern that eliminating the PIN requirement could lead to fraud. The Department clarifies this change does not remove the State agency's responsibility to ensure a secure transaction, nor the requirement for transaction authentication, but instead eliminates regulatory barriers, supporting State agency innovation, and allows State agencies to use new types of transaction authentication methods to better reflect industry modernization.

The Department expects State agencies that do not choose to use new transaction authentication methods will continue to use the PIN as the required transaction authentication methodology for their jurisdiction. Modifications to the provision at § 246.12(bb)(2) establish this expectation by requiring State agencies to receive written approval to adopt an authentication method other than the PIN. The Department will provide further detail on expectations for transaction authentication in forthcoming guidance, discussed in section 1.a.iv below.

Some commenters stated the differences in WIC and SNAP PIN requirements could lead to confusion among participants using both programs, as all SNAP online purchase transactions still require the PIN. Commenters encouraged the Department to implement uniform authentication standards and payment models across all programs that use EBT.

The Department agrees there is value in consistency across SNAP and WIC and works to achieve this where possible while allowing for new types of authentication methods when feasible and appropriate. With the implementation of new technologies in WIC, the Department encourages State agencies to continue educating participants on the use of any modern food instruments and how to transact their WIC benefits.

iv. Create new provisions to allow WIC State agencies to explore and identify options to authenticate EBT transactions and require vendors, farmers, and farmers' markets to authenticate EBT transactions in accordance with State agency policy. (§§ 246.12(bb)(2), 246.12(h)(3)(xxxii) and 246.12(v)(1)(iv))

[10] *https://www.fna.usda.gov/wic/ebt/technical-implementation-guide-operating-rules.*

This final rule codifies a new provision at § 246.12(bb)(2) requiring that State agencies have appropriate transaction authentication policies for the specific technologies they choose to allow in their jurisdiction, with modifications to remove reference to FNA standards that have not yet been developed. The Department has also modified this provision to establish PIN authentication as the default authentication method. As discussed above, the expectation that State agencies utilize a PIN until more modern technology meets or exceeds the security of a PIN is reinforced by codifying specific reference to the PIN in the amendatory text.

This final rule also codifies a new provision as proposed requiring vendors to authenticate transactions in accordance with State agency policies at § 246.12(h)(3)(xxxii), and that transactions at farmers and farmers' markets also occur in accordance with the procedures established by the State agency at § 246.12(v)(1)(iv).

Multiple commenters expressed support for these changes, agreeing they will allow State agencies flexibility to create a plan that works for their participants and a variety of modern vendors, while ensuring program integrity. No comments were opposed.

The Department appreciates the extensive feedback that commenters provided regarding the transaction authentication standards referenced in the proposed rule, including the recommendations on the content of the standards and on where the standards will be posted. Because the standards are not yet published, the Department is removing the reference to them in this final rule. The Department will, however, still develop guidance on transaction authentication for State agencies that incorporates this feedback. Commenters recommended that transaction authentication standards be developed via the Technical Standards Workgroup (TSW) to ensure they can continue to be updated on an ongoing basis with stakeholder feedback as technology evolves. The Department agrees that input from the WIC community is important for the development of standards in the evolving retail marketplace. Therefore, transaction authentication standards will be developed and finalized via the TSW to allow for maximum engagement with affected parties and partners.

Commenters requested that the implementation of the provisions related to new transaction authentication methods not be required until the Department's transaction authentication standards are published.

The Department recognizes the development of transaction authentication standards will take time and does not want to prevent State agencies from exploring modernization initiatives. Because FNA has not yet published such standards, the Department has removed the regulatory reference to the FNA standards as noted above. While the provisions in this section will be effective upon publication of the final rule to allow State agencies to take advantage of the flexibilities created in this rulemaking, State agencies will not be expected to wait for publication of final transaction authentication standards to continue their online shopping projects. Following this rulemaking, the Department will provide interim guidance on transaction authentication. The Department encourages State agencies to explore new payment technologies and expects that State agencies will continue to use PIN authentication until more modern technology meets or exceeds the security of a PIN.

Some commenters questioned how these changes would impact industry partners, such as vendors and EBT processors. They expressed concerns that competing transaction standards across WIC State agencies could result in challenges for multi-state retailers, and that current EBT contractual provisions may not allow new transaction authentication methods.

As discussed above, the Department will develop transaction authentication standards for State agencies, with interim guidance provided following this rulemaking, to support implementation of new technologies and encourage uniformity across State agencies. The Department recommends vendors continue to work closely with the State agencies in which they are authorized to ensure they are following all respective State agency specific policies. The Department also recognizes each State agency has different procurement policies and procedures and recommends that State agencies continue to work closely and maintain open communication with their procurement offices and EBT contractors as they pursue any new technologies.

Some commenters stated that participants should be able to use their EBT cards with farmers or farmers' markets and purchase farm fresh produce online. WIC regulations currently allow State agencies to authorize farmers and farmers' markets to accept cash-value benefits (CVB). The Department encourages all State agencies to allow participants to transact their CVB with farmers and at farmers' markets to support the purchase of local produce. With the changes from this rulemaking, authorized farmers and farmers' markets will be allowed to sell their produce online.

b. Create new types of vendors [§ 246.2]. The provisions to define ''Brick-and-mortar vendor'' and ''Above-50-percent vendor'' are finalized as proposed. The provisions to define ''Internet vendor'' and ''Mobile vendor'' are finalized with modifications to ensure all vendors are authorized separately and transactions that take place at each vendor are assigned specifically to that vendor.

There was a significant discussion from commenters regarding the new vendor types, and while many commenters supported the proposed definitions, other commenters shared concerns and requests for clarification from the Department. The following discussion is related to overarching concerns regarding the new vendor types. A discussion on the specific definitions for each vendor type follows.

Commenters requested guidance from USDA on how the creation of new vendor types will impact various State agency vendor management activities such as selection criteria, peer groups, preauthorization, above-50-vendor assessment, cost containment, monitoring, training, and sanctions. Many commenters also provided recommendations for how vendor management activities should take place for the new vendor types. Some commenters requested clarification on whether the authorization of internet and mobile vendors is a State agency option. The Department recognizes adding new vendor types warrants revised approaches to vendor management. The Department appreciates the feedback and recommendations on how to adequately manage the new vendor types and will incorporate this feedback into the development of guidance and technical assistance, expanding on current efforts to develop guidance and technical assistance based on lessons learned from online shopping projects. While the Department confirms the authorization of internet and mobile vendors is a State agency option, the Department also encourages State agencies to consider authorizing these new vendor types to better serve families across the country, including in rural areas.

Many commenters strongly agreed with the Department's proposal that all vendors, regardless of type, must adhere to all regulations pertaining to vendors

and discussed the importance of applying consistent and fair program requirements regardless of vendor type. However, some commenters disagreed and recommended different requirements by vendor type, such as different federal selection criteria or minimum stock for internet and mobile vendors than brick-and-mortar vendors.

The Department recognizes that different vendor types will inherently have different training, monitoring, and investigative needs, and the specific ways in which vendor management activities take place may be different. However, the State agency must hold all vendors to the same federal accountability measures and minimum requirements to ensure effective management and oversight. Therefore, the Department maintains that all authorized vendors, no matter the type, are subject to federal regulations governing authorized WIC vendors, but that State agencies may tailor their vendor management approach depending on vendor type. For example, State agency training for internet vendors may include new content for web designers, such as online shopping navigation and pricing, and may focus less on transaction details which may not be applicable for an internet vendor using automated product compliance controls. Further, as discussed in section 1.e, the Department is introducing virtual methods of oversight to provide State agencies with the appropriate tools for monitoring all vendor types. While different vendor types do not have distinct requirements, vendors of different types may be able to show compliance with requirements in distinct manners. For example, an authorized internet vendor sourcing orders from multiple fulfillment locations would not need to demonstrate that each fulfillment location meets stocking standards so long as the vendor can prove to the State agency that their online ordering operations as a whole meet those standards. Similarly, internet vendors may have different mechanisms for demonstrating compliance with inventory audits, which are just one State agency option for investigating their vendor population.

Some commenters stated that the word ''store'' as used throughout the current regulations appears to refer to a single, fixed location, and therefore would only apply to brick-and-mortar stores. Commenters requested clarification of the Department's application of the word ''store'' considering the new vendor types that do not have single, fixed store locations.

The Department clarifies that the word ''store'' as used throughout the regulation is synonymous with the term ''vendor'' and applies to brick-and-mortar, internet, and mobile vendors.

Many commenters requested the inclusion of a ''hybrid vendor'' defined by the Task Force Report as a ''physical store location that also operates a virtual platform,'' [11] so internet vendors do not have to be separately authorized if they fulfill orders from a brick-and-mortar vendor. Commenters requested a similar inclusion for mobile vendors.

The Department appreciates the input from commenters and thoroughly considered the Task Force report as well as the public comments recommending the inclusion of ''hybrid vendor'' as another vendor type. While the Department recognizes the fulfillment of many online orders may come from brick-and-mortar vendors, the Department determined ''hybrid vendors'' are not feasible due to challenges they would pose for cost containment and program integrity. State agencies must be able to apply cost containment methods to brick-and-mortar vendor operations independently from any affiliated internet operations as prices for food purchased online are often higher than prices for food purchased in-store.[12] To ensure vendors are charging State agencies appropriate and reasonable prices for WIC foods and are remaining cost competitive relative to peer vendors, State agencies must authorize internet, mobile, and brick-and-mortar vendors separately, regardless of any association. Further, State agencies must maintain the ability to take administrative action against individual vendors at fault for violations when they occur. If the State agency found a violation associated with the internet operations of a ''hybrid vendor'' while the brick-and-mortar operations remained in compliance, the State agency would be required to take action against both entities together if they were under one authorization. Such action could limit participant access if the brick-and-mortar operations were no longer authorized. By separating the authorizations by brick-and-mortar operations from internet operations, the State agency is better equipped to manage program integrity. Finally, it is an important component of vendor management and cross program integrity efforts that WIC and SNAP can take reciprocal administrative action against vendors when a vendor commits a violation. For these reasons, the Department decided the use of a ''hybrid vendor'' is not feasible for the WIC Program and maintains that brick-and-mortar, internet, and mobile vendors are the only three vendor types and must be separately authorized, with their own distinct vendor identification numbers (vendor IDs).

i. Create a new definition for ''brick-and-mortar vendor.'' (§ 246.2)

This final rule codifies the new definition of ''brick-and-mortar vendor'' as proposed, requiring this type of vendor to be defined separately and distinctly from internet or mobile vendors.

Multiple commenters supported the proposed definition and reasoned that permitting new types of WIC vendors enhances program modernization, and expanding vendor definitions supports small businesses and participant access. No comments were opposed.

Some commenters requested clarification if brick-and-mortar vendors can offer online ordering, that is, when a WIC participant places an order through the internet and then comes to the store to swipe their EBT card and pick up their order. Online ordering with curbside payment and pick-up remains allowable with the new vendor types. In this scenario, the transaction is occurring at the brick-and-mortar store, so this transaction would be assigned to the brick-and-mortar vendor.

ii. Create a new definition for ''internet vendor.'' (§ 246.2)

This final rule codifies the new definition of ''internet vendor'' with modifications to clarify transactions that take place at the internet vendor must be assigned to the internet vendor, and each internet vendor must be separately authorized.

Many commenters supported the creation of a new definition for internet vendor, stating it will enhance access to healthy foods for participants and could facilitate the use of more modern retail solutions. No comments were opposed.

Some commenters requested the language used in the brick-and-mortar vendor definition indicating ''transactions that take place at a brick-and-mortar vendor must be assigned to that vendor'' should be applicable to internet vendors as well. Further, multiple commenters requested clarification on the meaning of ''location'' for each vendor type, as the brick-and-mortar vendor explicitly specifies the meaning of a ''single, separate location'' for the vendor.

[11] Task Force on Supplemental Foods Delivery in the WIC Program—Recommendations Report, page 16 (September 2021). *https://www.fna.usda.gov/wic/food-delivery-task-force-recommendations-report.*

[12] Roerink, A.M. (June 2021). Grocery E-Commerce—Opportunity Remains. Produce Business, 37(6), p.12. *https://producebusiness.com/issue/produce-business-june-2021/.*

For internet vendors, the location of the transaction is online, which could include the online ordering system, platform, or site used by an internet vendor to transact benefits. To ensure consistency in the authorization of vendor types, the Department added language to the definition to indicate that all transactions taking place via an online ordering system, platform, or site must be assigned to the authorized internet vendor. This is to ensure all vendor types are held to the same requirements and that transactions are properly assigned. A similar change was made to the definition of ''mobile vendor.'' The Department recognizes that internet vendors may use different eCommerce platform providers, eCommerce Marketplaces, or delivery partners to transact WIC benefits. These third-party platforms may not be authorized as vendors themselves, and all transactions that take place on these platforms must be assigned to the internet vendor authorized to transact WIC benefits.

Some commenters requested clarification on whether an internet vendor can have any affiliation with a brick-and-mortar vendor, while others requested a new definition of ''internet only vendor'' for vendors that have no affiliation with a brick-and-mortar storefront.

The Department reiterates that internet vendors provide authorized supplemental foods to participants through internet-based transactions, regardless of their affiliation with any physical store. This includes, but is not limited to:

- Vendors operating only online with no physical storefront,
- Vendors operating online and fulfilling from a brick-and-mortar vendor, and
- Vendors operating online and fulfilling from a warehouse and a separately authorized brick-and-mortar vendor.

Regardless of where the order is fulfilled from or if the order is delivered to the participant or picked up in a physical store, the vendor type depends on the location of the transaction. Therefore, if the transaction happened online then it must be assigned to the internet vendor. This is consistent with SNAP's authorization and management of internet retailers.

iii. Create a new definition for ''mobile vendor.'' (§ 246.2)

This final rule codifies the new definition of ''mobile vendor'' with modifications to clarify transactions that take place at the mobile vendor must be assigned to the mobile vendor, and each mobile vendor must be authorized separately.

Multiple commenters supported the proposed definition, stating that allowing mobile vendors will enhance participant access to healthy foods. No comments were opposed.

Some commenters requested the language used in the ''brick-and-mortar vendor'' definition indicating ''transactions that take place at a brick-and-mortar vendor must be assigned to that vendor'' should be applicable to mobile vendors as well. Further, multiple commenters requested clarification on the meaning of ''location'' for each vendor type, as the definition of a brick-and-mortar vendor explicitly specifies there is a ''single, separate location'' for the vendor.

For a mobile vendor, the location of the transaction is the truck, bus, pushcart, or other mobile vehicle at which the transaction takes place. To ensure consistency in the authorization of vendor types, the Department added language to the definition to indicate that all transactions that take place at a mobile vendor must be assigned to that authorized mobile vendor. This is to ensure all vendor types are held to the same requirements and transactions are properly assigned.

Multiple commenters expressed concern about the feasibility for mobile vendors to operate the WIC Program, including their ability to meet minimum stocking requirements, manage updating the authorized product list (APL), and use EBT systems. Commenters also recommended prices for mobile vendors be restricted to the same prices as brick-and-mortar vendors.

The Department clarifies authorizing mobile vendors is an option, not a requirement, for State agencies. If a State agency chooses to authorize this type of vendor, all vendor requirements must be met. The Department highlights that State agencies have flexibility in managing their vendor populations and can set different minimum stocking requirements by peer group, as long as they meet the federal minimum stocking requirements defined at § 246.12(g)(3)(i). State agencies that choose to authorize mobile vendors as a new vendor type must meet all vendor regulations, including cost containment.

iv. Update the definition of ''above-50-percent vendors'' to be applicable to all vendor types. (§ 246.2)

This final rule codifies the revised definition of ''above-50-percent vendor'' as proposed to ensure any type of authorized vendor could also be classified as an above-50-percent vendor if it meets the conditions of the definition.

Commenters expressed general support for the new definition.

An opposed comment requested the ''above-50-percent vendor'' classification not apply to internet vendors for fear it would inhibit small vendors starting their internet presence with WIC. Other commenters stated that assessing for above-50-percent status would not be relevant for internet vendors as their statewide sales operations would be so large that they would never derive more than half of their sales from WIC.

Assessing for and monitoring above-50-percent vendors is an important part of the WIC Program's efforts to ensure State agencies can continue containing costs and avoiding fraudulent activity. The Department believes it remains important to evaluate all vendors, including internet and mobile vendors, for above-50-percent vendor status to ensure vendors that derive more than 50 percent of their annual sales revenue from WIC are appropriately monitored to prevent fraud. While it may be the case for some internet vendors, the Department cannot say with full certainty that all internet vendors will operate statewide and process enough in online sales to not meet the above-50-percent threshold. Therefore, it will remain a requirement for all vendor types to be assessed for ''above-50-percent vendor'' status.

The Department received a comment requesting clarification on whether an above-50-percent vendor is considered a vendor type, similar to how brick-and-mortar, internet, and mobile vendors are all types of vendors, or if instead it is a classification of vendor.

The Department clarifies an above-50-percent vendor is not a vendor type, but a classification of vendor. Any vendor that meets the definition of above-50-percent vendor, regardless of type, must be classified as an above-50-percent vendor.

Finally, a commenter recommended that USDA include a definition of ''regular vendor'' to account for vendors not classified as above-50-percent vendors.

The Department considered this request but concluded it was unnecessary and may cause additional confusion. The regulations at § 246.12 refer to ''regular vendors'' only when making comparisons to above-50-vendor vendors. As a ''regular vendor'' is any type of vendor that is not classified as an above-50-vendor, it is the assumed normal classification and does not need further defining.

c. Modernize the definition of ''vendor'' to be inclusive of new vendor types. [§§ 246.2 & 246.4(a)(14)(xv)]. The

provision revising the definition of vendor at § 246.2 is finalized with modifications to streamline the definition and remove the SNAP reference while maintaining that all vendors, regardless of type, must be separately authorized. The provision requiring State agencies to justify the need for mobile stores in their State Plans at § 246.4(a)(14)(xv) is removed as proposed.

i. Remove the requirement that vendors must have a single, fixed location, simplify the definition of vendor, and clarify that all vendors must be authorized separately. (§ 246.2)

This final rule codifies the revised definition of vendor at § 246.2 allowing State agencies to authorize the vendor types included in this final rule by removing the requirement that vendors must have a single, fixed location and that State agencies must delineate the different business structures of vendor applicants. The Department modified the provision to streamline the definition and removed the reference to SNAP.

Comments were overwhelmingly supportive of removing the requirement that State agencies may only authorize vendors with a single, fixed location. Commenters also supported simplifying the definition of vendor by replacing current regulatory language delineating different business structures that a vendor may have (*i.e.,* a sole proprietorship, partnership, cooperative association, corporation, or other business entity) with the term ''business entity.'' Commenters asserted this would benefit State agencies and vendors by decreasing the burden of determining the business structure during the vendor application process. No comments were opposed. Commenters generally supported the requirement that all vendors be authorized separately to support vendor management activities.

Some commenters stated the new vendor definition complicated whether each vendor, regardless of type, must be separately authorized, and recommended the definition be more concise. Some expressed concern about how to interpret the entity to be authorized as an internet or mobile vendor, as the proposed definition only discussed separate ''store'' locations. Some commenters expressed concern about the general reference to SNAP authorization in the definition, with some stating the reference should be either further clarified or removed.

The Department added ''each store, internet retailer, and mobile vehicle constitutes a unique vendor and must be authorized separately'' to the revised definition of vendor to clarify the unique entity that must be separately authorized as a vendor, regardless of affiliation with other vendors. This will require internet and mobile vendors to be separately authorized from brick-and-mortar vendors, which will support State agency vendor management activities such as authorizing, monitoring, and sanctioning individual vendors without impacting other authorized vendors that may be under the same responsible entity.

The Department agrees with streamlining the definition by removing the reference to SNAP authorization. At the time of the proposed rule, the Department believed that tying one SNAP authorization to one WIC authorization per State agency would be the most efficient way to ensure that cross-program integrity efforts could continue without interruption following the introduction of internet vendors. However, the WIC online shopping projects have since demonstrated that doing so may limit State agency options and flexibility for effectively managing their internet vendor population.

Requiring State agencies to authorize internet vendors separately from brick-and-mortar vendors (as discussed above in section V.1.b.ii) is sufficient to allow for ongoing coordination of vendor/retailer activities between WIC and SNAP (*e.g.,* reciprocal disqualifications, etc.) and enables WIC vendor integrity efforts to move forward consistently. Removing the reference to SNAP authorization in the vendor definition provides WIC State agencies the flexibility to authorize internet vendors using a method that best meets their vendor management needs. The separate authorization of each unique vendor is consistent with how the WIC Program currently authorizes vendors, and the separate authorization of internet vendors from brick-and-mortar vendors aligns with SNAP's authorization practices.

The Department would like to highlight that § 246.12(g)(9), which requires the State agency to collect a vendor applicant's SNAP authorization number if the vendor applicant is authorized in SNAP, is maintained in this final rule, which will continue to support State agency ability to ensure cross-program integrity efforts.

Commenters requested clarification on whether § 246.12(h)(1)(i) remains applicable, which permits State agencies to use a single agreement to cover multiple vendors operated by the same responsible entity (*e.g.,* chain stores).

The Department confirms § 246.12(h)(1)(i) remains applicable, and a vendor representative may obligate more than one vendor (*e.g.,* a single agreement to cover multiple vendors), as long as each vendor itself is authorized separately, and the agreement specifies all vendors covered by the agreement. Any administrative action the State agency applies must only be applied to the specific vendor with which the violation was found. This allows the State agency to, for example, disqualify a single store of a large chain without impacting other stores that are in compliance. This will continue to support State agencies in ensuring adequate participant access to vendors throughout their jurisdictions. As § 246.12(h)(1) is maintained in this final rule, State agencies can continue to sanction multiple vendors for a vendor violation committed by owners, officers, or managers of the responsible entity if the State agency determines that the vendor violation involves multiple vendors. Requirements related to changes in ownership of the vendor, per § 246.12(h)(3)(xviii), will apply to all vendors under the responsible entity as is currently required.

Some commenters expressed concern that the separate authorization of internet vendors would substantially increase the number of authorized vendors and associated vendor management activities.

The Department reiterates that an internet vendor completing internet-based WIC transactions through an online ordering system, platform, or site must be authorized as a unique vendor. However, the Department clarifies that a State agency may choose to authorize an internet vendor that fulfills its orders from any number of brick-and-mortar stores, fulfillment centers, or warehouses to serve throughout a State agency's entire jurisdiction as a single authorized vendor. The Department believes this will mitigate a State agency's vendor count increasing exponentially and allow retailers sourcing orders from multiple fulfillment locations the flexibility to participate in WIC in a minimally burdensome manner. The Department further notes an authorized internet vendor sourcing orders from multiple fulfillment locations would not need to show that each fulfillment location meets federal and State agency selection criteria, such as the minimum variety and quantity of supplemental foods, so long as the vendor can prove that their online ordering operations as a whole meet those criteria. State agencies retain the option to authorize each fulfillment location that meets the definition of a vendor and all federal and State agency selection criteria as a unique internet

vendor, if that approach allows them to best manage and oversee their internet vendor population.

ii. Remove a clause in the definition of ''vendor'' requiring a special needs justification for mobile vendors and remove associated language from the State Plan requirements. (§§ 246.2 and 246.4(a)(14)(xv))

This final rule codifies the removal of the requirement in the definition of vendor at § 246.2 for State agencies to justify mobile vendors in the State Plan at § 246.4(a)(14)(xv).

This change received overwhelming support, with commenters stating this will allow State agencies to authorize mobile vendors more efficiently and will remove the burden of justifying authorization. Commenters suggested this change will better serve WIC participants with barriers to accessing brick-and-mortar vendors. No comments were opposed.

d. Allow vendors to return electronic benefits to a participant's benefit balance [§§ 246.12(h)(3)(ii) No substitutions, cash, credit, cash refunds, or exchanges, (ii)(A) and (C), § 246.12(x)(2)(iii), and § 246.12(x)(4) Return of benefits, (4)(i), (4)(ii), and (4)(iii)]. The provisions clarifying cash refunds are still prohibited, § 246.12(h)(3)(ii) No substitutions, cash, credit, cash refunds, or exchanges, and (ii)(A), are finalized with modifications to clarify further what types of cash refunds are prohibited. The provision to update the exchange policy to accommodate recalls, § 246.12(h)(3)(ii)(C), is finalized with modifications to reflect changes from the Implementation of the Access to Baby Formula Act of 2022 and Related Provisions Final Rule by clearly defining a supplemental food recall in 7 CFR 246.2. The provision to allow vendors to return electronic benefits to a participant's balance, § 246.12(x)(4) Return of benefits, is finalized with modifications to allow returns with any vendor type, not just internet vendors, and to include timeframes in which benefits must be returned in § 246.12(x)(4)(i) and (ii), and to clarify State agencies must provide at least until the end of the original benefit issuance period for participants to use returned electronic benefits, and that it is a State agency option to allow participants to transact returned benefits after the last date of use (LDTU) for up to seven (7) days after the LDTU, § 246.12(x)(4)(iii). The provision describing the last date of use, § 246.12(x)(2)(iii), is finalized with modifications to reflect this new flexibility of using returned benefits after the last date of use.

i. Clarify that cash refunds are still prohibited and update the exchange policy to accommodate recalls, ensuring that WIC shoppers are treated the same as other customers in the event of a recall. (§ 246.12(h)(3)(ii) No substitutions, cash, credit, cash refunds, or exchanges, (ii)(A), and (ii)(C))

This final rule codifies the revised provision regarding prohibition of cash refunds, § 246.12(h)(3)(ii) No substitutions, cash, credit, cash refunds, or exchanges, and (ii)(A), with modification to specify the types of refunds for supplemental foods that are not allowable. This final rule also codifies the provision § 246.12(h)(3)(ii)(C) explaining the requirement for exchanging supplemental foods to ensure all customers, including WIC shoppers, are treated the same in the event of a supplemental food recall, as defined at § 246.2.

Multiple commenters supported the clear prohibition of cash refunds, and no comments were opposed. One commenter noted there are other types of refunds commonly used beyond cash that should also be prohibited, such as store credit and gift cards.

The Department agrees that refunds other than cash should not be provided in exchange for supplemental foods and modified § 246.12(h)(3)(ii)(A) accordingly to include a prohibition on cash-like refunds, including but not limited to store credit and gift cards.

Many commenters supported the new provision at § 246.12(h)(3)(ii)(C) requiring vendors to treat all customers, including WIC shoppers, the same in the event of a supplemental food recall. Commenters referenced the infant formula recall of 2022 and how the changes would help ensure that WIC participants can be treated like all other customers.

One commenter understood this new provision to conflict with the updated prohibition on cash refunds at § 246.12(h)(3)(ii)(A), and other commenters requested clarification on what is considered a ''substitute product.'' Others expressed concern that customers would be charged for new items in the replacement process.

The Department clarifies that under ordinary circumstances, cash refunds are not allowed in WIC. Vendors are only allowed to provide cash refunds when supplemental foods are recalled, as described in § 246.12(h)(3)(ii)(C), and only if (1) doing so aligns with store policies and (2) cash refunds are also provided to non-WIC customers impacted by the recall. Similarly, if the vendor provides replacement products or store credit during a recall, this provision requires WIC participants to be allowed those same courtesies.

Following publication of the Implementation of the Access to Baby Formula Act of 2022 and Related Provisions Final Rule, which codified the definition of recall at § 246.2 as it pertains to supplemental foods, the Department modified the provision at § 246.12(h)(3)(ii)(C) to clarify this provision only applies during a supplemental food recall, rather than any type of supply chain disruption. The Department will not strictly define ''substitute product'' or require the vendor or State agency to approve substitute products for supplemental foods in the event of a recall. The Department believes doing so would negate the intent of this provision, that vendors treat WIC participants the same as non-WIC shoppers in the event a supplemental food is recalled. Vendors treating WIC participants the same as any non-WIC shopper in the instance of a supplemental food recall includes not charging participants for replacement items.

ii. Allow for the return and use of returned electronic benefits. (§ 246.12(x)(4) Return of benefits, (4)(i), and (4)(ii))

This final rule codifies provisions for the return of electronic benefits to a participant's benefit balance at § 246.12(x)(4) Return of benefits, with modifications to allow for the return and use of electronic benefits for all WIC shoppers regardless of vendor type and clarifies the timeframes in which benefits must be returned in § 246.12(x)(4)(i) and (ii). Many commenters supported these provisions with no comments opposed.

The Department originally proposed that benefits only be returned in instances when an online order is not fulfilled. Multiple commenters discussed concerns related to this provision as proposed, stating that WIC participants shopping in-store do not have the option to make returns and suggesting the return of benefits should not only apply to those shopping online. Commenters also discussed the technical infeasibility of only allowing returns for online orders, and that if implemented as proposed, the burden of confirming the original transaction took place online would fall on each individual cashier.

The Department recognizes and agrees with the concerns raised by commenters. With the proposed provision, the Department intended to ensure WIC participants shopping online have recourse in the event an item is missing or incorrectly fulfilled and that the State agency is only

charged for foods received by the participant. The Department modified this provision to allow for the return of electronic benefits for all vendor types. This is intended to promote an improved WIC shopping experience for participants, to ensure vendors are treated consistently regardless of vendor type, and to accommodate the technical capabilities of vendor systems. If the State agency authorizes internet vendors, they must also allow for the return of electronic benefits for all other vendor types, to include transactions that take place at a brick-and-mortar or mobile vendor. If a State agency does not authorize internet vendors, they have the option—but are not required—to allow for the return of electronic benefits for other authorized vendor types.

Some commenters expressed concern with the lack of required timeframe for an internet vendor to initiate the return of electronic benefits. The Department agrees that a required timeframe for the return of electronic benefits will help ensure participants can use returned electronic benefits within a reasonable timeframe. Therefore, the Department modified the provision to include language requiring the timeframes in which the vendor must process the return of electronic benefits. If the participant returns an item in-person, regardless of where the item was purchased, the vendor must process the return of electronic benefits immediately so that the participant has the option to use their benefits while at the store. For post-delivery returns, such as those returned via mail or for an order that was incorrectly fulfilled or not fulfilled at all, the vendor must process the return of electronic benefits within two (2) company business days after receipt of the returned item or indication of an incorrectly fulfilled or unfulfilled item. This aligns with SNAP policies for returning items ordered online.

One commenter noted current regulations require State agencies to issue a three-year sanction to vendors that charge for food not received, without exceptions for returned electronic benefits.

The commenter is correct that per § 246.12(l)(1)(iii)(E), the State agency must disqualify a vendor for three years for a pattern of charging for supplemental foods not received by the participant. The Department highlights that each State agency develops their own definition of a pattern for each violation, with discretion over what constitutes a pattern including frequency of violation, time periods, and dollar amounts. As discussed above, the Department added language requiring vendors to initiate the return of electronic benefits within two (2) days of indication that an order was unfulfilled. So, for example, if the State agency determines there is a pattern of unfulfilled orders from a given vendor and the electronic benefits are not being appropriately returned to the participant's balance, the State agency may use its definition of pattern to identify this as a violation and take appropriate follow up action per § 246.12(l)(1)(iii)(E).

Some commenters stated that as EBT, MIS, and vendor systems exist now, it is not possible to return electronic benefits to the participant's balance. The Department understands that currently, systems do not allow for the return of electronic benefits because of the previous regulatory prohibition. With this final rulemaking, the Department encourages system updates to accommodate the return of electronic benefits, a requirement for State agencies authorizing internet vendors and an option for all others.

Many commenters highlighted the need for guidance on managing substitutions when an order is submitted but the specific item requested is not available when the order is fulfilled.

The Department agrees and intends to work with State agencies to develop guidance and provide best practices for managing substitutions separate from this rulemaking.

iii. At State agency option, allow participants the flexibility to transact returned electronic benefits up to seven (7) days beyond the last date of use (LDTU). (§§ 246.12(x)(2)(iii) and 246.12(x)(4)(iii))

This final rule codifies a State agency option to allow participants to use returned electronic benefits up to seven (7) days beyond the LDTU at § 246.12(x)(4)(iii) and makes related modifications to the last date of use provision at § 246.12(x)(2)(iii). This is a modification from the proposed rule which *required* State agencies to provide this flexibility. This final rule requests comment specifically on the impacts of requiring the return of benefits after the LDTU to better understand the costs and burdens that these required flexibilities could have on stakeholders and their systems.

Multiple commenters expressed support for this provision noting it allows participants time to use electronic benefits returned to their benefit balance.

The Department originally proposed that State agencies must allow returned benefits to be available for participant use for a minimum of seven (7) days after the return, which could extend into the next benefit period. Many commenters expressed concerns related to the technical challenges of allowing for the use of electronic benefits after the LDTU, explaining this would require significant changes to MIS and EBT systems, and could impact vendor systems. Many commenters strongly recommended that returned electronic benefits only be allowed for use within the current benefit period to implement this change more easily and cost-effectively. Multiple commenters also said the instances in which participants would need to use returned benefits after the LDTU would be rare and that these situations were better mitigated with continued participant education that encourages participants to use their electronic benefits well before the benefit LDTU.

The Department recognizes the technical challenges of allowing the use of returned electronic benefits after the LDTU and does not want these to be a barrier to innovating the WIC shopping experience, including implementing online shopping. Due to the concerns raised and the desire to support State agencies implementing online shopping, the Department modified the minimum amount of time State agencies must provide participants to use returned electronic benefits from ''no less than 7 calendar days'' to ''the remainder of the benefit issuance month.'' Electronic benefits that are returned to a participant's balance must be available for use within the original benefit issuance month, but the State agency is not required to allow use of returned electronic benefits beyond the LDTU. This minimum amount of time better aligns with program operations and benefit issuance systems. To support those State agencies with providing greater flexibility to their participants, the Department is making the use of returned electronic benefits after the LDTU allowable as a State agency option. The Department recognizes that for State agencies that do not take this option, there may be some participants who will have a reduced amount of time to transact their returned benefits if they are returned in the last few days of the benefit issuance month. However, the Department agrees with public comment that the instances in which participants would need to use returned benefits beyond the LDTU would be rare and are better mitigated with continued participant education. In these situations, where State agencies do not opt to allow the use of returned benefits beyond the LDTU, the Department notes

that all participants maintain the ability to exchange identical authorized supplemental foods per § 246.12(h)(3)(ii)(A).

To support State agencies in implementing this flexibility in the long term, the Department is requesting comment regarding the impact on stakeholders if State agencies were required to allow the use of returned electronic benefits beyond the LDTU. The Department requests input that includes a discussion of:

- The technical changes that would be necessary to allow this functionality,
- The cost of changing the MIS and EBT systems to allow this functionality,
- The cost of this type of change for vendor systems,
- The specific impact on reporting and infant formula rebates and contracts, and
- Any other comments or concerns related to this type of functionality.

The Department appreciates specific, detailed comments on the use of returned electronic benefits beyond the LDTU and will use feedback received to inform future rulemaking.

Commenters also requested clarification on whether there was a maximum number of days beyond the LDTU in which a participant may use returned electronic benefits, expressing concern that as proposed, returned electronic benefits would be available in the benefit balance indefinitely.

It is a core tenet of the WIC Program that benefits are intended to be used within the month they are issued, and it would be inconsistent with that tenet for benefits to be available indefinitely. The Department has modified the provision to establish a maximum of seven (7) days that returned electronic benefits can be used after the LDTU for State agencies that allow this flexibility. This provides uniform direction for State agencies regarding how long returned electronic benefits may be available for participants to transact, should State agencies pursue this option.

Commenters discussed issues of fairness with the provision as proposed, stating that participants facing transaction challenges in-store do not have an opportunity to use their electronic benefits beyond the LDTU in the event of issues such as vendor system problems, card errors, or family crises. As a solution to this issue, many commenters requested a full rollover of all unredeemed electronic benefits to the next month.

The Department clarifies that because the return of electronic benefits is allowed for all vendors and not just internet vendors, the option for using returned benefits beyond the LDTU applies to all participants, not just those using online shopping. Additionally, it is important to note this provision is addressing a specific situation that applies to those electronic benefits that have been transacted but subsequently returned to the participant's benefit balance. This provision is not permitting the ''rollover'' of electronic benefits that were never transacted. Other scenarios that impact benefit transaction, such as issues related to vendor system problems and card errors, are out of the scope of this rulemaking.

Some commenters expressed concern about the over-issuance of electronic benefits if participants are allowed to transact electronic benefits from one issuance month during the following issuance month. The Department clarifies that this is not over-issuance as the State agency is not issuing benefits in excess of the participant's maximum quantities of supplemental foods but is instead extending the dates of use for validly issued electronic benefits.

e. Allow State agencies to develop virtual methods of oversight [§§ 246.2 and 246.12(g)(5) and (j)(6)(ii)(B)]. Provisions in this section allowing virtual methods of routine monitoring, compliance buys, and preauthorization visits are finalized as proposed.

i. Update the definitions of ''routine monitoring'' and ''compliance buy'' to remove the on-site requirement. (§ 246.2)

This final rule codifies revisions to the definitions at § 246.2 of ''routine monitoring'' and ''compliance buy'' as proposed to remove the requirement that routine monitoring visits and compliance buys must occur on-site.

Multiple commenters expressed general support for allowing State agencies to develop virtual methods of oversight, stating that it will be necessary to support the authorization of internet vendors. Commenters also stated it would support consistent monitoring in the face of environmental challenges and referenced the success of virtual monitoring during the COVID–19 pandemic. No comments were opposed.

Commenters requested clarification on whether on-site monitoring is still an option, or if all oversight must take place virtually.

The new definitions do not require State agencies to use virtual methods of oversight, they instead provide State agencies the opportunity to develop virtual methods of oversight to ensure that monitoring and investigative methods are appropriate for the types of vendors authorized (*e.g.,* internet vendors) and environmental conditions. With this change, State agencies can pursue new types of monitoring and investigative methodologies, yet still retain discretion over how these activities are implemented.

Commenters requested clarification on if the new vendor types change the requirements regarding monitoring and compliance, specifically the number of monitoring and compliance activities the State agency must complete each fiscal year.

The only changes to routine monitoring and compliance buys in this rulemaking are to remove the on-site requirement. The number of monitoring and compliance investigation activities that the State agency must complete remains the same.

ii. Introduce virtual visits as an allowable type of preauthorization visit. (§ 246.12(g)(5))

This final rule codifies revisions as proposed to introduce virtual visits as an allowable type of preauthorization visit at § 246.12(g)(5). Commenters supported this provision, stating the proposed change is effective and will reduce costs, and the flexibility proved helpful in supporting State agencies in continued authorization of vendors during the COVID–19 pandemic. No comments were opposed.

Some comments sought clarification on whether virtual preauthorization visits were a requirement and asked the Department to define a virtual visit.

As with virtual options for routine monitoring and compliance buys made possible through this rulemaking, virtual preauthorization visits are not a requirement, but an option for the State agency to use to authorize new vendor types efficiently and to respond to environmental conditions appropriately. The Department clarifies virtual preauthorization visits can be used for any vendor type and are not just for internet vendors. The Department does not define a virtual visit in regulation but clarifies the purpose of the preauthorization visit is to verify the information provided on the vendor application, and to ensure the vendor applicant meets the selection criteria used by the State agency to select vendors for program authorization. This applies to internet and mobile vendors the same as it applies to brick-and-mortar vendors.

f. Prohibit vendors, farmers or farmers' markets from charging State agencies fees associated with WIC purchases and permit WIC shoppers to pay such fees [§§ 246.12(h)(3)(xxxiii) and (v)(1)(ix) and 246.14(b)(1)(i)]. The finalized provisions prohibiting vendors at § 246.12(h)(3)(xxxiii) and farmers or farmers' markets at § 246.12(v)(1)(ix)

from charging State agencies fees associated with online shopping are modified to include the prohibition of charging fees associated with any WIC purchase, not just online shopping purchases. The provisions clarifying that State agencies can still pay costs associated with home food delivery and direct distribution at § 246.14(b)(1)(i) and (c)(4) are modified to clarify that State agencies can continue using food funds to pay for the cost of transporting food under these two food delivery systems, as opposed to the retail food delivery system in which State agencies cannot use food funds to pay for the cost of transporting food.

i. Prohibit vendors, farmers, and farmers' markets from charging State agencies fees associated with WIC purchases and permit WIC shoppers to pay such fees. (§§ 246.12(h)(3)(xxxiii) and 246.12(v)(1)(ix))

This final rule codifies the provision at § 246.12(h)(3)(xxxiii) prohibiting vendors from charging State agencies fees associated with online ordering and with modifications to clarify this prohibition applies to all vendors and fees associated with WIC purchases to ensure consistency for vendors and shoppers. The provision at § 246.12(v)(1)(ix) regarding farmers and farmers' markets is finalized with similar modifications to reflect the prohibition on all fees, rather than just online shopping fees. This final rule also codifies in both provisions that participants must be allowed to pay such fees using a different form of tender.

Many commenters supported these provisions, expressing that State agencies should not pay online shopping fees as online shopping is a customer preference. Commenters also supported the requirement that participants be allowed to pay these fees using another tender type, if the same fees are charged to non-WIC shoppers, to ensure WIC customers are treated the same as non-WIC customers.

As the proposed provision only prohibited vendors from charging fees associated with online ordering, some commenters recommended modification to include fees charged by other WIC vendor types, such as bag fees or convenience fees. Commenters stated that to ensure vendor types are treated equally, any fees vendors charge shoppers as part of or in addition to their purchase should not be charged to State agencies.

The Department agrees the prohibition of vendors charging State agencies fees associated with WIC purchases should not be dependent on the type of vendor. To ensure State agencies hold all vendor types to the same federal regulatory requirements, the Department modified the regulatory language to reflect that vendors must not charge State agencies for any fees associated with a WIC purchase, including but not limited to delivery, service, convenience, or bag fees. If there is a fee associated with the purchase, the participant must have the opportunity to pay that fee using another tender type. To ensure the same policy applies to farmers and farmers' markets, related changes were made to § 246.12(v)(1)(ix). These provisions are not applicable to EBT costs, including operational costs, interchange fees, and third-party processing fees. The regulations related to EBT fees are governed by § 246.12(h)(3)(xxviii), (xxix), (xxx), § 246.12(aa)(3) and (4) and remain unchanged by this rulemaking.

The Department requested specific feedback on whether State agencies should have the option to pay for fees associated with online shopping in a retail food delivery system with either (1) non-federal funding at State agency discretion and/or (2) federal funding in situations where it is deemed necessary to meet special needs. The Department appreciates the robust discussion provided by commenters and addresses this below.

Many commenters requested State agencies retain discretion on the use of non-federal funds to pay for such fees. Commenters shared that the use of federal funds under special circumstances would be particularly helpful for rural, remote, isolated, under-resourced, and participants with disabilities, and those impacted by disasters and public health emergencies, if targeted appropriately. Some commenters, however, stated that expanding the food package and serving all eligible participants should be the focus of discretionary federal WIC funds, and expressed concern about adequately containing the costs and ensuring program integrity if paying such fees using federal funds was deemed necessary.

The Department appreciates concerns regarding access to WIC benefits and efficient use of taxpayer funds. The Department also acknowledges State agencies are best suited to understand the unique needs of their participant population and believes State agencies should have flexibility to use non-WIC funds when available. Therefore, the Department confirms that non-WIC funds can be used at State agency discretion. This includes but is not limited to funds provided to the State agency by state, tribal or territorial governments, funds provided from non-profit organizations, or non-WIC federal funds available to the State agency, if it is an allowable use of those funds.

The Department thoroughly considered the comments regarding the special circumstances under which it would benefit participants to use federal WIC funds to pay these fees, especially to support access for participants in rural and remote locations or participants with disabilities. However, the Department also recognizes the concerns related to the limited federal funding available and the many questions related to how costs would be adequately contained, and ensuring program integrity if federal funds were to be used to pay such fees. Therefore, to maintain the integrity of the WIC Program and ensure that federal WIC dollars continue to be used for only food costs and the administration of WIC, the Department finalizes that federal WIC funds may not be used to pay these fees.

Some commenters requested the Department amend the equal treatment provision at § 246.12(h)(3)(iii) to allow for preferential treatment of WIC shoppers so that vendors can waive delivery fees for WIC customers. Some commenters likened delivery fees to sales taxes, and requested the Department create a similar regulation to § 246.12(h)(3)(vii) which prohibits the collection of sales tax on WIC foods.

The equal treatment provision at § 246.12(h)(3)(iii) has implications for program integrity and vendor management, both of which support cost containment in the WIC Program. Any revision to the equal treatment provision is out of the scope of this rulemaking. The Department acknowledges the collection on sales tax on WIC foods is prohibited, pursuant to the Child Nutrition Act at 42 U.S.C. 1786(c)(4). However, sales tax generates revenue for government services and is inherently different from the costs associated with shopping, such as delivery fees, which are fees charged by the vendor to provide a service. If the Department were to prohibit vendors from charging these fees altogether, it could force vendors to cover a cost that they do not cover for non-WIC shoppers and discourage vendors from providing online shopping options for WIC.

ii. Clarify costs associated with home food delivery and direct distribution to ensure State agencies still pay for the cost of transporting food under these two food delivery systems. (§ 246.14(b)(1)(i))

This final rule codifies the provision § 247.14(b)(1)(i) with modifications clarifying that WIC State agencies operating home food delivery or direct distribution food delivery systems may

continue using the food grant to pay for the cost of transporting food under these delivery systems. Commenters expressed general support for the clarifications, and no comments were opposed.

One comment recommended revising the provision on the grounds that it was difficult to understand.

The revisions to § 246.14(b)(1)(i) are intended to differentiate the costs that the State agency can charge to the food grant by food delivery system. To summarize, food funds can be used to pay for:

- Supplemental foods purchased by participants using WIC electronic benefits in a retail food delivery system, and/or
- The acquisition of supplemental foods provided to State agencies, local agencies, or participants, whichever receives the supplemental foods first, in a home food delivery system or a direct distribution delivery system.

The edits clarify that in a retail food delivery system, participants, not State agencies, purchase supplemental foods from retail vendors and that food funds cannot be used to pay for the delivery of those foods. In home food delivery and direct distribution systems, food funds can continue to be used to pay for shipping supplemental foods to State or local agencies, or participants, whichever receives the supplemental foods first.

2. Streamline and Modernize WIC Food Delivery

This final rule permits the remote issuance of electronic benefits to a participant's benefit balance, expands the definition of food instrument, updates the uniform food delivery systems provision to support State agency innovation, streamlines food delivery operations by recognizing that EBT data are a sufficient replacement for routine shelf price collection, and allows State agencies using a non-retail, home food delivery system to ship supplemental foods to a location designated by participants.

a. Permit the remote issuance of electronic benefits to a participant's benefit balance [§§ 246.4(a)(23), 246.7(f)(2)(iv), and 246.12(r)(2), (4), and (5)]. The provisions clarifying that paper food instruments must be picked up in person when in-person nutrition education or certification appointments are scheduled, § 246.12(r)(4), is finalized as proposed. The provision updating processing timeframes to support the remote issuance of benefits, § 246.7(f)(2)(iv), and the State Plan provision discussing remote benefit issuance policies, § 246.4(a)(23), are finalized as proposed. The provision allowing for the remote issuance of benefits and mailing of EBT cards at § 246.12(r)(5) is finalized with modifications that ensure the State agency has adequate program integrity measures in place for proof of participant receipt when EBT cards are issued remotely, and the provision at § 246.12(r)(2) describing signature requirements for benefit issuance is finalized with modifications that clarify a signature is only required when benefits are received in person.

i. Allow for the remote issuance of electronic benefits by separating the benefit issuance provisions for paper food instruments and cash-value vouchers from electronic benefit issuance, and update signature requirements. (§§ 246.12(r)(2), (4) and (5), and 246.7(f)(2)(iv))

This final rule codifies revisions separating paper food instrument and cash-value voucher issuance requirements from EBT card and electronic benefit issuance requirements. Changes to § 246.12(r)(4) describing the paper food instrument and cash-value voucher pick up are finalized as proposed. The EBT card and electronic benefit issuance provision, § 246.12(r)(5), is finalized with modifications requiring the State agency to have program integrity procedures in place for EBT cards that are issued remotely. This final rule codifies signature requirements for benefit issuance at § 246.12(r)(2), modifying the language to more explicitly state that a signature is required only when benefits are received in person. Updates to the processing timeframe requirements to support remote benefit issuance at § 246.7(f)(2)(iv) are finalized as proposed.

Many commenters offered significant support for changes supporting remote benefit issuance, stating it would allow for benefit administration in the event of a disaster or other public health emergencies and would provide maximum flexibility for WIC participants and staff. No comments were opposed.

Commenters requested clarification as to when participants could receive EBT cards and electronic benefits remotely, stating the language was unclear.

The Department clarifies that State agencies may mail EBT cards and issue electronic benefits remotely under any circumstances, including when the participant is scheduled for in-person appointments, as long as participants are still offered nutrition education in accordance with § 246.11(a)(2), the EBT cards and electronic benefits are issued within the processing timeframe requirements at § 246.7(f)(2)(iv), and the integrity of the program is not jeopardized.

Some commenters requested clarification of when participants must sign for the receipt of food instruments, cash-value vouchers, or authorized supplemental foods. The comments noted that language in the proposed rule did not explicitly state when signatures are required. Other comments expressed concern regarding how State agencies can ensure program integrity when EBT cards are mailed and benefits are issued remotely, as the participant is not receiving the EBT card in-person.

To clarify when a signature is required, the Department modified language at § 246.12(r)(2) to specify a participant must sign for the receipt of their food instruments/benefits only when receiving them in person. When food instruments are mailed and/or benefits are issued remotely, a signature is not required.

The Department agrees it is important to maintain integrity while allowing for remote benefit issuance. While signatures are not required when EBT cards are mailed and benefits are remotely issued, the Department added language in § 246.12(r)(5) to clarify State agencies must have procedures in place to ensure receipt of the EBT card by the intended recipient. WIC State agencies have discretion in developing procedures, and the Department expects State agencies to utilize best practices and lessons learned from remote issuance previously available through time-limited waiver authority. The Department intends to assist State agencies by sharing such best practices and providing additional technical assistance, as needed, to ensure the security of mailed EBT cards.

ii. Create new definitions of ''electronic benefits'' and ''cash-value benefits'' and update the definition of ''cash-value voucher.'' (§ 246.2)

This final rule codifies as proposed the new definitions at § 246.2 of ''electronic benefits'' and ''cash-value benefits'' to clearly define the benefits available to participants in the modern WIC Program. The rule codifies as proposed the revised definition of ''cash-value voucher'' to differentiate this type of paper food instrument from the newly defined ''cash-value benefits,'' which are a type of electronic benefit.

Commenters largely supported these changes, stating the new and updated definitions provide important flexibility.

Commenters recommended that all instances of ''cash-value voucher'' throughout the regulations be updated

to ''cash-value benefit'' to reflect the new definition. Other commenters expressed concerns that without appropriate edits to existing mandatory sanction language, inadvertent gaps will inhibit State agencies' ability to sanction vendors and recommended amending the sanctions provisions to reflect the new definitions.

The intent of this rule is to remove barriers to online shopping and take the first step in modernizing the language to reflect today's program. Due to the nature of this rulemaking, the Department could not fully update all regulations to reflect the new definitions. The Department intends to fully update and modernize the language, including updating regulations from ''cash-value voucher'' to ''cash-value benefit'' and the mandatory sanction language, in future rulemaking. However, the Department recognizes the need for consistent application of the definition of ''electronic benefits'' to ensure program integrity with respect to sanctions, and therefore affirms the remaining regulatory language enables State agencies to issue appropriate sanctions in the instances of vendor violations related to food instruments, cash-value vouchers, WIC electronic benefits, and supplemental foods.

b. Expand the definition of food instrument [§ 246.2]. This final rule codifies the proposed definition of ''food instrument'' in § 246.2 to allow WIC State agencies to explore and adopt new food instrument technologies.

Many commenters supported the updated definition of food instrument, stating this would enhance program flexibility and that updates allowed by this change could draw in younger WIC participants, mitigate stigma associated with the checkout process, and decrease program costs. No comments were opposed.

Some commenters recommended removing the word ''food instrument'' altogether, while others included recommendations to allow specific technology types, such as mobile wallets, near field communication (NFC) and quick response (QR) technology. Commenters also urged alignment with the SNAP mobile payments pilot.[13]

The Department decided not to name types of allowable technologies so as to not limit future innovation. Maintaining the term ''food instrument'' allows the Department to be inclusive of any future technologies beyond the EBT card. Where possible, the Department works to implement WIC and SNAP consistently. However, this rulemaking only governs regulations related to the WIC Program. With the implementation of new technologies, the Department will glean information from pilot projects in SNAP to inform technology development in WIC.

c. Update the uniform food delivery systems provision to support State agency innovation [§§ 246.2 and 246.12(b)]. The definition of ''electronic benefit transfer'' at § 246.2 is finalized as proposed to clarify that it is a benefit delivery method and not a food delivery system, and the food delivery provision at § 246.12(b) is finalized with modifications, allowing State agencies to permanently use more than one food instrument throughout a food delivery system.

i. Allow State agencies to develop and test new WIC food instrument types and clarify uniform food delivery systems and system combinations (§ 246.12(b)).

This final rule codifies the proposed uniform food delivery systems provision at § 246.12(b) to clarify that there are three food delivery systems—retail, home food delivery, and direct distribution. Modifications to the provision allow State agencies to make permanent new food instruments as long as the food instrument type is uniform and described and approved in the State Plan.

Many commenters supported allowing State agencies to develop and test new WIC food instrument types within a single food delivery system (*e.g.,* retail food delivery system). Supporters stated that this could enhance access to nutritious foods and provide State agencies with the ability to address the needs of different participants. No comments were opposed.

Multiple comments were concerned the conditions placed on the development and implementation of new food instruments would prevent State agencies from maintaining more than one food instrument type permanently. Commenters requested clarification from the Department about the intent of this provision and recommended that more than one food instrument type be allowed permanently.

The intent of this provision is to allow State agencies to explore new food instrument types to meet the needs of their diverse vendor and participant populations and to modernize benefit delivery as the grocery and payment industries innovate. For that reason, the Department has revised the language in this provision to clarify that State agencies can have more than one food instrument type (*e.g.,* an EBT card and a mobile wallet) within a single food delivery system. State agencies may introduce and make permanent new food instrument types but must keep the technology and functionality uniform within each type of food instrument. The Department will still require the use of new food instrument types to be described in the State Plan and approved by FNA per § 246.4(a)(14)(i).

Many commenters supported updates clarifying State agencies may use a combination of retail, home food delivery, and direct distribution systems. Supporters stated that allowing all three food delivery systems mitigates barriers to participant access related to geographic limitations and cited feedback from WIC participants expressing support for home food delivery options. Commenters also supported updates to the definition of electronic benefit transfer (EBT) clarifying it is a benefit delivery method, not a food delivery system. Supporters said these changes facilitate a better understanding of the definition of the term EBT and would allow for future modernizations.

Some comments requested clarification on the meaning of ''procedurally uniform'' and whether it relates to food instrument types, authorization processes, or transaction procedures.

The Department clarifies the meaning of ''procedurally uniform'' extends to the management of each food delivery system, as well as the use of food instruments by participants, to be consistent throughout the entire jurisdiction of the State agency. The intent of this is to ensure that State agencies are consistently applying vendor management and food delivery operations and procedures, and that the participant's experience using each food delivery system remains consistent throughout the State agency's jurisdiction.

d. Remove the requirement for State agencies to collect shelf price data, as EBT data are a sufficient replacement [§ 246.12(g)(4) Vendor selection criteria: competitive price, (g)(4)(ii)(B), and (g)(9)]. The removal of shelf price collection requirements in § 246.12(g)(4) Vendor selection criteria: competitive price, and (g)(4)(ii)(B), which allows State agencies to use EBT redemption data instead of shelf prices to monitor vendor compliance, is finalized with modifications that clarify State agencies re-authorizing currently authorized WIC vendors can use existing EBT data for price analysis. This final rule also removes the requirement at § 246.12(g)(9) that State agencies obtain

[13] SNAP Mobile Payment Pilot. *https://www.fna.usda.gov/snap/mobile-payment-pilot.*

shelf price data at vendor authorization if they have access to EBT data.

Many commenters provided support for these changes, stating they could mitigate burden and save time for State agencies and vendors. Other supporters asserted that using EBT data is more efficient and accurate for pricing trend analysis. No comments were opposed.

Some commenters highlighted that currently, State agencies can use an applicant vendor's EBT data if they are re-applying for authorization and questioned whether this would remain allowable under the revised regulation.

The Department clarifies that State agencies may continue using EBT data for an applicant vendor that is reapplying for authorization and made conforming edits to regulatory text.

Multiple commenters sought more information as to how pricing will continue to be monitored so that WIC participants are not charged more for foods than non-WIC participants.

The Department agrees with commenters on the importance of ensuring that vendors are not charging WIC participants higher prices than non-WIC shoppers. The Department clarifies the purpose of shelf price collection was to ensure cost competitiveness of a vendor applicant and that authorized vendors remained cost competitive when compared to vendors within their peer groups. With EBT, State agencies receive current data about vendors' prices in real time and can consistently ensure vendors are meeting cost competitiveness. While the regulatory requirement for collecting shelf prices is removed, the requirement to ensure cost competitiveness remains. The Department encourages State agencies to continue using EBT data in combination with effective peer groups, regular routine monitoring, and compliance investigations to ensure that participants are not being charged inappropriate prices for WIC supplemental foods.

Some commenters pointed out that by removing the requirement for shelf prices to be collected every six months, the Department also removed any timeframe requirement in which State agencies must collect price data and requested clarification if any timeframe requirements for analyzing price data remain.

The Department removed the requirement to collect shelf prices every six months where State agencies have EBT data, as updated EBT data is available to the State agency in real time. While the Department is not imposing a requirement for how often this data must be monitored, the practice of sound cost containment requires ongoing monitoring of EBT prices. The Department expects this monitoring to continue according to the timeframes defined in § 246.12. State agencies remain responsible for having procedures in place to ensure authorized vendors do not increase prices to levels that would make them ineligible for authorization by the program, per § 246.12(g)(4)(iii).

e. Allow State agencies using a non-retail, home food delivery system to ship supplemental foods to a location designated by participants and approved by the State agency [§§ 246.2 and 246.12(m)]. This final rule codifies revisions to the definitions of ''home food delivery contractor'' and ''home food delivery system'' in § 246.2 and § 246.12(m) with modifications to allow participants receiving supplemental foods under a home food delivery system to designate the location of food delivery. As an additional measure of program integrity, the provisions are finalized with modifications to allow State agencies to approve the location of delivery so that supplemental foods are delivered to a reasonable location.

Many commenters supported this change, stating that it promotes access and convenience for participants in remote areas, and works to enhance food access for participants. Other commenters shared this would promote flexibility and choice for participants, especially those in vulnerable communities.

A few commenters shared concerns that this change leaves the program vulnerable to fraud and benefit misuse, and recommended changes to the description of where food can be delivered in home food delivery systems. These commenters suggested State agencies should have the opportunity to confirm supplemental foods are being delivered to a reasonable location as an additional measure of program integrity. Commenters also asked if participants are required to designate the location of the delivery.

The Department confirms the intent of this provision is to accommodate State agencies whose participants cannot receive foods at their home and agrees allowing the State agency to designate or approve the participant's preferred delivery location supports this intent and provides for continued program integrity. In response, the Department made appropriate modifications to the regulatory language. The Department also clarifies the participant is not required to designate the location of the delivery and that State agencies retain the option to designate the location of the delivery.

Many commenters requested clarification on whether this provision applies to delivery options for participants using online shopping. The Department clarifies this provision is specifically for home food delivery food systems and does not apply to participants using online shopping in a retail food delivery system.

The Department will not adopt the proposed revisions to § 246.12(g)(8) and § 246.12(h)(1)(i), which proposed to increase the maximum length of vendor agreement periods in § 246.12(h)(1)(i), and the minimum frequency that State agencies must accept and process applications in § 246.12(g)(8), from three to five years. The Department received extensive feedback, and while many commenters supported these changes, asserting the alleviation of administrative burden on State agencies would lead to improved program efficiency, other commenters expressed concern this could negatively impact participant access if State agencies with five-year application periods only review vendor applications with that frequency. Other commenters encouraged USDA to not allow State agencies to limit application periods to every five years.

The Department will not finalize these two proposed revisions in this rulemaking. Therefore, the minimum frequency that State agencies must accept and process applications in § 246.12(g)(8), and the maximum length of vendor agreement periods in § 246.12(h)(1)(i) will remain at three years.

The Department notes that State agencies may and are encouraged to continue to reassess compliance with vendor selection criteria on an ongoing basis to ensure that vendors are adequately serving the WIC Program. State agencies retain the discretion to accept vendors at any time or establish application periods, with procedures for processing vendor applications outside of their timeframes.

3. Meet the Needs of a Modern, Data-Driven Program

The final rule updates reporting requirements necessary for federal oversight but will not adopt the proposed staffing standards for the food delivery coordinator role or new WIC State agency staff position.

a. Update reporting requirements for federal oversight [§ 246.12(j)(5)]. The provision in this section updating the reporting requirements for WIC food delivery systems is finalized with modifications at § 246.12(j)(5) to better reflect what WIC State agencies report to the Food Delivery Portal, and to

maintain the current requirement that State agencies report data annually.

Multiple commenters expressed general support asserting this will support the WIC Program's transition to an enhanced data collection system.

Multiple opposed commenters stated that allowing the Department to request quarterly data submissions would create a larger administrative burden on State agencies and their staff.

The Department appreciates the feedback provided by stakeholders on the impact this change would have on State agencies. After further analysis of the burden estimate associated with this change, as well as a thorough review of the public feedback provided on the Agency Information Collection Activities: Special Supplemental Nutrition Program for Women, Infants and Children (WIC); Food Delivery Portal (FDP),[14] the Department will not include the ability to request quarterly data submissions for federal reporting in regulation at this time. Therefore, the frequency of federal reporting requirements will be maintained as annual, and the Department is confident that the continued submission of annual data is sufficient to ensure federal oversight.

The Department proposed revisions to § 246.3(e)(3) to update the WIC Food Delivery Coordinator standard and to create a new WIC State agency staff position, the WIC Customer Service Coordinator.

The Department received extensive feedback on the proposed staffing standards and appreciates input from various stakeholders on the impact the standards may have on State agencies and the program. Some commenters expressed concern related to the stringency of the standards and potential to limit the pool of candidates from which they can hire. Other commenters recommended the Department not regulate the education and experience of these positions but instead describe the roles and associated responsibilities, leaving education and experience requirements to State agency discretion. The Department believes it is vital that State agencies have staff with the skills necessary to successfully operate the modern WIC Program. While the Department is working to provide increased opportunities for State agency staff to build the necessary skills, including providing opportunities for technical assistance and digital services capacity building, the Department acknowledges the concerns raised and to retain State agency flexibility and discretion in hiring decisions, the Department will not finalize the proposed provisions in this rulemaking. State agencies may optionally implement more stringent standards at the State level. Additionally, the Department may consider options to address the above concerns in future rulemaking.

4. Request for Public Comment on Key Topic Areas of Proposed Rule

a. Exceptions to minimum stocking requirements.

The Department received significant feedback and input from stakeholders related to the specific request for public comment on whether there is a need to authorize vendors that sell a specific subset of supplemental foods (*e.g.,* dairies, bakeries, produce sellers) but would not meet the minimum variety and quantity of supplemental foods, as required by WIC regulations (*i.e.,* two different fruits, three different vegetables, and at least one whole grain cereal per § 246.12(g)(3)(i)).

Given the overwhelming majority of comments shared concerns about the implementation of this change, including the impact it would have on State agency costs and oversight capacity, as well as the possible negative impact on small vendors, the Department will not introduce any changes to the minimum stocking requirements in this rulemaking. Commenters shared concerns that specialty stores sell fewer options at higher prices than non-specialty counterparts which would likely mean higher food costs, impacting peer grouping and cost-containment. Commenters also shared concerns about the extra workload for State agencies to authorize and monitor additional vendors that will likely have only a small amount of WIC transactions, and that retaining minimum stocking requirements helps make it more challenging for bad actors to fraud the program. Some commenters expressed concern that specialty stores would create competition with small vendors who struggle to meet requirements currently, potentially resulting in small vendors leaving the program. Due to these concerns, the Department will not introduce any changes to the minimum stocking requirements in this rulemaking. The Department will use the feedback provided to inform any future rulemaking related to exceptions to minimum stock and specialty vendors.

VI. Implementation

As most of the changes in this rule are optional and increase flexibility for State agencies, the Department proposed that the final rule would take effect 30 days after publication, except for the provisions related to the return of electronic benefits which State agencies would have 18 months to implement. The Department requested comments in the proposed rule on the administrative burden associated with the proposed implementation timeline.

Commenters generally highlighted time, limited resources, and extensive system changes needed to successfully implement some of the provisions in this final rule, especially those related to developing new transaction authentication policies. The Department reiterates that this rulemaking in large part introduces optional flexibilities that State agencies can choose to pursue on their own timeline and based on their capacity and interest. However, the Department acknowledges that several provisions will require all State agencies to update vendor agreements, policies, and procedures, and that many State agencies are currently using waivers to offer flexibilities that will be codified in this rulemaking. The Department is therefore extending the implementation deadline for the final rule to 90 days after publication, or no later than February 4, 2027, except for the provisions related to the return of electronic benefits.

Among the implementation challenges that commenters discussed were the EBT and MIS updates necessary to enable the return of electronic benefits. To provide WIC State agencies the time to develop and refine the technological solutions needed to allow for the return of electronic benefits, State agencies have until 24 months after the publication of the final rule, or no later than November 6, 2028, to comply with § 246.12(x)(4) Return of benefits (x)(4)(i), (x)(4)(ii) and (x)(4)(iii).

The final rule's effective date remains 30 days after publication, or December 7, 2026, as proposed. State agencies may choose to implement the rule's provisions in advance of the implementation deadlines listed above, following the effective date.

VII. Procedural Matters

Executive Orders 12866, 13563, and 14192

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

[14] Agency Information Collection Activities: Special Supplemental Nutrition Program for Women, Infants and Children (WIC); Food Delivery Portal (FDP) (89 FR 14622). *https://www.federalregister.gov/d/2024-04064.*

approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been determined to be economically significant under Executive Order 12866 section 3(f)(1) and was reviewed by the Office of Management and Budget (OMB).

Executive Order 14192 directs agencies to ensure the cost of new regulations does not place unnecessary burdens on the public. This final rule is an enabling regulation and therefore a deregulatory action under Executive Order 14192. The rule provides WIC State agencies with the flexibility to expand shopping options and explore new payment technologies, thereby resulting in potential time savings for participants and more efficient operations for State agencies.

Regulatory Impact Analysis

As required for all rules that have been designated as economically significant by the Office of Management and Budget, a Regulatory Impact Analysis (RIA) was developed for this rule. The complete RIA follows this rule as an Appendix. The following summarizes the conclusions of the regulatory impact analysis:

Need for Action

To ensure that participants in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) have access to the same shopping options as non-WIC shoppers, with the expansion of online shopping in the retail grocery industry and the development of new payment types, the Department is removing barriers to online shopping and modernizing certain food delivery regulations in the WIC Program through this rulemaking. This rule complements the Program's complete transition to electronic benefit transfer (EBT) and aims to meet the needs of a modern, data-driven program that uses current technologies for food delivery. These changes are expected to improve the WIC shopping experience while increasing access to healthy foods for WIC participants.

Costs

The Department estimates that the provisions under this rule will reduce costs for some stakeholders and increase costs and/or transfers for other stakeholders (Table 1).

The Department estimates that allowing WIC online shopping will increase federal WIC food spending, in the form of transfers, by a total of $315 million over the 5-year estimate period of FY 2027 to FY 2031. This is driven by an understanding that shoppers sometimes pay higher prices for online groceries and an expectation that online shopping will moderately increase WIC benefit redemption by making the WIC shopping experience more convenient for some participants.

The Department estimates that the rule will also result in around $32 million in net WIC State agency savings from FY 2027 to FY 2031. State agency savings will be driven by a large reduction in State agency reporting burden and recordkeeping burden, which is estimated to result in a savings of $50 million over 5 years and is largely attributable to the removal of shelf price collection requirements for EBT State agencies.[15] These savings will be partially offset by an estimated $18 million in total 5-year expenses required to update State agency systems to enable online transaction of WIC electronic benefits in State agencies adopting online shopping during this time.

In State agencies that allow WIC online shopping, WIC participants who choose to redeem at least some of their food benefits online are expected to save time by reducing how often they travel to purchase groceries in-store. Over 5 years from FY 2027 to FY 2031, the amount of travel time WIC participants save by replacing one in-store shopping trip with an online order per month is expected to be valued at a total of $103 million. This time savings will increase as more State agencies offer online shopping and as more participants choose redeem benefits online. Similarly, the provision allowing remote issuance of benefits also generates notable time savings to WIC participants by enabling less frequent visits to WIC clinics to reload their benefits between regular appointments. This time savings is estimated to be worth $92 million over 5 years for WIC participants.

Finally, the removal of shelf price collection requirements is also expected to significantly reduce burden on WIC vendors. The Department estimates that the reductions in vendor reporting burden under the rule will save WIC vendors $18 million over 5 years.

TABLE 1—SUMMARY OF ESTIMATED IMPACTS ON TRANSFERS AND COSTS, FY 2027–2031

	Fiscal year (millions)					
	2027	2028	2029	2030	2031	Total
Federal Transfers:						
Impact of online shopping on federal WIC food spending	$33.5	$41.8	$59.0	$78.8	$101.4	$314.5
State Agency Costs:						
Systems development and maintenance for online shopping	2.8	1.9	3.1	4.7	5.2	17.7
Changes to reporting and recordkeeping burden	−9.5	−9.8	−10.0	−10.2	−10.4	−49.9
WIC Vendor Costs:						
Changes to administrative burden	−3.4	−3.5	−3.6	−3.7	−3.8	−18.0
WIC Participant Costs:						
Time savings of online grocery shopping	−11.0	−13.7	−19.4	−25.9	−33.3	−103.4
Changes to administrative burden	−17.6	−18.0	−18.4	−18.9	−19.3	−92.3

Notes: All monetary figures are adjusted for annual inflation.

[15] In a comment, one State agency noted that, since they have an exemption allowing them to forego collecting shelf prices, this provision does not result in administrative savings for them. Nevertheless, the Department recognizes this provision as a cost savings to State agencies in this analysis because this regulatory change makes the temporary savings permanent. This is consistent with how the Department has valued both savings and costs associated with making temporary program changes permanent via regulation in the past; see, for example, the Child Nutrition Program Integrity final rule (available online at *https://www.federalregister.gov/documents/2023/08/23/2023-17992/child-nutrition-program-integrity*) or the Revisions in the WIC Food Package final rule (available online at *https://www.federalregister.gov/documents/2024/04/18/2024-07437/special-supplemental-nutrition-program-for-women-infants-and-children-wic-revisions-in-the-wic-food*).

Benefits

The provisions under this rule modernize the ways that WIC participants can receive and transact their electronic benefits. An estimated 14 percent of the U.S. population lives in low-income census tracts with limited access to food stores,[16] and 21 percent of WIC participants report using a means of transportation other than their own personal car to travel to a vendor to use their WIC benefits.[17] By comparison, 95 percent of higher income households (above 185 percent of the federal poverty line) use their own vehicle to travel to a grocery store.[18] Once at the vendor, participants also report challenges shopping for WIC foods. Recent USDA survey data indicate that finding the right WIC-approved products in stores, WIC-approved products being out of stock, and feeling embarrassed shopping for WIC foods are some of the most cited challenges among WIC participants who report difficulties shopping for WIC supplemental foods.[19] Online shopping may alleviate some of these issues for WIC participants and has the potential to provide benefits during supply chain disruptions.

Enabling online shopping in WIC under this rule is expected to ensure that WIC participants have access to innovations in the retail marketplace while maintaining program integrity, and to increase participant purchases of supplemental foods. Online shopping may also expand WIC participants' choices when they shop, particularly for authorized substitutions needed to meet certain dietary restrictions that may not be readily available at the closest WIC-authorized grocery stores. The rule will further make WIC more convenient and accessible by encouraging State agencies to remotely issue electronic benefits and mail EBT cards whenever possible, potentially reducing the number of clinic visits that WIC participants are required to make. The rule also includes provisions that will streamline and modernize WIC food delivery by promoting innovation and ensuring that State agency reporting requirements reflect a modern, data-driven program. These provisions provide necessary measures to ensure that State agencies can deliver a more efficient and effective program for WIC participants.

Finally, preliminary evidence suggests online ordering generally supports higher diet quality or more healthful food purchasing decisions among SNAP participants.[20] [21] To the extent that this rule facilitates healthier food shopping among WIC participants, this rule is likely to lead to better nutrition outcomes for WIC participants.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires Agencies to analyze the impact of rulemaking on small entities and consider alternatives that would minimize any significant impacts on a substantial number of small entities. Pursuant to that review, it has been certified that this final rule does not have a significant impact on a substantial number of small entities.

The provisions of this final rule primarily affect WIC State agencies and WIC-authorized vendors. Otherwise, all other provisions apply to all State agencies administering the WIC Program, regardless of size, and largely can be implemented at State agency option. The Department does not expect this final rule to have a significant impact on small State agencies.

Large retailers may be able to implement WIC online shopping more readily than other store types. However, the Department does not expect the final rule to have a lasting or significant negative impact on smaller WIC vendors as WIC sales represent a relatively small share of these stores' revenue. The Department does not routinely track data necessary to determine how WIC benefit redemptions vary by most vendor characteristics, including indicators for whether the store is a small business or independent grocer. USDA's ERS estimated, by merging WIC and SNAP redemption databases, that 76 percent of WIC retail redemptions occurred in larger stores (super stores, supermarkets, or large grocery stores) in FY 2012; however, the study's definition of supermarkets and large grocery stores is inclusive of many independent grocers.[22] The Department does not have data on the extent to which small businesses and independent grocers have implemented online shopping to date, but is aware of products on the market being employed by independent grocers to provide online ordering currently for WIC participants (with in-store or curbside transactions).

If smaller WIC vendors (such as convenience stores or small and medium grocery stores) do not adopt online shopping solutions, then they may see some of their WIC revenues lost to larger retailers that provide online shopping. According to ERS data, in FY 2012, small grocery stores, medium grocery stores, and convenience stores accounted for 2.9 percent, 3.5 percent, and 3.8 percent of WIC retail redemptions, respectively. For example, the 3.8 percent of total WIC benefits transacted at convenience stores in FY 2012 amounts to about $228 million. U.S. convenience stores reported an estimated $193 billion in total in-store sales, not including fuel, in 2012, suggesting that WIC redemptions represented only about 0.12 percent of non-fuel sales for convenience stores that year.[23] As WIC sales make up a relatively small fraction of the total revenue of smaller stores, and especially convenience stores, the Department expects any lost revenue for smaller vendors that do not adopt an online

[16] Rhone, A., Williams, R., & Dicken, C. (June 2022). Low-Income and Low Foodstore-Access Census Tracts, 2015–19, EIB–236, U.S. Department of Agriculture, Economic Research Service. Available online at: *https://www.ers.usda.gov/publications/104157*.

[17] Magness, A., Williams, K. Gordon, E., Morrissey, N., Papa, F., Garza, A., Okyere, D., Nisar, H., Bajowski, F., & Singer, B. (2021). Third National Survey of WIC Participants: WIC Participant Satisfaction and Shopping Experience: Brief Report #6. Prepared by Capital Consulting Corporation and 2M Research Services. Contract No. AG–3198–K–15–0077. Alexandria, VA: U.S. Department of Agriculture, Food and Nutrition Service, Office of Policy Support, Project Officer: Karen Castellanos-Brown. Available online at: *https://www.fna.usda.gov/wic/third-national-survey-wic-participants*.

[18] Ver Ploeg, Michele, Lisa Mancino, Jessica E. Todd, Dawn Marie Clay, and Benjamin Scharadin. Where Do Americans Usually Shop for Food and How Do They Travel To Get There? Initial Findings From the National Household Food Acquisition and Purchase Survey, EIB–138, U.S. Department of Agriculture, Economic Research Service, March 2015. Available online at: *https://www.ers.usda.gov/publications/pub-details/?pubid=79791*.

[19] Gleason, S., Wroblewska, K., Trippe, C., Kline, N., Meyers Mathieu, K., Breck, A., Marr, J., Bellows, D. (2022). WIC Food Cost-Containment Practices Study. Prepared by Insight Policy Research, Contract No. AG–3198–C–15–0022. Alexandria, VA: U.S. Department of Agriculture, Food and Nutrition Service, Office of Policy Support, Project Officer: Ruth Morgan. Available online at: *https://www.fna.usda.gov/wic/wic-food-cost-containment-practices-study*.

[20] Avelino DC, Duffy VB, Puglisi M, Ray S, Lituma-Solis B, Nosal BM, Madore M, Chun OK. Can Ordering Groceries Online Support Diet Quality in Adults Who Live in Low Food Access and Low-Income Environments? Nutrients. 2023 Feb 8;15(4):862. https://doi/org/10.3390/nu15040862. PMID: 36839221; PMCID: PMC9964317.

[21] Kuan, I., Liu, Y., Jones, J., Zhou, P. (2025). ''SNAP Online Purchasing and the Healthfulness of Food Purchases.'' *Applied Economic Perspectives and Policy* 47(3): 914–932. *https://doi.org/10.1002/aepp.13528*.

[22] Tiehen, L. and Frazão, E. Where Do WIC Participants Redeem Their Food Benefits? An Analysis of WIC Food Dollar Redemption Patterns by Store Type, EIB–152, U.S. Department of Agriculture, Economic Research Service, April 2016. Available online at: *https://www.ers.usda.gov/publications/44076*.

[23] Statista. ''Sales of the convenience store industry in the United States from 2011 to 2020, by format'' 27 January 2022. Available online at: *https://www.statista.com/statistics/308767/sales-of-the-us-convenience-store-industry-by-format/*.

shopping solution to be relatively minor.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local and Tribal governments, and the private sector. Under section 202 of the UMRA, the Department generally must prepare a written statement, including a cost benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by State, local or Tribal governments, in the aggregate, or the private sector, of $100 million or more (adjusted annually for inflation) in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires the Department to identify and consider a reasonable number of regulatory alternatives and adopt the most cost effective or least burdensome alternative that achieves the objectives of the rule.

This final rule does not contain Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local and Tribal governments, or the private sector of $100 million or more (adjusted annually for inflation) in any one year. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Executive Order 12372

The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) is listed in the Catalog of Federal Domestic Assistance under Number 10.557 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials (see 2 CFR chapter IV). Since WIC is State-administered, USDA's FNA Regional Offices have formal and informal discussions with State and local officials, including representatives of Indian Tribal Organizations, on an ongoing basis regarding program requirements and operations. This provides USDA with the opportunity to receive regular input from program administrators and contributes to the development of feasible program requirements.

Federalism Summary Impact Statement

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under section (6)(b)(2)(B) of Executive Order 13132. The Department has considered the impact of this rule on State and local governments and has determined that this rule does not have federalism implications. Therefore, under section 6(b) of the executive order, a federalism summary is not required.

Executive Order 12988, Civil Justice Reform

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is intended to have preemptive effect with respect to any State or local laws, regulations, or policies which conflict with its provisions or which would otherwise impede its full and timely implementation. This rule is not intended to have retroactive effect. Prior to any judicial challenge to the provisions of this final rule, all applicable administrative procedures must be exhausted.

Civil Rights Impact Analysis

FNA has reviewed the final rule, in accordance with the Agriculture Improvement Act of 2018, ''2018 Farm Bill,'' Section 12403, Civil Rights Analyses, to identify and address any major civil rights impacts the final rule might have on participants on the basis of race, sex, national origin, disability, or age. The requirements outlined in the final rule aim to remove barriers to online ordering and internet-based transactions, streamline and modernize WIC food delivery, and meet the needs of a modern, data-driven program that uses current food delivery technologies. The changes impact WIC State agencies, including ITOs, WIC local agencies and clinics, and WIC vendors in ways that are expected to increase equity and access for WIC participants and enhance the overall shopping experience.

In particular, the final rule allows State agencies to authorize new types of vendors and explore modern payment technologies and authentication methods. To comply with revised regulations and implement the changes, staff at State agencies, local agencies, and WIC clinics will need to update operations and communicate these changes to participants. The rule will increase the number of WIC-authorized vendors by allowing different types of vendors (*e.g.,* internet and mobile vendors) to participate in WIC, while also reducing administrative burdens on vendors through the elimination of certain collection requirements. As a result, this rule will benefit participants by expanding participant shopping options and reducing in-person requirements.

To mitigate potential impacts on vital program access for populations with limited English proficiency and persons with disabilities, FNA will provide State agencies with technical assistance aimed at ensuring that online shopping platforms and communications about program changes are available in appropriate languages and in alternative formats for persons with disabilities. FNA will also support State agencies as they work to engage small vendors in online shopping in the WIC Program. After reviewing the potential impacts, FNA does not believe the final rule will result in civil rights impacts on specific groups of WIC participants and applicants. However, the FNA Civil Rights Division will propose further outreach and mitigation strategies to alleviate any unforeseen impacts, if deemed necessary.

Executive Order 13175

Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that 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. On November 30, 2021, FNA provided opportunity for consultation on the rule to discuss key issues related to the proposed rule. Tribal leaders were generally supportive of online ordering for WIC, which may increase access to food benefits for those with limited access to a physical store. Once the proposed rule was published in the **Federal Register**, FNA encouraged stakeholders representing ITOs to provide input on whether the proposed rule poses any adverse tribal implications. FNA requested and received public comment on the impacts on small and Tribal stores in response to the proposed rule, which included the importance of continuing to support small, Tribal-owned stores and brick-and-mortar vendors, and their concern for the barriers that fees related to online ordering could pose to participants using WIC online shopping. FNA is committed to providing targeted technical assistance to support small, Tribal-owned stores and brick-and-mortar vendors and will continue to explore additional opportunities for engagement. The Department

considered all comments, including those received by ITOs. No Tribes requested additional consultation after the proposed rule was published. We are unaware of any current Tribal laws that could be in conflict with this final rule. If a Tribe requests consultation in the future, FNA will work with the Office of Tribal Relations to ensure meaningful consultation is provided.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; 5 CFR part 1320) requires that the Office of Management and Budget (OMB) approve all collections of information by a Federal agency before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number.

In accordance with the Paperwork Reduction Act of 1995, this final rule revises existing information collection requirements currently approved under OMB Control Number 0584–0043, ''Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program Regulations—Reporting and Recordkeeping Burden'' (expiration date August 31, 2027), and contains new requirements for the same information collection. These information collection requirements are subject to review and approval by OMB.

The Department published the proposed rule, ''Special Supplemental Nutrition Program for Women, Infants, and Children (WIC): Online Ordering and Transactions and Food Delivery Revisions to Meet the Needs of a Modern, Data-Driven Program'' in the **Federal Register** on February 23, 2023 (88 FR 11516). The proposed rule requested public comment on proposed changes in the information collection burden that would result from this rule. The Department received approximately 20 comments on the proposed information collection requirements and associated burdens. Commenters also provided feedback on the burden associated with activities not impacted by this rule, which were incorporated as adjustments into this burden. Based on public comment feedback, the Department revised the burden estimates for this final rule as follows:

- Travel time for vendor visits: The Department received feedback that a 20-minute round trip travel time for visiting vendors for various activities was an underestimate. Therefore, the Department is adjusting the estimated travel time for round trip vendor visits to 30 minutes and incorporated this edit into the various activities involving vendor visits.
- On-site preauthorization visits: To reflect the feedback received related to travel time for State agencies visiting vendors, the Department adjusted the total burden for this activity from 60 minutes to 70 minutes (1.17 hours).
- Vendor applications and agreements: The Department proposed the burden for this activity to be 40 minutes (0.67 hours) per vendor applicant. However, multiple commenters stated that this underestimated the amount of time necessary to complete a full review and completion of vendor applications and agreements. Based on the feedback, the Department adjusted the estimated burden to 120 minutes (2 hours) per vendor applicant for this activity to account for the increased estimate of review and processing of applications and agreements.
- On-site routine vendor monitoring: To reflect feedback from stakeholders that routine monitoring takes longer than the proposed 80 minutes including travel time, the Department adjusted the estimated burden to 100 minutes (1.67 hours) per vendor for this activity to account for both increased estimates in travel time and the routine monitoring activities that take place.
- Virtual routine vendor monitoring: The Department proposed the burden for this activity to be 60 minutes per vendor. However multiple commenters stated that routine monitoring, including remote monitoring, is likely to take longer. Based on this feedback, the Department increased the estimated burden to 70 minutes (1.17 hours) per vendor for this activity to account for an increased estimate.
- On-site compliance investigations: To reflect feedback from stakeholders that on-site compliance investigations take longer than 120 minutes per vendor, the Department increased the estimated burden to 300 minutes (5 hours) per vendor for this activity to account for both increased estimates in travel time and the activities that take place.
- Virtual compliance investigations: The Department proposed the burden for this activity to be 120 minutes per vendor. Multiple commenters stated that compliance buys take a significantly longer amount of time, even if done remotely. Based on this feedback, the Department increased the estimated burden to 270 minutes (4.5 hours) per vendor for this activity, removing the 30-minute travel time accounted for in the on-site compliance investigations burden.
- System updates to allow online shopping, including return of benefits: The Department did not initially include the burden associated with updates to State agency systems (EBT and MIS) and vendor systems necessary to implement online shopping. Commenters discussed the significant cost and impact related to these necessary changes and based on feedback provided by State agencies currently implementing online shopping projects, FNA estimates that, on average, State agencies will need to spend 50 hours modifying their EBT and MIS to enable online shopping. The Department estimates that internet vendors will also have a 50-hour burden to update their systems to implement online shopping and incorporated that into this burden estimate.
- Development of transaction authentication policies: The Department proposed the burden for this activity to be 25 hours per State agency. Commenters stated that this was an underestimate and did not take into consideration the hours that it will take a State agency to clear these types of policies through State level review. Based on this feedback, and to account for modifications to this provision that require State agencies to receive written approval from FNA to adopt an authentication method other than the PIN, the Department increased the estimated burden to 50 hours for this activity.

The Department appreciates the feedback provided and incorporated it into the estimates for the final burden. The Department did not change the estimated burden based on public comment feedback for the following provisions:

- Shelf price exemptions: Some State agencies stated that because they utilize shelf price exemptions and do not collect shelf prices, they would not be realizing the benefits of the new provision and therefore the burden estimate was inaccurate. While FNA recognizes that some State agencies have already realized the benefits of not collecting shelf prices through the use of exemptions, the goal of this burden assessment is to recognize the decrease in burden hours from an overall regulatory perspective. As this rulemaking permanently removes the requirement to collect shelf prices, the burden reflects the impact on all State agencies, regardless of if they had an exemption.
- Participant travel time to clinic: One commenter stated that the participant travel time to the clinic for benefit pick-up was underestimated. The Department recognizes that the travel time for participants in the commenter's State agency may be different than the Department's

estimate. However, the Department's estimate was based on a survey data [24] that represents an accurate sample of participants nation-wide, rather than in just one State agency. Therefore, the Department maintains its estimate for participant benefit pick up travel time.

• Reporting requirements: Some commenters stated that the estimated burden impact of quarterly reporting submissions to Food Delivery Portal (FDP) were underestimated. The Department has reviewed this feedback and will incorporate changes to the burden related to FDP in a separate burden revision under OMB Control Number 0584–0401.

The Department has made several additional changes to the estimated burden:

• Baseline numbers: The baseline number of hours currently approved under OMB Control Number 0584–0043 have been updated since the proposed rule was published, due to the regular revision of the WIC Program Information Collection Request (ICR). The impact of this final rule on the overall WIC Program information collection burden therefore reflects estimated changes to the updated baseline numbers.

• Updated program data: Since the WIC Program ICR was last approved, there has been a decrease in the number of State agencies, an increase in the number of vendors, and an increase in the number of participants. The estimated burden associated with this final rule is calculated using the most recent available program data. Changes to the burden estimates from updated program data are classified as ''program adjustments,'' while changes to the burden as a result of the final rule are classified as ''program changes.''

• Revised estimates of online shopping uptake: In the proposed rule, the Department estimated that 80 State agencies would implement online shopping and that each State agency would authorize approximately 5 internet vendors, resulting in 400 internet vendors. These estimates were based on the number of State agencies with online EBT systems and SNAP's experiences with online shopping. The Department is revising these numbers to estimate that approximately half of WIC State agencies (44) will implement online shopping in the first five years following the rule's publication and that each State agency will authorize 2 to 3 internet vendors, resulting in 110 internet vendors. These updated estimates are based on experiences with ongoing WIC online shopping projects.

• Correction of error in a previous submission: The currently approved burden for State agency recordkeeping activities related to vendor incentive items has an inaccurate number of above-50-vendors. A more accurate, updated number is used in this revision and therefore the change in burden hours associated with vendor incentive items reflects both program changes from the final rule and adjustments from the updated program data.

• Additional implementation burden: The Department has also added a one-time implementation burden associated with activities that FNA may ask State agencies that are changing their food delivery systems to complete, such as status reports, additional trainings, and reviewing guidance materials.

• Adjusted for provisions that were not finalized: The Department is not adopting the proposed revisions that would have increased the maximum length of vendor agreement periods and the minimum frequency that State agencies must accept and process vendor applications from three to five years. Therefore, the burden associated with vendor agreements and applications have been adjusted to no longer reflect this decreased frequency.

As summarized above, this final rule changes the information collection requirements that were proposed in the proposed rule. The revisions to the existing information collection requirements and the introduction of new information collection requirements that will take effect with the final rule will result in an overall decrease in burden hours for State and local agencies, applicants for Program benefits and businesses responding to these requirements. These changes are contingent upon OMB approval under the Paperwork Reduction Act of 1995. When the information collection requirements have been approved, the Department will publish a separate action in the **Federal Register** announcing OMB approval.

1. Revisions to OMB Control Number 0584–0043

Title: Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program Regulations—Reporting and Recordkeeping Burden.

OMB Number: 0584–0043.

Expiration Date: August 31, 2027.

Type of Request: Revision of a currently approved collection.

Abstract: This is a revision of existing information collection requirements approved under OMB Control Number 0584–0043 that are affected by this rulemaking. This final rule removes regulatory barriers to online ordering and internet-based transactions in the WIC Program, streamlines and modernizes WIC food delivery, and meets the needs of a modern, data-driven program that uses current technologies for food delivery. This final rule impacts the burden associated with reporting requirements for State agencies, individuals and households, and vendors, as well as the burden associated with recordkeeping requirements for State agencies and vendors. The burden estimates affected by the rule have also been updated to include the most recent available program data, resulting in changes to the number of State agencies (a decrease from 89 to 88), vendors (an increase from 37,267 to 37,368), and participants (an increase from 6,243,960 to 6,866,085) since the last submission of OMB Control Number 0584–0043. The average burden per respondent and the annual burden hours are summarized and explained below.

a. Burden Revisions Related to Internet Vendor Authorization, Monitoring and Oversight, and Training

The final rule allows State agencies to authorize internet vendors, in addition to brick-and-mortar vendors and mobile vendors. In FY 2023, the most recent available year, there were 37,368 WIC-authorized vendors. Using the new definitions, all vendors authorized under current WIC regulations are classified as brick-and-mortar vendors except for one mobile vendor. FNA estimates that 110 internet vendors in 44 State agencies will be authorized initially following the rulemaking (this estimate takes into consideration recent experiences with online shopping projects and the fact that, due to technological constraints, offline EBT systems would not be able to support online transactions), increasing the total number of WIC-authorized vendors from 37,368 to 37,478 vendors. In the proposed rule, the Department had estimated that 400 internet vendors would be authorized by 80 State agencies. These estimates were based on SNAP's experiences and have been adjusted to better reflect information from the WIC online shopping grant projects.

Due to public comment feedback on the proposed rule, the Department removed the requirement for State agencies to justify their use of alternative food instruments in the State

[24] This estimate is based on the amount of time WIC participants reported traveling to the WIC clinic. U.S. Department of Agriculture, Food and Nutrition Service, ''Appendix G. Program Experiences Survey Tables.'' Third National Survey of WIC Participants, Alexandria, VA: 2021, Table 5c.2. Available online at: *https://www.fna.usda.gov/wic/third-national-survey-wic-participants*.

Plan. Instead, State agencies will have to indicate via a checkmark which food instrument types they are using as part of the annual State Plan submission. This check mark will have a negligible impact on the estimated burden hours needed to submit the annual State Plan and therefore there is no change to the burden associated with State Plan submissions due to this final rule. There is a decrease in the number of burden hours associated with State Plan submissions due to the decrease in the number of WIC State agencies since the previous ICR submission.

WIC regulations at § 246.12(g)(5) require that State agencies visit a vendor prior to their initial authorization in the Program. As noted above, based on feedback on the proposed rule, the Department is estimating that during an on-site preauthorization visit, State agency staff spend approximately 40 minutes verifying information provided by the vendor applicant, and 30 minutes traveling to and from the vendor, for a total of 70 minutes. The adjusted travel time, combined with the decrease in the number of WIC State agencies, results in an increase in the currently approved burden associated with on-site preauthorization by 237.32 total hours. The final rule allows initial preauthorization visits of internet vendors to take place virtually, therefore not requiring travel time for State agency staff. Therefore, the initial authorization of 110 internet vendors would add 73.48 reporting burden hours for both State agencies and vendors.

The proposed rule included a provision to increase the maximum length of vendor agreements and the minimum frequency that State agencies must accept and process applications from three to five years. The final rule does not include this change. Therefore, the only program change reflected in the State agency burden associated with reviewing vendor agreements is the added burden for internet vendors' applications and agreements (72.60 burden hours). In response to the proposed rule, FNA received feedback that the current estimate for reviewing, processing, and approving vendor applications was too low and therefore the Department adjusted the estimated burden from 40 minutes to 120 minutes. This adjustment, combined with the increase in the number of WIC-approved vendors since the previous ICR submission, increases the burden estimate by 16,447.74 hours. Taking the program change and the adjustments into account, the burden associated with this activity would increase by 16,520.34 hours over the currently approved burden, from 8,215.14 hours to 24,735.48 hours.

Additionally, the estimated burden for vendors to submit applications and agreements and the estimated burden for State agencies to maintain records of vendor applications and agreements would increase by 36.30 hours each due to the addition of internet vendors. The increase in the number of WIC-authorized vendors since the previous ICR submission also increases these burdens by 33.33 hours. Taken together, the program change and the adjustments to the number of vendors result in net increases in the vendor reporting burden and State agency recordkeeping burden associated with vendor applications and agreements by 69.63 hours each, from 12,298.11 to 12,367.74 hours.

Although the final rule does not change procedures for vendor oversight, the rulemaking allows routine vendor monitoring and compliance investigations to be conducted virtually so that State agencies may use oversight methods appropriate for the vendors they authorize. As with initial vendor preauthorization visits, the Department adjusted its estimate for round trip travel time to a brick-and-mortar or mobile vendor from 20 minutes to 30 minutes based on feedback on the proposed rule. The adjustment of the travel time, along with the increase in the number of WIC-authorized vendors since the previous ICR submission, increases the burden associated with on-site routine monitoring visits by 634.52 hours. The additional virtual routine monitoring visits of internet vendors authorized under the final rule adds 6.44 more hours to State agencies' reporting burden. The State agency recordkeeping burden for routine vendor monitoring would also increase by 5.27 hours, from 931.68 to 936.95 hours. Of this increase, 2.75 hours are due to the addition of internet vendors authorized under the final rule, and 2.52 hours are due to the increase in the number of WIC-authorized vendors since the previous ICR submission.

State agency staff conduct on-site compliance investigations of five percent of vendors each year. As with on-site vendor preauthorization visits and on-site routine monitoring visits, FNA adjusted its estimate for round trip travel time to a brick-and-mortar or mobile vendor from 20 minutes to 30 minutes based on feedback on the proposed rule. To reflect feedback that the compliance investigations take longer than the Department estimated, the Department adjusted the time to 4.5 hours, for a total of 5 hours including travel time. This adjustment, along with the increase in the number of WIC-authorized vendors since the previous ICR submission, increases the burden hours for on-site compliance investigations by 4,992.94 hours, from 4,349.06 hours to 9,342 hours.

The Department estimated that it would take State agencies 2 hours to conduct virtual compliance investigations of internet vendors each year. Public comments on the proposed rule provided feedback that virtual investigations will take more time. Therefore, the Department increased the burden associated with virtual compliance investigations to 4.5 hours, which adds a total of 24.75 hours to the State agency reporting burden. Additionally, the authorization of internet vendors as a result of this rulemaking would increase the State agency recordkeeping burden for compliance investigations by 11 hours, and the increase in WIC-authorized vendors since the previous ICR submission would add another 10.10 hours to this recordkeeping burden.

The addition of 110 internet vendors under the final rule would increase State agencies' reporting burden for vendor training by 220 hours per year. The Department estimates that it takes two hours for vendors to attend annual training provided by State agencies. Authorizing 110 internet vendors results in an additional 220 hours of reporting burden for those new vendors to receive the training. The Department estimates that it takes one hour for each vendor to subsequently train their staff. Due to the additional internet vendors, this will increase the burden for vendor training of their staff by 110 hours. Each of these estimated burdens for State agencies and vendors associated with vendor training activities would also increase due to the increase in the number of WIC-authorized vendors since the previous ICR submission.

Further, FNA estimates that the addition of internet vendors will result in proportionate increases in both the number of vendors that State agencies must assess for ''above-50-percent'' status and the number of vendors that demonstrate a pattern of violations during investigations. These changes would result in associated increases in: the State agency reporting burden related to assessing a vendor's food sales data to determine if they are an ''above-50-percent'' vendor (8.80 additional hours); the vendor reporting burden required to provide such sales data (4.40 additional hours); the reporting burden for above-50-percent vendors who request approval from their State agency to provide incentive items to WIC shoppers (0.98 additional hours); and

the State agency recordkeeping burden to collect information on above-50-percent vendors' incentive items (0.98 additional hours). Since the previous ICR submission, the number of vendors that State agencies assess for ''above-50-percent'' status has decreased from 840 to 795, the number of WIC State agencies has decreased from 89 to 88, and the number of WIC-authorized vendors has increased from 37,267 to 37,368. These program adjustments have additional impacts on each of the State agency and vendor burdens listed above.

Per 246.12(l)(3), State agencies are required to notify a vendor in writing when an investigation reveals an initial violation for which a pattern of violations must be established in order to impose a sanction before another violation is documented, unless the State agency determines notifying the vendor would compromise an investigation. Accounting for the addition of internet vendors due to this final rule, the associated reporting burden for this requirement would increase by 0.26 hours and the associated recordkeeping burden would increase by 3.09 hours. These burdens would also increase by 0.23 hours and 2.79 hours, respectively, due to the increase in the number of WIC-authorized vendors since the previous ICR submission.

Finally, vendors are required to maintain inventory records for federal tax reporting purposes, a recordkeeping burden that takes vendors approximately 10 minutes (0.167 hours) to complete. To account for the new internet vendors, the Department estimates an additional 18.37 hours associated with this requirement. The increase in the number of WIC-authorized vendors since the previous ICR submission also results in 16.87 additional hours for this requirement.

b. Burden Revisions Related to Program Modernization

In recognition of the efficiency of using electronic benefit redemption data to analyze the prices vendors charge for supplemental foods, the final rule removes the requirement that State agencies with access to EBT data collect shelf prices from vendors on a biannual basis or seek an exemption from FNA. As all State agencies are operating EBT at the time of this rule publication, removing the shelf price collection requirement for State agencies significantly decreases the reporting burden for WIC State agencies (−149,068 hours for collecting shelf prices and −40 hours for preparing exemption requests) and WIC-authorized vendors (−132,318.79 hours).

To operationalize online shopping, State agencies will have to update their systems to support new technology in alignment with the Department's standards per § 246.12(bb)(1). The proposed rule did not account for this burden and therefore the Department is adding a burden associated with system updates to allow online shopping, including the return of benefits. The Department estimates that these updates will take 50 hours, and therefore would increase the reporting burden by 2,200 total hours for the 44 State agencies implementing online shopping. Additionally, to fully account for any State agency status updates, FNA-provided trainings, or review of FNA guidance materials that may be required to update food delivery systems to incorporate online shopping, the Department estimates a 5-hour implementation burden per State agency, for a total of 220 hours. Similarly, the development of online shopping will require 50 burden hours to update vendor systems to allow online shopping, including returns. Therefore, the vendor reporting burden associated with vendor system updates to allow online shopping will result in 5,500 additional burden hours for the 110 new internet vendors.

State agencies are required to submit requests for approval for costs of capital expenditures per § 246.14(d). The proposed rule estimated that the number of State agencies submitting such requests would increase as a result of the rule. However, based on project costs from State agencies currently implementing online shopping, the MIS and EBT changes necessary to implement online shopping projects are not meeting the cost threshold requiring that they submit approval. Therefore, the Department is no longer estimating that there will be an increase in the number of State agencies submitting requests for approval, and there is no estimated increase in the burden associated with this activity.

The final rule allows State agencies to adopt EBT transaction authentication technologies other than PIN authentication. Regardless of whether State agencies adopt new transaction authentication technologies or maintain use of the PIN, they must develop transaction authentication policies for the technology they use. Additionally, the Department has modified this provision from what was proposed to require that State agencies receive written approval from FNA if they adopt an authentication method other than the PIN. Based on public comment feedback, the Department increased the burden hours associated with this activity from 25 to 50 hours, and adjusted the number of estimated respondents in recognition that all State agencies will be creating policies and, in the future, may request FNA approval to adopt authentication methods other than the PIN. This increases the reporting burden for this activity to 4,400 hours.

The final rule encourages State agencies to issue electronic benefits remotely and mail EBT cards to participants to reduce the number of clinic visits households make to receive benefits. This decreases the burden associated with picking up food instruments and receiving benefits outside of a certification clinic visit by a total of 1,747,698.87 hours. These estimates assume that: on average, WIC households consist of two WIC participants, requiring only one trip to the clinic to pick up both participants' benefits; currently, households in State agencies without an online EBT system are required to travel to a clinic to reload offline EBT cards three times a year outside of another scheduled appointment; and currently, new participants in State agencies with online EBT systems are required to pick up their EBT card in person. With this final rulemaking, only participants who need to reload an offline EBT card would be required to travel to a clinic to receive benefits in person. These estimates also account for a decrease in the number of offline EBT State agencies (from 9 to 8) and an increase in the number of WIC participants (from 6,243,960 to 6,866,085) since the previous ICR submission.

c. Costs Associated With the Final Rule and OMB Control Number 0584–0043

In addition to the changes to the information collection burdens discussed in this section, implementing the final rule is expected to create additional costs for State agencies and WIC participants. FNA estimates that it will cost each State agency approximately $185,000 to update their EBT and MIS to implement online shopping in the year that they choose to do so. Across the estimated 44 State agencies implementing online shopping, these one-time implementation costs would total $8.14 million. After implementation, the Department anticipates that maintenance of such systems will cost approximately $4,500 per month. Therefore, in an average year following implementation of online shopping in 44 State agencies, these ongoing maintenance costs would total $2.38 million.

The final rule adds a provision at § 246.12(h)(3)(xxxiii) that allows WIC participants who choose to shop for supplemental foods online to pay for fees associated with such services using another tender type, as long as those fees are also assessed to non-WIC customers using the same services. Adjusting for annual inflation, the Department estimates that an average online grocery order in 2027 will be assessed $10.66 in delivery and service fees, increasing to $11.63, adjusting for inflation, in FY 2031 (see the Regulatory Impact Analysis that follows this rule as an Appendix for a full explanation of these estimates). Additionally, FNA estimates that once online shopping has been implemented across 44 State agencies, 28 percent of WIC participants in those State agencies, or about 961,252 participants, would make one online WIC order each month. Further, FNA estimates that 33 percent of those WIC online shopping orders (317,213 orders) would be placed for home delivery. On average, each WIC household consists of two WIC participants. Therefore, FNA estimates that approximately 158,607 households would place an online order for home delivery each month, costing WIC participants a total of about $1.84 million per month, or $22.14 million per year in delivery fees if 44 State agencies have implemented online shopping by 2031.

d. Summary of Revisions to OMB Control Number 0584–0043

The current approved burden for OMB Control Number 0584–0043 is 17,362,904 hours, 67,867,960 responses, and 6,283,126 respondents. Changes to the burden due to the rulemaking decrease the total burden by 1,589,524 hours and changes due to program adjustments decrease the burden by 403,908 hours. Together, these changes and adjustments decrease the burden by 1,993,432 hours, resulting in a total burden of 15,369,471 hours. The rule and program adjustments decrease the total number of responses by 3,634,621, resulting in a total of 64,233,339 responses. The addition of internet vendors due to the final rule is estimated to increase the total number of respondents for this information collection by 110, and the program adjustments (changes in the number of State agencies, vendors, and participants since the previous ICR submission) are estimated to increase the total number of respondents by 622,335. Taken together, these program changes and adjustments increase the number of respondents for this information collection from 6,283,126 to 6,905,461. One-time costs associated with the final rule are estimated to total $8.14 million and annual costs and fees following implementation of online shopping are estimated to total $24.52 million. The average burden per response, the annual burden hours, and the total fees and costs related to this final rule are explained below and summarized in the tables which follow.

The change in burden hours to OMB Control Number 0584–0043 and costs associated with the final rule are best estimates.

Respondents: State agencies, including Indian Tribal Organizations and U.S. Territories (note that burden estimates for local agencies are not affected by this proposed rule).

Estimated Number of Respondents: 88.

Reporting

Estimated Number of Reporting Responses per Respondent: 651.54.

Estimated Number of Responses: 57,336.

Estimated Hours per Reporting Response: 2.48.

Estimated Total Annual Reporting Burden Hours for Respondents: 142,324.

Recordkeeping

Estimated Number of Recordkeeping Responses per Respondent: 199.14.

Estimated Number of Responses: 17,524.

Estimated Hours per Recordkeeping Response: 1.05.

Estimated Total Annual Recordkeeping Burden Hours for Respondents: 18,461.

Respondents: Individuals and households.

Reporting

Estimated Number of Respondents: 3,433,043.

Estimated Number of Responses per Respondent: 0.24.

Estimated Number of Responses: 819,249.

Estimated Hours per Response: 0.50.

Estimated Total Annual Burden on Respondents: 409,624.

Respondents: WIC-authorized vendors.

Reporting

Estimated Number of Respondents: 37,478 (37,367 brick-and-mortar vendors, 110 internet vendors, and 1 mobile vendor).

Estimated Number of Responses per Respondent: 2.41.

Estimated Number of Responses: 90,193.

Estimated Hours per Response: 1.48.

Estimated Total Annual Burden on Respondents: 133,326.

Recordkeeping

Estimated Number of Recordkeeping Responses per Respondent: 1.00.

Estimated Number of Responses: 37,478.

Estimated Hours per Recordkeeping Response: 0.17.

Estimated Total Annual Recordkeeping Burden Hours for Respondents: 6,259.

Estimated Capital, Start-up, Operation, Maintenance and Implementation Costs and Fees:

SUMMARY OF COSTS ASSOCIATED WITH THE FINAL RULE

Description of cost	Number of respondents	One-time costs (millions)	Annual costs (millions)	Total costs (millions)
State Agencies				
Systems development and maintenance for online shopping	44	$8.14	$2.38	$10.52
Individuals and Households				
Fees associated with online shopping	158,607	0.00	22.14	22.14
Total Costs	8.14	24.52	32.66	

Regulatory citation	Description of activities	Estimated number of respondents	Frequency of responses	Total annual responses	Average burden hours per response	Estimated total burden hours	Current burden hours in OMB #0584–0043	Estimated change due to program changes	Estimated change due to adjustments	Total change due to rulemaking and adjustments
REPORTING BURDEN ESTIMATES										
Affected Public: State and Local Agencies (including Indian Tribal Organizations and U.S. Territories)										
246.4	State Plan	88.00	1.00	88.00	170.62	15,014.56	*15,185.18*	0.00	−170.62	−170.62
246.12	Implementation of food delivery system changes.	44.00	1.00	44.00	5.00	220.00	*0.00*	220.00	0.00	220.00
246.12(g)(4)(i)	Vendor food sales data	88.00	9.07	798.28	4.00	3,193.13	*3,360.00*	8.80	−175.67	−166.87
246.12(g)(4)(ii)(B)	Vendor shelf prices	0.00	0.00	0.00	2.00	0.00	*149,068.00*	−149,068.00	0.00	−149,068.00
246.12(g)(4)(ii)(B)	Vendor shelf prices exemption	0.00	0.00	0.00	8.00	0.00	*40.00*	−40.00	0.00	−40.00
246.12(g)(5)	Vendor initial preauthorization visits (onsite).	88.00	17.00	1,496.00	1.17	1,750.32	*1,513.00*	0.00	237.32	237.32
246.12(g)(5)	Vendor initial preauthorization visits (virtual).	44.00	2.50	110.00	0.67	73.48	*0.00*	73.48	0.00	73.48
246.12(h)	Review vendor applications & agreements.	88.00	140.54	12,367.74	2.00	24,735.48	*8,215.14*	72.60	16,447.74	16,520.34
246.12(i)(1)	Vendor training	88.00	425.89	37,478.00	2.00	74,956.00	*74,534.00*	220.00	202.00	422.00
246.12(j)(2)	Routine vendor monitoring (onsite)	88.00	21.23	1,868.40	1.67	3,120.23	*2,485.71*	0.00	634.52	634.52
246.12(j)(2)	Routine vendor monitoring (virtual)	44.00	0.13	5.50	1.17	6.44	*0.00*	6.44	0.00	6.44
246.12(j)(4), (6)	Vendor compliance investigations (onsite).	88.00	21.23	1,868.40	5.00	9,342.00	*4,349.06*	0.00	4,992.94	4,992.94
246.12(j)(4), (6)	Vendor compliance investigations (virtual).	44.00	0.13	5.50	4.50	24.75	*0.00*	24.75	0.00	24.75
246.12(l)(3)	Notification of vendor violations	88.00	11.98	1,053.88	0.0835	88.00	*87.51*	0.26	0.23	0.49
246.12(bb)(1)	System updates to allow online shopping, including return of benefits.	44.00	1.00	44.00	50.00	2,200.00	*0.00*	2,200.00	0.00	2,200.00
246.12(bb)(2)	Transaction authentication policy development.	88.00	1.00	88.00	50.00	4,400.00	*0.00*	4,400.00	0.00	4,400.00
246.14(d)	ADP proposals	20.00	1.00	20.00	160.00	3,200.00	*3,200.00*	0.00	0.00	0.00
Subtotal Reporting: State and Local Agencies		88	651.54	57,335.70	2.48	142,324.38	*262,037.60*	−141,881.68	22,168.46	−119,713.22
Affected Public: Individuals and Households: Applicants for Program Benefits										
246.12(r)(4) & (r)(5).	Offline EBT State agencies: Food instrument and cash-value voucher pick up (non-certification clinic visits).	312,094.77	2.63	819,248.78	0.50	409,624.39	*894,499.89*	−58,517.77	−426,357.73	−484,875.50
246.12(r)(4) & (r)(5).	Online EBT State agencies: Food instrument and cash-value voucher pick up (non-certification clinic visits).	3,120,947.73	0.00	0.00	0.00	0.00	*1,262,823.37*	−1,262,823.37	0.00	−1,262,823.37
Subtotal Reporting: Applicants		3,433,043	0.24	819,248.78	0.50	409,624.39	*2,157,323.26*	−1,321,341.14	−426,357.73	−1,747,698.87
Affected Public: Business: Retail Vendors (WIC-Authorized Food Stores) and Nonprofit Businesses										
246.12(g)(4)(i)	Vendor food sales data for A50s	798.28	1.00	798.28	2.00	1,596.56	*1,680.00*	4.40	−87.84	−83.44
246.12(g)(4)(ii)(B)	Vendor shelf prices	0.00	0.00	0.00	0.00	0.00	*132,318.79*	−132,318.79	0.00	−132,318.79
246.12(g)(5)	Vendor initial preauthorization visits	1,606.00	1.00	1,606.00	0.67	1,072.81	*1,010.68*	73.48	−11.36	62.12
246.12(h)	Vendor applications & agreements	12,367.74	1.00	12,367.74	1.00	12,367.74	*12,298.11*	36.30	33.33	69.63
246.12(h)(3)(xiii)	Vendor training of staff	37,478.00	1.00	37,478.00	1.00	37,478.00	*37,267.00*	110.00	101.00	211.00
246.12(h)(8)(i)	Vendor incentive items	354.79	1.00	354.79	1.00	354.79	340.00	0.98	13.81	14.79
246.12(i)	Vendor training	37,478.00	1.00	37,478.00	2.00	74,956.00	*74,534.00*	220.00	202.00	422.00
246.12(bb)(1)	System updates to allow online shopping, including return of benefits.	110.00	1.00	110.00	50.00	5,500.00	*0.00*	5,500.00	0.00	5,500.00
Subtotal Reporting: Businesses		37,478	2.41	90,192.81	1.48	133,325.90	*259,448.58*	−126,373.63	250.95	−126,122.68
Grand Subtotal: Reporting		3,470,609	0.28	966,777.29	0.71	685,274.67	*2,678,809.44*	−1,589,596.45	−403,938.32	−1,993,534.77

RECORDKEEPING BURDEN ESTIMATES

Affected Public: State and Local Agencies (including Indian Tribal Organizations and U.S. Territories)										
246.12(h)(1)(i)	Vendor applications & Agreements ...	88.00	140.54	12,367.74	1.00	12,367.74	*12,298.11*	36.30	33.33	69.63
246.12(h)(8)(i)	Vendor incentive items	4.00	88.70	354.79	1.00	354.79	*389.20*	0.98	−35.39	−34.41
246.12(j)(6)	Routine vendor monitoring	88.00	21.29	1,873.90	0.50	936.95	*931.68*	2.75	2.52	5.27
246.12(j)(6)(ii)	Vendor compliance Investigations	88.00	21.29	1,873.90	2.00	3,747.80	*3,726.70*	11.00	10.10	21.10
246.12(l)(3)	Vendor notice of violations	88.00	11.98	1,053.88	1.00	1,053.88	*1,048.00*	3.09	2.79	5.88
Subtotal Recordkeeping: State and Local Agencies ...		88	199.14	17,524.21	1.05	18,461.16	*18,393.69*	54.12	13.35	67.47
Affected Public: Business: Retail Vendors (WIC-Authorized Food Stores) and Nonprofit Businesses										
246.12(h)(3)(xvi)	Vendor Inventory Records	37,478.00	1.00	37,478.00	0.17	6,258.83	*6,223.59*	18.37	16.87	35.24
Subtotal Recordkeeping: Businesses		37,478	1.00	37,478	0.17	6,259	*6,224*	18.37	16.87	35.24
Grand Subtotal: Recordkeeping		37,566	1.46	55,002.21	0.45	24,719.99	24,617.28	72.49	30.22	102.71
Grand Total: Reporting, Recordkeeping, and Public Disclosure.		3,470,609	0.29	1,021,779.51	0.69	709,994.66	2,703,426.72	−1,589,523.96	−403,908.10	−1,993,432.06

2. Revisions to OMB Control Number 0584–0401

Title: Food Delivery Portal (FDP) Data Collection.

OMB Number: 0584–0401.

Expiration Date: 1/31/2028.

Type of Request: N/A.

Abstract: The Department proposed revising regulations around data submission timelines for information that State agencies must report to FNA using the Food Delivery Portal (FDP). All WIC State agencies are required to submit information on their vendor monitoring and investigation activities, in accordance with § 246.12(j)(5). The revisions in the proposed rule removed the annual submission deadline of February 1 of each fiscal year and proposed to replace it with submission timelines that ''may be as frequent as quarterly but not less than annually, based on system capabilities and reporting needs'' along with other proposed edits.

FNA received comments on the Department's proposed rule burden estimate incorporating the possibility of quarterly reporting. The comments largely expressed that the Department's estimate that this change would not increase the burden was inaccurate, and instead quarterly reporting would quadruple the workload and burden on WIC State agencies.

After further analysis of the FDP system and the current data upload process, as well as considering the public comment feedback received on the proposed rule and the FDP burden, the Department agrees that an increase in the frequency of reporting would put an unnecessary burden on State agencies.

The Department has removed the language allowing federal reporting requests to be as frequently as quarterly. Instead, the Department is finalizing this rule maintaining the current annual federal reporting requirement. Because of this, there will be no change to the existing information collection requirements in the information collection under OMB Control Number 0584–0401. The Department is confident that the data submitted on an annual basis provides the information necessary to ensure federal oversight and support the research work that uses this data.

a. Summary of Revisions to OMB Control Number 0584–0401

The current approved burden for OMB Control Number 0584–0401 is 3,576 hours and 541 total responses. As this final rulemaking does not implement the proposed changes, the burden due to the rulemaking will have no effect on the total number of burden hours, which would remain 3,576 hours.

E-Government Act Compliance

The Department is committed to complying with the E-Government Act of 2002, 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.

List of Subjects in 7 CFR Part 246

Administrative practice and procedure, Civil rights, Food assistance programs, Foods, Grants administration, Grant programs—health, Grant programs—social programs, Indians, Infants and children, Maternal and child health, Nutrition, Penalties, Public health, Reporting and recordkeeping requirements, Women.

Accordingly, the FNA amends 7 CFR part 246 as follows:

PART 246—SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS AND CHILDREN

■ 1. The authority citation for part 246 continues to read as follows:

Authority: 42 U.S.C. 1786.

■ 2. In § 246.2:
■ a. Remove the definition of ''Above-50-percent vendors'';
■ b. Add the definitions of ''Above-50-percent vendor'', ''Brick-and-mortar vendor, and ''Cash-value benefit'' in alphabetical order;
■ c. Revise the definitions of ''Cash-value voucher'' and ''Compliance buy'';
■ d. Add the definition of ''Electronic benefits'' in alphabetical order;
■ e. Remove the definition of ''Electronic Benefit Transfer'';
■ f. Add the definition of ''Electronic benefit transfer'';
■ g. Revise the definitions of ''Food instrument'' and ''Home food delivery contractor'';
■ h. Add the definitions of ''internet vendor'' and ''Mobile vendor'' in alphabetical order; and
■ i. Revise the definitions of ''Routine monitoring'' and ''Vendor''.
■ The additions and revisions read as follows:

§ 246.2 Definitions.

* * * * *

Above-50-percent vendor means any type of vendor that derives more than 50 percent of its annual food sales revenue from WIC food instruments, and new vendor applicants expected to meet this criterion under guidelines approved by FNS.

* * * * *

Brick-and-mortar vendor means a type of vendor authorized to provide authorized supplemental foods to participants through transactions at a single, physical, fixed location. All transactions that take place at the brick-and-mortar vendor will be assigned to that vendor.

Cash-value benefit means a type of electronic benefit that is a fixed-dollar amount used to obtain authorized fruits and vegetables.

Cash-value voucher means a fixed-dollar amount check, voucher, or other document which is used to obtain authorized fruits and vegetables.

* * * * *

Compliance buy means a covert investigation in which a representative of the Program poses as a participant, parent or caretaker of an infant or child participant, or proxy, transacts food instruments, cash-value vouchers, or electronic benefits, and does not reveal during the visit their identity as a program representative.

* * * * *

Electronic benefits mean the WIC benefits for supplemental foods prescribed to a participant and contained within the participant's benefit balance.

Electronic benefit transfer (EBT) means a benefit delivery method that permits electronic access to WIC food benefits using a card or other electronic benefit access device or technology approved by the Secretary.

* * * * *

Food instrument means a paper voucher, check, coupon, other document; or an EBT card or other electronic benefit access device or technology that is used to obtain supplemental foods.

* * * * *

Home food delivery contractor means a business entity that contracts directly with a State agency to deliver authorized supplemental foods to a location designated by the State agency or designated by the participant and approved by the State agency under a home food delivery system.

* * * * *

Internet vendor means a type of vendor authorized to provide authorized supplemental foods to participants through internet-based transactions. All transactions that take place via an online ordering system, platform, or site used by an internet vendor will be assigned to that vendor.

* * * * *

Mobile vendor means a type of vendor authorized to provide authorized supplemental foods to participants through transactions that take place at a truck, bus, pushcart, or other mobile vehicle. All transactions that take place at the mobile vendor will be assigned to that vendor.

* * * * *

Routine monitoring means overt monitoring during which program representatives identify themselves to vendor personnel.

* * * * *

Vendor means a business entity authorized by the State agency to provide authorized supplemental foods to participants under a retail food delivery system. Each store, internet retailer, and mobile vehicle constitutes a unique vendor and must be authorized separately.

* * * * *

■ 4. In § 246.4:
■ a. Remove and reserve paragraph (a)(14)(xv); and
■ b. Revise paragraph (a)(23).

The revision reads as follows:

§ 246.4 State Plan.

* * * * *

(a) * * *

(23) A plan to improve access to the Program for participants and prospective applicants, with additional focus on those who are employed and/or reside in rural areas. The plan must identify and address the needs of these individuals, and must include, at a minimum, policies and procedures to minimize the time they must spend away from work and the distances they must travel. This plan must include measures to improve access to the Program through the remote issuance of food instruments, cash-value vouchers, and/or electronic benefits, as applicable, to participants through means other than direct participant pick-up, pursuant to § 246.12(r)(4) and (5). The State agency must also describe the State agency's policy for approving transportation of participants to and from WIC clinics per § 246.14(c)(7). This plan must describe how the State agency will ensure the integrity of Program services and fiscal accountability.

* * * * *

■ 5. In § 246.7, revise paragraph (f)(2)(iv) to read as follows:

§ 246.7 Certification of participants.

* * * * *

(f) * * *

(2) * * *

(iv) Each local agency using a retail food delivery system must issue food instruments, cash-value vouchers, or electronic benefits, as applicable, to the participant at the same time as notification of certification. Such food instruments, cash-value vouchers, and electronic benefits must be provided for the current month or the remaining portion thereof and must be transactable immediately upon receipt by the participant. Local agencies may issue electronic benefits remotely or mail the food instruments and cash-value vouchers with the notification of certification, as provided in § 246.12(r)(4) and (5).

* * * * *

■ 6. In § 246.12:
■ a. Revise paragraph (b);
■ b. In paragraph (g)(4) introductory text, revise the third sentence and add a sentence after the third sentence.
■ c. Revise paragraphs (g)(4)(ii)(B) and (g)(5);
■ d. In paragraph (g)(9), revise the last sentence;
■ e. Revise paragraphs (h)(3)(ii), (v), and (vi);
■ f. Add paragraphs (h)(3)(xxxii) and (xxxiii);
■ g. Revise paragraphs (j)(5) and (j)(6)(ii)(B);
■ h. In paragraph (m) introductory text, revise the first sentence;
■ i. Revise paragraphs (r)(2) and (4);
■ h. Redesignate paragraphs (r)(5) and (6) as paragraphs (r)(6) and (7), respectively, and add a new paragraph (r)(5);
■ i. Remove the period at the end of newly redesignated paragraph (r)(6) and add ''; and'' in its place;
■ j. Revise paragraphs (v)(1)(iv) and (ix);
■ k. Revise paragraph (x)(2)(iii);
■ l. Add paragraph (x)(4);
■ m. Redesignate paragraphs (bb)(2) and (3) as paragraphs (bb)(3) and (4), respectively, and add a new paragraph (bb)(2).

The revisions and additions read as follows:

§ 246.12 Food delivery methods.

* * * * *

(b) *Uniform food delivery systems.* The State agency may operate a combination of up to three types of food delivery systems under its jurisdiction—retail, home food delivery, and direct distribution. These three food delivery systems must be procedurally uniform throughout the jurisdiction of the State agency and the combination of systems used must ensure adequate participant access to supplemental foods. When used, each food instrument type must be uniform and described and approved in the State agency's State Plan per § 246.4(a)(14)(i).

* * * * *

(g) * * *

(4) * * * The State agency must consider a vendor applicant's prices for non-WIC customers or the prices it bids for supplemental foods, which must not exceed the price charged to non-WIC customers. The State agency may consider the vendor applicant's EBT data when available. * * *

* * * * *

(ii) * * *

(B) The analysis of vendor prices to monitor vendor compliance with paragraphs (g)(4)(i)(C), (g)(4)(ii)(C), and (g)(4)(iii) of this section and to ensure State agency policies and procedures dependent on price data are efficient and effective. State agencies without access to electronic benefit redemption data must collect vendor shelf prices at least every six months to ensure compliance with this paragraph (g)(4)(ii)(B). FNS may grant an exemption from the requirement to collect shelf prices if the State agency demonstrates to FNS' satisfaction that an alternative methodology for monitoring vendor compliance with paragraphs (g)(4)(i)(C), (g)(4)(ii)(C), and (g)(4)(iii) of this section is efficient and effective and other State agency policies and procedures are not dependent on frequent collection of shelf price data. Such exemption would remain in effect until the State agency no longer meets the conditions on which the exemption was based, until FNS revokes the exemption, or for three years, whichever occurs first; and

* * * * *

(5) *Preauthorization visit.* The State agency must conduct an on-site or virtual visit prior to or at the time of a vendor's initial authorization.

* * * * *

(9) * * * In addition, if the State agency does not have access to electronic benefit redemption data, the State agency must collect the vendor applicant's current prices for supplemental foods.

* * * * *

(h) * * *

(3) * * *

(ii) *No substitutions, cash, credit, cash refunds, or exchanges.* The vendor may provide only the authorized supplemental foods listed on the paper food instrument and cash-value voucher or available in the participant's benefit balance.

(A) Except as specified in paragraph (h)(3)(ii)(C) of this section, the vendor must not provide unauthorized food items, non-food items, cash, or credit (including rain checks) in exchange for benefits. The vendor must not provide cash refunds (including but not limited

to gift cards or store credit) or permit exchanges for authorized supplemental foods obtained with benefits, except for exchanges of an identical authorized supplemental food item when the original authorized supplemental food item is defective, spoiled, or has exceeded its ''sell by,'' ''best if used by,'' or other date limiting the sale or use of the food item. An identical authorized supplemental food item means the exact brand, type, physical form, and size as the original authorized supplemental food item obtained and returned by the participant.

(B) The vendor may provide only the authorized infant formula which the vendor has obtained from sources included on the list described in paragraph (g)(10) of this section to participants in exchange for food instruments specifying infant formula.

(C) During a supplemental food recall, as defined in § 246.2, the vendor must treat all customers, including WIC participants, parents or caretakers of infant or child participants, and proxies the same. This should be reflected in store recall exchange policies, including policies related to replacements (which may include, but are not limited to, the same product, a substitute product, store credit, or a cash refund).

* * * * *

(v) *Purchase price.* The vendor must ensure that the purchase price is calculated in accordance with the procedures described in the vendor agreement. The purchase price must include only the amount(s) for the authorized supplemental food items actually provided, and the WIC participant, parent or caretaker of an infant or child participant, or proxy must be made aware of the total purchase price of the transaction before the transaction is completed.

(vi) *Signature on paper food instruments and cash-value vouchers.* For paper food instruments and cash-value vouchers, the vendor must ensure the participant, parent or caretaker of an infant or child participant, or proxy signs the paper food instrument or cash-value voucher after the purchase price is entered.

* * * * *

(xxxii) *Transaction authentication.* The vendor must authenticate transactions in accordance with the policies established by the State agency.

(xxxiii) *Fees associated with WIC purchases.* A vendor must not charge the State agency for fees associated with WIC purchases (*e.g.,* delivery, service, convenience, bag fees). If such fees are assessed to non-WIC customers using the same services, WIC participants must be allowed to pay them using another tender type.

* * * * *

(j) * * *

(5) *Reporting.* The State agency must send FNS certain vendor, direct distribution contractor, home food delivery contractor, farmer, and farmers' market data containing information stipulated by FNS via reporting requirements that will be provided to WIC State agencies with advance notification. Reporting requirements will include required data fields and annual data submission timelines. Plans for improvement in the coming year must be included in the State Plan in accordance with § 246.4(a)(14)(iv).

(6) * * *

(ii) * * *

(B) A description of the cashier involved in each transaction, if applicable;

* * * * *

(m) * * * Home food delivery systems are systems in which authorized supplemental foods are delivered to a location designated by the State agency or designated by the participant and approved by the State agency. * * *

* * * * *

(r) * * *

(2) *Signature requirement.* Ensure that the participant, parent or caretaker of an infant or child participant, or proxy signs for receipt of food instruments, cash-value vouchers, or authorized supplemental foods, when receiving them in person;

* * * * *

(4) *Paper food instrument and cash-value voucher pick up.* Require participants, parents and caretakers of infant and child participants, and proxies to pick up paper food instruments and cash-value vouchers in person when scheduled for in-person nutrition education or for an in-person appointment to determine whether participants are eligible for a second or subsequent certification period. In all other circumstances the State agency may opt to mail paper food instruments or cash-value vouchers unless FNS determines that it would jeopardize the integrity of program services or program accountability;

(5) *EBT card and electronic benefit issuance.* Ensure participants receive their EBT cards and electronic benefits in accordance with §§ 246.7(f)(2)(iv) and 246.11(a)(2), without jeopardizing the integrity of program services or program accountability. The State agency is encouraged to remotely issue electronic benefits and mail EBT cards, when possible, unless FNS determines that it would jeopardize the integrity of program services or program accountability. When EBT cards are issued remotely, the State agency must have procedures in place to ensure receipt by the intended recipient;

* * * * *

(v) * * *

(1) * * *

(iv) Transact and redeem cash-value vouchers or cash-value benefits in accordance with procedures established by the State agency. Such procedures must include:

(A) A requirement for the farmer or farmers' market to allow the participant, parent or caretaker of an infant or child participant, or proxy to pay the difference when the purchase price of fruits and vegetables exceeds the value of the cash-value vouchers or cash-value benefits. This is known as a split tender transaction; and

(B) Procedures to ensure that the WIC participant, parent or caretaker of an infant or child participant, or proxy is made aware of the total purchase price of the transaction before the transaction is completed;

* * * * *

(ix) Offer WIC participants, parents or caretakers of infant or child participants, or proxies the same courtesies as other customers. The farmer or farmers' market must not charge the State agency for fees associated with WIC purchases (*e.g.,* delivery, service, convenience, bag fees). If such fees are assessed to non-WIC customers using the same services, WIC participants must be allowed to pay them using another tender type;

* * * * *

(x) * * *

(2) * * *

(iii) *Last date of use.* The last date on which the electronic benefit may be used to obtain authorized supplemental foods. This date must be a minimum of 30 days, or in the month of February 28 or 29 days, from the first date on which it may be used to obtain authorized supplemental foods except for the participant's first month of issuance when it may be the end of the month or cycle for which the electronic benefit is valid. This may be extended, as applicable, per paragraph (x)(4)(iii) of this section; and

* * * * *

(4) *Return of benefits.* If a State agency authorizes internet vendors, the State agency must allow for the return of electronic benefits to a participant's balance and the return of electronic benefits for all vendor types. The return of electronic benefits must comply with the following requirements:

(i) *In-person returns.* If the participant returns an item in person, the return of electronic benefits must be processed immediately;

(ii) *Post-delivery returns.* Post-delivery return of benefits, such as those for items returned via mail or unfulfilled items from an internet-based transaction, must be processed within two (2) business days after receipt of the returned item or indication of an unfulfilled item;

(iii) *Use of returned electronic benefits.* When electronic benefits are returned to a participant's benefit balance, the State agency must provide the participant the remainder of the benefit issuance month to transact the returned benefits. The State agency may allow the participant a maximum of seven (7) calendar days beyond the last date of use to transact returned benefits.

* * * * *

(bb) * * *

(2) The State agency must develop policies to ensure that each transaction is authenticated (*e.g.,* using a Personal Identification Number (PIN)). The State agency must receive written approval from FNS to adopt an authentication method other than the PIN.

* * * * *

■ 7. In § 246.14, revise paragraphs (b)(1)(i) and (c)(4) to read as follows:

§ 246.14 Program costs.

* * * * *

(b) * * *

(1) * * *

(i) Supplemental foods purchased by participants using WIC benefits in a retail food delivery system and/or acquiring supplemental foods provided to State or local agencies or participants, whichever receives the supplemental foods first in a home food delivery system or a direct distribution food delivery system;

* * * * *

(c) * * *

(4) The cost of administering the food delivery system, including the cost of transporting supplemental foods, except as prohibited at § 246.12(h)(3)(xxxiii) and (v)(1)(ix).

* * * * *

Shiela Corley,

Acting Administrator.

[FR Doc. 2026–22679 Filed 11–5–26; 8:45 am]

BILLING CODE 3410–30–P



FEDERAL REGISTER

Vol. 91 Friday,
No. 214 November 6, 2026

Part V

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 416, et al.
Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; including the Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Program; Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency (HPT) Data; Prior Authorization; Accrediting Organization (AO) Deeming for Emergency Medical Treatment and Labor Act (EMTALA); and Notices of Closure of Teaching Hospitals and Opportunities To Apply for Available Slots; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 416, 419, 427, and 488

[CMS–1850–FC]

RIN 0938–AV83

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; including the Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Program; Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency (HPT) Data; Prior Authorization; Accrediting Organization (AO) Deeming for Emergency Medical Treatment and Labor Act (EMTALA); and Notices of Closure of Teaching Hospitals and Opportunities To Apply for Available Slots

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare Hospital Outpatient Prospective Payment System (OPPS) and the Medicare Ambulatory Surgical Center (ASC) payment system for calendar year 2027 based on our continuing experience with these systems. We also 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 systems. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting Program and the Ambulatory Surgical Center Quality Reporting Program. There are no changes to the Rural Emergency Hospital Quality Reporting Program. We finalized the expansion of the prior authorization requirement to include additional Botulinum Toxin Injection services. We also finalized implementation of certain provisions of the Consolidated Appropriations Act, 2026, for off-campus outpatient departments of a provider. In addition, this final rule with comment period announces notices of closure of teaching hospitals and opportunities to apply for available slots. Additionally, we finalized the policy that hospital accrediting organizations (AOs) with deeming authority may assess compliance with certain Emergency Medical Treatment and Labor Act (EMTALA) administrative requirements under 42 CFR 489.20 during accreditation and reaccreditation surveys.

DATES:

Effective Date: The provisions of this rule are effective January 1, 2027.

Comment period: To be assured consideration, comments must be received at one of the addresses provided below, by [January 4, 2027.

ADDRESSES: In commenting, please refer to file code CMS–1850–FC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov/docket/CMS-2026-2344.* 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–1850–FC, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1850–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Regulation coordination questions, contact Gina Aughenbaugh via email at *OutpatientPPS@cms.hhs.gov.*

Accrediting Organization (AO) Deeming for Emergency Medical Treatment and Labor Act (EMTALA), contact Melissa Daly via email at *Melissa.Daly@cms.hhs.gov.*

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at *APCPanel@cms.hhs.gov.*

Ambulatory Surgical Center Covered Procedures List (ASC CPL), contact Abigail Cesnik via email at *Abigail.Cesnik@cms.hhs.gov.*

Ambulatory Surgical Center Quality Reporting Program measures, contact Marsha Hertzberg via email at *Marsha.Hertzberg@cms.hhs.gov.*

Ambulatory Surgical Center Quality Reporting Program policies, contact Grace Snyder via email at *Grace Snyder@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 Edna Ayah via email at *Edna.Ayah@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 Gina Aughenbaugh via email at *Gina.Aughenbaugh@cms.hhs.gov.*

Composite APCs (Multiple Imaging and Mental Health) and Comprehensive APCs (C–APCs), contact Elise Barringer via email at *Elise.Barringer@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.*

Hospital Outpatient Quality Reporting Program measures, contact Kristina Rabarison via email at *Kristina.Rabarison@cms.hhs.gov.*

Hospital Outpatient Quality Reporting Program policies, contact Kimberly Go via email at *Kimberly.Go@cms.hhs.gov.*

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov.*

Hospital Price Transparency, contact Sarah Wheat via email at *PriceTransparencyHospitalCharges@cms.hhs.gov.*

Inpatient Only (IPO) Procedures List, contact Abigail Cesnik via email at *Abigail.Cesnik@cms.hhs.gov.*

Medicare OPPS Drug Acquisition Cost Survey, contact Cory Duke via email at *Cory.Duke@cms.hhs.gov* or Nate Vercauteren at *Nathan.Vercauteren@cms.hhs.gov.*

Method to Control Unnecessary Increases in the Volume of Outpatient Services, contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov.*

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov.*

Non-Opioid Policy or Implementation of Section 4135 of the Consolidated Appropriations Act (CAA), 2023, contact Cory Duke via email at *Cory.Duke@cms.hhs.gov* or Nicole Marcos via email at *Nicole.Marcos@cms.hhs.gov.*

OPPS Brachytherapy, contact 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.*

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Nonyem Oguejiofor via email at *Nonyem.Oguejiofor@cms.hhs.gov,* Cory Duke via email at *Cory.Duke@cms.hhs.gov,* or Nate Vercauteren via email at *Nathan.Vercauteren@cms.hhs.gov.*

OPPS New Technology Procedures/Services, contact the New Technology APC mailbox at *NewTechAPCapplications@cms.hhs.gov.*

OPPS Packaged Items/Services, contact 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* or Tonya Gierke at *Tonya.Gierke@cms.hhs.gov.*

Outpatient Department Prior Authorization Requirements, contact Yuliya Cook via email at *Yuliya.Cook@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.*

Consideration of Potential Approaches for Separate IPPS Payment for Domestic Procurement of Personal Protective Equipment and Essential Medicines Issues, please contact *DAC@cms.hhs.gov.*

Provider-Based Attestation Requirements, please contact *CAA_2026_Section_6225@cms.hhs.gov.*

Rural Emergency Hospital Quality Reporting Program policies, contact Grace Snyder via email at *Grace.Snyder@cms.hhs.gov.*

Rural Emergency Hospital Quality Reporting Program measures, contact Melissa Hager via email at *Melissa.Hager@cms.hhs.gov.*

Skin Substitute Products, contact Nicole Marcos via email at *Nicole.Marcos@cms.hhs.gov.*

Software as a Medical Service, contact Nicole Marcos via email at *Nicole.Marcos@cms.hhs.gov.*

All Other Issues Related to Hospital Outpatient Payments Not Previously Identified, contact the OPPS mailbox at *OutpatientPPS@cms.hhs.gov.*

All Other Issues Related to the Ambulatory Surgical Center Payments Not Previously Identified, contact the ASC mailbox at *ASCPPS@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Addenda Available Only Through the Internet on the CMS Website

In the past, a majority of the addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the calendar year (CY) 2012 OPPS/ASC proposed rule, the addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules, in order to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these addenda are published and available only on the CMS website. The addenda relating to the OPPS are available at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.* The addenda relating to the ASC payment system are available at *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices.*

Current Procedural Terminology (CPT) Copyright Notice

Throughout this final rule with comment period, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2026 American Medical Association (AMA). All Rights Reserved. CPT is a registered trademark of the AMA. Applicable Federal Acquisition Regulations and Defense Federal Acquisition Regulations apply.

I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this final rule with comment period, we are updating the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), beginning January 1, 2027. 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 to 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)(2)(D)(v) of the Act, we annually review and update the ASC payment rates. This final rule with comment period also includes additional policy changes made in accordance with our experience with the OPPS and the ASC payment system and recent changes in our statutory authority. We describe these and various other statutory authorities in the relevant sections of this final rule with comment period. In addition, this final rule with comment period announces the closure of a teaching hospital and the opportunity to apply for available slots. In addition, this final rule with comment period updates and refines requirements for the Hospital Outpatient Quality Reporting Program and the Ambulatory Surgical Center Quality Reporting Program. There are no changes to the Rural Emergency Hospital Quality Reporting Program. We finalized the expansion of the prior authorization requirement to include additional Botulinum Toxin Injection services. This final rule with comment period also includes changes to implement certain provisions of the Consolidated Appropriations Act, 2026, for off-campus outpatient departments of a provider. Additionally, we are finalizing a policy that hospital

accreditation organizations (AOs) with deeming authority may assess compliance with certain EMTALA administrative requirements under 42 CFR 489.20 during accreditation and reaccreditation surveys.

2. Summary of the Major Provisions

• *OPPS Update:* For CY 2027, we are increasing the payment rates under the OPPS by an outpatient department (OPD) fee schedule increase factor of 2.3 percent. This increase factor is based on the inpatient hospital market basket percentage increase of 3.2 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), reduced by the productivity adjustment of 0.9 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) 2027 will be approximately $114.4 billion, an increase of approximately $11 billion compared to estimated CY 2026 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 0.9804 to the OPPS payments and copayments for all applicable services. Under the final 340B remedy offset, payments for services at hospitals subject to the 340B remedy offset will be reduced by 2.0 percentage points.

• *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 public health emergency (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. For CY 2026, we extended this interim period an additional year—through CY 2026. In this final rule, we are extending our utilization of the hospital market basket update as the update factor for the ASC payment system for one additional year (through CY 2027). Using the hospital market basket update, for CY 2027, we are increasing payment rates under the ASC payment system by 2.3 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This increase is based on a hospital market basket percentage increase of 3.2 percent reduced by a final productivity adjustment of 0.9 percentage point. Based on this update, we estimate that total payments to ASCs (including beneficiary cost sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2027 will be approximately $9.9 billion, an increase of approximately $560 million compared to estimated CY 2026 Medicare payments.

• *Adjustment for Cost-of-Living in Alaska and Hawaii:* For CY 2027, we are establishing a cost-of-living adjustment (COLA) for outpatient hospital services provided in Alaska and Hawaii that applies the same COLA factors as finalized in the FY 2027 IPPS/LTCH PPS final rule for FY 2027 for hospitals located in these States.

• *Device Pass-Through Payment Applications:* For CY 2027, we received 19 complete applications for device pass-through payments. We sought public comment on 13 applications (six applicants withdrew) and are approving device pass-through payment status for nine applications. We are also denying device pass-through payment status for four applications in this final rule with comment period.

• *Changes to the List of ASC Covered Surgical Procedures and Ancillary Services Lists:* For CY 2027, we are continuing to expand the ASC covered procedures list (CPL) by adding 618 codes to the ASC CPL that were recommended by interested parties or were finalized for removal from the IPO list for CY 2027.

• *Changes to the Inpatient Only (IPO) List:* We are continuing to phase out the IPO list by removing 637 services from the auditory, digestive, endocrine, female genital, hemic and lymphatic systems, integumentary, male genital, maternity care and delivery, mediastinum and diaphragm, respiratory and urinary clinical families from the IPO list for CY 2027.

• *Cross-Program Updates for the Hospital Outpatient Quality Reporting and Ambulatory Surgical Center Quality Reporting Programs:* We are removing the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure from the Hospital Outpatient Quality Reporting and Ambulatory Surgical Center Quality Reporting Programs.

• *Hospital Outpatient Quality Reporting Program:* In addition to finalizing the cross-program proposal to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, we are updating and refining validation and validation reconsideration procedures, including policies applicable to electronic clinical quality measures (eCQMs).

• *Rural Emergency Hospital Quality Reporting Program:* We are not making any updates to the Rural Emergency Hospital Quality Reporting Program in this final rule with comment period.

• *Ambulatory Surgical Center Quality Reporting Program:* We are finalizing the cross-program measure proposal to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure.

• *Expansion of Category for Hospital Outpatient Department Prior Authorization Process:* We added Botulinum Toxin Injection codes to the existing category of services subject to the Hospital Outpatient Department prior authorization process for dates of service on or after July 1, 2027.

• *Partial Hospitalization and Intensive Outpatient Programs:* We are updating the Partial Hospitalization Program (PHP) and Intensive Outpatient Program (IOP) payment rates for CY 2027 using the methodology we finalized in CY 2026.

• *Payment Adjustment for 340B-Acquired Drugs Based on Results of the Medicare OPPS Drug Acquisition Cost Survey:* Section 1833(t)(14)(D)(ii) of the Act requires the Secretary to periodically conduct surveys of hospital acquisition costs for each specified covered outpatient drug for use in setting the payment rates for such drugs. Additionally, on April 18, 2025, President Trump signed Executive Order (E.O.) 14273, ''Lowering Drug Prices by Once Again Putting Americans First''. Section 5 of the E.O., ''Appropriately Accounting for Acquisition Costs of Drugs in Medicare'', which directs the Secretary of HHS to publish in the **Federal Register** a plan to conduct a survey under section 1833(t)(14)(D)(ii) of the Act so he can determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments. Accordingly, from January 1, 2026 through April 7, 2026, we conducted a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS. Taking the survey results into account, for CY 2027 we are paying ASP minus 28 percent for 340B acquired drugs. Statute requires that this policy be implemented in a budget neutral manner, so this will increase OPPS payments for non-drug services by an equivalent amount, which is estimated to be a 7.50 percent increase to non-drug service payments for this final rule with comment period.

• *Prospective Adjustment to Payments for Non-Drug Items and Services to Offset the Increased Payments for Non-Drug Items and*

Services Made in CY 2018 Through CY 2022 as a Result of the 340B Payment Policy: The Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022 (88 FR 77150) codified an annual 0.5 percent reduction in the OPPS conversion factor applicable to non-drug items and services, excluding hospitals that enrolled in Medicare after January 1, 2018, until we estimated that the reduction had fully offset the additional $7.8 billion in non-drug services payments made as part of the prior 340B drug payment policy. This reduction was effective January 1, 2026. For CY 2027, we are increasing the annual percent reduction to the OPPS conversion factor used to determine the payment amounts for non-drug items and services for hospitals for whom this adjustment applies from 0.5 percent to 2 percent.

• *Method to Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs):* For CY 2027, we are using our authority under section 1833(t)(2)(F) of the Act to apply the Physician Fee Schedule equivalent rate for any Healthcare Common Procedure Coding System (HCPCS) codes assigned to the imaging without contrast APCs when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. We will exempt rural Sole Community Hospitals from this method to control the unnecessary volume of imaging without contrast services.

• *Payment for Software as a Medical Service (SaMS):* Recently, there have been rapid developments in the use of software-based technologies to diagnose disease and support clinical decision-making in outpatient and physician office settings. For CY 2027, we are finalizing terminology for this group of services to be designated as Software as a Medical Service (SaMS) for Medicare payment purposes. As an interim policy as we continue to consider a longer-term payment methodology for this group of services, we are finalizing assignment of SaMS technologies to new technology APCs with payment rates that closely align with current CY 2026 payment rates. We are finalizing the creation of new status indicator (SI) ''O1'' (Software as a Medical Service, paid under OPPS; separate APC payment) and assigning the relevant HCPCS codes to this new (SI).

Similarly, for CY 2027, we are moving payment for stand-alone algorithmic analyses performed on data from prior laboratory tests, such as secondary genomic sequencing analyses, from the Clinical Laboratory Fee Schedule (CLFS) as ''diagnostic laboratory tests'' to the OPPS as ''other diagnostic tests'' as provided in section 1861(s)(3) of the Act.

3. Summary of Costs and Benefits

In section XXVI. of this final rule with comment period, we provide a detailed analysis of the regulatory and Federalism impacts that the changes will have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of all OPPS Changes

Table 112 in section XXVI.C. of this final rule with comment period displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2027 compared to all estimated OPPS payments in CY 2026. We estimate that the finalized policies in this final rule with comment period will result in a 1.7 percent increase in OPPS payments to providers for services. We estimate that total OPPS payments for CY 2027, including beneficiary cost-sharing, to the approximately 3,600 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) will increase by approximately $1.78 billion compared to CY 2026 payments due to the OPD update, excluding changes in enrollment, utilization, and case-mix. However, for providers subject to the 340B remedy offset, the 340B remedy offset is estimated to reduce payments by $1.6 billion in CY 2027.

We estimated the isolated impact of our OPPS policies on CMHCs because CMHCs have historically only been paid for partial hospitalization services under the OPPS. Beginning CY 2024, they are also paid for IOP services under the OPPS. Based on our policy to calculate CMHC PHP and IOP costs based on 40 percent of the corresponding proposed hospital-based PHP and IOP costs, we estimate a 29.0 percent increase in CY 2027 payments to CMHCs relative to their CY 2026 payments.

b. Impacts of the Updated Wage Index

We estimate that our update of the wage indexes based on the fiscal year (FY) 2027 IPPS final rule wage indexes will result in no change for urban hospitals under the OPPS and a 0.3 percent increase for rural hospitals. These wage indexes include continued utilization 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 final rule with comment period.

c. Impacts of the Rural Adjustment and the Cancer Hospital Payment Adjustment

For CY 2027, we will continue to provide additional payments to cancer hospitals so that a cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. Section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. For CY 2027, we are targeting PCR of 0.88 to determine the CY 2027 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 0.88 for each cancer hospital.

There are no significant impacts of our CY 2027 payment policies for hospitals that are eligible for the rural sole community hospital adjustment, as we are maintaining the current policy in the CY 2027 OPPS.

d. Impacts of the OPD Fee Schedule Increase Factor

For the CY 2027 OPPS/ASC, we are establishing an OPD fee schedule increase factor of 2.3 percent and applying that increase factor to the conversion factor for CY 2026. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals will experience an increase in payments of 2.0 percent and that rural hospitals will experience an increase in payments of 5.6 percent. Classifying hospitals by teaching status, we estimate non-teaching hospitals will experience an increase in payments of 6.5 percent, minor teaching hospitals will experience an increase in payments of 3.5 percent, and major teaching hospitals will experience a decrease in payments of 2.0 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership will experience an increase of 2.1 percent in payments, while hospitals with government ownership will experience a decrease of 1.1 percent in payments. We estimate that hospitals with proprietary ownership will experience an increase of 10.5 percent in payments.

e. Impacts of the 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 final CY 2027 payment rates, compared to estimated CY 2026 payment rates, ranges between an increase of 35 percent and a decrease of 5 percent.

f. Impact of the Changes to the Hospital Outpatient Quality Reporting Program

Across 3,000 hospitals participating in the Hospital Outpatient Quality Reporting Program, we estimate that our finalized changes will reduce total information collection burden by 17,439 hours for a cost savings of $997,143 beginning with the CY 2029 reporting period/CY 2031 payment determination.

g. Impact of the Changes to the Ambulatory Surgical Center Quality Reporting Program

Across 5,149 ASCs participating in the Ambulatory Surgical Center Quality Reporting Program, we estimate that our finalized changes will reduce total information collection burden by 16,753 hours for a cost savings of $957,937 beginning with the CY 2027 reporting period/CY 2029 payment determination.

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 (HCERA, 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; the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), enacted December 29, 2022; and the Consolidated Appropriations Act, 2026 (CAA, 2026; Pub. L. 119–75), enacted on February 3, 2026.

Under the OPPS, we generally pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of this final rule with comment period. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use, as required by section 1833(t)(2)(B) of the Act. In accordance with section 1833(t)(2)(B) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the ''2 times rule''). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as ''transitional pass-through payments'', for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow

us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is generally temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. In addition, section 1833(t)(1)(B)(v) of the Act does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider (as defined in subparagraph (B) of paragraph (21)). We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPPS. These excluded hospitals are:

- Critical access hospitals (CAHs);
- Hospitals located in Maryland and paid under Maryland's All-Payer or Total Cost of Care Model;
- Hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico;
- Indian Health Service (IHS) hospitals; and
- Rural emergency hospitals (REHs).

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practices, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 106–113, requires that we consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to annually review (and advise the Secretary concerning) the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the Public Health Service Act (the PHS Act), which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel). The HOP Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the Panel, and, at that time, named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) who review clinical data and advise CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that the Panel—

- May advise on the clinical integrity of Ambulatory Payment Classification (APC) groups and their associated weights;
- May advise on the appropriate supervision level for hospital outpatient services;
- May advise on OPPS APC rates for ASC covered surgical procedures;
- Continues to be technical in nature;
- Is governed by the provisions of the FACA;
- Has a Designated Federal Official (DFO); and
- Is chaired by a Federal Official designated by the Secretary.

The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add critical access hospital (CAH) representation to its membership. The Panel's charter was also amended on November 6, 2014 (80 FR 23009), and the number of members was revised from up to 19 to up to 15 members. The Panel's current charter was approved on November 21, 2024, 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 24, 2026. The recommendations of the Panel for the most recent meeting are available on the CMS website at *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/hospital-outpatient-payment.* 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). We are 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 two subcommittee workgroups to provide preparatory meeting and subject support to the larger panel. The two 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; and
- Data Subcommittee, which is responsible for studying the data issues confronting the Panel and for recommending options for resolving them.

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 24, 2026, meeting that these subcommittees continue. We accepted this recommendation.

For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS website mentioned earlier in this section, and the FACA database at *https://facadatabase.gov.*

F. Public Comments Received on the CY 2026 OPPS/ASC Final Rule With Comment Period

We received approximately 48 timely pieces of correspondence on the CY 2026 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 25, 2025 (90 FR 53448).

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for Ambulatory Payment Classifications (APCs). In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights for each APC group; this methodology was implemented on August 1, 2000.

For the CY 2027 OPPS, we proposed to recalibrate the APC relative payment weights for services furnished on or after January 1, 2027, and before January 1, 2028 (CY 2027), using CY 2025 claims data and the same basic methodology that we described in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53455 through 53457). That is, we proposed to recalibrate the relative payment weights for each APC using a database constructed from claims and cost report data for hospital outpatient department (HOPD) services.

For the purpose of recalibrating the proposed APC relative payment weights for CY 2027, we began with approximately 147 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, 2025 and before January 1, 2026, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 74 million final action claims to develop the proposed CY 2027 OPPS payment weights (91 FR 41740). For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under ''Downloads'' for the CY 2027 OPPS/ASC proposed rule on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

Addendum N to the CY 2027 OPPS/ASC proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*), includes the proposed list of bypass codes for CY 2027. Bypass codes allow the ratesetting process to use multiple-procedure claims to develop ''pseudo'' single claims, which are then used to develop OPPS payment rates. The proposed list of bypass codes contains codes that are reported on claims for services in CY 2025 and, therefore, includes codes that were in effect in CY 2025 and used for billing. We proposed to retain these deleted bypass codes on the proposed CY 2027 bypass list because these codes existed in CY 2025 and were covered HOPD services in that period, and CY 2025 claims data were used to calculate proposed CY 2027 payment rates (91 FR 41740). Keeping these deleted bypass codes on the bypass list potentially allows us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to the CY 2027 OPPS/ASC proposed rule. HCPCS codes that we proposed to add for CY 2027 are identified by asterisks (*) in the fourth column of Addendum N.

We did not receive any public comments on our general proposal to recalibrate the relative payment weights for each APC based on claims and cost report data for HOPD services or on our proposed bypass code process. We are finalizing as proposed the ''pseudo'' single claims process and the CY 2027 proposed list of bypass codes, finalized in Addendum N to this final rule with comment period (which is available via the internet on the CMS website). For this final rule with comment period, for the purpose of recalibrating the final APC relative payment weights for CY 2027, we used approximately 81 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, 2025, and before January 1, 2026. For the exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for this final rule with comment period on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

b. Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2027, we proposed to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center

crosswalk (91 FR 41740). To calculate the APC costs on which the proposed CY 2027 APC payment rates are based, we calculated hospital-specific departmental CCRs for each hospital for which we had CY 2025 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2024. For the proposed CY 2027 OPPS payment rates, we used the set of claims processed during CY 2025. 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 2025 (the year of claims data we used to calculate the proposed CY 2027 OPPS payment rates) and updates to the National Uniform Billing Committee (NUBC) 2025 Data specifications Manual (91 FR 41740 through 41741). 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/regulations-notices* and included with every proposed and final OPPS rule.

In accordance with our longstanding policy, similar to our finalized policy for CY 2026 OPPS ratesetting, we proposed to calculate CCRs for the standard cost centers—cost centers with a predefined label—and nonstandard cost centers—cost centers defined by a hospital—accepted by the electronic cost report database. In general, the most detailed level at which we calculate CCRs is the hospital-specific departmental level.

While we generally view the use of additional cost data as improving our OPPS ratesetting process, we have historically not included cost report lines for certain nonstandard cost centers in the OPPS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. We believe it is important to further investigate the accuracy of these cost report data before including such data in the ratesetting process. Further, we believe it is appropriate to gather additional information from the public as well before including the data in OPPS ratesetting. For CY 2027 and future years, we proposed not to include the nonstandard cost centers reported in this way in the OPPS ratesetting database construction (91 FR 41741).

We did not receive any public comments on the general CCR process, and therefore, we are finalizing our proposal for CY 2027 to continue to use the hospital-specific overall ancillary and departmental CCRs to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. We are also finalizing the proposed methodology regarding the treatment of nonstandard cost centers.

2. Final Data Development and Calculation of Costs Used for Ratesetting

In this section of this final rule with comment period, we discuss the use of claims to calculate the OPPS payment rates for CY 2027. The Hospital OPPS page on the CMS website on which this final rule with comment period is posted (*https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient)* provides an accounting of claims used in the development of the final payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, later in this section we discuss the file of claims that comprises the data set that is available upon payment of an administrative fee under a CMS data use agreement. The CMS website *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient,* includes information about obtaining the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM) diagnosis codes and revenue code payment amounts. This file is derived from the CY 2025 claims that are used to calculate the final payment rates for the CY 2027 OPPS/ASC final rule with comment period.

Previously, the OPPS established the scaled relative weights on which payments are based using APC median costs, a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost.

We used the methodology described in sections II.A.2.a. through II.A.2.c. of this final rule with comment period to calculate the costs we used to establish the proposed relative payment weights used in calculating the OPPS payment rates for CY 2027 shown in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*). We refer readers to section II.A.4. of this final rule with comment period for a discussion of the conversion of APC costs to scaled payment weights.

We note that under the OPPS, CY 2019 was the first year in which the claims data used for setting payment rates (CY 2017 data) contained lines with the modifier ''PN,'' which indicates nonexcepted items and services furnished and billed by off-campus provider-based departments (PBDs) of hospitals. Because nonexcepted items and services are not paid under the OPPS, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58832), we finalized a policy to remove those claim lines reported with modifier ''PN'' from the claims data used in ratesetting for the CY 2019 OPPS and subsequent years. For the CY 2027 OPPS, we proposed to continue to remove claim lines with modifier ''PN'' from the ratesetting process (91 FR 41741).

We did not receive any public comments on our proposal to continue to remove claim lines reported with modifier ''PN'' from the ratesetting process and are finalizing as proposed.

For details of the claims accounting process used in this CY 2027 OPPS/ASC final rule with comment period, we refer readers to the claims accounting narrative under supporting documentation for this final rule with comment period on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

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 proposed to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology (90 FR 53457), which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. To address the differences in CCRs and to better reflect hospitals' costs, our methodology simulates blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers and applies this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports. We proposed to calculate the costs upon which the proposed payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific, simulated, blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific, simulated, blood-specific CCR methodology takes into account the unique charging and cost accounting structure of each hospital, 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 (91 FR 41742).

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.

We received one public comment on these proposals. The following is a summary of the comment we received and our response.

Comment: A commenter supported CMS's proposal to continue to pay for blood and blood derived products in the HOPD rather than packaging the payment.

Response: We appreciate the commenter's support of our proposal.

After consideration of the public comment, we are finalizing our proposal to continue separate payment for blood and blood derived products in the HOPD for CY 2027.

We refer readers to Addendum B to this final rule with comment period (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*) for the final CY 2027 payment rates for blood and blood products (which are generally identified with status indicator ''R'').

(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 2013 OPPS/ASC final rule with comment period (77 FR 68240 and 68241). For purposes of setting payment rates, as we have stated in prior OPPS updates, we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for several 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 most 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 2027, except where otherwise indicated, we proposed to continue our policy and use the costs derived from CY 2025 claims data to set the proposed CY 2027 payment rates for brachytherapy sources because we proposed to use CY 2025 data to set the proposed payment rates for most other items and services that would be paid under the CY 2027 OPPS (91 FR 41742). With the exception of the proposed payment rates for brachytherapy sources A9527 (Iodine i-125, sodium iodide solution, therapeutic, per millicurie), C2636 (Brachytherapy linear source, non-stranded, palladium-103, per 1 mm), 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 final rule with comment period, we proposed to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we proposed for other items and services paid under the OPPS, as discussed in section II.A.2. of this final rule with comment period.

We also proposed for CY 2027 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 2027 and subsequent years, we proposed to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise specified, per source) and C2699 (Brachytherapy source, nonstranded, 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 2027 and subsequent years, we also proposed to continue the policy we 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, for 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 2027 payment rates for brachytherapy sources are included in 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*) and identified with status indicator ''U (Brachytherapy Sources, Paid under OPPS; separate APC payment).''

For CY 2018, we assigned status indicator ''U'' to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) in the absence of claims data and established a payment rate using external data (invoice price) at $4.69 per mm^2 for the brachytherapy source's APC—APC 2648 (Brachytx planar, p-103) (82 FR 59233 through 59234). For CY 2019, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at $4.69 per mm^2 for APC 2648 (Brachytx planar, p-103) (83 FR 58834 through 58836). Our CY 2018 claims data available for the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142) included two claims with a geometric mean cost for HCPCS code C2645 of $1.02 per mm^2. In response to comments from interested parties, we agreed that, given the limited claims data available and a new outpatient indication for C2645, a payment rate for HCPCS code C2645 based on the geometric mean cost of $1.02 per mm^2 may not adequately reflect the cost of HCPCS code C2645. In the CY 2020 OPPS/ASC final rule with comment period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2020 (84 FR 61157 through 61158). Similarly, in the absence of sufficient claims data to establish an APC payment rate, in the CY 2021, CY 2022, CY 2023, CY 2024, CY 2025, and CY 2026 OPPS/ASC final rules with comment period (85 FR 85879 through 85880, 86 FR 63469, 87 FR 71760 through 71761, 88 FR 81553, 89 FR 93925, and 90 FR 53458), we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CYs 2021 through 2026.

There were no CY 2025 claims available that reported HCPCS code C2645 for the CY 2027 OPPS/ASC proposed rule. Therefore, in the absence of claims data, we proposed to continue to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2026 payment rate of $4.69 per mm^2 for HCPCS code C2645, which we proposed to be assigned to APC 2648 (Brachytx planar, p-103) for CY 2027 (91 FR 41743). Similarly, there were no CY 2025 claims available for the proposed rule that reported HCPCS A9527 (Iodine i-125, sodium iodide solution, therapeutic, per millicurie), which is assigned to APC 2632, or HCPCS code C2636 (Brachytherapy linear source, non-stranded, palladium-103, per 1 mm), which is assigned to APC 2636. While both APC 2632 and 2636 have historically been designated as Low Volume APCs, which uses up to 4 years of claims data, we are concerned that 4 years of historical claims data would only yield 2 claims for each APC, and that may not be reliable for ratesetting for these APCs for CY 2027. Therefore, we proposed to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states in part 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 2026 payment rates for APC 2632 and APC 2636 for CY 2027. Specifically, for CY 2027, we proposed a payment rate of $396.32 per millicurie for APC 2632 and a payment rate of $89.40 per 1 mm for APC 2636 (91 FR 41743).

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 APCs 2632, 2636, and 2648 as detailed above.

For CY 2027, we proposed to designate five brachytherapy APCs as Low Volume APCs as these APCs met our criteria to be designated as Low Volume APCs (91 FR 41743).

We invited 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.*

We did not receive public comments on the proposed brachytherapy payment policies discussed above, and therefore, we are finalizing them as proposed. With the exception for brachytherapy APCs designated as Low Volume APCs and APCs 2632, 2636, and 2648, we will continue our policy and use the costs derived from CY 2025 claims data to set the final CY 2027 payment rates for brachytherapy sources. We will continue to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS code C2698 (Brachytherapy source, 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. Further, we will use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2026 payment rate of $4.69 per mm^2 for HCPCS code C2645, the CY 2026 payment rate of $396.32 per millicurie for APC 2632, and the CY 2026 payment rate of $89.40 per 1 mm for APC 2636 for CY 2027. We refer readers to section III.D. of this final rule with comment period for information on the brachytherapy APCs we are finalizing to designate as Low Volume APCs.

b. Comprehensive APCs (C–APCs) for CY 2027

(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 costliest primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014, but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C–APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C–APC policy (79 FR 66798 through 66810).

A C–APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C–APCs as a category broadly for OPPS payment and implemented 25 C–APCs beginning in CY 2015 (79 FR 66809 through 66811). We have gradually added new C–APCs since the policy was implemented beginning in CY 2015, with the number of C–APCs now totaling 74 (80 FR 70332; 81 FR 79584 through 79585; 83 FR 58844 through 58846; 84 FR 61158 through 61166; 85 FR 85885; 86 FR 63474; 87 FR 71769; 88 FR 81562; 89 FR 93926; and 90 FR 53448).

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 through 66801). A list of services excluded from the C–APC policy is included in Addendum J to this final rule with comment period (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*). If a service does not appear on this list of excluded services, payment for it will be packaged into the payment for the primary C–APC service when it appears on an outpatient claim with a primary C–APC service.

The C–APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period and modified and implemented beginning in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPS/ASC final rule with comment period, we define the C–APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator ''J1,'' [1] excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS. Services and procedures described by HCPCS codes assigned to status indicator ''J1'' are assigned to C–APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC.

In the CY 2016 OPPS/ASC final rule with comment period, we expanded the C–APC payment methodology to qualifying extended assessment and management encounters through the ''Comprehensive Observation Services'' C–APC (C–APC 8011). Services within this APC are assigned status indicator ''J2.'' [2] Specifically, we make a payment through C–APC 8011 for a claim that:

- Does not contain a procedure described by a HCPCS code to which we have assigned status indicator ''T;'' [3]
- Contains 8 or more units of services described by HCPCS code G0378 (Hospital observation services, per hour);
- Contains services provided on the same date of service or 1 day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379 (Direct admission of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and

[1] Status indicator ''J1'' denotes Hospital Part B Services Paid Through a Comprehensive APC. Further information can be found in CY 2027 Addendum D1 to this final rule with comment period.

[2] Status indicator ''J2'' denotes Hospital Part B Services That May Be Paid Through a Comprehensive APC. Further information can be found in CY 2027 Addendum D1 to this final rule with comment period.

[3] Status Indicator ''T'' is defined as a ''Procedure or Service, Multiple Procedure Reduction Applies'' the OPPS payment status is ''Paid under OPPS; separate APC payment.'' Definitions to all OPPS payment status indicators are available in Addenda D1 to this final rule with comment period.

• 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)[4] 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 self-administered drugs (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.[5]

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 previously). 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 final rule with comment period, in the originating C–APC (cost threshold).

These criteria identify paired code combinations that occur commonly and exhibit materially greater resource requirements than the primary service. The CY 2017 OPPS/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment

[4] *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r3523cp.pdf.*

[5] *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 previously) 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 previously, 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 2027, we apply the frequency and cost criteria thresholds discussed previously, 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 previously), 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 proposed complexity adjustments for ''J1'' and add-on code combinations for CY 2027, along with all the other proposed complexity adjustments, in Addendum J to this final rule with comment period (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

Addendum J to this final rule with comment period includes the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to this final rule with comment period also contains summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and be reassigned to the next higher cost C–APC within the clinical family. The combined statistics for all proposed reassigned complex code combinations are represented by an alphanumeric code with the first four digits of the designated primary service followed by a letter. For example, the final geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3320R, which is assigned to C–APC 5224 (Level 4 Pacemaker and Similar Procedures), includes all paired code combinations that will be reassigned to C–APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to this final rule with comment period allows interested parties the opportunity to better assess the impact associated with the assignment of claims with each of the paired code combinations eligible for a complexity adjustment.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received support from commenters for a variety of existing and proposed complexity adjustments.

Response: We thank the commenters for their support.

Comment: Multiple commenters requested that CMS apply a complexity adjustment to additional code combinations. The specific C–APC complexity adjustment code combinations requested by the commenters for CY 2027 are listed in Table 1.

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TABLE 1: C-APC COMPLEXITY ADJUSTMENTS REQUESTED BY COMMENTERS FOR CY 2027

Primary "J1" HCPCS/CPT Code	Secondary "J1" HCPCS/CPT code	Primary C-APC Assignment	Requested complexity adjusted C-APC assignment
28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint)	**28299** (Correction, hallux valgus, with bunionectomy, with sesamoidectomy, when performed; with double osteotomy, any method)	5114	5115
	28308 (Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; other than first metatarsal, each)	5114	5115
28750 (Arthrodesis, great toe; metatarsophalangeal joint)	**27691** (Transfer or transplant of single tendon (with muscle redirection or rerouting); deep (for example, anterior tibial or posterior tibial through interosseous space, flexor digitorum longus, flexor hallucis longus, or peroneal tendon to midfoot or hindfoot))	5114	5115
	28296 (Correction, hallux valgus with bunionectomy, with sesamoidectomy when performed; with distal metatarsal osteotomy, any method)	5114	5115
	28299 (Correction, hallux valgus, with bunionectomy, with sesamoidectomy, when performed; with double osteotomy, any method)	5114	5115
37187 (Percutaneous transluminal mechanical thrombectomy, vein(s), including intraprocedural pharmacological thrombolytic injections and fluoroscopic guidance)	**37248** (Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; initial vein)	5193	5194
	37252 (Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; initial noncoronary vessel)	5193	5194

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Response: We reviewed each of the requested code combinations suggested by commenters, listed in Table 1, against our complexity adjustment criteria. The following code combination met our cost and frequency criteria, qualifying for a complexity adjustment for CY 2027:

- Primary HCPCS code 37187 with secondary HCPCS code 37248.

All the remaining code combinations listed failed to meet our cost or frequency criteria and do not qualify for complexity adjustments for CY 2027. Addendum J to this final rule with comment period includes the cost statistics for each code combination that was evaluated for a complexity adjustment.

Comment: Several commenters addressed the application of the C–APC complexity adjustment policy to the new lower extremity revascularization (LER) CPT code set. Commenters noted that CPT codes 37220 through 37235 were discontinued effective January 1, 2026, and replaced by CPT codes 37254 through 37299. Commenters stated that CMS used claims data from the predecessor codes to inform both C–APC assignment and complexity adjustment eligibility for the new LER

codes for CY 2026 and continues to use predecessor-code information to establish C–APC assignments for the new codes for CY 2027. However, commenters noted that the CY 2027 proposed rule complexity adjustment analysis reflected combinations involving the discontinued predecessor codes rather than the corresponding new LER codes. Commenters recommended that CMS apply the predecessor-code crosswalk methodology to the new LER codes for purposes of determining CY 2027 complexity adjustment eligibility under the OPPS and ASC payment systems. Commenters stated that doing so would ensure that a change in coding structure does not result in the loss of complexity-adjusted payment for clinically comparable and resource-intensive procedure combinations and would provide continuity until sufficient claims data are available for the new codes.

Response: We thank the commenters for their comments and bringing to our attention the application of the complexity adjustment policy to the new LER code set. As discussed in prior rulemaking (79 FR 66802), for a new HCPCS code, we determine the initial C–APC assignment and qualification for a complexity adjustment using the best available information, crosswalking the new HCPCS code to a predecessor code or codes when appropriate. Consistent with this policy, for this final rule we used the applicable predecessor-code information to evaluate the new LER codes for purposes of determining complexity adjustment eligibility for CY 2027. The results of our CY 2027 complexity adjustment evaluation, including the applicable LER code combinations and their complexity adjustment determinations, are reflected in Addendum J to this final rule. We refer readers to Addendum J for the final CY 2027 complexity adjustment assignments.

Comment: One commenter reviewed the proposed complexity adjustment evaluations and identified certain code combinations that met the applicable cost and frequency criteria for a complexity adjustment but that the commenter believed were not assigned to the appropriate next higher-paying C–APC within the applicable clinical family. The commenter requested that CMS review these combinations and assign qualifying combinations to the appropriate higher-level C–APC consistent with the complexity adjustment methodology.

Response: We thank the commenter for bringing this to our attention. It has been our longstanding policy to promote coding pairings that qualify for complexity adjustments to the next highest APC in their clinical family. In Addendum J to this final rule with comment period, all code pairings that qualify for complexity adjustments are mapped to the next highest APC in their clinical family. All code pairings that qualify for complexity adjustments can be found in both ''Complexity Adjustment Evaluation'' tab and the ''Complexity Adjustments'' tab of Addendum J.

Comment: Several commenters encouraged CMS to modify or further refine the C–APC complexity adjustment methodology, including recommendations previously submitted in response to the CY 2026 OPPS/ASC proposed rule request for information. These prior recommendations included modifying the cost threshold used to determine eligibility for a complexity adjustment, expanding the methodology to evaluate clusters of a primary ''J1'' service and multiple associated add-on codes rather than only code pairs, expanding the types of codes eligible for consideration, and allowing qualifying code combinations involving a primary service already assigned to the highest level C–APC within a clinical family to receive an adjustment. Commenters generally stated that the current methodology may not adequately recognize certain complex and resource-intensive combinations of services, particularly as additional higher-cost procedures transition to the outpatient setting.

Commenters recommended a variety of changes, including modifying the cost threshold used to determine eligibility, particularly for higher-cost APCs and APCs with wider cost bands; harmonizing the methodology for evaluating different types of code combinations; and evaluating clusters of services in addition to code pairs. Several commenters also recommended expanding the types of codes eligible for complexity adjustment consideration to include certain packaged HCPCS device codes. These commenters stated that a primary J1 procedure furnished with a costly packaged device may represent a more resource-intensive encounter in the same manner as combinations currently eligible for a complexity adjustment, and, therefore, recommended that CMS evaluate J1 procedure and device code combinations when applicable cost and frequency criteria are met. Some commenters specifically cited arthroscopic rotator cuff repair furnished with a graft augmentation device as an example of a procedure and device combination they believed should be eligible for consideration.

Commenters also recommended establishing a mechanism to provide additional payment when an otherwise qualifying combination involves a primary procedure already assigned to the highest-level or only APC in a clinical family, providing greater stability for qualifying combinations, such as maintaining complexity adjustments for a specified period before reevaluation, extending adjustments to clinically similar combinations or related code families, and increasing transparency regarding the claims accounting, inclusion and exclusion criteria, and other aspects of the complexity adjustment methodology. Commenters urged CMS to consider these and other refinements to improve payment accuracy and ensure that the C–APC methodology appropriately accounts for the resources associated with complex outpatient procedures.

Response: We thank the commenters for their thoughtful and detailed recommendations regarding potential refinements to the C–APC complexity adjustment methodology. We appreciate commenters' continued engagement on these issues, including their perspectives on how the complexity adjustment methodology could better account for complex and resource-intensive combinations of services as clinical practice evolves and additional procedures are furnished in the hospital outpatient setting. We recognize the importance of appropriately accounting for differences in resource use under the C–APC payment methodology while maintaining a methodology that is consistent, transparent, and based on reliable claims data. We appreciate the specific recommendations regarding the complexity adjustment cost threshold, the types and combinations of services considered for complexity adjustments, the treatment of packaged device codes and clusters of services, payment for qualifying combinations at the highest level of a clinical family, payment stability, and other aspects of the methodology. We will take these comments and recommendations into consideration as we continue to evaluate the C–APC complexity adjustment methodology and consider whether refinements may be appropriate in future rulemaking.

After consideration of public comments, we are finalizing the C–APC complexity adjustment methodology and criteria for CY 2027 as proposed. We are also finalizing the specific C–APC complexity adjustments identified in the proposed rule, with the addition

of the code combination of CPT codes 37187 and 37248, which was suggested by commenters and which we determined meets our complexity adjustment criteria.

(2) Exclusion of Procedures Assigned to New Technology APCs From the C–APC Policy

Services that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for them. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected (82 FR 59277).

The C–APC payment policy packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. Prior to CY 2019, when a procedure assigned to a New Technology APC was included on the claim with a primary procedure, identified by OPPS status indicator ''J1,'' payment for the new technology service was typically packaged into the payment for the primary procedure. Because the new technology service was not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service was reduced. This was contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable us to assign the service to an appropriate clinical APC.

To address this issue and ensure that there are sufficient claims data for services assigned to New Technology APCs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58847), we finalized excluding payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a ''J1'' service assigned to a C–APC. In the CY 2020 OPPS/ASC final rule with comment period, we finalized that beginning in CY 2020, payment for services assigned to a New Technology APC would be excluded from being packaged into the payment for comprehensive observation services assigned status indicator ''J2'' when they are included on a claim with a ''J2'' service (84 FR 61167).

(3) Exclusion of Drugs and Biologicals Described by HCPCS Code C9399 (Unclassified Drugs or Biologicals) From the C–APC Policy

Section 1833(t)(15) of the Act, as added by section 621(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), provides for payment under the OPPS for new drugs and biologicals until HCPCS codes are assigned. Under this provision, we are required to make payment for a covered outpatient drug or biological that is furnished as part of covered outpatient department services but for which a HCPCS code has not yet been assigned in an amount equal to 95 percent of average wholesale price (AWP) for the drug or biological.

In the CY 2005 OPPS/ASC final rule with comment period (69 FR 65805), we implemented section 1833(t)(15) of the Act by instructing hospitals to bill for a drug or biological that is newly approved by the Food and Drug Administration (FDA) and that does not yet have a HCPCS code by reporting the National Drug Code (NDC) for the product along with the newly created HCPCS code C9399 (Unclassified drugs or biologicals). We explained that when HCPCS code C9399 appears on a claim, the Outpatient Code Editor (OCE) suspends the claim for manual pricing by the Medicare Administrative Contractor (MAC). The MAC prices the claim at 95 percent of the drug or biological's AWP, using Red Book or an equivalent recognized compendium, and processes the claim for payment. We emphasized that this approach enables hospitals to bill and receive payment for a new drug or biological concurrent with its approval by the FDA. The hospital does not have to wait for the next quarterly release or for approval of a product-specific HCPCS code to receive payment for a newly approved drug or biological or to resubmit claims for adjustment. We instructed that hospitals would discontinue billing HCPCS code C9399 and the NDC upon implementation of a product-specific HCPCS code, status indicator, and appropriate payment amount with the next quarterly update. We also note that HCPCS code C9399 is paid in a similar manner in the ASC setting, as 42 CFR 416.171(b) outlines that certain drugs and biologicals for which separate payment is allowed under the OPPS are considered covered ancillary services for which the OPPS payment rate, which is 95 percent of AWP for HCPCS code C9399, applies.

Since the implementation of the C–APC policy in 2015, payment for drugs and biologicals described by HCPCS code C9399 had been included in the C–APC payment when these products appear on a claim with a primary C–APC service. Packaging payment for these drugs and biologicals that appear on a hospital outpatient claim with a primary C–APC service is consistent with our C–APC packaging policy under which we make payment for all items and services, including all non-pass-through drugs, reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing components of a complete comprehensive service, with certain limited exceptions (78 FR 74869). It was our position that the total payment for the C–APC with which payment for a drug or biological described by HCPCS code C9399 is packaged includes payment for the drug or biological at 95 percent of its AWP.

However, we determined that in certain instances, drugs and biologicals described by HCPCS code C9399 are not being paid at 95 percent of their AWPs when payment for them is packaged with payment for a primary C–APC service. In order to ensure payment for new drugs and biologicals 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 or biological described by HCPCS code C9399 from packaging when the drug or biological 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 to this final rule with comment period for the final CY 2027 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 current definition of status indicator ''A'', including the finalized changes from the CY 2023 OPPS/ASC final rule with comment period, can be found in Addendum D1 to this final rule with comment period. This change ensures the MAC prices claims for drugs or biologicals billed with HCPCS code C9399 at 95 percent of the drug or biological's AWP and pays separately for the drug or biological 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 with comment period (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.

As discussed in the CY 2025 OPPS/ASC proposed rule (89 FR 59201 through 59204), 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 SADs, unless they function as supplies (78 FR 74868 through 74869 and 74909).

However, we recognized in the CY 2025 OPPS/ASC proposed rule (89 FR 59201 through 59204) that there are rare instances in which cell and gene therapies 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. As stated in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93932 through 93938), 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 primary C–APC services. Additionally, we stated that 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.

Therefore, we finalized a policy for CY 2025 and subsequent years (89 FR 93932 through 93938), to not package payment for cell and gene therapies into C–APCs, when those cell and gene therapies are not functioning as integral, ancillary, supportive, dependent, or adjunctive to the primary C–APC service. For new cell and gene therapy products that are not integral, ancillary, supportive, dependent, or adjunctive to any C–APC primary service, we will continue to add their product-specific HCPCS codes, when created, to the C–APC exclusion list. The proposed list of qualifying products can be found in Table 2.

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TABLE 2: CELL AND GENE THERAPIES PROPOSED FOR EXCLUSION FROM C-APC PACKAGING FOR CY 2027

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
CARVYKTI	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
Skysona	J3387	Injection, elivaldogene autotemcel, per treatment
Lenmeldy	J3391	Injection, atidarsagene autotemcel, per treatment
CASGEVY	J3392	Injection, exagamglogene autotemcel, per treatment
Luxturna	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes
Zolgensma	J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 vector genomes
Ryoncil	J3402	Injection, remestemcel-l-rknd, per therapeutic dose
Hemgenix	J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose

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We list all final C–APC exclusion categories for CY 2027 in Addendum J to this final rule with comment period (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

Comments on our proposed exclusions are below:

Comment: Commenters generally supported our proposal to continue excluding qualifying cell and gene therapies from C–APC packaging when those therapies are not integral, ancillary, supportive, dependent, or adjunctive to the primary C–APC service. Commenters stated that cell and gene therapies are generally the primary treatment being furnished to the patient and that separate payment appropriately recognizes the unique clinical and resource characteristics of these therapies. Commenters also stated that

continuation of the policy would support appropriate payment and beneficiary access, including access to cell and gene therapies furnished in the outpatient setting. Several commenters encouraged CMS to continue adding qualifying cell and gene therapy product-specific HCPCS codes to the C–APC exclusion list as new codes are created.

Response: We thank commenters for their support. We continue to believe that, when cell and gene therapies do not function as integral, ancillary, supportive, dependent, or adjunctive to a primary C–APC service, packaging payment for these therapies under the C–APC policy would not appropriately reflect the role of these products in the outpatient encounter. As discussed in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93932 through 93938), when these products are administered under these circumstances, they are the primary treatment being administered to the patient. Therefore, we are continuing our policy of excluding qualifying cell and gene therapies from C–APC packaging. Consistent with our existing policy, we will continue to review new cell and gene therapy products and add product-specific HCPCS codes to the C–APC exclusion list, as appropriate, when those codes are created.

Comment: One commenter recommended that CMS establish additional mechanisms to facilitate the identification of qualifying cell and gene therapies and provide greater transparency regarding their exclusion from C–APC packaging. Specifically, the commenter recommended adding a checkbox to the MEARIS HCPCS Level II code application to allow applicants to identify products that may qualify for the exclusion, establishing and publishing a formal off-cycle process through which interested parties could request additions to the exclusion list, and creating a new OPPS status indicator to identify products that are excluded from C–APC packaging but no longer have pass-through payment status. The commenter stated that these changes could help ensure that qualifying products are identified when their pass-through payment status expires and allow interested parties to more readily confirm whether a particular product is excluded from C–APC packaging.

Response: We thank the commenter for these recommendations. As discussed in prior rulemaking, under our existing policy, for new cell and gene therapy products that are not integral, ancillary, supportive, dependent, or adjunctive to any C–APC primary service, we will continue to add their product-specific HCPCS codes, when created, to the C–APC exclusion list. We also review products through our regular quarterly update processes to identify qualifying cell and gene therapies that should be excluded from C–APC packaging. We appreciate the commenter's recommendations regarding additional mechanisms for identifying and communicating the C–APC exclusion status of qualifying products and will take these suggestions into consideration for potential future rulemaking and other appropriate associated processes.

Comment: Several commenters recommended that CMS expand the C–APC exclusion policy beyond cell and gene therapies to include other drugs and biologicals that commenters stated similarly constitute the primary treatment furnished during an outpatient encounter rather than an integral, ancillary, supportive, dependent, or adjunctive service. Commenters specifically discussed certain oncology therapies administered through procedures or novel delivery mechanisms, including bladder cancer diagnostics and therapies, and bispecific T-cell engager therapies that may be furnished with observation services. Commenters stated that, in these circumstances, the associated procedure or observation service facilitates the administration or monitoring of the drug, while the drug or biological itself is the primary therapeutic intervention.

Commenters expressed concern that, following expiration of transitional pass-through payment status or other temporary separate payment, packaging these therapies into a C–APC could result in payment that does not adequately reflect hospitals' acquisition costs, potentially creating financial disincentives to furnish the therapies and affecting beneficiary access. Some commenters also asserted that the costs of relatively low-volume, high-cost therapies may not be adequately reflected in C–APC rates because those rates are based on claims that include substantially higher volumes of lower-cost services. Commenters recommended various approaches, including establishing an exclusion for directly administered oncology therapies furnished via a procedure, excluding bispecific T-cell engager therapies, applying the rationale underlying the cell and gene therapy exclusion to other similarly situated drugs and biologicals, or soliciting public comment on such approaches in future rulemaking.

Response: We thank commenters for their feedback, analyses, and recommendations regarding the application of the C–APC packaging policy to other drugs and biologicals. As we have previously stated, the C–APC policy generally packages payment for items and services that are integral, ancillary, supportive, dependent, or adjunctive to the primary C–APC service, and historically this has included drugs and biologicals furnished in conjunction with a primary C–APC service, except where an applicable packaging exclusion applies. We established the cell and gene therapy exclusion based on our consideration of the unique nature of those therapies and our determination that, under the circumstances described in our policy, they do not function as integral, ancillary, supportive, dependent, or adjunctive to the primary C–APC service.

We acknowledge commenters' assertions that certain other drugs and biologicals may similarly represent the primary therapeutic intervention in an outpatient encounter. However, we do not believe that the fact that a drug or biological may be characterized as the primary therapeutic intervention alone provides sufficient basis to establish a categorical exclusion from the C–APC packaging policy. The recommendations described by commenters encompass different types of therapies, methods of administration, associated services, and clinical circumstances and would represent a broader expansion of the C–APC packaging exclusions beyond the specific category of cell and gene therapies considered in prior rulemaking. We believe additional consideration and data would be necessary to determine whether, and under what circumstances, an exclusion for other classes of drugs or biologicals that are not supportive of a primary C–APC service but may nonetheless appear on the same claim as the primary C–APC procedure would be appropriate under the C–APC methodology.

We strongly believe in the principles of our prospective payment system and the C–APC policy; therefore, we want to ensure that any potential changes to our C–APC packaging policy maintain these principles.

We appreciate commenters' concerns regarding other therapies that may be furnished in conjunction with a C–APC service and their recommendations regarding potential alternative approaches to payment for such therapies. We are not expanding the C–APC exclusion policy to additional categories of drugs or biologicals for CY 2027. We will take commenters' feedback and recommendations into consideration as we continue to

evaluate the C–APC methodology in future rulemaking.

Comment: A commenter asked CMS to add HCPCS codes J1413 (Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose), J3401 (Beremagene geperpavec-svdt for topical administration, containing nominal 5 × 10^9 pfu/mL vector genomes, per 0.1 mL), and J9029 (Intravesical instillation, nadofaragene firadenovec-vncg, per therapeutic dose) to the list of cell and gene therapies excluded from C–APC packaging for CY 2027. The commenter noted that these products currently have drug pass-through payment status that expires December 31, 2026, and stated that they should be excluded from C–APC packaging beginning January 1, 2027, consistent with our existing policy for qualifying cell and gene therapies.

Response: We thank the commenter for recommending the addition of HCPCS codes J1413, J3401, and J9029 to the cell and gene therapy C–APC exclusion list. These HCPCS codes have been added to the table of cell and gene therapies excluded from C–APC packaging for CY 2027. We note that these products currently have drug pass-through payment status through December 31, 2026, and therefore are already excluded from C–APC packaging through the end of CY 2026. Beginning January 1, 2027, following expiration of their drug pass-through payment status, we will exclude HCPCS codes J1413, J3401, and J9029 from C–APC packaging consistent with our policy finalized in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93932 through 93938).

We note that we did not propose to alter the substance of our existing policy excluding qualifying cell and gene therapies from C–APC packaging. After consideration of the public comments received, we are continuing this policy without modification for CY 2027. We are also finalizing the list of qualifying cell and gene therapy products for CY 2027 in Table 3, including the additions discussed in response to comments, consistent with the policy finalized in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93932 through 93938).

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TABLE 3: CELL AND GENE THERAPIES FINALIZED FOR EXCLUSION FROM C-APC PACKAGING FOR CY 2027

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

Trade Name	HCPCS Code	Long Descriptor
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
CARVYKTI	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
Skysona	J3387	Injection, elivaldogene autotemcel, per treatment
Kresladi	J3388	Injection, marnetegragene autotemcel, per treatment
Lenmeldy	J3391	Injection, atidarsagene autotemcel, per treatment
CASGEVY	J3392	Injection, exagamglogene autotemcel, per treatment
Zynteglo	J3393	Injection, betibeglogene autotemcel, per treatment
Lyfgenia	J3394	Injection, lovotibeglogene autotemcel, per treatment
Luxturna	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes
Zolgensma	J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 vector genomes
Ryoncil	J3402	Injection, remestemcel-l-rknd, per therapeutic dose
OTARMENI	J3407	Injection, lunsotogene parvec-cwha, per treatment
Hemgenix	J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose
Roctavian	J1412	Injection, valoctocogene roxaparvovec-rvox, per mL, containing nominal 2 × 10^13 vector genomes
Elevidys	J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose
Beqvez	J1414	Injection, fidanacogene elaparvovec-dzkt, per therapeutic dose
Vyjuvek	J3401	Beremagene geperpavec-svdt for topical administration, containing nominal 5 × 10^9 pfu/mL vector genomes, per 0.1 mL
Adstiladrin	J9029	Intravesical instillation, nadofaragene firadenovec-vncg, per therapeutic dose

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(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 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)(iv) 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. 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, in the CY 2025 OPPS/ASC final rule with comment period, we finalized a policy 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 (89 FR 93938 through 93939).

(6) C–APCs for CY 2027

For CY 2027 and subsequent years, we proposed to continue to apply the C–APC payment policy methodology (91 FR 41749). We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583) for a discussion of the C–APC payment policy methodology- and revisions.

Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As a result of our annual review of the services and the APC assignments under the OPPS, we did not propose to convert any standard APCs to C–APCs in CY 2027; thus, we proposed that the number of C–APCs for CY 2027 (see Table 4) would be the same as the number for CY 2026, which is 74 C–APCs (91 FR 8384).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters expressed concerns with the C–APC methodology for surgical insertion procedures for brachytherapy treatment, stating that these concerns may affect beneficiary access to brachytherapy in the HOPD setting. Commenters stated that the C–APC methodology lacks appropriate charge capture mechanisms to accurately reflect the services associated with the C–APC, that there is significant variation in clinical practice and billing patterns reflected in the hospital claims data used for ratesetting, and that C–APC payment rates do not accurately or fully reflect the services and costs associated with the primary procedure. Commenters urged CMS to explore alternatives to the current methodology, including discontinuing the C–APC payment policy for brachytherapy insertion codes. Alternatively, one commenter recommended that CMS continue to pay for brachytherapy insertion codes assigned status indicator ''J1'' under the C–APC payment methodology but exclude certain preparation and planning services from C–APC packaging and make separate payment for those services. Another commenter requested that CMS provide education or guidance clarifying whether services assigned status indicator ''J1'' that are furnished over multiple patient encounters, such as certain brachytherapy services, may be reported separately for each encounter.

Response: We appreciate the commenters' concerns and recommendations regarding the application of the C–APC methodology to surgical insertion procedures for brachytherapy treatment. We continue to believe that application of the C–APC methodology to these surgical insertion procedures is appropriate and appropriately accounts for the costs associated with furnishing these services, particularly because the brachytherapy sources used in these procedures are excluded from C–APC packaging and instead are separately payable. Therefore, we are not adopting the commenters' recommendations to discontinue the C–APC payment policy for brachytherapy insertion procedures or to exclude designated preparation and planning services from C–APC packaging and make separate payment for those services. We will consider whether additional provider education regarding the reporting of services furnished over multiple patient encounters may be appropriate. We will continue to examine these concerns and consider whether modifications to the C–APC methodology are warranted in future rulemaking.

After consideration of public comments we received, we are finalizing the C–APCs as proposed. Table 4 lists the final C–APCs for CY 2027. All C–APCs are displayed in Addendum J to this CY 2027 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website). Addendum J to this final rule with comment period also contains all the data related to the C–APC payment policy methodology, including the list of complexity adjustments and other information for CY 2027.

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TABLE 4: FINAL CY 2027 C-APCs

C-APC	CY 2027 APC Group Title	Clinical Family
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
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
5117	Level 7 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

C-APC	CY 2027 APC Group Title	Clinical Family
5165	Level 5 ENT Procedures	ENTXX
5166	Cochlear Implant Procedure	COCHL
5182	Level 2 Vascular Procedures	VASCX
5183	Level 3 Vascular Procedures	VASCX
5184	Level 4 Vascular Procedures	VASCX
5191	Level 1 Endovascular Procedures	EVASC
5192	Level 2 Endovascular Procedures	EVASC
5193	Level 3 Endovascular Procedures	EVASC
5194	Level 4 Endovascular Procedures	EVASC
5200	Implantation Wireless PA Pressure Monitor	WPMXX
5211	Level 1 Electrophysiologic Procedures	EPHYS
5212	Level 2 Electrophysiologic Procedures	EPHYS
5213	Level 3 Electrophysiologic Procedures	EPHYS
5222	Level 2 Pacemaker and Similar Procedures	AICDP
5223	Level 3 Pacemaker and Similar Procedures	AICDP
5224	Level 4 Pacemaker and Similar Procedures	AICDP
5231	Level 1 ICD and Similar Procedures	AICDP
5232	Level 2 ICD and Similar Procedures	AICDP
5244	Level 4 Blood Product Exchange and Related Services	SCTXX
5302	Level 2 Upper GI Procedures	GIXXX
5303	Level 3 Upper GI Procedures	GIXXX
5313	Level 3 Lower GI Procedures	GIXXX
5331	Complex GI Procedures	GIXXX
5341	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
5433	Level 3 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

C-APC	CY 2027 APC Group Title	Clinical Family
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE
5627	Level 7 Radiation Therapy	RADTX
5881	Ancillary Outpatient Services When Patient Dies	N/A
8011	Comprehensive Observation Services	N/A

C-APC Clinical Family Descriptor Key:
AENDO = Airway Endoscopy
AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.
BREAS = Breast Surgery
COCHL = Cochlear Implant
EBIDX = Excision/ Biopsy/Incision and Drainage
ENTXX = ENT Procedures
EPHYS = Cardiac Electrophysiology/
EVASC = Endovascular Procedures
EXEYE = Extraocular Ophthalmic Surgery
GIXXX = Gastrointestinal Procedures
GYNXX = Gynecologic Procedures
INEYE = Intraocular Surgery
LAPXX = Laparoscopic Procedures
NERVE = Nerve Procedures
NSTIM = Neurostimulators
ORTHO = Orthopedic Surgery
PUMPS = Implantable Drug Delivery Systems
RADTX = Radiation Oncology
SCTXX = Stem Cell Transplant
UROXX = Urologic Procedures
VASCX = Vascular Procedures
WPMXX = Wireless PA Pressure Monitor

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c. Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high-quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for mental health services and multiple imaging services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66614 and 66650 through 66652) for a full discussion of the development of the composite APC methodology, and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59241, 59242, and 59246 through 52950) for further background.

(1) Mental Health Services Composite APC

For CY 2027, we proposed to continue our longstanding policy of limiting the aggregate payment for specified less resource intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services (88 FR 49572). We refer readers to the April 7, 2000, OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for further background.

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33580 through 33581 and 82 FR 59246 through 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 four or more hospital-based partial hospitalization program (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 the CY 2024 OPPS/ASC final rule with comment period, 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 PHP represent the most resource intensive of all outpatient mental health services. For CY 2027 and subsequent years, we proposed 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 four 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 (91 FR 41752). In addition, we proposed to continue to set the payment rate for composite APC 8010 at the same payment rate that we proposed for APC 5864, which is a partial hospitalization per diem payment rate for four partial hospitalization services furnished in a day by a hospital.

Under the 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 8010.

Comment: Commenters expressed concerns regarding the Mental Health Services Composite APC policy and requested that CMS evaluate the effects and adequacy of the policy. One commenter stated that because the payment rate for APC 8010 is based on the payment rate for the highest PHP APC, the PHP service-count tier effectively establishes a payment ceiling for other hospital outpatient mental health services. The commenter expressed concern that the policy may discourage hospitals from furnishing multiple clinically appropriate mental health services on the same date of service, including for beneficiaries in rural areas who may travel significant distances for care and for whom consolidation of services may be appropriate. The commenter requested that CMS analyze how frequently the composite payment applies and whether it disproportionately affects beneficiaries receiving consolidated same-day care or those traveling significant distances to receive care.

Another commenter requested that CMS evaluate whether APC 8010 appropriately recognizes and pays for hospital outpatient services furnished to beneficiaries with substance use disorder (SUD). The commenter stated that it is unclear to what extent addiction treatment services are included in determining whether the Mental Health Services Composite APC payment applies or are reflected in the utilization and cost data underlying the payment rate. The commenter also recommended that CMS evaluate other APCs that may include addiction treatment services.

Response: We thank the commenters for their recommendations regarding the Mental Health Services Composite APC policy. As discussed in prior rulemaking, the Mental Health Services Composite APC policy establishes a payment limit for specified less resource-intensive mental health services furnished to a beneficiary on the same date of service (90 FR 53475). When the aggregate payment for those specified services exceeds the payment rate for the highest-paying PHP APC, payment is made through APC 8010 at the rate for the highest-paying PHP APC. We continue to believe it is appropriate to apply this payment limit because a day of care under a PHP represents a highly intensive level of outpatient mental health care, and we do not believe that payment for the specified individual mental health services furnished on the same date of service should exceed payment for such a day of care.

We appreciate the commenters' recommendations that we further evaluate how the Mental Health Services Composite APC policy operates in practice. As part of our ongoing review of OPPS payment policies, we can examine how frequently payment through APC 8010 occurs and the combinations of services to which it applies. We will consider what the available data show about same-day care for beneficiaries in rural areas and the treatment of services furnished to beneficiaries with SUD under this policy. We will consider whether the findings warrant further discussion or proposals in future rulemaking.

We are finalizing our proposal regarding APC 8010 without modification. 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 four 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 for CY 2027. In addition, we are finalizing setting the payment rate for composite APC 8010 for CY 2027 at the same payment rate that we set for APC 5864, which is the maximum partial hospitalization per diem payment rate for a hospital.

(2) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569) we finalized a policy that effective January 1, 2009, we would provide a single payment each time a hospital submitted 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. 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 5.

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 2027, we proposed to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology (91 FR 41753). 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 2027, except where otherwise indicated, we proposed to use the costs derived from CY 2025 claims data to set the proposed CY 2027 payment rates. Therefore, for CY 2027, 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 2025 claims available for the CY 2027 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) (91 FR 41753). 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 final rule with comment period (which is available via the internet on the CMS website *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*) and are discussed in more detail in section II.A.1.a. of this final rule with comment period.

We did not receive public comments on this policy. We are finalizing without modification our proposal to continue the use of multiple imaging composite APCs to pay for the provision of more than one imaging procedure from the same imaging family on the same date. Table 5 lists the final HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC final geometric mean costs for CY 2027.

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TABLE 5: OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2027 APC 8004 (Ultrasound Composite)	**CY 2027 Approximate APC Geometric Mean Cost = $299.79**
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76981	Us parenchyma
76982	Us 1st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2027 APC 8005 (CT and CTA without Contrast Composite) *	**CY 2027 Approximate APC Geometric Mean Cost = $230.01**
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 2027 APC 8006 (CT and CTA with Contrast Composite)	CY 2027 Approximate APC Geometric Mean Cost = $451.13
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
70471	Cta h&n c+ w/noncontrast img
70473	Ct cere prfu aly c+wo ct/cta
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 2027 APC 8007 (MRI and MRA without Contrast Composite) *	**CY 2027 Approximate APC Geometric Mean Cost = $546.85**
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 2027 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2027 Approximate APC Geometric Mean Cost = $885.44**
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o & w/dye
70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye
70549	Mr angiograph neck w/o & w/dye

70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye
72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o & w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o & w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o & w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o & w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o&w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr

* If a “without contrast” MRI or MRA procedure is performed during the same session as a “with contrast” MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.

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3. Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular beneficiary. The OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which may occur if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging our payments into larger bundles promotes predictability and accuracy. Finally, packaging may reduce the importance of refining service-specific payments 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. Packaging encourages efficiency and is an essential component of a prospective payment system; therefore, packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, categories of items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make payments under the OPPS more consistent with a prospective payment system and less like a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

b. Final CY 2027 Policy on Packaged Items and Services

For CY 2027, we examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment for the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and hospital outpatient department billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies.

For CY 2027, we did not propose any changes to the current overall packaging policy discussed previously in section II.A.3.a. of this final rule with comment period. We proposed to continue to conditionally package the costs of selected newly identified ancillary services into payment for a primary service where we believe that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code (91 FR 41758).

We received public comments on our proposal to continue conditionally packaging selected newly identified ancillary services. The following is a summary of the comments we received and our responses.

Comment: Several commenters requested that CMS unpackage payments in certain scenarios. For example, several commenters stated that unpackaging payment could support patient access and innovations, including increased access to certain drugs, biologicals, and services. A commenter, a manufacturer of a contrast agent, suggested that CMS consider unpackaging their product, a contrast agent, and believed CMS should unpackage high cost and low volume cancer drugs. This commenter believed CMS's historic reasoning for unpackaging and paying separately for diagnostic radiopharmaceuticals applies equally or even more to their product, since the cost of their product is significantly greater than the amount reported for the policy packaged drugs offset associated with the assigned APC for the procedure used to administer the contrast agent. The commenter believed lack of separate payment was a barrier to beneficiary access and recommended CMS pay for products like theirs when the product costs exceeded a certain threshold. The commenter cited recent proposed FDA changes to increase patient access to this diagnostic agent and associated diagnostic test, as well as the recent introduction of the Facilitating Access to Innovation in Cancer Care (FAIC) Act, as support for their recommendation.

Response: We thank the commenters for their perspectives on packaging within the OPPS, including specific examples showing that a product's cost, such as a drug, may exceed the offset amount associated with the procedure in which the product is utilized. We note that our decision to unpackage certain diagnostic radiopharmaceuticals was based on evidence that packaged payment was creating an access barrier for a narrow set of high-cost, low-utilization products. We continue to believe that packaging is a fundamental component of a prospective payment system, which distinguishes it 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. We, therefore, do not find it appropriate to revise our longstanding ''policy'' packaged drug policies or our comprehensive-APC payment policies to facilitate separate payment for these products. We appreciate the input from commenters, and we will continue to monitor our packaging policies.

Additionally, we received specific recommendations regarding C–APC packaging, including the C–APC packaging of certain cancer treatments and of Cell and Gene Therapies and associated products. We address these recommendations in section II.A.2.b.(4) of this final rule with comment period. The packaging of non-opioid treatments for pain relief is addressed in section XIII.F. of this final rule with comment period.

Commenters also made recommendations on our packaging policies in the context of our diagnostic radiopharmaceutical proposal, which is discussed in the next section.

After consideration of public comments, we are finalizing our proposal 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. Final Payment for Diagnostic Radiopharmaceuticals

(1) Background on OPPS Packaging Policy for Diagnostic Radiopharmaceuticals

Under the OPPS, we package several categories of non-passthrough 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, prior to CY 2025, all radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure are packaged with the payment for the related procedure or service.

In the CY 2008 OPPS/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 OPPS and subsequent years (72 FR 66635 through 66641). Importantly, we noted that we 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, making it appropriate to package the payment for the diagnostic radiopharmaceutical into the payment for the related nuclear medicine procedure. Accordingly, prior to CY 2025, diagnostic radiopharmaceuticals were policy packaged under § 419.2(b)(15), regardless of cost, including higher-cost products.

In the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222) and CY 2025 OPPS/ASC final rule with comment period (89 FR 93950), we stated that 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. However, we stated 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.

Additionally, in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963) we finalized a policy to pay separately for any diagnostic radiopharmaceutical with a per day cost greater than $630 for CY 2025. To calculate those per-day costs, we also finalized, for CY 2026 and subsequent years, a policy of applying a methodology similar to that used to determine the per day costs of drugs and biologicals (89 FR 93953 through 93955). We noted that any diagnostic radiopharmaceutical with a per day cost at or below that threshold will continue to be policy packaged under our longstanding policy at § 419.2(b)(15) (89 FR 93962 through 93963). Additionally, we finalized the policy that starting in CY 2026 and for subsequent years, we will update the threshold amount of $630 by a forecast of the Producer Price Index (PPI) for Pharmaceuticals for Human Use, Prescription (Bureau of Labor Statistics (BLS) series code WPUSI07003) from IHS Global, Inc (IGI) (89 FR 93955).

In the CY 2025 OPPS/ASC final rule with comment period, we also finalized that, for non-passthrough, separately payable diagnostic radiopharmaceuticals with per day costs above the designated threshold, payment would be determined based on our authority under section 1833(t)(14)(A)(iii)(II) of the Act. Because we found that the ASP data we had was not usable for the purpose of paying for diagnostic radiopharmaceuticals, we finalized a policy to use mean unit cost data derived from hospital claims to determine the payment amount for qualifying non-passthrough diagnostic radiopharmaceuticals. Additionally, we finalized corresponding modifications to the regulation text at § 419.2(b)(15) and § 419.41 to codify our finalized payment policy for diagnostic radiopharmaceuticals and our existing policy for therapeutic radiopharmaceuticals. In the CY 2026 OPPS/ASC final rule with comment period, we finalized a technical refinement to the diagnostic radiopharmaceutical packaging threshold methodology and finalized the CY 2026 diagnostic radiopharmaceutical packaging threshold of $655. For additional information regarding the policy finalized, please reference the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963) and the CY 2026 OPPS/ASC final rule with comment period (90 FR 53482 through 53488).

(2) Final Diagnostic Radiopharmaceutical Packaging Threshold

For CY 2027, we proposed to continue the policy finalized in CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963). Specifically, we proposed to continue to calculate the per day cost of diagnostic radiopharmaceuticals based on the methodology described in section V.B.1.b. of this final rule with comment period, which relies on the methodology finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638).

As finalized in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93955), starting in the OPPS/ASC rulemaking for CY 2026 and for subsequent years, we stated we would update the proposed threshold amount of $630 by a forecast of the PPI for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) from IHS Global, Inc (IGI) by using most recently available four-quarter moving average PPI levels to trend from the third quarter of the year 2 years prior to the applicable calendar year to the third quarter of the year prior to the applicable calendar year (for example, from the third quarter of 2024 to the third quarter of 2025 for CY 2026). In the CY 2026 OPPS/ASC final rule with comment period, we finalized a technical refinement to this policy to use the most recently available four-quarter moving average PPI levels to trend the CY 2025 final threshold forward from the third quarter of the CY 2025 to the third quarter of the payment year (CY 2026) and round the resulting dollar amount to the nearest $5 increment (90 FR 53482 through 53483). We believed using the most recently available four-quarter moving average PPI levels more appropriately updated the packaging threshold from CY 2025 for payment in CY 2026. For CY 2026 and subsequent updates, we finalized to trend the CY 2025 threshold of $630 forward using the four-quarter moving average PPI levels for Pharmaceuticals

for Human Use, Prescription for CY 2025 (third quarter) forward using the PPI for Pharmaceuticals for Human Use, Prescription for the applicable payment year (third quarter) (90 FR 53482 through 53488). This is the same as the update factor used for the OPPS drug packaging threshold, where we originally used the four-quarter moving average PPI levels for Pharmaceutical Preparations, Prescription (BLS series code WPUSI07003, formerly BLS series code 32541DRX) 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 payment year (71 FR 68085 and 68086).

Therefore, for CY 2027, we proposed to update the CY 2025 $630 threshold amount by the four-quarter moving average PPI levels for Pharmaceuticals for Human Use, Prescription to trend the $630 threshold forward (91 FR 41759). Specifically, we proposed using the most recently available forecast of the four-quarter moving average PPI levels for Pharmaceutical for Human Use, Prescription from the third quarter of 2025 to the third quarter of 2027, and to round the resulting dollar amount to the nearest $5 increment. Based on this methodology, we trended the $630 threshold forward and rounded the resulting dollar amount ($667.44) to the nearest $5 increment, which yielded a proposed figure of $665 per day for CY 2027. Consistent with our methodology and practices listed in section V.B.1.b. of this final rule with comment, we also proposed that if more recent data subsequently became available (for example, a more recent estimate of the PPI for Pharmaceuticals for Human Use, Prescription), we would use such data, if appropriate, to determine the CY 2027 diagnostic radiopharmaceutical packaging threshold in the final rule.

We received public comments on these proposals. The following is a summary of the comments received and our responses.

Comment: Most comments were supportive of continued separate payment for diagnostic radiopharmaceuticals above a certain per day cost threshold. Most commenters were supportive of the proposed update methodology and the corresponding updated per day cost threshold of $665. Some commenters also recommended CMS continue to monitor the effects of this policy.

Response: We thank the commenters for their support of our proposal. We will continue to consider updates to this policy as necessary.

After consideration of public comments, we are finalizing our policy as proposed. We are finalizing our proposal to update the CY 2025 $630 threshold amount by the four-quarter moving average PPI levels for Pharmaceuticals for Human Use, Prescription to trend the threshold forward. Specifically, we are using the most recently available forecast of the four-quarter moving average PPI levels for Pharmaceutical for Human Use, from the third quarter of 2025 to the third quarter of 2027, and to round the resulting dollar amount to the nearest $5 increment. We also proposed, and are now finalizing, a policy that if more recent data were to subsequently become available (for example, a more recent estimate of the PPI for Pharmaceuticals for Human Use, Prescription), we would use such data, if appropriate, to determine the CY 2027 diagnostic radiopharmaceutical packaging threshold in the final rule. Based on this methodology, using the most recent data available for this final rule with comment period, we trended the $630 threshold forward and rounded the resulting dollar amount ($634.80) to the nearest $5 increment, which yields a final diagnostic radiopharmaceutical packaging threshold figure of $635 per day for CY 2027.

(3) Amount of Separate Payment for Diagnostic Radiopharmaceuticals Exceeding the Threshold

As discussed in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93955 through 93959), once we determine that the per day cost of a non-passthrough diagnostic radiopharmaceutical exceeds the cost threshold, proposed to be $665 per day for CY 2027, we will then assign that radiopharmaceutical to an APC, making it a specified covered outpatient drug (SCOD) per section 1833(t)(14)(B) of the Act. We proposed to continue our current policy for CY 2027 and proposed to pay for those non-passthrough, 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 continue to find that the ASP data we had was not usable for payment purposes. We continue to believe that arithmetic mean unit cost (MUC) would be 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. Therefore, we proposed to continue our current policy and propose for CY 2027 to pay for qualifying diagnostic radiopharmaceuticals with per day costs above the diagnostic radiopharmaceutical packaging threshold based on their arithmetic MUC, which would be derived from calendar year 2025 claims data.

Although we proposed to base payment for qualifying radiopharmaceuticals on their arithmetic MUC for CY 2027, we continue to encourage manufacturers to submit ASP information for diagnostic radiopharmaceuticals, if possible. While we proposed to continue to use MUC to pay for separately payable diagnostic radiopharmaceuticals in CY 2027, we note that manufacturers can begin, or continue, to report ASP data for potential future use in paying for diagnostic radiopharmaceuticals. For CY 2027, ASP reporting is voluntary for diagnostic radiopharmaceuticals paid under the OPPS. We encouraged interested parties to submit comments regarding potential issues that may arise that prevent appropriate ASP reporting for diagnostic radiopharmaceuticals. We referred readers to the CY 2025 OPPS/ASC final rule with comment period as it discusses some of the known concerns regarding ASP reporting for diagnostic radiopharmaceuticals (89 FR 93948 through 93963) as well as the CY 2026 OPPS/ASC final rule with comment period (90 FR 53482 through 53488). We reiterated our stance from the CY 2025 OPPS/ASC final rule with comment period, that if we were to use average sales price as the basis of calculating a payment, we believe there must be more consistent, validated, and universal reporting in order for ASP to be a viable payment methodology (89 FR 93961).

As we stated in the CY 2025 and CY 2026 OPPS/ASC final rules with comment period (89 FR 93957 and 90 FR 53484), there could be 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 continue to 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 for therapeutic radiopharmaceuticals. Previously, to facilitate potential future payment for diagnostic radiopharmaceuticals based on ASP, we sought comment from

interested parties on how CMS could ensure more consistent, validated, and universal reporting in order for ASP to be a viable payment methodology utilized in future rulemaking. For example, we sought comment on how CMS could update its past guidance, *Submission of OPPS ASP Data for Non-passthrough Separately Payable Therapeutic Radiopharmaceuticals and Radiopharmaceuticals with Pass-Through Status,*[6] to reflect current clinical practices and to reflect ASP reporting for diagnostic radiopharmaceuticals.

Additionally, as discussed in section V.B.5. of the proposed rule (Proposed Payment for Non-passthrough Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes but Without OPPS Hospital Claims Data), we proposed to continue our policy for determining the payment rate for new diagnostic radiopharmaceuticals that exceed the diagnostic radiopharmaceutical packaging threshold and have HCPCS codes, but which do not have pass-through status and are without claims data. Under this policy, we proposed to pay these products at ASP plus 6 percent (91 FR 41868). If ASP data for these diagnostic radiopharmaceuticals are not available, we proposed to pay WAC plus 3 percent during the product's initial sales period, consistent with our policy described in section V.B.2. of the proposed rule (91 FR 41865). If the WAC also is unavailable, we proposed to make payment for new diagnostic radiopharmaceuticals at 95 percent of the products' most recent AWP (91 FR 41867). Following the initial sales period, a payment rate of WAC plus 6 percent would apply if ASP data for these diagnostic radiopharmaceuticals remained unavailable. We continue to believe the volume of products in this category would typically be very low; however, in these rare situations, we continue to believe it would continue to be appropriate to use ASP plus 6 percent, WAC plus 3 or 6 percent, or 95 percent of AWP until a MUC is available. As we stated in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93955 through 93962), it is appropriate to use this payment hierarchy until a MUC is available. 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 (89 FR 93958). We continue to believe the hierarchy previously specified is appropriate to determine the payment for a diagnostic radiopharmaceutical that is new and described by a HCPCS code, but without claims data, as it is consistent with the typical hierarchy associated with payment for drugs and biologicals paid under the OPPS as discussed in sections V.A. and V.B. of this final rule with comment period.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally in favor of separate payment for diagnostic radiopharmaceuticals. Commenters supported the separate payment, rather than packaged payment, to ensure patient access to these products. Many commenters were appreciative of the transitionary MUC based payment approach, but recommended CMS promptly move to an ASP based payment either for CY 2027 or CY 2028.

Commenters discussed a variety of reasons why MUC is less preferred over ASP based payments. For example, commenters explained that MUC is dependent on individual hospital reporting and that reporting practices may vary from hospital to hospital. Additionally, commenters explained that cost to charge ratios, charge compression, and varied revenue code use, among other concerns, may inappropriately lower a diagnostic radiopharmaceutical's MUC, thus leading to inadequate payment in their view. Many commenters explained how volatile MUC is relative to ASP, and many of these same commenters discussed that ASP data is much more current than MUC data.

A few commenters presented research comparing MUC to ASP amounts for certain products based on the commenters' calculations. According to the commenters' analyses, several of these products had MUCs below the ASP, and a smaller number of these products had MUCs above ASP. Commenters believed that the volatility of MUC made it an inferior payment methodology compared to ASP. These commenters recommended CMS transition to the more accurate ASP based payment methodology for these products. Further, commenters explained additional benefits of ASP over MUC in their view.

Several commenters stated that they already report ASP, they might have received ASP based payments while on OPPS pass-through status, and that they recommended that CMS continue to pay those products based on ASP. These commenters also contended that MUC put their products at a competitive disadvantage once off of pass-through status, compared to products paid under OPPS pass-through status. These commenters stated that ASP is the correct methodology for diagnostic radiopharmaceuticals, and that MUC should not be used as a proxy for ASP. In addition, other commenters contended that MUC is not a methodology that the statute contemplated for payment of these products and that the best reading of the law requires CMS to use ASP for these products. Commenters also suggested that CMS can use its authority to require ASP to be reported for diagnostic radiopharmaceuticals, while other commenters believed ASP was already required to be reported.

A few commenters also recommended compendia-based payment methodologies, such as WAC, as an alternative payment methodology to MUC if CMS found that ASP was unavailable.

Response: We thank commenters for their support of our proposal to continue to pay diagnostic radiopharmaceuticals separately. We appreciate those comments that explained the value of ASP-based payment rates rather than MUC-based payment rates, including data comparing the two payment methodologies for certain products. As we have stated in previous rulemaking cycles, we recognize the complexities of ASP reporting for radiopharmaceuticals given the unique nature of the products. CMS will continue to assess the appropriateness of an ASP based payment methodology; however, we continue to believe that there must be more consistent, validated, and universal reporting of ASP data for diagnostic radiopharmaceuticals. For those currently reporting ASP, we encourage continued reporting. We encourage manufacturers to share their best practices for ASP reporting to

[6] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/opps_asp_radiopharm_guidance10302009.pdf.*

facilitate industry-wide adoption of consistent ASP reporting.

As we have stated in prior rulemaking, while the number of products reporting ASP has slightly increased, we continue to have concerns regarding the accuracy of the reported data. For several diagnostic radiopharmaceuticals that have reported their ASP, their reported ASP exceeds the calculated arithmetic MUCs by several thousand percent. One of these radiopharmaceuticals would be estimated to be among the top 10 highest paid HCPCS codes in all of the OPPS if CMS adopted this payment rate. Based on the claims data and claims volume for these diagnostic radiopharmaceuticals, these extremely high ASP data appear to be erroneously reported. Of the non-passthrough diagnostic radiopharmaceuticals, including those above and below the threshold, we estimate that currently less than 20 percent of diagnostic radiopharmaceuticals are submitting ASP to CMS. As previously mentioned, even when the ASP is reported, in some instances CMS strongly questions the validity of the data and the ability to use it to inform payment in certain instances. Based on this, among other factors, we continue to believe that an ASP-based methodology is inappropriate for setting CY 2027 payment for separately paid diagnostic radiopharmaceuticals.

We find that the ASP data we have are not usable for the purpose of paying for diagnostic radiopharmaceuticals. Instead, we are paying based on mean unit cost data derived from hospital claims, which we believe would appropriately pay for the average price of non-passthrough separately payable diagnostic radiopharmaceuticals for the applicable year under section 1833(t)(14)(A)(iii)(II). We believe MUC is an appropriate proxy for the average price and average cost 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. Historic hospital claims data is used as the basis for the vast majority of OPPS payments, making payment for diagnostic radiopharmaceuticals based on cost data consistent with the rest of the OPPS. This approach is also consistent with our authority under section 1833(t)(14)(A)(iii)(II) of the Act to calculate and adjust the average price as necessary, particularly when, as previously discussed, we continue to find that the ASP data available to us is not usable for payment purposes for diagnostic radiopharmaceuticals. We will continue to explore our authority regarding requiring ASP reporting for diagnostic radiopharmaceuticals under the OPPS.

In response to comments suggesting we adopt WAC or AWP based payment methodologies, we continue to believe that neither WAC nor AWP is an appropriate proxy to provide OPPS payment for average radiopharmaceutical acquisition costs and associated handling costs when manufacturers are not required to submit ASP data. This is 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. WAC and AWP reported to compendia may not be reflective of a patient ready dose.

The absence of an ASP reporting requirement and inappropriate or no reporting of ASP 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.

We appreciate the insight from commenters regarding their concerns with CMS continuing to use arithmetic MUC as the payment methodology for diagnostic radiopharmaceuticals. We are taking these comments into consideration for future rulemaking and for future guidance development.

In regard to concerns regarding the MUC data received by CMS, we remind readers that we rely on providers to accurately report the use of HCPCS codes in accordance with code descriptors and CPT and CMS instructions, to report services accurately on claims, and to report charges and costs accurately for the services on their Medicare hospital cost reports.

Comment: Some commenters expressed hesitations with using ASP based payments for diagnostic radiopharmaceuticals. A commenter stated that manufacturers do not universally report ASP currently because they are not required to do so. A commenter suggested that voluntary ASP reporting may not capture complete market dynamics and could result in payment rates that do not accurately reflect acquisition costs, particularly if the data are incomplete, inconsistently reported, or from a limited subset of manufacturers. Some commenters recommended CMS maintain MUC as a payment option for diagnostic radiopharmaceuticals, as it is difficult, or impossible, for some forms of diagnostic radiopharmaceuticals to report ASP for reasons outside of the manufacturer's control. For example, diagnostic radiopharmaceuticals from multi-dose generators and multi-dose vial cold kits could be products in which a manufacturer is unable to report ASP.

Response: We appreciate the information presented by these commenters. The information in these comments will be used to help inform any potential changes in future policy and any additional ASP reporting guidance. These comments reinforce our concerns regarding the use of ASP for all diagnostic radiopharmaceuticals. For CY 2027, non-passthrough diagnostic radiopharmaceuticals with claims data will continue to be paid based on arithmetic MUC.

Comments: Many commenters appreciated the CMS mention of an ASP Reporting Framework for Diagnostic Radiopharmaceuticals and encouraged CMS to release such guidance prior to the end of CY 2026. Many commenters offered to collaborate with CMS on such guidance and welcomed the opportunity to provide feedback.

Response: We thank the commenters for their support. We will continue to consider additional ASP reporting guidance for diagnostic radiopharmaceuticals and we welcome input from interested parties on the framework's content.

After consideration of public comments, we are finalizing our proposal without modification. In summary, for CY 2027 we are paying separately for any diagnostic radiopharmaceutical with a per-day cost greater than $635 using the methodology described. Any diagnostic radiopharmaceutical with a per-day cost at or below that threshold would continue to be policy packaged under our longstanding policy codified at § 419.2(b)(15).

As discussed in section V.B.5. of this final rule with comment period, we proposed and are finalizing a policy to set the payment rate for new diagnostic radiopharmaceuticals with HCPCS codes that exceed the diagnostic radiopharmaceutical packaging threshold, but which do not have pass-through status and are without claims data, at ASP plus 6 percent. If ASP data for these diagnostic radiopharmaceuticals are not available, we are finalizing a policy to pay WAC plus 3 percent during the product's initial sales period, consistent with our

policy described in section V.B.2. of this final rule with comment period. If the WAC also is unavailable, we are finalizing a policy to make payment for new diagnostic radiopharmaceuticals at 95 percent of the products' most recent AWP. Following the initial sales period, we are finalizing a payment rate of WAC plus 6 percent would apply, if ASP data for these diagnostic radiopharmaceuticals remain unavailable.

Additionally, we refer readers to section V.B.8. of this final rule with comment period for discussion of payment for 340B drugs, including diagnostic radiopharmaceuticals acquired through the 340B program.

(4) Qualifying Diagnostic Radiopharmaceuticals Above the Diagnostic Radiopharmaceutical Packaging Threshold

The HCPCS codes that describe diagnostic radiopharmaceuticals with per day costs that exceed the proposed diagnostic radiopharmaceutical packaging threshold were proposed to be assigned to a status indicator of ''K'', indicating separate payment to be paid based on that HCPCS code's arithmetic MUC. The proposed APC and the proposed payment rate were assigned as shown in *Addendum B to the proposed rule.* HCPCS codes that describe diagnostic radiopharmaceuticals with per day costs that are at or below the proposed diagnostic radiopharmaceutical packaging threshold were proposed to continue to be assigned to a status indicator of ''N'', indicating packaged payment.

The proposed list of diagnostic radiopharmaceuticals that we calculated as having per day costs that exceeded $665 and their proposed status indicators can be found in Table 6.

TABLE 6: PROPOSED QUALIFYING DIAGNOSTIC RADIOPHARMACEUTICALS WITH PER DAY COSTS EXCEEDING $665

HCPCS Code	Short Descriptor	Proposed CY 2027 Status Indicator Assignment
A4642	In111 satumomab	K
A9507	In111 capromab	K
A9508	I131 iodobenguate, dx	K
A9515	Choline C 11, diagnostic	K
A9521	Tc99m exametazime	E1*
A9532	I125 serum albumin, dx	K
A9547	In111 oxyquinoline	K
A9548	In111 pentetate	K
A9551	Tc99m succimer	K
A9554	I125 iothalamate, dx	K
A9557	Tc99m bicisate	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
A9601	Flortaucipir inj 1 millicuri	K
A9602	Fluorodopa f-18 diag per mci	K
A9608	Flotufolastat f18 diag 1 mci	K
A9800	Gallium locametz 1 millicuri	K
C9067	Gallium ga-68 Dotatoc	K
Q9982	Flutemetamol F18	K
Q9983	Florbetaben F18	K

*Proposed Status Indicator assignment is E1 until compliance with the Medicaid National Drug Rebate Agreement occurs. Once compliance is met, status indicator K would apply.

The proposed definitions of status indicators can be found in Addendum D1 to the proposed rule. Addenda to the proposed rule can be found on the CMS OPPS web page at *https://www.cms.gov/medicare/payment/prospective-*

payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices/cms-1850-p?utm.

Based on the policy finalized in this section to continue paying separately at arithmetic MUC for non-passthrough diagnostic radiopharmaceutical with a HCPCS code and claims data, and with a per day cost greater than $635 using the methodology previously described, the HCPCS codes that describe diagnostic radiopharmaceuticals with per day costs that exceed the finalized diagnostic radiopharmaceutical packaging threshold are assigned to a status indicator of ''K'', indicating separate payment to be paid based on that HCPCS code's arithmetic MUC. A final APC and payment rate are assigned as shown in Addendum B to this final rule with comment period. HCPCS codes that describe diagnostic radiopharmaceuticals with per day costs that are at or below the proposed diagnostic radiopharmaceutical packaging threshold are assigned to a status indicator of ''N'', indicating packaged payment. The finalized list of diagnostic radiopharmaceuticals that we calculated as having per day costs that exceed $635 and their final status indicators can be found in Table 7.

TABLE 7: FINAL QUALIFYING DIAGNOSTIC RADIOPHARMACEUTICALS WITH PER DAY COSTS EXCEEDING $635

HCPCS Code	Short Descriptor	Final CY 2027 Status Indicator Assignment
A4642	In111 satumomab	K
A9507	In111 capromab	K
A9508	I131 iodobenguate, dx	K
A9515	Choline C 11, diagnostic	K
A9521	Tc99m exametazime	K
A9532	I125 serum albumin, dx	K
A9547	In111 oxyquinoline	K
A9548	In111 pentetate	K
A9551	Tc99m succimer	K
A9554	I125 iothalamate, dx	K
A9557	Tc99m bicisate	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
A9601	Flortaucipir inj 1 millicuri	K
A9602	Fluorodopa f-18 diag per mci	K
A9608	Flotufolastat f18 diag 1 mci	K
A9800	Gallium locametz 1 millicuri	K
C9067	Gallium ga-68 Dotatoc	K
Q9982	Flutemetamol F18	K
Q9983	Florbetaben F18	K

Finalized definitions of status indicators can be found in Addendum D1 to this final rule with comment period. Addenda to this rule can be found on the CMS OPPS web page.

4. Implementation of Section 4135 of the Consolidated Appropriations Act (CAA), 2023

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)(iv) 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.

The additional payments required under section 1833(t)(16)(G) of the Act began on January 1, 2025, based on the policy finalized in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94343 through 94361). In section XIII.E. of this final rule with comment period, we are finalizing our proposal to continue the payment policy finalized in the CY 2025 OPPS/ASC final rule with comment period for CY 2027. We are also finalizing non-opioid treatments for pain relief that would qualify under this policy for CY 2027 and responded to public comments on the proposed rule.

We refer readers to section XIII.E. of this final rule with comment period for a summary of the finalized policy.

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) using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53489 through 53490), we applied this policy and calculated the relative payment weights for each APC for CY 2026 that were shown in Addenda A and B of the CY 2026 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 2026 OPPS/ASC final rule with comment period (90 FR 53455 through 53480). For CY 2027, as we did for CY 2026, we proposed to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2027 using geometric mean-based APC costs (91 FR 41762).

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 2027, as we did for CY 2026, we proposed to continue to standardize all 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 2027, as we did for CY 2026, we proposed to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2027 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 2026 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2027 unscaled relative payment weights.

For CY 2026, we multiplied the CY 2026 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2025 claims to calculate the total relative payment weight for each service (90 FR 53489). We then added together the total relative payment weight for each of these services to calculate an estimated aggregate weight for the year. For CY 2027, we proposed to apply the same process using the estimated CY 2027 unscaled relative payment weights rather than scaled relative payment weights. We proposed to calculate the weight scalar by dividing the CY 2026 estimated aggregate weight by the unscaled CY 2027 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-notices.* Click on the link labeled ''Hospital Outpatient Prospective Payment—Notice of Proposed Rulemaking'' for 2027, which can be found under the heading ''Hospital Outpatient Regulations and Notices'' and open the claims accounting document link, which is labeled ''2027 Proposed Rule OPPS Claims Accounting.''

We proposed to compare the estimated unscaled relative payment weights in CY 2027 to the estimated total relative payment weights in CY 2026 using CY 2025 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we proposed to adjust the calculated CY 2027 unscaled relative payment weights for purposes of budget neutrality. We proposed to adjust the estimated CY 2027 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4582 to ensure that the proposed CY 2027 relative payment weights are scaled to be budget neutral. The proposed CY 2027 relative payment weights listed in Addenda A and B to the CY 2027 OPPS/ASC 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*) are scaled and include the recalibration adjustments discussed in sections II.A.1. and II.A.2. of the CY 2027 OPPS/ASC proposed rule.

Section 1833(t)(14) of the Act provides the methodology for 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 section

1833(t)(9) of the Act but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.2. of this final rule with comment period) is included in the budget neutrality calculations for the CY 2027 OPPS.

We did not receive any public comments on the proposed weight scalar calculation, and we are finalizing our proposal to use the calculation process described in the CY 2027 OPPS/ASC proposed rule, without modification, for CY 2027. For CY 2027, as we did for CY 2026, we will continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2027 using geometric mean-based APC costs. For CY 2027, as we did for CY 2026, we will assign APC 5012 a relative payment weight of 1.00; and we will divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. To comply with this requirement concerning the APC changes, we will compare the estimated aggregate weight using the CY 2026 scaled relative payment weights to the estimated aggregate weight using the CY 2027 unscaled relative payment weights.

Using updated final rule claims data, we are updating the estimated CY 2027 unscaled relative payment weights by multiplying them by a weight scalar of 1.4614 to ensure that the final CY 2027 relative payment weights are scaled to be budget neutral. The final CY 2027 relative payment weights listed in Addenda A and B of this final rule with comment period (available via the internet on the CMS website) were scaled and include the recalibration adjustments discussed in sections II.A.1 and II.A.2. of this final rule with comment period.

B. Final 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 of the Act (or an amount that is computed and applied with respect to covered OPD services). In the FY 2027 IPPS/Long Term Care Hospital (LTCH) proposed rule (91 FR 19496), consistent with current law, based on IHS Global, Inc.'s (IGI's) fourth quarter 2025 forecast, the proposed FY 2027 IPPS market basket percentage increase was 3.2 percent. We noted that under our regular process for the CY 2027 OPPS/ASC final rule with comment period, we would use the market basket update for the FY 2027 IPPS/LTCH PPS final rule. If that forecast is different than the IPPS market basket percentage increase used for this final rule with comment period, the CY 2027 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 2027, we proposed to use the estimate of the hospital inpatient market basket percentage increase of 3.2 percent as one component to calculate the OPD fee schedule increase factor (91 FR 41763).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposed CY 2027 OPD fee schedule increase factor. Another commenter appreciated the proposed positive update while requesting that CMS monitor the combined effects of the conversion factor, APC assignments, site-neutral policies, and other payment changes on particular services.

Response: We thank the commenters for their support.

Comment: Several commenters stated that the proposed OPD fee schedule increase factor would not keep pace with the cost of furnishing hospital outpatient care. Commenters cited increase costs in labor, pharmaceuticals, supplies, technology, infrastructure, regulatory compliance, and other operating expenses, and stated that the effect is particularly acute for rural hospitals, safety-net providers, academic medical centers, and hospitals furnishing complex or high-acuity services. Some commenters stated that forecast-based market basket data lag actual cost growth and requested that CMS use more current or alternative data, correct for prior forecast error, conduct a broader review of the rate-setting methodology, or provide an update of at least 3.2 percent.

Response: We acknowledge the commenters' concerns regarding the proposed CY 2027 market basket update, including the challenging financial circumstances commenters described for rural hospitals, safety-net providers, academic medical centers, and other hospitals furnishing complex services. Section 1833(t)(3)(C)(iv) of the Act requires the OPD fee schedule increase factor for a year to be equal to the IPPS market basket percentage increase factor applicable under section 1886(b)(3)(B)(iii) of the Act to hospital discharges in the fiscal year ending in that year. Therefore, we are unable to adopt a final OPD fee schedule increase factor different from the IPPS market basket percentage increase factor finalized in the FY 2027 IPPS/LTCH PPS final rule. We refer commenters to the FY 2027 IPPS/LTCH PPS final rule for responses regarding the market basket issues commenters raised (91 FR 49835 through 49838).

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 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. 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 ((TFP) previously referred to as multifactor productivity).[7] Please see *https://www.bls.gov/productivity/* for the BLS historical published TFP data. A complete description of IGI's 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 the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19496), the proposed productivity adjustment for FY 2027 was 0.8 percentage point.

Therefore, we proposed that the productivity adjustment for the CY 2027 OPPS/ASC proposed rule would be a reduction of 0.8 percentage point. We also proposed that if more recent data subsequently become available after the publication of the CY 2027 OPPS/ASC proposed rule (for example, a more recent estimate of the market basket percentage increase and/or the

[7] *https://www.bls.gov/productivity/notices/2021/mfp-to-tfp-term-change.htm.*

productivity adjustment), we would use such data, if appropriate, to determine the CY 2027 hospital inpatient market basket update and the productivity adjustment for the final rule with comment period, 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 (91 FR 41763).

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 later in this section, we proposed for CY 2027 an OPD fee schedule increase factor of 2.4 percent for the CY 2027 OPPS/ASC (which is the proposed estimate of the hospital inpatient market basket percentage increase of 3.2 percent, less the proposed 0.8 percentage point productivity adjustment).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters objected to the proposed 0.8 percentage point productivity adjustment or requested that it be modified. Commenters stated that hospital care is labor intensive and hospitals, therefore, must be in a constant state of readiness; meet staffing and regulatory requirements; and treat patients with complex conditions; and that hospitals could not achieve productivity gains across the economy the same way other private nonfarm businesses did. Commenters also noted that the proposed adjustment was higher than those made in recent years and requested that CMS provide further explanation or reevaluate the data and methodology. Some suggestions included removing the adjustment, capping it to between 0.2 and 0.3 percentage point, using a hospital-specific productivity index, or creating hardship exceptions for safety-net and academic medical centers.

Response: We acknowledge the commenters' concerns. Section 1833(t)(3)(F)(i) of the Act requires that after determining the OPD fee schedule increase factor under subparagraph (C)(iv), the Secretary shall reduce such increase factor by the productivity adjustment described in section 1886(b)(3)(B)(xi) of the Act. As required by statute, the FY 2027 productivity adjustment is derived based on the 10-year moving average growth in economy-wide productivity for the period ending FY 2027. Accordingly, CMS does not have discretion under these provisions to eliminate the adjustment, cap it at a different level, substitute a hospital-specific productivity index, or establish provider-specific hardship exceptions.

We thank the commenters for their comments. After consideration of the comments received and consistent with our proposal, we are finalizing an OPD fee schedule increase factor with modification of 2.3 percent for CY 2027, which consists of the IPPS market basket increase factor of 3.2 percent, less a 0.9 percentage point productivity adjustment calculated using more recent data.

3. Other Conversion Factor Adjustments

To set the OPPS conversion factor for 2027, we proposed to increase the CY 2026 conversion factor of $91.415 by 2.4 percent (91 FR 41763). In accordance with section 1833(t)(9)(B) of the Act, we proposed to further adjust the conversion factor for CY 2027 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We proposed to apply an overall budget neutrality factor of 1.0098 for wage index changes by comparing proposed total estimated payments from our simulation model using the FY 2027 IPPS wage indexes to those payments using the CY 2026 OPPS wage indexes. We further proposed to calculate an additional budget neutrality factor of 0.9951 to account for our policy to cap wage index reductions for hospitals at 5 percent on an annual basis and the CY 2027 proposed transitional exception for low-wage index hospitals.

For CY 2027, we proposed to maintain the current rural adjustment policy, as discussed in section II.E. of this final rule with comment period. Therefore, the proposed budget neutrality factor for the rural adjustment is 1.0000 (91 FR 41763).

We proposed to calculate a CY 2027 budget neutrality adjustment factor for the cancer hospital payment adjustment. We finalized transitioning from the target PCR of 0.89 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. We proposed a CY 2027 target PCR equal to 0.88 for the cancer hospital payment adjustment, which includes the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act. The proposed CY 2027 estimated payments applying the proposed CY 2027 cancer hospital payment adjustment are greater than the estimated payments applying the CY 2026 final cancer hospital payment adjustment. Therefore, we proposed to apply a budget neutrality adjustment factor of 0.9994 to the conversion factor for the cancer hospital payment adjustment (91 FR 41763).

We proposed to establish a cost-of-living adjustment (COLA) for hospitals in Alaska and Hawaii in the CY 2027 OPPS. We proposed a budget neutrality factor of 0.9993 to account for the CY 2027 COLA by comparing proposed total estimated payments from our simulation model without a COLA policy to those with the proposed CY 2027 COLA (91 FR 41763).

For the CY 2027 OPPS/ASC proposed rule, we estimated that proposed pass-through spending for drugs, biologicals, and devices for CY 2027 would equal approximately $195.3 million, which represents 0.18 percent of total projected CY 2027 OPPS spending. Therefore, we stated that the proposed conversion factor would be adjusted by the difference between the 0.30 percent estimate of pass-through spending for CY 2026 and the 0.18 percent estimate of proposed pass-through spending for CY 2027, resulting in a proposed increase to the conversion factor for CY 2027 of 0.12 percentage point (91 FR 41763).

We proposed that estimated payments for outliers would be 1.0 percent of total OPPS payments for CY 2027. We estimated in the proposed rule that outlier payments would be approximately 1.19 percent of total OPPS payments in CY 2026; the 1.00 percent for proposed outlier payments in CY 2027 would constitute a 0.19 percentage point decrease in payment in CY 2027 relative to CY 2026 (91 FR 41763).

In the CY 2027 OPPS/ASC proposed rule, we estimated an 8.44 percent increase to nondrug OPPS payment rates as a budget neutral adjustment for the $4.85 billion reduction in OPPS drug payment as a result of the proposed 340B drug payment policy. As part of that proposed policy, we noted that our adjustment in the final rule could potentially change as a result of changes such as updated data, modifications to the estimate methodology, and other factors. For additional discussion of the proposed 340B drug payment policy, please see

section V.B.7. of this final rule with comment period.

For CY 2027, we proposed to use a conversion factor of $102.004 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 1.024 (2.4 percent for CY 2027), the required proposed wage index budget neutrality adjustment of approximately 1.0098, the proposed 5 percent annual cap for individual hospital wage index reductions adjustment and the proposed transitional exception of approximately 0.9951, the proposed cost-of-living adjustment of 0.9993, the proposed cancer hospital payment adjustment of 0.9994, the adjustment for drugs purchased under the 340B Program of 1.0844, and the proposed adjustment factor of 1.0012 (an increase of 0.12 percentage point) for the difference in pass-through spending, which resulted in a proposed conversion factor for CY 2027 of $102.004 (91 FR 41764).

For CY 2027, we also proposed that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we proposed to make all other adjustments discussed previously in this section and apply an adjustment factor to further reduce the update factor by 2.0 percentage points. We proposed that the hospitals that fail to meet the requirements of the Hospital OQR Program would use a reduced OPD fee schedule update factor of 0.4 percent (that is, the proposed OPD fee schedule increase factor of 2.4 percent reduced by 2.0 percentage points) (91 FR 41764).

For CY 2027, as discussed in section V.B.7. of the CY 2027 OPPS/ASC proposed rule, we proposed to reduce payments for non-drug items and services for hospitals for whom the annual reduction to payment amounts under § 419.32(b)(1)(iv)(B)(12) applies with a 3 percentage point reduction to the OPD fee schedule increase factor. This would result in a proposed reduced conversion factor for CY 2027 of approximately $99.015 for this group of hospitals (91 FR 41764).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters stated that CMS should evaluate the combined effect of the conversion-factor adjustments and other proposed payment policies rather than evaluating each policy in isolation. Commenters noted that the proposed OPD update could be offset by other adjustments and that the resulting payment effects would vary across providers and services, including 340B hospitals, academic medical centers, and advanced cardiovascular imaging programs.

Response: We acknowledge commenters' concerns regarding the combined effect of the conversion-factor adjustments and other payment policies on different providers and services. The OPD fee schedule increase factor is only one component of the OPPS payment-rate calculation. The impact analysis in section XXVII. of this final rule with comment period presents the estimated combined effects of the finalized OPPS policies by hospital category. Actual payment effects for particular hospitals and services may vary based on factors such as service mix, wage-index adjustments, and other applicable payment policies. However, several conversion-factor components are required by statute or calculated to maintain budget neutrality for specific policies. Accordingly, we calculate each component under the applicable statutory and methodological requirements and apply the resulting adjustments in determining the final conversion factor. We address comments concerning the underlying payment policies in the relevant sections of this final rule with comment period.

Comment: A few commenters supported the proposed CY 2027 budget neutrality adjustment factor for the cancer hospital payment adjustment. One of the commenters requested that CMS retain flexibility to reinstate a gradual transition if future recalculations result in significant or unexpected changes to the target PCR, to avoid abrupt reductions in reimbursement for cancer hospitals.

Response: We thank the commenters for their support. We address the CY 2027 cancer hospital payment adjustment, including the target payment-to-cost ratio and commenters' request concerning a possible future transition, in section II.F. of this final rule with comment period.

Comment: Several commenters opposed CMS's proposed reduction in payment for drugs acquired under the 340B program and the associated 8.44 percent budget-neutral increase to the OPPS conversion factor for non-drug items and services. Commenters characterized the adjustment as a redistribution of payments from 340B hospitals to non-340B and for-profit hospitals and stated that it would disproportionately disadvantage safety-net, rural, teaching, and academic hospitals, particularly those furnishing substantial volumes of high-cost oncology and specialty drugs. Commenters also opposed the proposed treatment of nonexcepted off-campus provider-based departments, including the application of the drug-payment reduction without a corresponding budget-neutral payment increase. A commenter requested that CMS disclose the data and methodology used to calculate the aggregate drug payment reduction and conversion factor adjustment, including its methods for identifying 340B hospitals and determining the providers and claims included in the calculation. That commenter also requested that CMS recalculate the budget neutrality adjustment annually, citing CMS's use of an unchanged 3.19 percent adjustment from CY 2018 through CY 2022 despite subsequent increases in the amount of the drug payment reductions.

Response: We address comments on the payment rate for drugs acquired under the 340B program and the associated budget-neutrality adjustment, including comments on the affected hospital groups, claims methodology, and nonexcepted off-campus provider-based departments, in section V.B.7. of this final rule with comment period.

For this CY 2027 OPPS/ASC final rule with comment period, based on more recent data available, the OPD fee schedule increase factor for the CY 2027 OPPS is 2.3 percent (which reflects the 3.2 percent final estimate of the hospital inpatient market basket percentage increase with a −0.9 percentage point productivity adjustment). For CY 2027, we are using a conversion factor of $99.970 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the OPD fee schedule increase factor of 2.3 percent for CY 2027, the required wage index budget neutrality adjustment of 0.9952, the 5 percent annual cap for individual hospital wage index reductions of 0.9996, the budget neutrality adjustment of 0.9992 for the COLA, the cancer hospital payment adjustment of 0.9996, the budget neutrality adjustment of 1.075 for the final 340B-drug payment adjustment, and the adjustment of 0.07 (or 0.30 less 0.23) percentage point of projected OPPS spending for the difference in pass-through spending that results in a conversion factor for CY 2027 of $99.970. We are also finalizing a reduced conversion factor of $98.011 in

the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.959 in the conversion factor relative to hospitals that met the requirements). The calculations we performed to determine the CY 2027 final conversion factor are shown in Table 8.

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TABLE 8: CALCULATION OF CY 2027 FINAL OPPS CONVERSION FACTOR

Start: CY 2026 Final OPPS Conversion Factor = **$91.415**
Step 1a: Adjust the conversion factor to temporarily account for additional drug and device pass-through spending and outlier spending in CY 2026. This action causes an increase in the conversion factor. So, the amount of both drug and device pass-through spending (0.0030), the percentage of outlier spending (0.01) and the percentage of domestic NIOSH/N95 policy (0.0001) as a share of total OPPS outpatient hospital spending is subtracted from 1.0000, which represents total OPPS outpatient hospital spending for CY 2026. ➢ 1.0000 – (0.0030 + 0.01 + 0.0001) = 0.9869
Step 1b: Divide $91.415 by 0.9869 ➢ $91.415/0.9869 = **$92.628**
Step 2: Adjust the conversion factor by the required wage index budget neutrality adjustment of approximately 0.9952. This adjustment increases the amount of OPPS outpatient hospital spending and is multiplied with $92.628. ➢ $92.628* 0.9952 = **$92.184**
Step 3: Adjust the conversion factor by the 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9996. This adjustment reduces the amount of OPPS outpatient hospital spending and is multiplied with $92.184. ➢ $92.184* 0.9996 = **$92.147**
Step 4: Adjust the conversion factor by cost-of-living adjustment (COLA) of 0.9992. This adjustment reduces the amount of OPPS outpatient hospital spending and is multiplied with $92.147. ➢ $92.147*0.9992 = **$92.073**
Step 5: Adjust the conversion factor by the cancer hospital payment adjustment of 0.9996. This adjustment reduces the amount of OPPS outpatient hospital spending and is multiplied with $92.073. ➢ $92.073*0.9996 = **$92.036**
Step 6: Adjust the conversion factor by rural SCH adjustment policy of 1.0000. Since we maintain our current policy, there is no impact on the conversion factor by this policy. ➢ $92.036*1.0000 = **$92.036**
Step 7: Adjust the conversion factor by the final 340B drug payment budget neutrality adjustment policy of 1.0750. This adjustment increases the amount of OPPS outpatient hospital spending and is multiplied with $92.036. $92.036*1.0750 = **$98.939**
Step 8a: Adjust the conversion factor by the OPD fee schedule increase factor of 0.023 for CY 2027. The OPD fee schedule increase factor increases outpatient hospital spending in CY 2027 over CY 2026 and is added to 1.0000 which represents total outpatient hospital OPPS spending in CY 2026. ➢ 1.0000+0.023 = 1.0230
Step 8b: Multiply $98.939 by 1.0230.

➢ $98.939*1.0230 = **$101.215**
Step 9a: Adjust the conversion factor to remove additional drug and device pass-through spending and outlier spending for CY 2027. This action causes a decrease in the conversion factor. So, the amount of both drug and device pass-through spending (0.0023) 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 2027. ➢ 1.0000 – (0.0023+0.01) = 0.9877
Step 9b: Multiply $101.215 by 0.9877 to get the CY 2027 final OPPS conversion factor. $101.215*0.9877 = **$99.970**
Finish: **CY 2027 final OPPS Conversion Factor = $99.970**
* *Reduction for Providers Subject to the 340B Remedy Offset* *Step 8:* Multiply $99.970 by 0.9804 to get the CY 2027 final OPPS conversion factor for the providers subject to the 340B remedy offset. $99.970*0.9804 = **$98.011**

Please note rounding may affect the numbers in the calculations above.

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C. Final 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 in regulation at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related portion or OPPS labor-related share. The scaled weight budget neutrality calculation methodology is discussed in section II.A.5. of this final rule with comment period.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). We proposed to continue this policy for CY 2027. We refer readers to section II.C. of this final rule with comment period 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 under ''Downloads'' for this final rule with comment period (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*), for estimating APC costs, we would standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2027 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 §§ 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000, final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998, OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State, and amended section 1833(t) of the Act to add paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and stipulates 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 2027, we proposed to implement this provision in the same manner as we have since CY 2011 (91 FR 41766). 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 2026 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 to 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; FY 2024, 88 FR 58977; for FY 2025, 89 FR 69300; for FY 2026, 90 FR 36851, and for FY 2027, 91 FR 49806.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2027 IPPS wage indexes continue to reflect a number of adjustments implemented in past years, including, but not limited to, an adjustment for occupational mix, reclassification of hospitals to different geographic areas, the rural floor provisions, the imputed floor wage index adjustment in all-urban States, an adjustment to the wage index based on commuting patterns of hospital employees (the out-migration adjustment), the 5 percent cap on any decrease to a hospital's wage index from its wage index in a prior FY, and the transitional payment exception for hospitals significantly impacted by the discontinuation of the low-wage index hospital policy. Beginning with FY 2024, we include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and we 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 refer readers to the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19459 through 19479) for a detailed discussion of all proposed changes to the FY 2027 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 2027 would not be less than 95 percent of its final wage index for FY 2026. 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).

Consistent with the FY 2026 IPPS/LTCH PPS final rule (90 FR 36852 through 36854), we discontinued for CY 2026 and subsequent years the low-wage index hospital policy under the OPPS (90 FR 53495 through 53496). Under the low-wage index hospital policy that we previously adopted for the OPPS (84 FR 61186 through 61188), we increased the wage index for hospitals with a wage index value below the 25th percentile wage index value for a calendar 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 IFC (89 FR 80405 through 80421), FY 2026 IPPS/LTCH PPS final rule (90 FR 36852 through 36854) and CY 2026 OPPS/ASC final rule with comment period (90 FR 53495 through 53496) for a detailed discussion regarding the removal of the low-wage index hospital policy from the IPPS for FYs 2025 and 2026 and the OPPS for CY 2026.

Comment: A couple commenters supported the proposal to adopt the FY 2027 IPPS wage index post reclassification wages into the CY 2027 OPPS, and they also recommended that CMS continue to evaluate the impact of wage index changes across the IPPS and OPPS as well as potential refinements to the wage index to narrow geographic and rural-urban payment disparities in labor cost adjustments.

Response: We thank commenters for their support and note that we continue to review the wage index.

Comment: Several commenters opposed the proposal to adopt the IPPS wage index into the OPPS and requested that we evaluate the impact of the wage index on rural hospitals. Additionally, some commenters opposed the CY 2026 discontinuation of the low-wage index hospital policy, expressing concerns around the impact of the changes and urging CMS to restore the low-wage index policy in CY 2027 or develop a permanent alternative.

Response: We understand the commenters' concerns regarding the discontinuation of the low-wage index hospital policy for CY 2026. We continue to believe that it is appropriate for the IPPS wage index and the OPPS wage index to be aligned, which required discontinuation of the low-wage index policy in the OPPS for CY 2026. 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. Finally, we note that we continue to review the impact of wage index changes on hospitals, and some of those impacts are included in the impact analysis in section XXVII. of this final rule with comment period as well as through the impact file made available online at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

Comment: Multiple commenters supported CMS's policy to apply a 5 percent cap on any decrease to a hospital's wage index from its wage index in the prior FY. Commenters also requested that the proposed 5 percent cap policy be applied in a non-budget neutral manner.

Response: We appreciate the commenters' support of our policy to apply a 5 percent cap on any decrease to a hospital's wage index from its wage index in the prior FY. We stated in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49021) that, under the IPPS, we apply the cap in a budget neutral manner through a national adjustment to the standardized amount each fiscal year. Specifically, we apply a budget neutrality adjustment to ensure that estimated aggregate payments under our wage index cap policy for hospitals that would have a decrease in their wage indexes for the upcoming fiscal year of more than 5 percent would equal what estimated aggregate payments would have been without the wage index cap policy. We have continued to apply a similar budget neutrality adjustment in the OPPS for each calendar year as well as in the CY 2027 OPPS proposed rule (91 FR 41763). For the OPPS, section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor- related costs across geographic regions in a budget neutral manner, which is inconsistent with the commenters'

request to exclude the wage index cap policy from budget neutrality.

After consideration of the public comments we received, we are finalizing our proposal without modification to use the FY 2027 IPPS post reclassified wage index for urban and rural areas as finalized in the FY 2027 IPPS final rule as the wage index for the OPPS. We are also finalizing our proposal without modification to apply a 5 percent cap on any decrease to a hospital's wage index from its wage index in the prior FY.

In the FY 2026 IPPS final rule (90 FR 36855 through 36857), using our authority under section 1886(d)(5)(I)(i) of the Act, we adopted a narrow transitional exception to the calculation of FY 2026 IPPS payments for low-wage index hospitals significantly impacted by the discontinuation of the low-wage index hospital policy. As indicated in that rule, we adopted this temporary payment exception ''to mitigate short-term instability and payment fluctuations that can negatively impact hospitals consistent with principles of certainty and predictability under prospective payment systems.'' To address these same concerns under the OPPS, we correspondingly adopted a transitional payment exception for CY 2026 under the OPPS using our equitable adjustment authority under section 1833(t)(2)(E) of the Act (90 FR 53496 through 53497). This authority allows the Secretary to establish, in a budget neutral manner, adjustments as determined to be necessary to ensure equitable payments.

The CY 2026 transitional exception policy under the OPPS applied to hospitals that benefited from the CY 2024 low-wage index hospital policy. For those hospitals, we compared the hospital's proposed CY 2026 wage index to the hospital's CY 2024 wage index. If the hospital was significantly impacted by the discontinuation of the low-wage index hospital policy, meaning the hospital's proposed CY 2026 wage index was decreasing by more than 9.75 percent from the hospital's CY 2024 wage index, then the transitional payment exception for CY 2026 for that hospital was equal to the additional CY 2026 amount the hospital would be paid under the OPPS if its CY 2026 wage index were equal to 90.25 percent of its CY 2024 wage index. This transitional payment exception was applied after the application of the 5 percent cap described at 42 CFR 412.64(h)(7). This policy was budget neutral under the OPPS through the second wage index budget neutrality adjustment applied to the OPPS conversion factor (which currently includes the 5 percent cap on wage index decreases policy).

In the FY 2027 IPPS/LTCH proposed rule (91 FR 19476 through 19478) we proposed, using our authority under section 1886(d)(5)(I)(i) of the Act, to continue to apply the narrow transitional payment exception to the calculation of FY 2027 IPPS payments for low-wage index hospitals significantly impacted by the discontinuation of the low-wage index hospital policy that we adopted in CY 2026. As indicated in that rule, we proposed to continue this temporary payment exception because ''[s]ome hospitals that previously benefitted from the low-wage index hospital policy would continue to experience decreases of approximately 5 percent or more per year from their FY 2024 wage index (with the low-wage index hospital policy applied)'' (91 FR 19477). To address these same concerns under the OPPS, we correspondingly proposed to continue the transitional payment exception for CY 2027 under the OPPS that we adopted in CY 2026 using our equitable adjustment authority under section 1833(t)(2)(E) of the Act (91 FR 41767).

Comment: Several commenters supported CMS's proposal to establish a transitional payment exception for CY 2027. Commenters also requested that the proposed transitional payment exception be applied in a non-budget neutral manner.

Response: We appreciate the commenters' support of our policy to establish a transitional payment exception for CY 2027. For the OPPS, section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner. In addition, section 1833(t)(2)(E) of the Act requires adjustments under that provision to be established in a budget neutral manner. Commenters' request to exclude the proposed transitional payment exception from budget neutrality is inconsistent with the budget neutrality requirement under 1833(t)(2)(D) and (E) of the Act.

Comment: A commenter requested specific detail on the calculation for how the transitional exception would apply under the CY 2027 OPPS. That commenter also requested that the budget neutrality for the transitional exception only apply to hospitals at or above the 75th percentile of wage indexes.

Response: With regard to the calculation of the transitional exception policy under the CY 2027 OPPS, it would mirror the calculation for the policy under the FY 2027 IPPS. That is, for hospitals that benefitted from the low-wage index policy in CY 2024, if their CY 2027 wage index decreased by more than 14.2625 percent from the hospital's CY 2024 wage index, then its CY 2027 transitional payment exception would be equal to the additional CY 2027 amount the hospital would be paid under the OPPS if its CY 2027 wage index were equal to 85.7375 percent of its CY 2024 wage index (91 FR 49808). This narrow transitional payment exception would be applied after the application of the 5 percent cap described at 42 CFR 412.64(h)(7). Similar to the policy in the CY 2026 OPPS, we proposed to make this policy budget neutral under the OPPS through the second wage index budget neutrality adjustment applied to the OPPS conversion factor, which currently includes the 5 percent cap on wage index decreases policy (91 FR 41767).

While we recognize the commenter's concern regarding the impact that wage index budget neutrality has with regard to payments through the rest of the OPPS, we do not believe that it is appropriate to budget neutralize specifically for hospitals with wage indexes above the 75th percentile. Developing wage index budget neutrality in this manner would result in different wage indexes between the IPPS and OPPS, and as discussed throughout this section, we believe it is important to maintain alignment of the IPPS and OPPS wage indexes.

After consideration of the public comments we received, we are finalizing our proposal without modification to adopt a transitional payment exception for CY 2027 under the OPPS using our equitable adjustment authority under section 1833(t)(2)(E) of the Act.

Core Based Statistical Areas (CBSAs) are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38130) discussed the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the IPPS and OPPS wage indexes. However, the SSA county codes are no longer being maintained and updated, although the FIPS codes continue to be maintained by the U.S.

Census Bureau. The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at *https://www.census.gov/programs-surveys/geography/technical-documentation/county-changes.html.* In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), for purposes of crosswalking counties to CBSAs for the IPPS wage index, we finalized our proposal to discontinue the use of the SSA county codes and begin using only the FIPS county codes. Similarly, for the purposes of crosswalking counties to CBSAs for the OPPS wage index, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59260), we finalized our proposal to discontinue the use of SSA county codes and begin using only the FIPS county codes. For CY 2027, under the OPPS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs (91 FR 41768).

We proposed to use the FY 2027 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2027. Therefore, any policies and adjustments that are finalized for the FY 2027 IPPS post-reclassified wage index would be reflected in the final CY 2027 OPPS wage index beginning on January 1, 2027, if appropriate (91 FR 41768). We refer readers to the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19459 through 19479) and the proposed FY 2027 hospital wage index files posted on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2027-ipps-proposed-rule-home-page.*

Regarding budget neutrality for the CY 2027 OPPS wage index, we refer readers to section II.C. of this final rule with comment period. We continue to believe that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding (65 FR 18495 through 18498) policy to assign the wage index that would be applicable if the hospital was paid under the IPPS, based on its geographic location and any applicable wage index policies and adjustments. We proposed to continue this policy for CY 2027 (91 FR 41768). We refer readers to the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19459 through 19479) for a detailed discussion of the proposed changes to the FY 2027 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'' (that is, a county identified under 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 2027, we proposed to continue our policy of allowing 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 MMA) (88 FR 49585 through 49586). Furthermore, we proposed that the wage index that would apply for CY 2027 to non-IPPS hospitals paid under the OPPS would continue to include the rural floor adjustment and any other policies and adjustments applied to the IPPS wage index. In addition, we proposed that the wage index that would apply to non-IPPS hospitals paid under the OPPS would include the 5 percent cap on wage index decreases and the previously described proposed transitional payment exception for hospitals significantly impacted by the discontinuation of the low-wage index hospital policy.

For CMHCs, for CY 2027, we proposed to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. Furthermore, we proposed that the wage index that would apply to a CMHC for CY 2027 would continue to include the rural floor adjustment and any other policies and adjustments applied to the IPPS wage index. In addition, the wage index that would apply to CMHCs would include the 5 percent cap on wage index decreases and proposed transitional exception. Also, we proposed that the wage index that would apply to CMHCs would not include the out-migration adjustment because that adjustment only applies to hospitals (91 FR 41768).

We did not receive any public comments on these proposals, and, therefore, we are finalizing our proposals regarding CMHC wage index calculations without modification.

Table 4A associated with the FY 2027 IPPS/LTCH PPS final rule (available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2027-ipps-final-rule-home-page*) identifies counties that would be eligible for the out-migration adjustment. Table 2 associated with the FY 2027 IPPS/LTCH PPS final rule (available for download via the website noted previously) identifies IPPS hospitals that would receive the out-migration adjustment for FY 2027. We are including the out-migration adjustment information from Table 2 associated with the FY 2027 IPPS/LTCH PPS final rule as Addendum L to this final rule with comment period, with the addition of non-IPPS hospitals that would receive the section 505 out-migration adjustment under this final rule with comment period. Addendum L is available via the internet on the CMS website. We refer readers to the CMS website for the OPPS at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.* At this link, readers will find a link to the final FY 2027 IPPS wage index tables and Addendum L, associated with this final rule with comment period.

D. Final 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 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 new hospitals, defined for this purpose as entities 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 statewide average CCRs (also referred to as statewide average 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 final rule with comment period, which is posted on the CMS website. We proposed to calculate the default ratios for CY 2027 using the most recent cost report data (91 FR 41769).

We did not receive any public comments on our proposal, and, therefore, we are finalizing our proposal without modification to calculate the default ratios for CY 2027 using the most recent cost report data, which are from a June 2026 HCRIS cost report extract.

The statewide average CCRs are available on our website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices;* 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 limits in the ''Downloads'' section of the web page.

E. Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) Under Section 1833(t)(13)(B) of the Act for CY 2027

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 OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised our regulations at § 419.43(g) to clarify that essential access community hospitals (EACHs) are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. As detailed in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53499), we provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2026.

For CY 2027, we proposed to continue the current policy of a 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, applied in a budget neutral manner (91 FR 41769).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Multiple commenters supported our proposal to continue to apply the 7.1 percent payment adjustment for rural SCHs and EACHs in CY 2027.

Response: We thank the commenters for their support of our proposal.

Comment: Several commenters recommended extending the 7.1 percent payment adjustment to all SCHs, including urban SCHs, and conducting a study to determine if a similar adjustment is appropriate for Medicare dependent hospitals (MDHs); and one commenter requested a similar payment adjustment under OPPS for rural hospitals that are not SCHs.

Response: We note that our authority for an adjustment under section 1833(t)(13)(B) of the Act only applies to rural hospitals, so we would not have authority to expand the types of hospitals eligible for the payment adjustment to non-rural hospitals. With respect to rural hospitals that are not SCHs, we did not separately study this specific group during the CY 2027 rule cycle. However, the original study under section 1833(t)(13)(A) of the Act examined cost differences by APC for broader categories of rural hospitals and identified a significant difference only for rural SCHs. We will consider whether such a study is appropriate for future rulemaking.

After consideration of these public comments, we are finalizing our proposal, without modification, to continue our current policy of utilizing a budget neutral 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, devices paid under the pass-through payment policy, and items paid at charges reduced to costs (91 FR 41769).

F. Payment Adjustment for Certain Cancer Hospitals for CY 2027

1. Background

Since the inception of the OPPS, which was authorized by the BBA, Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient department services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), Congress added section 1833(t)(7) of the Act, ''Transitional Adjustment to Limit Decline in Payment,'' which requires the Secretary to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (these hospitals are often referred to under this policy as ''held harmless'' and their payments are often referred to as ''hold harmless'' payments).

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient department services under the OPPS and a ''pre-BBA amount.'' That is, cancer hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA amount'' is the product of the hospital's reasonable costs for covered outpatient department services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The ''pre-BBA amount'' and the determination of the base PCR are defined at § 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10 (OMB No. 0938–0050), respectively), as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals' costs are higher than those of other hospitals, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the ''target PCR'') for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recently submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. Table 9 displays the target PCR for purposes of the cancer hospital adjustment for CY 2012 through CY 2026.

TABLE 9: CANCER HOSPITAL ADJUSTMENT TARGET PAYMENT-TO-COST RATIOS (PCRS), CY 2012 THROUGH CY 2026

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
2025	0.87
2026	0.87

2. Policy for CY 2027

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 Secretary shall use a target PCR that is 1.0 percentage point less than the target PCR that would otherwise apply. Section 16002(b) of the 21st Century Cures Act 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, section 16002(b) of the 21st Century Cures Act provides that the Secretary shall not consider the reduced expenditures that result from application of section 1833(t)(18)(C) of the Act.

We proposed to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's proposed PCR is equal to the weighted average PCR (or ''target PCR'') for the other OPPS hospitals, generally using the most recent submitted or settled cost report data that are available, reduced by 1.0 percentage point, to comply with section 16002(b) of the 21st Century Cures Act (91 FR 41770). As discussed further later in this section of the preamble, we did not propose an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2027.

To calculate the proposed CY 2027 target PCR, we proposed to use the same extract of cost report data from HCRIS used to estimate costs for the CY 2027 OPPS which, in most cases, would be the most recently available hospital cost reports (91 FR 41770). 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 2025 claims data that we used to model the impact of the proposed CY 2027 APC relative payment weights (3,374 hospitals) because we believe it is appropriate to use the same set of hospitals that are being used to calibrate the modeled CY 2027 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2023 to 2025; however, the cost reporting periods were predominantly from fiscal years ending in 2024 and 2025 (91 FR 41770). We then removed the cost report data of the 50 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 nine 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 3,315 hospitals with cost report data (91 FR 41771).

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 89 percent of reasonable cost (weighted average PCR of 0.89). 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 proposed target PCR equal to 0.88 for each cancer hospital (91 FR 41771).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our cancer hospital payment adjustment methodology and our proposed target PCR of 0.88. Some commenters also recommended we reinstate our gradual transition policy in the future if changes in the underlying data yield a target PCR change of greater than 1 percentage point.

Response: We thank the commenters for their support of our cancer hospital payment methodology. With respect to their recommendation to reinstate the transition policy we finalized in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81586 through 81589) for CYs 2024 and 2025, we did not propose such a policy but may take this comment into consideration in future rulemaking.

After consideration of public comments, we are finalizing without modification our proposal to calculate the target PCR based on our longstanding target PCR calculation methodology described in this final rule with comment period and then apply the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act. For this final rule with comment period, we are using the most recent cost report data through June 30, 2026 to update the adjustment. We limited the dataset to hospitals with CY 2025 claims data that we used to model the impact of the CY 2027 APC relative payment weights (3,387 hospitals) because we believe it is appropriate to use the same set of hospitals that are being used to calibrate the modeled CY 2027 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2023 to 2025; however, the cost reporting periods were predominantly from fiscal years ending in 2024 and 2025. We then removed the cost report data of the 50 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 10 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 3,327 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 89 percent of reasonable cost (weighted average PCR of 0.89). 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 final target PCR equal to 0.88 for each cancer hospital.

Table 10 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2027, due to the cancer hospital payment adjustment policy. The actual, final amount of the CY 2027 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2027 payments and costs from the settled CY 2027 cost report. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 10: ESTIMATED CY 2027 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 2027 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	35.2%
050660	USC Norris Cancer Hospital	19.8%
100079	Sylvester Comprehensive Cancer Center	31.3%
100271	H. Lee Moffitt Cancer Center & Research Institute	16.3%
220162	Dana-Farber Cancer Institute	45.4%
330154	Memorial Sloan-Kettering Cancer Center	39.5%
330354	Roswell Park Cancer Institute	7.8%
360242	James Cancer Hospital & Solove Research Institute	27.1%
390196	Fox Chase Cancer Center	5.3%
450076	M.D. Anderson Cancer Center	52.9%
500138	Seattle Cancer Care Alliance	41.8%

G. Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain dollar amount). In CY 2026, 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 $6,225 (the fixed-dollar amount threshold) (90 FR 53502 through 53504). 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 2025 OPPS payments, using CY 2025 claims available for the CY 2027 OPPS/ASC proposed rule (91 FR 41772) was approximately 0.93 percent of the total aggregate OPPS payments. Using an updated claims dataset for this final rule with comment period, we estimate that we paid approximately 0.88 percent of the total aggregated OPPS payments in outliers for CY 2025. Therefore, for CY 2025, we estimate that we did not meet the outlier target by 0.12 percent of total aggregated OPPS payments.

For the CY 2027 OPPS/ASC proposed, using CY 2025 claims data and CY 2026 payment rates, we estimated that the aggregate outlier payments for CY 2026 would be approximately 1.21 percent of the total CY 2026 OPPS payments (91 FR 41772). We provided estimated CY 2027 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 2027

For CY 2027, we proposed to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We proposed that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments), would be allocated to CMHCs for partial hospitalization program (PHP) and intensive outpatient program (IOP) outlier payments (91 FR 41772). This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. We proposed to 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 (91 FR 41772).

For further discussion of CMHC outlier payments, we refer readers to section VIII.C. of this final rule with comment period.

To ensure that the estimated CY 2027 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we proposed that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus the fixed-dollar threshold (91 FR 41772).

We calculated the proposed fixed-dollar threshold using the standard methodology most recently used for CY 2026 (90 FR 53502 through 53504). For purposes of estimating outlier payments for CY 2027, we used the hospital-specific overall ancillary CCRs available in the April 2026 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.

To estimate CY 2027 hospital outlier payments, we inflated the charges on the CY 2025 claims using the same proposed charge inflation factor of 1.15154 that we used to estimate the IPPS fixed-loss cost threshold for the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19807 through 19809). We used an inflation factor of 1.07310 to estimate CY 2026 charges from the CY 2025 charges reported on CY 2025 claims before applying CY 2026 CCRs to estimate the percent of outliers paid in CY 2026. The proposed methodology for determining these charge inflation factors is discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19807 through 19809). 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 were concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we proposed to apply the same CCR adjustment factor that we proposed to apply for the FY 2027 IPPS outlier calculation to the CCRs used to simulate CY 2027 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2027, we proposed to apply an adjustment factor of 0.977497 to the CCRs that were in the April 2026 OPSF to trend them forward from CY 2026 to CY 2027 (91 FR 41772). The methodology for calculating the proposed CCR adjustment factor is discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19807 through 19809).

To model hospital outlier payments for this CY 2027 OPPS/ASC proposed rule, we applied the overall CCRs from the April 2026 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.977497 to approximate CY 2027 CCRs) to charges on CY 2025 claims that were adjusted (using the proposed charge inflation factor of 1.15154 to approximate CY 2027 charges). We simulated aggregated CY 2027 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 2027 OPPS payments. We estimate that a proposed fixed dollar- threshold of $7,100 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 CY 2027. For CMHCs, we proposed that, if a CMHC's cost for partial hospitalization or intensive outpatient services exceeds 3.40 times the APC payment rate, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC payment rate (91 FR 41772).

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 (91 FR 41772). For more information on the Hospital OQR Program, we refer readers to section XV. of this final rule with comment period.

We received public comments on these proposals. The following is a summary of the comments we received and our response.

Comment: Commenters expressed concern regarding the proposed increase in the fixed-dollar loss threshold from $6,225 in CY 2026 to the proposed fixed-dollar loss threshold of $7,100 for CY 2027. Commenters were concerned that fewer cases would qualify for outlier payments under the increased threshold and recommended we freeze the CY 2026 fixed-dollar threshold for CY 2027. One commenter recommended we evaluate alternative trend factors for determining charge inflation in a prospective year, such as a multi-year rolling average charge inflation factor or the hospital market basket update.

Response: We understand the commenters' concerns; however, we believe our current methodology, which allocates 1.0 percent of total OPPS spending to outlier payments, helps mitigate the financial risk to hospitals posed by high-cost cases. We do not believe an increase beyond 1.0 percent would be appropriate at this time as it would reduce OPPS payment rates by shifting dollars from standard OPPS APC payments to outlier OPPS payments under budget neutrality. Additionally, we do not believe using the CY 2026 fixed-dollar loss threshold of $6,225 would be appropriate as well as our modeling suggests we would exceed our 1.0 percent target and such excess expenditures would require recoupment in future ratesetting. As previously discussed, CY 2025 OPPS outlier payments were approximately 0.88 percent of total CY 2025 OPPS spending. Therefore, we believe the overall methodology (including using the most recent charge inflation factor) for calculating prospective OPPS outlier payments yields a high degree of accuracy, but we will take the commenters' suggestions into consideration to analyze and evaluate our existing methodology for calculating the OPPS outlier fixed-dollar loss for potential refinement in the future.

After consideration of public comments, we are finalizing our proposal, without modification, to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS and to use our established methodology to set the OPPS outlier fixed-dollar loss threshold for CY 2027.

3. Final Outlier Calculation for CY 2027

Consistent with historical practice, we used updated data for this final rule with comment period for outlier calculations. For CY 2027, we are applying the overall ancillary CCRs

from the July 2026 OPSF file after adjustment (using the CCR adjustment factor of 0.971037 to approximate CY 2027 CCRs) to charges on CY 2025 claims that were adjusted using a charge inflation factor of 1.15064 to approximate CY 2027 charges. These are the same CCR adjustment and charge inflation factors that were used to set the IPPS fixed-dollar thresholds for the FY 2027 IPPS/LTCH PPS final rule (91 FR 50383 and 61333). We simulated aggregated CY 2027 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 2027 OPPS payments. We estimate that a final fixed dollar- threshold of $7,150 combined with the multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments for CY 2027.

For CMHCs, if a CMHC's cost for partial hospitalization or intensive outpatient services exceeds 3.40 times the APC payment rate, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC payment rate.

H. Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment

The national unadjusted payment rate is the payment rate for most APCs before accounting for the wage index adjustment or any applicable adjustments. The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this final rule with comment period, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this final rule with comment period and the relative payment weight described in section II.A. of this final rule with comment period. The national unadjusted payment rate for most APCs contained in Addendum A to this final rule with comment period (which is available on the CMS website at ''*Hospital Outpatient Regulations and Notices*'') and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this final rule with comment period (which is available on the CMS website, see previous link) is calculated by multiplying the final CY 2027 scaled weight for the APC by the CY 2027 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 Outpatient Quality Reporting (OQR) Program requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIV. of this final rule with comment period.

As discussed later in this section of the preamble, we demonstrate the steps used to determine the APC payments that will be made in a CY under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: ''J1,'' ''J2,'' ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''Q4,'' ''R,'' ''S,'' ''T,'' ''U,'' or ''V'' (as defined in Addendum D1 to the proposed rule, which is available via the internet on the CMS website), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of ''Q1'' and ''Q2'') qualify for separate payment. We note that, although blood and blood products with status indicator ''R'' and brachytherapy sources with status indicator ''U'' are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they would receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this final rule (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 0.9804 times the ''full'' national unadjusted payment rate. The national unadjusted payment rate used in the calculations as discussed later in this section of the preamble 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 2027 OPPS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

$X = .60 *$ (national unadjusted payment rate).

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. 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 2027 under the IPPS, reclassifications through the Medicare Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) ''Lugar'' hospitals, and reclassifications under section 1886(d)(8)(E) of the Act, as implemented in § 412.103 of the regulations. For CY 2027, we proposed to apply for the CY 2027 OPPS wage index any adjustments for the FY 2027 IPPS post-reclassified wage index,

including, but not limited to, the rural floor adjustment and a wage index floor of 1.00 in frontier States, in accordance with section 10324 of the Affordable Care Act of 2010. For further discussion of the wage index we are applying for the CY 2027 OPPS, including the low wage index hospital policy, we refer readers to section II.C. of this final rule with comment period.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173). Addendum L to this final rule with comment period (which is available via the internet on the CMS website) contains the qualifying counties and the associated wage index increase developed for the final FY 2027 IPPS wage index, which are listed in Table 3 associated with the FY 2027 IPPS final rule and available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.* (Click on the link on the left side of the screen titled ''FY 2027 IPPS Final Rule Home Page'' and select ''FY 2027 Final Rule Tables''.) This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) of the Act or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate. The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

X_a = labor-portion of the national unadjusted payment rate * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

Y = 0.40 * (national unadjusted payment rate).

Step 6. If a provider is a sole community hospital (SCH), as set forth in the regulations at § 412.92, or an essential access community hospital (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 as discussed later in this section of the preamble, 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 CY 2027 full national unadjusted payment rate for APC 5071 is $796.21. The reduced national adjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is $780.60. This reduced rate is calculated by multiplying the reporting ratio of 0.9804 by the full unadjusted payment rate for APC 5071.

Step 1. The labor-related portion of the full national unadjusted payment is approximately $477.73 (0.60 * $796.21). The labor-related portion of the proposed reduced national adjusted payment is approximately $468.36 (0.60 * $780.60).

Step 2 & 3. The FY 2027 wage index for a provider located in CBSA 35614 in New York, which includes the adoption of the IPPS 2027 wage index policies, is 1.4267.

Step 4. The wage adjusted labor-related portion of the full national unadjusted payment is approximately $681.58 ($477.73 * 1.4267). The wage adjusted labor-related portion of the reduced national adjusted payment is approximately $668.21 ($468.36* 1.4267).

Step 5. The nonlabor-related portion of the full national unadjusted payment is approximately $318.48 (0.40 * $796.21). The nonlabor-related portion of the reduced national adjusted payment is approximately $312.24 (0.40 * $780.60).

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 $1,000.06 ($681.58 + $318.48). The sum of the portions of the reduced national adjusted payment is approximately $980.45 ($668.21 + $312.24) as shown in Table 11.

TABLE 11: FINAL FULL NATIONAL UNADJUSTED PAYMENT RATE AND FINAL REDUCED NATIONAL ADJUSTED PAYMENT RATE

Final Full national unadjusted payment rate	Final Reduced national adjusted payment rate
$1,000.06	$980.45

We did not receive public comments on these steps under the methodology that we included in the CY 2027 OPPS/ASC proposed rule to determine the APC payments for CY 2027. Therefore, we are using the steps in the methodology specified previously to demonstrate the calculation of the final CY 2027 OPPS payments using the same parameters.

I. Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in CYs thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure (including items such as drugs and biologicals) performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Medicare Part B coinsurance for preventive services furnished on and after January 1, 2011, that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. For a discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, we refer readers to section XII.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

Section 122 of the Consolidated Appropriations Act (CAA), 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)(C), the Medicare Part B payment percentage for colorectal cancer screening tests described in the regulation at § 410.37(j) that are furnished in CY 2027 through CY 2029 is 90 percent, with beneficiary coinsurance equal to 10 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 were initially implemented through program instruction, as permitted under section 1847A(c)(5)(C) of the Act. On February 9, 2023 and December 14, 2023, we issued initial [8] and revised [9] guidance, respectively, implementing the Medicare Part B Inflation Rebate Program, including 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.[10] 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) of the Act requires under the ASC payment system that, in the case of a Part B rebatable drug for which payment is not packaged into a payment for a service, 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 described under section 1192(c) of the Act.

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

[8] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

[9] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-revised-guidance.pdf.*

[10] In addition, beginning with the April 2023 ASP Drug Pricing file, the file includes the coinsurance percentage for each drug and specifies ''inflation-adjusted coinsurance'' in the ''Notes'' column if the coinsurance for a drug is less than 20 percent of the Medicare Part B payment amount. Drug pricing files are available at *https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice.*

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 described under section 1192(c) of the Act, 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 (88 FR 79043).

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81594), we codified the OPPS program payment and cost as required by section 1833(t)(8)(F) of the Act 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 the cost sharing amounts for Part B rebatable drugs with prices increasing at a rate faster than inflation.

In the CY 2025 PFS final rule (89 FR 98228 through 98275), we codified regulations implementing section 11101 of the IRA in newly added 42 CFR part 427, chapter IV, including 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. As finalized, § 427.201(a) establishes that CMS will use the methodology established in such section to calculate the inflation-adjusted beneficiary coinsurance and associated adjusted Medicare payment percentage and includes references to the existing provisions at §§ 410.152(m), 419.41(e), and 489.30(b)(6). Section 427.201(c) provides 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.

Section 427.201(b) sets forth the calculation of the inflation-adjusted beneficiary coinsurance. We will compare the payment amount in paragraph (b)(3) of such section to the inflation-adjusted payment amount for an applicable calendar quarter; if the payment amount exceeds the inflation-adjusted payment amount, the inflation-adjusted beneficiary coinsurance is calculated by multiplying the inflation-adjusted payment amount by 0.20. Section 427.201(b)(3) specifies that CMS will use the published payment amount in quarterly pricing files [11] [12] [13] to determine if a Part B rebatable drug should have an adjusted beneficiary coinsurance. If so, such adjusted beneficiary coinsurance shall be equal to 20 percent of the inflation-adjusted payment amount as described in section 1847A(i)(3)(C) of the Act for a calendar quarter. This approach deviates from the rebate calculation approach set forth 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.

We note that the cost sharing amounts of rebatable drugs paid under the OPPS published in the quarterly Addendum A and B updates reflect the inflation-adjusted coinsurance applied as a percent of the payment amount that would otherwise apply in accordance with section 1847A(b)(1)(B) or (C) of the Act, as determined by the Secretary pursuant to 1847A(i)(5) of the Act using the methodology in § 427.201. As we explained in the CY 2025 PFS final rule (89 FR 98237), this policy is intended to hold beneficiaries harmless in situations where the payment amount is calculated differently from the specified amount, and we believe 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 full discussion at 89 FR 98237 and 98238 for additional details.

2. OPPS Copayment Policy

For CY 2027, we proposed to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. We refer readers to the November 7, 2003 OPPS final rule with comment period for a discussion of that methodology (68 FR 63458). In addition, we proposed to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles. The final national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2027, are included in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website).

As discussed in section XIV.E. of this final rule with comment period, for CY 2027, 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).

[11] See *https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files.*

[12] See *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates.*

[13] See *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-payment-rates-addenda.*

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs, and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.
- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than* the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.
- If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).
- If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in the CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which achieves a 20 percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459).

We received a public comment on our proposals. The following is a summary of the comment we received and our response.

Comment: One commenter stated they appreciated CMS staying close to the 20 percent copayment amount and recommended finalizing our calculation.

Response: We thank the commenter for their support of our proposed methodology.

After consideration of the public comment we received, we are finalizing our proposal to determine copayment amounts for new and revised APCs using the same methodology that we implemented in CY 2004. In addition, we are finalizing the use of the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The finalized national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2027 are included in Addenda A and B to this CY 2027 OPPS/ASC final rule with comment period (which are available on the CMS website.)

3. Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 5071, $159.24 is 20 percent of the full national unadjusted payment rate of $796.21. For APCs with only a minimum unadjusted copayment in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website), the beneficiary payment percentage is 20 percent.

The formula as discussed later in this section of the preamble is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of this final rule with comment period. Calculate the rural adjustment for eligible providers, as indicated in Step 6 under section II.H. of this final rule with comment period.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H. of this final rule with comment period, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B.*

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B.*

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.9804.

The unadjusted copayments for services payable under the OPPS that would be effective January 1, 2027, are shown in Addenda A and B to this final rule with comment period (which are available via the CMS website). We note that the final national unadjusted payment rates and copayment rates

shown in Addenda A and B to this final rule with comment period reflect the CY 2027 OPD fee schedule increase factor discussed in section II.B. of this final rule with comment period.

In addition, as noted earlier, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

We also note that the co-insurance for a separately payable drug under the OPPS shall not exceed the amount of inpatient hospital deductible for that year.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

A. OPPS Treatment of New and Revised HCPCS Codes

Payments for OPPS procedures, services, and items are generally based on medical billing codes, specifically, Healthcare Common Procedure Coding System (HCPCS) codes, that are reported on hospital outpatient department (HOPD) claims. HCPCS codes are used to report surgical procedures, medical services, items, and supplies under the hospital OPPS. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system that is established and maintained by the American Medical Association (AMA), and consists of Category I, II, III, 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 OPPS payment system. Specifically, we recognize the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures;
- MAAA CPT codes, which describe laboratory multianalyte assays with algorithmic analyses (MAAA);
- PLA CPT codes, which describe proprietary laboratory analyses (PLA) services; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

The codes are updated and changed throughout the year. CPT and Level II HCPCS code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or October 1. CPT code changes are released by the AMA (via their website) while Level II HCPCS code changes are released to the public via the CMS HCPCS website. CMS recognizes the release of new CPT and Level II HCPCS codes outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that more accurately describe the items or services furnished and provides payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on the new CPT and Level II HCPCS codes, status indicators, and APC assignments through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. The items, procedures, or services not exclusively paid separately under the hospital OPPS are assigned to appropriate status indicators. Certain payment status indicators provide separate payment while other payment status indicators do not. In section X.I. ''CY 2027 Payment Status and Comment Indicators'' of this final rule with comment period, we discuss the various status indicators and comment indicators used under the OPPS. We also provide a complete list of the status indicators and their definitions in Addendum D1 to this final rule with comment period.

1. April 2026 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2026 update, 61 new HCPCS codes were established and made effective on April 1, 2026. Through the April 2026 OPPS quarterly update CR (Transmittal 13686, Change Request 14380, dated March 13, 2026), we recognized several new HCPCS codes for payment and assigned them to appropriate interim OPPS status indicators and APCs. We solicited public comments on the proposed APC and status indicator assignments for the codes listed in Table 9 (New HCPCS Codes Effective April 1, 2026) of the CY 2027 OPPS/ASC proposed rule (91 FR 41779 through 41781), which are also displayed in Table 12.

We received some public comments on the proposed OPPS APC and SI assignments for the new Level II HCPCS codes that were effective on April 1, 2026. The comments and our responses are addressed in the applicable sections of this final rule with comment period, which include, but are not limited to sections III.C. (New Technology APCs), III.E. (OPPS APC-Specific Policies), and IV. (OPPS Payment for Devices). For those April 2026 codes for which we received no comments, we are finalizing the proposed APC and status indicator assignments as proposed. Additionally, in prior years we included the final OPPS status indicators and APC assignments in the coding preamble tables, however, because the same information can be found in Addendum B, we no longer include them in Table 12. Therefore, readers are advised to refer to the OPPS Addendum B for the final OPPS status indicators, APC assignments, and payment rates for all codes reportable under the hospital OPPS. These new codes that were effective April 1, 2026, were assigned comment indicator ''NP'' in Addendum B to the CY 2027 OPPS/ASC proposed rule to indicate that the codes are assigned to an interim APC assignment, and comments would be accepted on their interim APC assignments. The complete list of status indicators and definitions used under the OPPS can be found in Addendum D1 to this final rule with comment period, while the complete list of comment indicators and definitions can be found in Addendum D2 to this final rule with comment period. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

BILLING CODE 4169–69–P

CY 2026 HCPCS Code	CY 2027 HCPCS Code	CY 2027 Long Descriptor
C1743	C1743	Scaffold, endovascular non-coronary, resorbable drug eluting, with delivery system (implantable)
C8007 (retroactive to January 1, 2026)	C8007	Open implantation of hypoglossal nerve neurostimulator array and pulse generator, not requiring an insertion of a separate distal respiratory sensor electrode or electrode array
C8008 (retroactive to January 1, 2026)	C8008	Revision or replacement of hypoglossal nerve neurostimulator array including connection to existing pulse generator
C8009 (retroactive to January 1, 2026)	C8009	Removal of hypoglossal nerve neurostimulator array and pulse generator
C8010	1091T	Percutaneous placement of permanent common carotid embolic protection device, including all system components and imaging guidance; bilateral
C8011 (retroactive to January 1, 2026)	C8011	Open implantation of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver, including external power source and all system components
C8012 (retroactive to January 1, 2026)	C8012	Revision or replacement of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver
C8013 (retroactive to January 1, 2026)	C8013	Removal of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver
C9309	C9309	Injection, onasemnogene abeparvovec-brve, per treatment
C9818 (effective January 23, 2026)	C9818	Suzetrigine, oral, 1 mg
G0680	G0680	Detection and quantification of coronary artery calcium and/or aortic valve calcification from algorithmic analysis of computed tomography of the chest with report
G0681	G0681	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute for a wound surface area up to 100 sq cm; first 25 sq cm or less of wound surface area
J0463	J0463	Injection, atropine sulfate (fresenius and therapeutically equivalent), 0.01 mg
J1164	J1164	Injection, diltiazem hydrochloride in 0.72% sodium chloride, 0.5 mg
J1553	J1553	Injection, immune globulin (yimmugo), 100 mg
J3404	J3404	Injection, zopapogene imadenovec-drba suspension, per therapeutic dose
C9145	J8502	Injection, aprepitant (aponvie), 1 mg
J9003	J9003	Leuprolide injectable (camcevi etm), 1 mg
J9183	J9183	Gemcitabine intravesical system, 225 mg
J9277	J9277	Injection, pembrolizumab, 1 mg and berahyaluronidase alfa-pmph
C9308	J9278	Injection, carboplatin (avyxa), 1 mg
C9307	J9601	Injection, linvoseltamab-gcpt, 1 mg
M0233	M0233	Intravenous infusion, tocilizumab-aazg, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal

CY 2026 HCPCS Code	CY 2027 HCPCS Code	CY 2027 Long Descriptor
		oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, first dose
M0234	M0234	Intravenous infusion, tocilizumab-aazg, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, second dose
Q0238	Q0238	Injection, tocilizumab-aazg, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, 1 mg
Q4418	Q4418	Biolab membrane wrap flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4419	Q4419	Biolab membrane wrap lite flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4421	Q4421	Biolab membrane wrap solo, per square centimeter (add-on, list separately in addition to primary procedure)
Q4422	Q4422	A/c wrap, per square centimeter (add-on, list separately in addition to primary procedure)
Q4423	Q4423	Biolab tri-membrane wrap flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4424	Q4424	Revive ft, per square centimeter (add-on, list separately in addition to primary procedure)
Q4425	Q4425	Revive tl, per square centimeter (add-on, list separately in addition to primary procedure)
Q4426	Q4426	Dermabind tl + or dermabind tl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4427	Q4427	Dermabind dl n or dermabind dl + or dermabind dl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4428	Q4428	Dermabind sl n or dermabind sl + or dermabind sl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4429	Q4429	Dermabind ch n or dermabind ch x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4435	Q4435	Renati membrane, per square centimeter (add-on, list separately in addition to primary procedure)
Q4436	Q4436	Renati ac membrane, per square centimeter (add-on, list separately in addition to primary procedure)
Q4437	Q4437	Revival ac, per square centimeter (add-on, list separately in addition to primary procedure)
Q4438	Q4438	Pretect, per square centimeter (add-on, list separately in addition to primary procedure)
Q4439	Q4439	Instagraft, per square centimeter (add-on, list separately in addition to primary procedure)
Q4440	Q4440	Curamatrix, per square centimeter (add-on, list separately in addition to primary procedure)
Q5161	Q5161	Injection, denosumab-kyqq (aukelso/bosaya), biosimilar, 1 mg
Q5162	Q5162	Injection, denosumab-nxxp (bildyos/bilprevda), biosimilar, 1 mg
0614U	0614U	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 4 enzyme complexes by stained blue native polyacrylamide gel electrophoresis (PAGE), frozen tissue (muscle, liver, heart, cultured skin fibroblasts), diagnostic qualitative result
0615U	0615U	Borrelia burgdorferi (Lyme disease), antibody detection of 26 recombinant protein groups, by immunoassay, IgM
0616U	0616U	Neurology (dementia), DNA methylation analysis of more than 30,000 sites, whole blood, algorithm reported as positive or negative risk

CY 2026 HCPCS Code	CY 2027 HCPCS Code	CY 2027 Long Descriptor
0617U	0617U	Cardiovascular (atherosclerotic cardiovascular disease [ASCVD]), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk
0618U	0618U	Psychiatry (bipolar disorder), DNA methylation analysis of more than 10,000 sites, whole blood, algorithm reported as positive or negative risk
0619U	0619U	Pulmonary (chronic obstructive pulmonary disease [COPD]), DNA methylation analysis of more than 18,000 sites, whole blood, algorithm reported as positive or negative risk
0620U	0620U	Oncology (hepatocellular carcinoma), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk
0621U	0621U	Infectious disease (Lyme borreliosis), DNA methylation analysis of more than 10,000 sites, whole blood, algorithm reported as positive or negative risk
0622U	0622U	Psychiatry (major depressive disorder), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk
0623U	0623U	Autoimmune (multiple sclerosis), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk
0624U	0624U	Hepatology (nonalcoholic steatohepatitis [NASH]), DNA methylation analysis of 5,000 sites, whole blood, algorithm reported as positive or negative risk
0625U	0625U	Endocrinology (osteoporosis), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk
0626U	0626U	Neurology (Parkinson disease), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk
0627U	0627U	Psychiatry (schizophrenia), DNA methylation analysis of more than 15,000 sites, whole blood, algorithm reported as positive or negative risk
0628U	0628U	Nephrology (kidney disease-related genetic conditions), genomic analysis, renal disease panel, saliva, DNA, next-generation sequencing of 449 genes, reported as pathogenic or likely pathogenic variants of uncertain significance or risk alleles
0629U	0629U	Infectious disease (tuberculosis), DNA, analysis of 1 target by PCR with clustered regularly interspaced short palindromic repeat (CRISPR)-based probe detection, plasma or serum, qualitative report as detected or not detected
0630U	0630U	Oncology (breast), mRNA, gene expression profiling by microarray of 80 genes (80 content and 465 housekeeping), utilizing formalin-fixed paraffin-embedded tissue (FFPE), algorithm reported as an index that is diagnostic of a molecular subtype (luminal, basal, Her2)

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2. July 2026 HCPCS Codes Proposed Rule Comment Solicitation

For the July 2026 update, 98 new codes were established and made effective July 1, 2026. Through the July 2026 OPPS quarterly update CR (Transmittal R13832CP Change Request 14477, dated June 16, 2026) we recognized several new codes for payment and assigned them to appropriate interim OPPS status indicators and APCs. We solicited public comments on the proposed APC and status indicator assignments for the codes listed in Table 10 (New HCPCS Codes Effective July 1, 2026) of the CY 2027 OPPS/ASC proposed rule (91 FR 41782 through 41786), which are listed in Table 13.

We received some public comments on the proposed OPPS APC and SI assignments for the new Level II HCPCS codes implemented on July 1, 2026. The comments and our responses are addressed in pertinent sections of this final rule with comment period, which include, but are not limited to sections III.C (New Technology APCs), III.E (OPPS APC-Specific Policies), and IV (OPPS Payment for Devices). For those July 1, 2026, codes for which we received no comments, we are finalizing the proposed APC and status indicator assignments. Additionally, we note that in prior years we included the final OPPS status indicators and APC assignments in the coding preamble tables, however, because the same information can be found in Addendum B, we no longer include them in Table 13. Therefore, readers are advised to refer to the OPPS Addendum B for the final OPPS status indicators, APC assignments, and payment rates for all codes reportable under the OPPS. These new codes that were effective July 1, 2026, were assigned to comment indicator ''NP'' in Addendum B to the CY 2027 OPPS/ASC proposed rule to indicate that the codes are assigned to an interim APC assignment, and comments would be accepted on their interim APC assignments. The complete list of status indicators and definitions used under the OPPS can be found in Addendum D1 to this final rule with comment period, while the complete list of comment indicators and definitions can be found in Addendum D2 to this

final rule with comment period. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

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TABLE 13: NEW HCPCS CODES EFFECTIVE JULY 1, 2026

CY 2026 HCPCS Code	CY 2027 HCPCS Code	CY 2027 Long Descriptor
A9574	A9574	Injection, ferumoxytol, 1 mg
C1609	C1609	Vertebral device, motion-preserving, with screw fixation
C8014	C8014	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, including use of a suction enabled ureteral access sheath, with irrigation (if performed)
C9310	C9310	Injection, leucovorin calcium (avyxa), 1 mg

CY 2026 HCPCS Code	CY 2027 HCPCS Code	CY 2027 Long Descriptor
G0572	G0572	Management of new patient with dementia residing in an eligible memory care unit, for use only in a medicare-approved cmmi model (services must be furnished within a patient's eligible memory care unit, including specialized dementia care units within assisted living facilities or other qualifying memory care settings designed to provide specialized care for individuals with dementia and cognitive impairment)
G0573	G0573	Management of established patient with dementia residing in an eligible memory care unit, for use only in a medicare-approved cmmi model (services must be furnished within a patient's eligible memory care unit, including specialized dementia care units within assisted living facilities or other qualifying memory care settings designed to provide specialized care for individuals with dementia and cognitive impairment)
G0574	G0574	Management of new patient with dementia residing in an eligible residential care community, for use only in a medicare-approved cmmi model (services must be furnished within a patient's eligible residential care community, including assisted living facilities, board and care homes, or other qualifying residential settings where dementia care services are provided)
G0575	G0575	Management of established patient with dementia residing in an eligible residential care community, for use only in a medicare-approved cmmi model (services must be furnished within a patient's eligible residential care community, including assisted living facilities, board and care homes, or other qualifying residential settings where dementia care services are provided)
G0669	G0669	Outcome-Aligned Payment (OAP) for technology-enabled chronic care management of early cardio-kidney-metabolic (eCKM) conditions (hypertension, or two or more of: dyslipidemia, obesity/overweight with central obesity marker, prediabetes); initial 12-month period; per month.
G0670	G0670	Outcome-Aligned Payment (OAP) for technology-enabled chronic care management of early cardio-kidney-metabolic (eCKM) conditions (hypertension, or two or more of: dyslipidemia, obesity/overweight with central obesity marker, prediabetes); follow-on 12-month period; per month.
G0671	G0671	Outcome-Aligned Payment (OAP) for technology-enabled chronic care management of cardio-kidney-metabolic (CKM) conditions (one or more of: diabetes mellitus, chronic kidney disease Stage 3a or 3b, atherosclerotic cardiovascular disease); initial 12-month period; per month.
G0672	G0672	Outcome-Aligned Payment (OAP) for technology-enabled chronic care management of cardio-kidney-metabolic (CKM) conditions (one or more of: diabetes mellitus, chronic kidney disease Stage 3a or 3b, atherosclerotic cardiovascular disease); follow-on 12-month period; per month.
G0673	G0673	Outcome-Aligned Payment (OAP) for technology-enabled chronic care management of musculoskeletal (MSK) conditions (chronic musculoskeletal pain); initial 12-month treatment period; per month.
G0674	G0674	Outcome-Aligned Payment (OAP) for technology-enabled chronic care management of behavioral health conditions (BH) conditions (one or more of: depression, anxiety); initial 12-month period; per month.
G0675	G0675	Outcome-Aligned Payment (OAP) for behavioral health (BH) conditions (one or more of: depression, anxiety); follow-on 12-month period; per month.
G0676	G0676	Standard Co-Management service payment for documented review of clinical updates from ACCESS Participant managing cardio-kidney-metabolic conditions (early cardio-kidney-metabolic [eCKM] or cardio-kidney-metabolic [CKM] track); per review.
G0677	G0677	Standard Co-Management service payment for documented review of clinical updates from ACCESS Participant managing musculoskeletal (MSK) conditions; per review.
G0678	G0678	Standard Co-Management service payment for documented review of clinical updates from ACCESS Participant managing behavioral health (BH) conditions (depression, anxiety); per review.

CY 2026 HCPCS Code	CY 2027 HCPCS Code	CY 2027 Long Descriptor
G0685	G0685	Algorithmic analysis for identification of new lesions and determination of change of existing lesions for advanced metastatic cancer using data sets from 2 or more previously acquired pet or pet/ct studies
J0528	J0528	Injection, fosfomycin disodium, 20 mg
J1289	J1289	Injection, narsoplimab-wuug, 1 mg
J1577	J1577	Injection, immune globulin (qivigy), 100 mg
J2361	J2361	Injection, depemokimab-ulaa, 1 mg
J2374	J2374	Apraclonidine hydrochloride ophthalmic, 1% solution, 0.1 mL
J2789	J2789	Riboflavin 5'-phosphate, ophthalmic solution (epioxahd/epioxa), up to 2 mL
J3386	J3386	Injection, etuvetidigene autotemcel, per treatment
C9309	J3405	Injection, onasemnogene abeparvovec-brve, per treatment
J9062	J9062	Injection, amivantamab 5 mg and hyaluronidase-lpuj
J9232	J9232	Injection, docetaxel (hospira), not therapeutically equivalent to j9171, 1 mg
M0231	M0231	Intravenous infusion, tocilizumabbavi, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation only, includes infusion and post administration monitoring, first dose
M0232	M0232	Intravenous infusion, tocilizumabbavi, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation only, includes infusion and post administration monitoring, second dose
Q0234	Q0234	Injection, tocilizumab-bavi, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation only, 1 mg
Q5164	Q5164	Injection, ustekinumab-hmny (starjemza), biosimilar, 1 mg
Q5165	Q5165	Injection, denosumab-mobz (oziltus), biosimilar, 1 mg
Q5166	Q5166	Injection, denosumab-desu (osvyrti/jubereq), biosimilar, 1 mg
Q5167	Q5167	Injection, denosumab-qbde (enoby/xtrenbo), biosimilar, 1 mg
Q5168	Q5168	Injection, ranibizumab-leyk (nufymco), biosimilar, 0.1 mg
Q5169	Q5169	Injection, pegfilgrastim-unne (armlupeg), biosimilar, 0.5 mg
Q5170	Q5170	Injection, aflibercept-boav (eydenzelt), biosimilar, 1 mg
Q5171	Q5171	Injection, denosumab-mobz (boncresa), biosimilar, 1 mg
1026T	1026T	Transvaginal laser photobiomodulation therapy of pelvis, provided by a physician or other qualified health care professional
1027T	1027T	Percutaneous insertion or replacement of neurostimulation catheter via left subclavian or left jugular vein into the superior vena cava, with verification of capture of phrenic nerves, mapping and programming, and delivery of transvenous phrenic neurostimulation therapy in ventilated patients, with repositioning when performed, including imaging guidance
1028T	1028T	Mapping and programming of neurostimulation catheter with delivery of transvenous phrenic neurostimulation therapy in ventilated patients, with repositioning and verification of left phrenic nerve capture, per session
1029T	1029T	Mapping and programming of neurostimulation catheter with delivery of transvenous phrenic neurostimulation therapy in ventilated patients, without catheter repositioning, per session

CY 2026 HCPCS Code	CY 2027 HCPCS Code	CY 2027 Long Descriptor
1030T	1030T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]), cumulative time for up to 30 days; initial 30 minutes
1031T	1031T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]), cumulative time for up to 30 days; each additional 30 minutes (List separately in addition to code for primary procedure)
1032T	1032T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]) and digital simulation, cumulative time for up to 30 days; initial 60 minutes
1033T	1033T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]), cumulative time for up to 30 days; each additional 30 minutes (List separately in addition to code for primary procedure)
1034T	1034T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]) digital simulation, and computational analyses (eg, computational fluid dynamics, finite element analysis), cumulative time for up to 30 days; initial 90 minutes
1035T	1035T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]), digital simulation, and computational analyses (eg, computational fluid dynamics, finite element analysis), cumulative time for up to 30 days; each additional 30 minutes (List separately in addition to code for primary procedure)
1036T	1036T	Noninvasive hemodynamic assessment with pulmonary pressures and ejection fraction when performed, including passive acquisition of acoustic and electrical signals, augmentative algorithmic analysis, and generation of a clinical report with review, interpretation, and clinical integration by a physician or other qualified health care professional
1037T	1037T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant pancreatic tissue, including imaging guidance
1038T	1038T	Autologous muscle cell therapy, injection(s) of muscle progenitor cells into the tongue, including esophagoscopy, when performed
1039T	1039T	Connectomic analysis of previously performed multi-modal brain magnetic resonance imaging (MRI) requiring physician or other qualified health care professional (QHP) analysis of software- and physician-generated structural and functional maps for integration of cortical grey matter correlation based on resting state functional MRI and mapping of white matter connectivity based on diffusion weighted MRI relative to brain regions, with physician or other QHP interpretation and report
1040T	1040T	Bronchoscopy, flexible, with bronchial cryotherapy, 1 lung, including trachea, when performed
1041T	1041T	Augmentative algorithmic analysis of encephalographic waveforms to identify the source and propagation of epileptiform activity, including artifact reduction with analysis of 3D localization of spike sources throughout the examination, 3D animations over time of high-amplitude event locations, high-frequency activity locations, and temporal relationships among locations, with interpretation and report by physician or other qualified health care professional, related to a previously performed electroencephalogram (EEG)
1042T	1042T	Implantation of absorbable urologic scaffold for prosthetic urethra restoration of reconstructed bladder neck and urethral anastomosis (List separately in addition to code for primary procedure)
1043T	1043T	Quantitative magnetic resonance, without imaging, for analysis of liver tissue, including assessment of 1 or more parameters (eg, proton density fat fraction [PDFF], water diffusion, T1-water relaxation time), with automatically generated report.
1044T	1044T	Harvest of full-thickness skin for autologous heterogeneous skin-construct graft, including direct closure of donor site; first 5 sq cm or less
1045T	1045T	Harvest of full-thickness skin for autologous heterogeneous skin-construct graft, including direct closure of donor site; each additional 5 sq cm, or part thereof (List separately in addition to code for primary procedure)

CY 2026 HCPCS Code	CY 2027 HCPCS Code	CY 2027 Long Descriptor
1046T	1046T	Autologous heterogeneous skin-construct graft application, trunk, arms, legs; first 50 sq cm or less, or 0.5% of body area of infants and children
1047T	1047T	Autologous heterogeneous skin-construct graft application, trunk, arms, legs; each additional 50 sq cm, or each additional 0.5% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
1048T	1048T	Autologous heterogeneous skin-construct graft application, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 50 sq cm or less, or 0.5% of body area of infants and children
1049T	1049T	Autologous heterogeneous skin-construct graft application, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 50 sq cm, or each additional 0.5% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
1050T	1050T	Insertion, subcutaneous heart failure decompensation monitor, containing sensors that measure, at a minimum, heart rate, impedance, respiration rate, physical activity, heart sounds
1051T	1051T	Removal of subcutaneous heart failure decompensation monitor
1052T	1052T	Interrogation device evaluation(s), (in person or remote) up to 30 days, insertable subcutaneous heart failure decompensation monitor, analysis of physiologic parameters, including, at a minimum, heart rate, impedance, respiration rate, physical activity, heart sounds, with generation of a report, review and interpretation by a physician or other qualified health care professional
1053T	1053T	Programming device evaluation (in person or remote) of subcutaneous heart failure decompensation monitor, with analysis of physiologic parameters, including, at a minimum, heart rate, impedance, respiration rate, physical activity, heart sounds, with generation of a report and review and interpretation by a physician or other qualified health care professional
0631U	0631U	Oncology (solid tumor), DNA, sequence analysis of 15 genes including BRCA1 and BRCA2 for identification of clonal hematopoiesis, blood, reported as tumor-derived or nontumor-derived
0632U	0632U	Red blood cell antigen (fetal RhD gene analysis), multiplex polymerase chain reaction (PCR) and next-generation sequencing (NGS) of circulating cell-free DNA (cfDNA), plasma from pregnant individuals known to be RhD negative, reported as detected or not detected
0633U	0633U	Obstetrics (single-gene noninvasive prenatal test), cell-free DNA (cfDNA), next-generation sequencing (NGS) analysis of 1 or more targets (eg, CFTR, SMN1, HBB, HBA1, HBA2) to identify paternally inherited pathogenic variants and to determine fetal inheritance of maternal mutation, using maternal blood sample, algorithm reported as a fetal risk score
0634U	0634U	Oncology (breast cancer), cell-free DNA (cfDNA), evaluation of 11 ESR1 variants (E380Q, S463P, L536R, Y537C, Y537N, Y537S, D538G, V422del, L536H, L536P, Y537D) using droplet digital PCR (ddPCR), plasma, reported as positive or negative
0635U	0635U	Autoimmune (atopic dermatitis), mRNA, next-generation sequencing (NGS), gene expression profiling of 487 genes, noninvasive skin-surface scraping, algorithm reported as likelihood of response to therapy
0636U	0636U	Babesia (Babesiosis), antibody detection of 20 recombinant protein groups, by immunoassay, IgG
0637U	0637U	Babesia (Babesiosis), antibody detection of 20 recombinant protein groups, by immunoassay, IgM
0638U	0638U	Bartonella (Bartonellosis), antibody detection of 32 recombinant protein groups, by immunoassay, IgG
0639U	0639U	Bartonella (Bartonellosis), antibody detection of 32 recombinant protein groups, by immunoassay, IgM
0640U	0640U	Oncology (leptomeningeal metastases), tumor cell selection, identification, detection and enumeration based on differential CD318(CDCP1), SUSD2, CD340(erbB2/HER2), HGFR/cMET, FOLR1, EGFR, N cadherin, MUC1, EpCAM,

CY 2026 HCPCS Code	CY 2027 HCPCS Code	CY 2027 Long Descriptor
		and TROP2 antibody biomarkers, cerebrospinal fluid, reported as detection and quantification of tumor cells
0641U	0641U	Oncology (minimal residual disease [MRD]), tumor DNA, next-generation sequencing (NGS), using formalin-fixed paraffin-embedded (FFPE) tissue and blood samples, initial (baseline) assessment
0642U	0642U	Oncology (minimal residual disease [MRD]), tumor DNA, next-generation sequencing (NGS), whole blood, comparison to previously performed analyses, reported as trend in circulating tumor DNA (ctDNA) level
0643U	0643U	Oncology (genitourinary cancer), cell-free circulating tumor DNA (ctDNA), 200 genes, next-generation sequencing (NGS), interrogation for single-nucleotide variants (SNVs), insertions/deletions, gene rearrangements, copy number alterations, and tumor mutation burden, using urine, identify and report mutations with clinical actionability
0644U	0644U	Oncology (leukemia), minimal residual disease (MRD) detection for rearrangements, blood or bone marrow, personalized assay design and baseline quantification
0645U	0645U	Oncology (leukemia), minimal residual disease (MRD) detection for rearrangements, based on digital PCR, blood or bone marrow, reported as not detected or detected with estimated abundance
0646U	0646U	Oncology (molecular residual disease), whole genome sequence analysis, cell-free DNA, whole blood, and formalin-fixed paraffin-embedded (FFPE) tumor tissue DNA, baseline assessment
0647U	0647U	Oncology (molecular residual disease), whole genome sequence analysis, cell-free DNA (cfDNA), whole blood, assessment utilizing patient-specific tumor information, reported as negative or percent circulating tumor DNA (ctDNA)
0648U	0648U	Oncology (solid tumor), targeted genomic sequencing analysis, to detect deletions, insertions, and substitutions in 42 genes, copy number amplifications in 10 genes, and fusions and splice variants in 18 driver genes from DNA and RNA extracted from formalin-fixed paraffin-embedded (FFPE) tissue
0649U	0649U	Neurology (Alzheimer disease), DNA, targeted next-generation sequencing (NGS) of AD-1 and AD-2 target regions, whole blood, prognostic algorithmic analysis, reported as categorization of cognitive status
0650U	0650U	Drug metabolism (adverse drug reactions and drug response), genotyping of 9 genes (ie, CYP2D6, CYP2C19, G6PD, SLCO1B1, HLA-B*58:01, NAT2, CYP2C9, VKORC1, ABCG2), reported as metabolizer status and transporter function
0651U	0651U	Oncology (hereditary cancer), genomic DNA, 55 hereditary cancer pre-dispositioned genes, next-generation sequencing (NGS) and digital multiplex ligation-dependent probe amplification for variants, small indels (<40 base pairs), using saliva, whole blood or nail clipping, interpretive clinical report with variant classification
0652U	0652U	Drug metabolism (adverse drug reactions), DNA analysis of 13 genes by targeted genotyping, using saliva or buccal swab, reported as diplotype and metabolizer status
0653U	0653U	Nephrology (inherited kidney disorders), DNA, analysis of approximately 700 genes associated with inherited kidney diseases by exome sequencing, using whole blood, saliva, or nail clipping, reported as an interpretive clinical report classifying pathogenic and likely pathogenic variants
0654U	0654U	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by western blot analysis, using cultured skin fibroblasts, diagnostic qualitative result
0655U	0655U	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by spectrophotometric kinetic assay, using cultured skin fibroblasts, diagnostic quantitative result
0656U	0656U	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by radioactive activity assay, using cultured skin fibroblasts, diagnostic quantitative result
0657U	0657U	Rare diseases (constitutional/heritable disorders), rapid whole genome sequence analysis of comparator nuclear and mitochondrial DNA by next-generation

CY 2026 HCPCS Code	CY 2027 HCPCS Code	CY 2027 Long Descriptor
		sequencing (NGS), using blood or buccal sample, relevant variants reported with proband results
0658U	0658U	Rare diseases (constitutional/heritable disorders), rapid whole genome sequence analysis of nuclear and mitochondrial DNA by next-generation sequencing (NGS) for single-nucleotide variants (SNVs), insertions/deletions, copy number variants, uniparental disomy, and repeat expansions, using blood or buccal sample, identification and categorization of genetic variants
0659U	0659U	Rare diseases (constitutional/heritable disorders), ultrarapid whole genome sequence analysis of nuclear and mitochondrial DNA by next-generation sequencing (NGS) for single-nucleotide variants (SNVs), insertions/deletions, copy number variants, uniparental disomy, and repeat expansions, using blood or buccal sample, identification and categorization of genetic variants
90616	90616	Influenza virus vaccine, trivalent (tIRV), mRNA, 37.5 mcg/0.38 mL dosage, for intramuscular use
90639	90639	Influenza virus vaccine, quadrivalent (qIRV), mRNA; 50 mcg/0.5 mL dosage, for intramuscular use

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3. October 2026 HCPCS Codes Final Rule Comment Solicitation

For the October 2026 update, 144 codes were established and made effective October 1, 2026. Through the October 2026 OPPS quarterly update CR (Transmittal 13978, Change Request 14589, dated September 29, 2026), we recognized these new codes for separate payment and assigned them to appropriate interim OPPS status indicators and APCs. We note that because the AMA revised their release/effective date schedule for Category III CPT codes, there were a number of Category III codes that became effective October 1, 2026 instead of January 1, 2027 as proposed.

For CY 2027, consistent with our established policy, we proposed in the CY 2027 OPPS/ASC proposed rule (91 FR 41787) that the HCPCS codes that would be effective October 1, 2026, would be flagged with comment indicator ''N1'' in Addendum B to the CY 2027 OPPS/ASC final rule with comment period to indicate that we have assigned the codes to interim OPPS status indicators for CY 2027. Table 14 lists the codes that were effective October 1, 2026. We note that several of the temporary C-codes have been replaced with permanent J-codes effective January 1, 2027. We are inviting public comments in this final rule with comment period on the interim payment indicators, which will be finalized in the CY 2028 OPPS/ASC final rule with comment period. We note the proposed APC assignments and status indicators for these same codes will be subject to comment in the CY 2028 OPPS/ASC proposed rule with comment period and will be finalized in the CY 2028 OPPS/ASC final rule with comment period.

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TABLE 14: NEW HCPCS CODES EFFECTIVE OCTOBER 1, 2026

October 2026 HCPCS Code	CY 2027 HCPCS Code	CY 2027 Long Descriptor
87638	87638	Infectious agent detection by nucleic acid (DNA or RNA); rubeola (measles) virus
0660U	0660U	Human papillomavirus (HPV), genotypes 18, 31, 33, and 35, cell-free DNA (cfDNA), whole blood, multiplex digital droplet PCR (ddPCR), quantitative
0661U	0661U	Human papillomavirus (HPV), genotype 16, cell-free DNA (cfDNA), whole blood, digital droplet PCR (ddPCR), quantitative
0662U	0662U	Transplantation medicine (kidney allograft rejection), mRNA, gene-expression profiling by real-time quantitative PCR of 12 genes (11 content and 1 housekeeping), urine, algorithm reported as a rejection risk score
0663U	0663U	Obstetrics (fetal platelet antigen noninvasive prenatal test [NIPT]), cell-free DNA (cfDNA) sequence analysis for detection of fetal presence or absence of 1 human platelet antigen or more (HPA-1a, HPA-1b, HPA-3a, HPA-5b, and others) when performed, reported as maternal/fetal incompatibility detected or not detected per selected antigen
0664U	0664U	Transplantation medicine (kidney allograft failure), RNA expression transcriptome by next-generation sequencing (NGS), profiling of 13 genes, post-transplant peripheral blood, algorithm reported as a risk score for predicting progressive fibrosis in the kidney allograft
0665U	0665U	Hepatology (metabolic dysfunction-associated steatohepatitis [MASH]), enzyme-linked immunosorbent assay (ELISA) for YKL40 and quantitative reverse transcription polymerase chain reaction (RT-qPCR) for miR34a-5p, serum, algorithm reported as a single score for MASH activity and fibrosis
0666U	0666U	Infectious disease (wound infection), DNA, multiplex real-time PCR, wound swab, detection of 27 microbial targets and 28 antibiotic resistance targets, reported as semiquantitative for bacterial and fungal targets, and qualitative for viral- and antibiotic-resistance targets
0667U	0667U	Inborn error of metabolism (primary mitochondrial disease), determination of fibroblast growth factor 21 (FGF21) concentration by enzyme-linked immunosorbent assay (ELISA), serum or plasma, diagnostic quantitative result
0668U	0668U	Oncology (pancreas), DNA, genome sequence with 5hydroxymethylcytosine (5hmC) enrichment and glycan biomarker analysis, whole blood or plasma, algorithm reported as cancer detected or not detected
0669U	0669U	Infectious disease (Bartonella species, Borrelia species, and Babesia species), multiplex digital PCR for detection of DNA at the genus level for each species, blood, qualitative reporting of presence or absence of each pathogen at the genus level
0670U	0670U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis combination of short and long reads for single-nucleotide variants, insertions/deletions and characterized intronic variants, copy number variants, duplications/deletions, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, mitochondrial DNA sequence and deletions, short tandem repeat (STR) genes, methylation status of

October 2026 HCPCS Code	CY 2027 HCPCS Code	CY 2027 Long Descriptor
		selected regions, blood, saliva, amniocentesis, chorionic villus sample or tissue, identification and categorization of genetic variant, proband and comparator
0671U	0671U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis combination of short and long reads for single-nucleotide variants, insertions/deletions and characterized intronic variants, copy number variants, duplications/deletions, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, mitochondrial DNA sequence and deletions, short tandem repeat (STR) genes, methylation status of selected regions, blood, saliva, amniocentesis, chorionic villus sample or tissue, identification and categorization of genetic variant, proband and 2 comparators
0672U	0672U	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat (STR) gene expansions, and variants in nonuniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband and comparator
0673U	0673U	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat (STR) gene expansions, and variants in nonuniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband and 2 comparators
0674U	0674U	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, insertions/deletions, copy number variants, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, short tandem repeat (STR) gene expansions, blood, saliva, or genomic DNA, identification and categorization of genetic variants, proband and comparator
0675U	0675U	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, insertions/deletions, copy number variants, duplications/deletions, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, short tandem repeat (STR) gene expansions, blood, saliva, or genomic DNA, identification and categorization of genetic variants proband and 2 comparators
0676U	0676U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions and maternal cell contamination, fetal sample, identification and categorization of genetic variants, proband and maternal comparator
0677U	0677U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions and maternal cell contamination, fetal sample, identification and categorization of genetic variants, proband and 2 comparators
0678U	0678U	Oncology (hereditary cancer), genome sequence for 117 genes (single-nucleotide variants, deletions/insertions, and characterized intronic variants), copy number variants, duplications/deletions, mobile element insertions and inversions, blood, saliva, cultured skin fibroblasts (skin biopsy) or extracted genomic DNA, diagnostic, identification and categorization of genetic variants
0679U	0679U	Oncology (hereditary hematologic cancer), genomic DNA, whole genome sequence (single-nucleotide variants, deletions/insertions, and characterized intronic variants), copy number variants,

October 2026 HCPCS Code	CY 2027 HCPCS Code	CY 2027 Long Descriptor
		duplications/deletions, mobile element insertions and inversions, analysis of over 105 genes, genomic DNA isolated from blood, saliva, cultured skin fibroblasts (skin biopsy), identification and categorization of genetic variants
0680U	0680U	Tobacco use, DNA analysis of 1 methylation marker (cg05575921 [AHRR]), methylation-sensitive digital PCR, whole blood, algorithm reported as quantitative percentage methylation and estimated average cigarette use per day
0681U	0681U	Tobacco use, DNA analysis of 2 methylation markers (1 content: cg05575921 [AHRR] and 1 normalizing: cg08141395), methylation-sensitive digital PCR, saliva, algorithm reported as quantitative percent methylation and estimated average cigarette use per day
0682U	0682U	Oncology (lung cancer), DNA analysis of 1 methylation marker (cg05575921), methylation-sensitive digital PCR, whole blood, algorithm results reported as the 20-year-hazard ratio for lung cancer
0683U	0683U	Oncology (lung cancer), DNA analysis of 2 methylation markers (1 content: cg05575921 and 1 normalizing: cg08141395), methylation-sensitive digital PCR, saliva, algorithm results reported as the 20-year-hazard ratio for lung cancer
0684U	0684U	Alcohol use disorder, DNA analysis of 4 methylation markers (cg02583484, cg04987734, cg09935388, cg04583842), methylation-sensitive digital PCR, whole blood, algorithm reported as a summed T-score
0685U	0685U	Alcohol use disorder, DNA analysis of 5 methylation markers (4 content: cg02583484, cg04987734, cg09935388, cg04583842, and 1 normalizing: cg08141395), methylation-sensitive digital PCR, whole blood or saliva, algorithm reported as a summed T-score
0686U	0686U	Oncology (prostate), mRNA, next-generation sequencing (NGS) gene expression profiling of 22 genes, formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as risk score
0687U	0687U	Comparative analysis using short tandem repeat (STR) markers, patient and comparative specimen, DNA, buccal swab and tissue, reported match or mismatch
0688U	0688U	Oncology (colorectal cancer), analysis of minimal residual disease (MRD), next-generation sequencing (NGS), circulating tumor DNA (ctDNA) analysis in whole blood and tumor for baseline assessment to evaluate current MRD status and for comparisons to subsequent MRD assessments
0689U	0689U	Oncology (colorectal cancer), analysis of minimal residual disease (MRD) using patient-specific assays, reported as amount of circulating tumor DNA (ctDNA) detection and trend over time
0690U	0690U	Transplantation medicine (allograft rejection), quantification of donor-derived cell-free DNA (cfDNA) using digital PCR analysis of 45 single-nucleotide polymorphisms, plasma, reported as quantity of donor-derived cfDNA in plasma to determine the probability of allograft rejection
0691U	0691U	Carrier screening (cystic fibrosis, spinal muscular atrophy, beta hemoglobinopathies [including sickle cell disease], alpha thalassemia, and Duchenne muscular dystrophy), genomic sequence analysis panel, 6 genes (CFTR, SMN1, HBB, HBA1, HBA2, DMD) (Do not report 0691U in conjunction with 81443)
0692U	0692U	Cardiology (peripheral artery disease [PAD]), analysis of 3 proteins (midkine, angiopoietin-1, and kidney injury molecule-1 [KIM-1]), immunoassay, plasma, algorithm reported as a risk score for obstructive PAD
0693U	0693U	Oncology (head and neck), circulating tumor DNA (ctDNA), tumor-informed next-generation sequencing (NGS) analysis for 699 genes of patient-specific somatic variants identified from primary tumor tissue,

October 2026 HCPCS Code	CY 2027 HCPCS Code	CY 2027 Long Descriptor
		postoperative lymphatic exudate specimen, algorithm reported as presence or absence of ctDNA
0694U	0694U	Oncology (monoclonal gammopathy), immunoprecipitation and matrix-assisted laser desorption/ionization time-of-flight (MALDI-TOF) mass spectrometry, identification of intact monoclonal immunoglobulin isotypes (IgG, IgA, IgM, kappa, lambda), and M-protein concentrations in conjunction with turbidimetry, blood, semiquantitative
0695U	0695U	Oncology (central nervous system), low-pass whole genome sequence analysis of cerebrospinal fluid, interrogation for chromosome arm-level and focal losses and gains
0696U	0696U	Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffin-embedded (FFPE) tumor tissue, RNA analysis, 350 or more genes for RNA alterations (eg, gene rearrangements and splice isoforms)
0697U	0697U	Focused non-shock wave ultrasonic propulsion of residual stone fragment(s) post-lithotripsy, unilateral, including ultrasound guidance, fragment(s) less than or equal to 5 mm
0698U	0698U	Intraoperative radiofrequency ablation of lumpectomy cavity, unilateral, including applicator placement and removal (List separately in addition to code for primary procedure)
1054T	1054T	Focused non-shock wave ultrasonic propulsion of residual stone fragment(s) post-lithotripsy, unilateral, including ultrasound guidance, fragment(s) less than or equal to 5 mm
1055T	1055T	Intraoperative radiofrequency ablation of lumpectomy cavity, unilateral, including applicator placement and removal (List separately in addition to code for primary procedure)
1056T	1056T	Cochlear infusion of pharmacologic agent (ie, gene therapy vector), including mastoidectomy, labyrinthotomy, and repair of fenestrations
1057T	1057T	Insertion or replacement of subcutaneous neurostimulator pulse generators, with tunneling of 4 electrode arrays, bilateral supraorbital and occipital nerves, including all interrogation, programming, and imaging guidance, when performed
1058T	1058T	Revision of implanted subcutaneous unilateral supraorbital and occipital neurostimulator system, including all interrogation, programming, and imaging guidance, when performed
1059T	1059T	Removal of implanted subcutaneous unilateral supraorbital and occipital neurostimulator system
1060T	1060T	Electronic analysis of implanted subcutaneous supraorbital-occipital neurostimulator pulse generator (eg, frequency, amplitude, pulse width, leads, electrode configuration); with complex programming by physician or other qualified health care professional
1061T	1061T	Electronic analysis of implanted subcutaneous supraorbital-occipital neurostimulator pulse generator (eg, frequency, amplitude, pulse width, leads, electrode configuration); with simple programming by physician or other qualified health care professional
1062T	1062T	Artificial insemination, transcervical intratubal, unilateral or bilateral, including imaging guidance
1063T	1063T	Oncology (bladder), augmentative algorithmic analysis of histomorphologic features in digitized slides from formalin-fixed paraffin-embedded (FFPE) bladder cancer tissue (high-grade, non-muscle invasive), with clinicopathologic variables entered by the qualified health care professional; algorithm-derived parameters reported as prognostic of recurrence and progression, including hematoxylin and eosin staining of tissue sections, and digitization of glass microscope slides, when performed
1064T	1064T	Oncology (bladder), augmentative algorithmic analysis of histomorphologic features in digitized slides from formalin-fixed paraffin-embedded (FFPE) bladder cancer tissue (high-grade, non-muscle invasive), with clinicopathologic variables entered by the qualified health

October 2026 HCPCS Code	CY 2027 HCPCS Code	CY 2027 Long Descriptor
		care professional; algorithm-derived parameters reported as predictive of response to Bacillus Calmette-Guérin (BCG) therapy, including hematoxylin and eosin staining of tissue sections, and digitization of glass microscope slides, when performed
1065T	1065T	Cystourethroscopy, with CO2 cryotherapy spray, in a gaseous bladder environment with pressure monitoring, for treatment of; minor bladder lesion(s) (total lesion[s] diameters less than 0.5 cm)
1066T	1066T	Cystourethroscopy, with CO2 cryotherapy spray, in a gaseous bladder environment with pressure monitoring, for treatment of; small bladder lesion(s) (total lesion[s] diameters greater than or equal to 0.5 cm and less than 2.0 cm)
1067T	1067T	Cystourethroscopy, with CO2 cryotherapy spray, in a gaseous bladder environment with pressure monitoring, for treatment of; medium bladder lesion(s) (total lesion[s] diameters greater than or equal to 2.0 cm and less than 5.0 cm)
1068T	1068T	Cystourethroscopy, with CO2 cryotherapy spray, in a gaseous bladder environment with pressure monitoring, for treatment of; large bladder lesion(s) (total lesion[s] diameters greater than or equal to 5.0 cm)
1069T	1069T	Mechanical extremity (ie, hands and feet) cryocompression; individual glove and boot supplies with initial measurement, fitting, and therapy education
1070T	1070T	Mechanical extremity (ie, hands and feet) cryocompression; individual glove and boot placement, initiation of cooling pre-chemotherapy and continuing through chemotherapy administration
1071T	1071T	Mechanical extremity (ie, hands and feet) cryocompression; post-chemotherapy treatment continuation, each 30 minutes (List separately in addition to code for primary procedure)
1072T	1072T	Liver allograft, normothermic machine perfusion; each additional hour of monitoring and management (List separately in addition to code for primary procedure)
1073T	1073T	Liver allograft, normothermic machine perfusion; decannulation
1074T	1074T	Liver allograft, hypothermic oxygenated perfusion; cannulation
1075T	1075T	Liver allograft, hypothermic oxygenated perfusion; connection to perfusion device
1076T	1076T	Liver allograft, hypothermic oxygenated perfusion; monitoring and management, first 2 hours
1077T	1077T	Liver allograft, hypothermic oxygenated perfusion; each additional hour of monitoring and management (List separately in addition to code for primary procedure)
1078T	1078T	Liver allograft, hypothermic oxygenated perfusion; decannulation
1079T	1079T	3D quantitative transmission water bath volumetric ultrasound tomography, breast, with augmentative algorithmic derivation of breast tissue composition (ie, fibroglandular volume), bilateral, with physician or other qualified health care professional interpretation and report
1080T	1080T	Insertion, intracapsular magnifier, with attachment to previously placed intraocular lens
1081T	1081T	Microvascular anastomosis between a lymph node and a vein, including robot assistance, when performed; initial anastomosis
1082T	1082T	Microvascular anastomosis between a lymph node and a vein, including robot assistance, when performed; each additional anastomosis (List separately in addition to code for primary procedure)
1083T	1083T	Stereotactic placement of infusion catheter(s), brain, for delivery of therapeutic agent(s), including computerized stereotactic planning and burr hole(s)
1084T	1084T	Implantation of scaffolding allograft to reinforce the suprachoroidal space
1085T	1085T	Assistive algorithmic analysis for identification of new lesions and determination of inter-lesion heterogeneity of change in metabolic activity

October 2026 HCPCS Code	CY 2027 HCPCS Code	CY 2027 Long Descriptor
		and volume for advanced metastatic cancer, data sets from 2 or more previously acquired positron emission tomography (PET) and/or PET computed tomography (CT) (PET/CT) studies
1086T	1086T	Intraprocedural estimate of coronary fractional flow derived by augmentative algorithmic analysis of data from real-time coronary angiography, with creation of functional map of coronary circulation, when performed, with review and interpretation (List separately in addition to code for primary procedure)
1087T	1087T	Estimate of coronary fractional flow derived by augmentative algorithmic analysis of data from previously acquired coronary angiogram, with creation of functional map of coronary circulation, when performed, with automated result
1088T	1088T	Percutaneous application of high-frequency neuromodulation signals using microneedle electrode array for the treatment of nociceptive or neuropathic pain, including electrode placement and patient training, per day
1089T	1089T	Intraoperative quantitative micro-elastography tissue characterization, including real-time imaging and physician assessment, per breast
1090T	1090T	Attachment and insertion of intraocular lens prosthesis–mounted drug-eluting implant (List separately in addition to code for primary procedure)
C8010	1091T	Placement of permanent common carotid artery filter, percutaneous, bilateral, including ultrasound guidance, when performed
1092T	1092T	Implantation of acellular scaffold (eg, hyaluronan), knee, single implant; into chondral defect, open
1093T	1093T	Implantation of acellular scaffold (eg, hyaluronan), knee, single implant; into a chondral or osteochondral defect, arthroscopic
1094T	1094T	Implantation of acellular scaffold (eg, hyaluronan), knee, single implant; each additional acellular scaffold implantation (List separately in addition to code for primary procedure)
1095T	1095T	Harvesting and processing of autologous bone marrow aspirate concentrate (BMAC), with application onto scaffold or injection into anatomical recipient site (eg, subchondral bone, joint space, chondral lesion), including imaging guidance, when performed, for therapeutic musculoskeletal treatment, excluding spinal procedures
1096T	1096T	Injection(s) of thermoregulated multiphase suspension to demyelinate nerves innervating the knee joint, including imaging guidance, when performed
1097T	1097T	Oncology (pancreas), augmentative algorithmic analysis of histomorphologic features in digitized slides from formalin-fixed paraffin-embedded pancreatic cancer tissue, algorithm-derived parameters reported as prediction of response to fluorouracil backbone versus gemcitabine backbone chemotherapy, including hematoxylin and eosin staining of tissue sections and digitization of glass microscope slides, when performed
1098T	1098T	Placement of subretinal prosthesis, including vitrectomy
1099T	1099T	Ablation of incompetent vein(s), extremity, transcutaneous, high intensity–focused ultrasound (HIFU), inclusive of all imaging guidance and monitoring
1100T	1100T	Transcutaneous spinal neuromodulation programming, including history and physical examination, safety screening, selection and external placement of a multichannel spinal electrode pad, baseline spinal motor mapping, creation of individualized stimulation parameter sets for therapeutic activities, and patient and/or caregiver instruction, each 30 minutes
1101T	1101T	Transcutaneous spinal neuromodulation application in combination with therapeutic activities, direct (one-on-one) patient contact using dynamic activities to improve functional performance, including individualized external placement of a multichannel spinal electrode pad, optimization of

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		stimulation parameters across multiple channels, and delivery of transcutaneous spinal neuromodulation during functional task performance, each 15 minutes
1102T	1102T	Intraoperative molecular assessment for lung tumor tissue, in-vivo (including assessment, when performed following lung resection), using computer-aided fluorescence imaging (List separately in addition to code for primary procedure)
1103T	1103T	Intraoperative molecular assessment for ovarian, tubal, or peritoneal tumor tissue, in-vivo (including assessment, when performed following ovarian, tubal, or peritoneal resection), using computer-aided fluorescence imaging (List separately in addition to code for primary procedure)
1104T	1104T	Noninvasive cardiopulmonary assessment, including quantitative parameters, respectively predictive of significant epicardial coronary artery disease, pulmonary hypertension, and/or elevated pulmonary capillary wedge pressure, derived by augmentative algorithmic analysis of orthogonal voltage gradient and photoplethysmography signals, with automated report
1105T	1105T	Personalized neurostimulation pulse rate derived by augmentative algorithmic analysis of data from electroencephalogram (EEG) and electrocardiogram (ECG), including acquisition of EEG and single-lead ECG, with automated report
1106T	1106T	Oncology (breast), augmentative algorithmic analysis of histomorphologic features in digitized hematoxylin and eosin stained slides from formalin-fixed paraffin-embedded (FFPE) breast cancer tissue, algorithm-derived parameters reported as 5-year and 10-year risks of distant metastasis, including digitization of glass microscope slides and hematoxylin and eosin staining of tissue sections, when performed
1107T	1107T	Oncology (prostate), augmentative algorithmic analysis of histomorphologic features in digitized hematoxylin and eosin stained slide(s) from formalin-fixed paraffin-embedded (FFPE) prostate cancer tissue, algorithm-derived parameters reported as 10-year risk of distant metastasis and prostate cancer specific mortality, including hematoxylin and eosin staining of tissue sections and digitization of glass microscope slides, when performed
1108T	1108T	Stereotactic intracerebral implantation of therapeutic agent, unilateral, including cranial access and intraoperative imaging guidance, when performed; 1 or more injections along a single trajectory
1109T	1109T	Stereotactic intracerebral implantation of therapeutic agent, unilateral, including cranial access and intraoperative imaging guidance, when performed; 1 or more injections along multiple trajectories
1110T	1110T	Stereotactic intracerebral delivery of therapeutic agent, by controlled infusion, unilateral, including cranial access and intraoperative imaging guidance, when performed; single trajectory
1111T	1111T	Stereotactic intracerebral delivery of therapeutic agent, by controlled infusion, unilateral, including cranial access and intraoperative imaging guidance, when performed; multiple trajectories
A2046	A2046	Dermisphere hdrt, per square centimeter (add-on, list separately in addition to primary procedure)
A2047	A2047	Lacertamatrix, per square centimeter (add-on, list separately in addition to primary procedure)
A2048	A2048	Puraply mz, per milligram
A2049	A2049	Theracor, per square centimeter (add-on, list separately in addition to primary procedure)
A2050	A2050	Fibrillar collagen wound dressing, per milligram
A4228	A4228	Supplies for maintenance of non-insulin, device-drug combination infusion catheter, per week

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A6614	A6614	Supplies and accessories for use with an external ocular negative pressure pump, any type, per month
A9613	A9613	Piflufolastat f 18 (pylarify truvu), diagnostic, 1 millicurie
C9311	C9311	Injection, eplontersen, 1 mg (code may be used for medicare when drug administered under the direct supervision of a physician, not for use when drug is self administered)
C9312	C9312	Injection, trabectedin (apotex), not therapeutically equivalent to J9352, 0.01 mg
C9313	C9313	Injection, pivekimab sunirine-pvzy, 0.01 mg
E0788	E0788	Ambulatory infusion pump, specific device-drug combination, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient
E2403	E2403	External ocular negative pressure pump, electric
G0577	G0577	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 performed in the non-facility setting
G0685	G0685	Algorithm-based assessment of likelihood of autism spectrum disorder (asd), derived from validated analysis of eye-gaze data or other technology
J0014	J0014	Cocaine hydrochloride nasal solution (goprelto), 1 mg
J0643	J0643	Injection, leucovorin calcium, not otherwise specified, 1 mg
C9310	J0644	Injection, leucovorin calcium (avyxa), 1 mg
J0871	J0871	Injection, daptomycin (endo), not therapeutically equivalent to j0878, 1 mg
J1757	J1757	Injection, tividenofusp alfa-eknm, 1 mg
J1818	J1818	Injection, pegzilarginase-nbln, 0.05 mg
J1946	J1946	Injection, furosemide (lasix onyu), 1 mg
J1947	J1947	Injection, furosemide (furoscix), 1 mg
J1957	J1957	Injection, levetiracetam, 5 mg
J1958	J1958	Injection, levetiracetam in sodium chloride, 5 mg
C9462	J3268	Injection, delafloxacin, 1 mg
J3406	J3406	Injection, omidubicel-onlv, per therapeutic dose
J7524	J7524	Mycophenolate mofetil, oral, 5 mg
J7526	J7526	Injection, mycophenolate mofetil, 5 mg
J7529	J7529	Mycophenolate mofetil, for suspension, oral, 5 mg
J7530	J7530	Mycophenolate mofetil (myhibbin), oral suspension, 5 mg
J7531	J7531	Prednisolone sodium phosphate, orally disintegrating tablet, 1 mg
J9066	J9066	Injection, bendamustine hydrochloride (avyxa), 1 mg
J9186	J9186	Injection, etoposide (avyxa), 1 mg
J9187	J9187	Injection, etoposide, 1 mg
J9191	J9191	Injection, fluorouracil (avyxa), 10 mg
J9192	J9192	Injection, fluorouracil, 10 mg
J9362	J9362	Injection, trabectedin, 0.01 mg
L1330	L1330	Thoracic orthosis, sternal and/or sternocostal compression, may include anterior and/or posterior pads, panels, with or without frame, prefabricated, includes fitting and adjustment
L1972	L1972	Ankle foot orthosis, plastic or other material with ankle joint, with or without dorsiflexion assist, prefabricated, off-the shelf
L8697	L8697	External accessory for use with implantable phrenic nerve stimulation device, replacement, each

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Q4207	Q4207	Carbon life, per square centimeter (add-on, list separately in addition to primary procedure)
Q4223	Q4223	Dermabind sl optic, per square centimeter (add-on, list separately in addition to primary procedure)
Q4243	Q4243	Amchomatrix, per square centimeter (add-on, list separately in addition to primary procedure)
Q5172	Q5172	Injection, filgrastim-laha (filkri), biosimilar, 1 microgram
Q5173	Q5173	Injection, denosumab-adet (ponlimsi), biosimilar, 1 mg

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4. January 2027 HCPCS Codes

a. New Level II HCPCS Codes Final Rule Comment Solicitation

Consistent with past practice, we are soliciting comments on the new Level II HCPCS codes that will be effective January 1, 2027, in the CY 2027 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2028 OPPS/ASC final rule with comment period. Unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the proposed new C-codes and G-codes listed in Addendum O of the 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 2027, we proposed to include the new Level II HCPCS codes effective January 1, 2027, in Addendum B to the CY 2027 OPPS/ASC final rule with comment period, which would be included in the January 2027 OPPS quarterly update CR. Specifically, for CY 2027, we proposed to continue our established policy of assigning comment indicator ''N1'' in Addendum B to the OPPS/ASC final rule with comment period to the new HCPCS codes that will be effective January 1, 2027, to indicate that we are assigning them an interim status indicator, which is subject to public comment. We are inviting public comments in this final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2028 OPPS/ASC final rule with comment period. Similar to the codes effective October 1, 2026, the proposed APC assignments and status indicators for these new Level II HCPCS codes that will be effective January 1, 2027, will also be subject to comment in the CY 2028 OPPS/ASC proposed rule, and will be finalized in the CY 2028 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 with comment period, and to finalize the specific APC and status indicator assignments for those codes in the following year's rule.

For the CY 2027 OPPS update, we received the CPT codes that will be effective January 1, 2027, from the AMA in time to be included in the CY 2027 OPPS/ASC proposed rule. We note, however, that in early August, the AMA revised their release and effective dates for the Category III CPT codes to a tri-annual schedule.[14] The Category III codes that were initially slated to be effective January 1, 2027, became effective October 1, 2027. The new, revised, and deleted CPT codes, including the new Category III codes that became effective October 1, can be found in Addendum B to the proposed rule (which is available via the internet on the CMS website). See *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1850-p.*

We note that the new and revised CPT codes are assigned to comment indicator ''NP'' in Addendum B to the proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed APC assignment, and that comments would be accepted on the proposed APC assignment and status indicator.

Further, we noted that the CPT code descriptors that appeared in Addendum B were short descriptors and did not accurately describe the complete procedure, service, or item described by the CPT code (91 FR 41787). Therefore, we included the 5-digit placeholder codes and the long descriptors for the new and revised CY 2027 OPPS/ASC proposed rule (which is available via

[14] See the American Medical Association's website for the updated release and effective dates. *https://www.ama-assn.org/system/files/category-3-early-release.pdf.*

the internet on the CMS website) so that the public could adequately comment on the proposed APCs and SI assignments. The 5-digit placeholder codes were included in Addendum O to the ''CY 2027 OPPS/ASC Proposed Rule 5-Digit AMA/CMS Placeholder Code.'' We noted that the final CPT code numbers would be included in this CY 2027 OPPS/ASC final rule with comment period. We also noted that not every code listed in Addendum O is subject to public comment. For the new and revised Category I and III CPT codes, we requested public comments on only those codes that are assigned comment indicator ''NP''. Finally, we would like to note that the CY 2027 OPPS/ASC proposed rule Addendum O contained two errors. First, we inadvertently included placeholder code 'C75X6', which should not have been included. Second, the long descriptor for C75X5 should have read, ''*Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation, with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, with 3d echocardiographic imaging and postprocessing during transesophageal echocardiography, or during transthoracic echocardiography for congenital cardiac anomalies, for the assessment of cardiac structure(s) (e.g., cardiac chambers and valves, left atrial appendage, interatrial septum, interventricular septum) and function, when performed*''. These errors have been corrected in the CY 2027 OPPS/ASC final rule Addendum O.

In summary, in the CY 2027 OPPS/ASC proposed rule, we solicited public comments on the proposed CY 2027 status indicators and APC assignments for the new and revised CPT codes that would be effective January 1, 2027. The CPT codes listed in Addendum B to the CY 2027 OPPS/ASC proposed rule appear with short descriptors only. We listed them again, with long descriptors, in Addendum O to the CY 2027 OPPS/ASC proposed rule. We also proposed to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2027 OPPS/ASC final rule with comment period. The proposed status indicator and APC assignments for these codes were included in Addendum B to the CY 2027 OPPS/ASC proposed rule (which is available via the internet on the CMS website). We received comments on several of the new CPT codes that were assigned to comment indicator ''NP'' in Addendum B to the CY 2027 OPPS/ASC proposed rule. We have responded to those public comments in sections III.C., III.E., and IV. of this final rule with comment period.

The final SIs, APC assignments, and payment rates for the new CPT codes that are effective January 1, 2027, can be found in Addendum B to this final rule with comment period. In addition, the SI definitions can be found Addendum D1 to this final rule with comment period. Addenda B and D1 are available via the internet on the CMS website.

Finally, Table 15, which is a reprint of Table 11 from the CY 2027 OPPS/ASC proposed rule (91 FR 41788), shows the comment timeframe for new and revised HCPCS codes. The table provides information on our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these codes under the OPPS.

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TABLE 15: 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 2026	HCPCS (CPT and Level II Codes)	April 1, 2026	CY 2027 OPPS/ASC proposed rule	CY 2027 OPPS/ASC final rule with comment period
July 2026	HCPCS (CPT and Level II Codes)	July 1, 2026	CY 2027 OPPS/ASC proposed rule	CY 2027 OPPS/ASC final rule with comment period
October 2026	HCPCS (CPT and Level II Codes)	October 1, 2026	CY 2027 OPPS/ASC final rule with comment period	CY 2028 OPPS/ASC final rule with comment period
January 2027	CPT codes	January 1, 2027	CY 2027 OPPS/ASC proposed rule	CY 2027 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2027	CY 2027 OPPS/ASC final rule with comment period	CY 2028 OPPS/ASC final rule with comment period

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B. OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. 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 final rule with comment period.

Under the OPPS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For CY 2027, we proposed that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services) (91 FR 41788). 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 section 1833(t)(2) of the Act 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 2027 OPPS update will be discussed in the relevant specific sections throughout the CY 2027 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 median cost (or mean cost if so elected) for an item or service within the same group (referred to as the ''2 times rule'').

The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as for low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that both have more than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 or fewer claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and that comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost (75 FR 71832). In the CY 2027 OPPS/ASC proposed rule, we proposed to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as for certain low-volume items and services (91 FR 41789).

For the CY 2027 OPPS update, we identified the APCs with violations of the 2 times rule, and we proposed changes to the procedure codes assigned to these APCs (with the exception of those APCs for which we have proposed a 2 times rule exception) in Addendum B to CY 2027 OPPS/ASC proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of the proposed rule. Rather, it was published and made available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

To eliminate a violation of the 2 times rule and improve clinical and resource homogeneity in the APCs for which we have not proposed a 2 times rule exception, we proposed to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed procedure code reassignments and associated APC reconfigurations for CY 2027 included in the CY 2027 OPPS/ASC proposed rule are related to changes in costs of services that were observed in the CY 2025 claims data available for CY 2027 ratesetting. Addendum B to the CY 2027 OPPS/ASC proposed rule identifies with a comment indicator ''CH'' those procedure codes for which we proposed a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2026, OPPS Addendum B Update, which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/quarterly-addenda-updates.*

3. APC Exceptions to the 2 Times Rule

While considering the APC changes that we proposed for CY 2027, 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 2025 claims data available for the CY 2027 OPPS/ASC proposed rule, we found 27 APCs with violations of the 2 times rule. We applied the criteria as described previously in this section to identify the APCs for which we proposed to make exceptions under the 2 times rule for CY 2027 and found that all of the 27 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2025 claims data available for the CY 2027 OPPS/ASC proposed rule. We note that, on an annual basis, based on our analysis of the latest claims data, we identify violations to the 2 times rule and propose changes when appropriate. Those APCs that violate the 2 times rule are identified and appear in Table 16. 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 12 of the CY 2027 OPPS/ASC proposed rule (90 FR41790) listed the APCs for which we proposed to make an exception under the 2 times rule for CY 2027 based on the criteria cited previously and claims data submitted between January 1, 2025, and December 31, 2025, and CCRs, if available. The proposed geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of the CY 2027 OPPS/ASC proposed rule can be found via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1850-p.*

Based on the updated final rule CY 2025 claims data used for this final rule with comment period, we found a total of 28 APCs with violations of the 2 times rule. Of these 28 total APCs, 24 were identified in the proposed rule and four are newly identified in this final rule with comment period. The following APCs appeared in Table 12 of the CY 2027 OPPS/ASC proposed rule (91 FR41790) as violating the 2 times rule. However, after conducting data analysis for this final rule with comment period, we found that the following APCs no longer violate the 2 times rule:

- APC 5613 (Level 3 Therapeutic Radiation Treatment Preparation).
- APC 5674 (Level 4 Pathology).
- APC 5735 (Level 5 Minor Procedures).

In addition, the following four APCs are newly identified with 2 times rule violations using updated data for this final rule with comment period:

- APC 5024 (Level 4 Type A ED Visits).
- APC 5051 (Level1 Skin Procedures).
- APC 5622 (Level 2 Radiation Therapy).
- APC 5672 (Level 2 Pathology).

We received comments on the APCs located in Table 12 of the CY 2027 OPPS/ASC proposed rule (91 FR 41790), along with comments on APC assignments for specific HCPCS codes. These comments and our responses can be found in section III.E. of this final rule with comment period. Based on our analysis of the CY 2025 costs from hospital claims and cost report data available for this final rule with comment period, we are finalizing our proposals with some modifications. Specifically, we are finalizing our proposal to except the 24 proposed APCs that continue to have 2 times violations in this final rule with comment period data from the 2 times rule for CY 2025 claims data and also except four additional APCs that did not violate the 2 times rule in the CY 2027 OPPS/ASC proposed rule data, but do violate the 2 times rule in this final rule with comment period data, for a total of 28 APCs for which we identified 2 times rule violations but that qualify for exceptions.

In summary, Table 16 lists the 28 APCs that we are excepting from the 2 times rule for CY 2027 based on the criteria described earlier and a review of updated claims data for dates of service between January 1, 2025, and December 31, 2025, that were processed on or before June 30, 2026, and updated CCRs, if available. We note that, for cases in which a recommendation by the HOP Panel appears to result in or allow a violation of the 2 times rule, we frequently accept the HOP Panel's recommendation because those recommendations are based on explicit consideration of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates. The geometric mean costs for hospital outpatient services for these and all other APCs that were used in the development of this final rule with comment period can be found via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-paymentsystems/hospitaloutpatient/regulations-notices.*

TABLE 16: FINAL CY 2027 APC EXCEPTIONS TO THE 2 TIMES RULE

APC	APC Group Title
5012	Clinic Visits and Related Services
5024	Level 4 Type A ED Visits
5051	Level 1 Skin Procedure
5054	Level 4 Skin Procedures
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5301	Level 1 Upper GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5572	Level 2 Imaging with Contrast
5573	Level 3 Imaging with Contrast
5611	Level 1 Therapeutic Radiation Treatment Preparation
5612	Level 2 Therapeutic Radiation Treatment Preparation
5622	Level 2 Radiation Therapy
5671	Level 1 Pathology
5672	Level 2 Pathology
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5722	Level 2 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5741	Level 1 Electronic Analysis of Devices
5742	Level 2 Electronic Analysis of Devices
5791	Pulmonary Treatment
5821	Level 1 Health and Behavior Services
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. New Technology APCs

1. Background

In the CY 2002 OPPS final rule (66 FR 59903), we finalized changes to the time period in which a service can be eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

We also adopted in the CY 2002 OPPS final rule the following criteria for assigning a complete or comprehensive service to a New Technology APC: (1) the service must be truly new, meaning it cannot be appropriately reported by an existing HCPCS code assigned to a clinical APC and does not appropriately fit within an existing clinical APC; (2) the service is not eligible for transitional pass-through payment (however, a truly new, comprehensive service could qualify for assignment to a new technology APC even if it involves a device or drug that could, on its own, qualify for 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 OPPS New Technology APC applications.[15]

In the CY 2004 OPPS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs: one set with a status indicator of ''S'' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of ''T'' (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

For CY 2026, 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

[15] Currently approved under OMB control number 0938–0860; expires October 31, 2027.

which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for APC 1507 (New Technology—Level 7 ($501–$600)) is made at $550.50.

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is intended to be budget neutral in comparison to what would have been paid under the previous reasonable-cost payment system, 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 continue to be adequate to ensure access to services. For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the technologies and their clinical utility. Quite often, parties request that Medicare make higher payments under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per-use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.

Some services assigned to New Technology APCs have 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 of new technologies, which ultimately limits our ability to assign the service to the appropriate clinical APC. To mitigate these issues, we finalized a policy in the CY 2019 OPPS/ASC final rule with comment period to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determine the costs for low-volume services assigned to New Technology APCs (83 FR 58892 through 58893). Specifically, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58893), we established that, in each of our annual rulemakings, we would calculate and present the result of each statistical methodology (arithmetic mean, geometric mean, and median) based on up to 4 years of claims data and solicit public comment on which methodology should be used to establish the payment rate for the low-volume new technology service. However, in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63529), we replaced the New Technology APC low volume policy with the universal low volume APC policy. Unlike the discontinued New Technology APC low volume policy, the universal low volume APC policy applies to clinical APCs and brachytherapy APCs, in addition to procedures assigned to New Technology APCs, and uses the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data to set the payment rate for the APC. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63529) for further discussion regarding this policy.

Despite the universal low volume APC policy, we continued to see payment instability for 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. For CY 2025, we finalized a policy 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 maintained the New Technology APC assignment for each service from the prior year, CY 2024. We refer readers to the CY 2025 OPPS/ASC final rule with comment period for a discussion on the policy (89 FR 94016 through 94018). Consistent with our overall policy regarding use of updated claims data in the final rule with comment period, we finalized our proposal to perform a similar analysis for the final rule with comment period using updated claims data, including determining whether specific HCPCS codes continue to meet the criteria for our universal low volume APC policy or would be subject to our proposed policy to continue exempting services with fewer than 10 claims in the 4-year lookback period from the universal low volume APC policy and maintain the New Technology APC assignment from the previous year (91 FR 41791).

In the CY 2026 OPPS/ASC final rule with comment period we finalized a continuation of the policy to exempt services assigned to New Technology APCs with fewer than 10 claims over the 4-year lookback period from the universal low volume policy moving forward. We finalized to continue this policy in future years, until, or unless, an alternative policy was finalized. We refer readers to the CY 2026 OPPS/ASC final rule with comment period for a discussion on the policy (90 FR 53530 through 53531).

In addition to the universal low volume policy and the policy to exempt services with fewer than 10 claims in the 4-year lookback period, it has been our policy to maintain the New Technology APC assignment for services with zero claims in the claims year used for rulemaking. For CY 2027, since we proposed CY 2027 OPPS payment rates based on CY 2025 claims data, if a service has no CY 2025 claims, we proposed to maintain the same New Technology APC assignment for CY 2027 (91 FR 41791). We continue to believe this approach is appropriate because, in the absence of new claims data, there is no additional information upon which to base a reassignment. This policy ensures consistency and stability in payment until sufficient claims data become available to support a reassignment to a different New Technology APC or appropriate clinical APC.

Finally, we note that, in a budget-neutral system, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high-cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital

outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice.

For CY 2027, the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 are provided in Addendum A to the proposed rule (which is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.*

2. Services in New Technology APCs With Zero Claims for the Rulemaking Period or Under 10 Claims in the 4-year Lookback Period

For CY 2027, there are several services that have either zero claims for CY 2027 rulemaking (based on CY 2025 claims) or fewer than 10 claims in the previous 4-year lookback period. For CY 2027, we proposed to maintain the New Technology APC assignments for services listed in Table 17.

TABLE 17: SERVICES WITH FEWER THAN 10 CLAIMS IN THE LOOKBACK PERIOD OR ZERO CLAIMS FOR CY 2027 RATESETTING

Name of Service	HCPCS Code	# of Single Frequency Claims Over Previous 4-years	Final CY 2026 OPPS FR APC & SI Assignments	Proposed CY 2027 OPPS NPRM APC & SI Assignments	Final CY 2027 OPPS FR APC & SI Assignments
Blinded Procedure for NYHA Class III/IV Heart Failure	C9758	9 claims	1590, T	1590, T	1590, T
CardiAMP	C9782	3 claims	1590, T	1590, T	1590, T
Corvia Medical Interatrial Shunt	C9760	3 claims	1592, T	1592, T	1592, T
DARI Motion Procedure	0693T	0 claims	1505, S	1505, S	1505, S
Magnetic Resonance Imaging With Inhaled Hyperpolarized Xenon-129 Contrast Agent	C9791	6 claims	1551, T	1551, T	1551, T
Surfacer Inside-Out Access Catheter	C9780	7 claims	1534, S	1534, S	1534, S
Transcatheter Atrial Shunt System (TASS)	C9792	2 claims	1537, S	1537, S	1537, S

We did not receive public comments on these proposals. We are therefore finalizing our proposal without modification to continue to exempt services assigned to New Technology APCs with fewer than 10 claims over the 4-year lookback period from the universal low volume policy.

3. Procedures Assigned to New Technology APC Groups for CY 2027

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. Additionally, 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 2027, we proposed to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to an appropriate clinical APC (91 FR 41793). The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if we have obtained sufficient claims data. It also allows us to retain a service in a New Technology APC for more than 2 years if we have not obtained sufficient claims data upon which to base a reassignment decision (66 FR 59902).

a. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1563)

Effective January 1, 2021, CMS established HCPCS code C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) and assigned it to a New Technology APC based on the geometric mean cost of CPT code 67036 (Vitrectomy, mechanical, pars plana approach) due to

similar resource utilization. For CY 2021, HCPCS code C9770 was assigned to APC 1561 (New Technology—Level 24 ($3001–$3500)). This code may be used to describe the administration of HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes). This procedure was previously discussed in depth in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85939 through 85940). For CY 2022, we maintained the APC assignment of APC 1561 (New Technology—Level 24 ($3001–$3500)) for HCPCS code C9770 (86 FR 63531 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 (LUXTERNA®) 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.[16] 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 LUXTERNA® as, ''after completing a vitrectomy, identify the intended site of administration. The subretinal injection cannula can be introduced via pars plana''.

Interested parties, including the manufacturer of LUXTERNA®, recommended CPT code 67036 (Vitrectomy, mechanical, pars plana approach) for the administration of the gene therapy.[17] However, the manufacturer previously contended the administration was not accurately described by any existing codes as CPT code 67036 (Vitrectomy, mechanical, pars plana approach) does not account for the administration itself. CMS recognized the need to accurately describe the unique procedure that is required to administer the therapy described by HCPCS code J3398. Therefore, in the CY 2021 OPPS/ASC final rule with comment period, we established a new HCPCS code, C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) to describe this process (85 FR 85940). For CY 2021, we assigned HCPCS code C9770 to APC 1561 (New Technology—Level 24 ($3001–$3500)) using the geometric mean cost of CPT code 67036. For CY 2022, we continued to assign HCPCS code C9770 to APC 1561 (New Technology—Level 24 ($3001–$3500)) using the geometric mean cost of CPT code 67036 (86 FR 63532).

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 APC 1562 (New Technology—Level 25 ($3501–$4000)). Therefore, we finalized our proposal to assign HCPCS code C9770 to APC 1562 for CY 2023 (87 FR 71810).

For CY 2024, we proposed and finalized deletion of 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 ($4001–$4500)) (88 FR 81618). For 2025, claims data for CPT code 0810T was not yet available. Therefore, we continued to use claims data for HCPCS code C9770 to determine the appropriate APC for CPT code 0810T and finalized to continue to assign CPT code 0810T to APC 1563 for CY 2025 (89 FR 94018 and 94019).

CY 2026 was the first year that we had claims data available for CPT code 0810T, and there were 7 claims available. Since the procedure described by CPT code 0810T was billed using HCPCS code C9770 prior to January 1, 2024, we used the available combined 43 claims for both codes during this time period to allow for a more accurate picture of the costs associated with this procedure. For CY 2026, we designated CPT code 0810T as a low volume procedure under our universal low volume APC policy, given that there were only 43 combined claims available. Therefore, we used the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data from a 4-year lookback period to calculate an appropriate payment rate for purposes of assigning CPT code 0810T to a New Technology APC, which was the arithmetic mean cost of $4,327. This fell within the cost band for APC 1563 (New Technology—Level 26 ($4001–$4500)), and therefore, we continued to assign CPT code 0810T to APC 1563 for CY 2026 (90 FR 53532).

For the CY 2027 proposed rule, there were nine claims available for CPT code 0810T, with a geometric mean cost of $4,183. Since the procedure described by CPT code 0810T was billed using HCPCS code C9770 prior to January 1, 2024, we proposed to use the available combine claims for both codes during this time period to allow for a more accurate picture of the costs associated with this procedure. For CY 2027, we proposed to designate CPT code 0810T as a low volume procedure under our universal low volume APC policy, given that there were only 39 combined claims available. 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. Using all available claims for CPT code 0810T and HCPCS code C9770 from the 4-year lookback period, based on 39 claims, we determined the geometric mean cost to be approximately $4,239, the arithmetic mean cost to be $4,587, and the median cost to be $4,502. Because the arithmetic mean is the statistical methodology that estimated the highest cost for the service, we proposed to use this cost to determine the New Technology APC placement. The arithmetic mean of $4,587 falls within the cost band for APC 1564 (New Technology—Level 27 ($4501–$5000)). Therefore, we proposed to reassign CPT code 0810T to APC 1564 for CY 2027. Additionally, we

[16] *https://www.fda.gov/media/109906/download.*

[17] *https://mysparkgeneration.com/uploads/2022/09/LUXTURNA-Reimbursement-Guide-for-Treatment-Centers-ISI-Update-April-2022-P-RPE65-US-320025.pdf.*

proposed 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 2027 OPPS/ASC final rule with comment period and update the APC assignment as needed (91 FR 41793 through 41794).

We did not receive any public comments on our proposal to reassign HCPCS code 0810T to APC 1564 for CY 2027. Three additional claims for CY 2025 have been processed since the CY 2027 OPPS/ASC proposed rule. Our analysis of the updated claims data found that the greater of the geometric mean, arithmetic mean, or median cost calculated for HCPCS codes C9770 and 0810T is approximately $4,473. This falls into the cost band of New Technology APC 1563. Therefore, we are finalizing our proposal with modification to continue to assign CPT code 0810T to APC 1563 (New Technology—Level 26 ($4001–$4500)). Refer to Table 18 for the final OPPS New Technology APC and status indicator assignment for CPT codes 0810T for CY 2027. The final CY 2027 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 18: PROPOSED AND FINAL CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR CPT CODE 0810T

CPT Code	Long Descriptor	Proposed CY 2027 OPPS APC, SI	Final CY 2027 OPPS, SI APC
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies	1564, T	1563, T

b. BgRT (APC 1518 and 1523)

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 ($1901–$2000)) and HCPCS code C9795 to APC 1525 (New Technology—Level 25 ($3501–$4000)) for CY 2024.

For CY 2025, we continued to assign HCPCS code C9794 to APC 1521 (New Technology—Level 21 ($1901–$2000)) with a payment rate of $1,950.50 and HCPCS code C9795 to APC 1525 (New Technology—Level 25 ($3501–$4000)) with a payment rate of $3,750.50 because we did not have any claims data for the service.

Effective January 1, 2025, HCPCS codes C9794 and C9795 were replaced by HCPCS codes G0562 and G0563, respectively. For CY 2026, we utilized available claims data for HCPCS codes C9794 and C9795 to propose payment rates for HCPCS codes G0562 and G0563. Due to concerns given the extremely limited number of claims and the substantial decrease that would occur if the proposed rates were finalized, we did not finalize the proposed payment rate changes (90 FR 53533 and 53534). For CY 2026, we finalized the assignment of HCPCS code G0562 to APC 1521 and status indicator ''S'' and HCPCS code G0563 to APC 1524 (New Technology—Level 24 ($3001–$3500)) and status indicator ''S'' (90 FR 53534).

Since HCPCS code G0562 and G0563 were made effective January 1, 2025, and the proposed OPPS payment rates for CY 2027 are based on available CY 2025 claims data, this is the first time that we have available claims for HCPCS codes G0562 and G0563, specifically, for ratesetting. For CY 2027, we proposed to designate HCPCS codes G0562 and G0563 as low volume procedures under our universal low volume APC policy, given that there were 24 single frequency claims for G0562 and 47 claims for G0563 during the claims period (91 FR 41794). For HCPCS code G0562, we determined the arithmetic mean cost to be approximately $1,461, the median cost to be approximately $1,601, and the geometric mean cost to be approximately $1,398. Because the median cost is the statistical methodology that estimated the highest cost for the service, we proposed to use this cost to determine the New Technology APC placement. The median cost of $1,601 falls within the cost band for APC 1518 (New Technology—Level 18 ($1601–$1700)). Therefore, we proposed to assign HCPCS code G0562 to APC 1518 (New Technology—Level 18 ($1601–$1700) with a payment rate of $1,650.50 for CY 2027 (91 FR 41794). For HCPCS code G0563, we determined the arithmetic mean cost to be approximately $2,644, the median cost to be approximately $2,218, and the geometric mean cost to be approximately $2,467. The arithmetic mean cost is the statistical methodology that estimated the highest cost for the service; therefore, we proposed to use this cost to determine the New Technology APC placement. The arithmetic mean cost of $2,644 falls within the cost band for APC 1523 (New Technology—Level 23 ($2501–$3000)). Therefore, we proposed to assign HCPCS code G0563 to APC 1523 (New Technology—Level 23 ($2501–$3000) with a payment rate of $2750.50 for CY 2027 (91 FR 41795).

Additionally, we proposed to perform a similar analysis using updated claims data, including determining if HCPCS codes G0562 and G0563 continue to meet the criteria for our universal low volume APC policy, in the CY 2027

OPPS/ASC final rule with comment period and update the APC assignments as needed.

We did not receive public comments on our proposals for HCPCS codes G0562 or G0563, and therefore, we are finalizing as proposed.

We note that since the CY 2027 OPPS/ASC proposed rule published, we have additional claims for HCPCS codes G0562 and G0563 to use for ratesetting. For HCPCS code G0562, the revised statistical methodologies based on 29 single frequency claims are: the geometric mean cost is $1,221.60; the arithmetic mean cost is $1,321.64; and the median cost is $1,543.65. The highest of these is the median cost, which falls outside of the proposed APC assignment for HCPCS code G0562 of APC 1518 (New Technology—Level 18 ($1601–$1700). For HCPCS code G0563, the revised statistical methodologies based on 89 single frequency claims are: the geometric mean cost is $ 2,967.16; the arithmetic mean cost is $3,156.16; and the median cost is $3,231.70. The highest of these is the median cost, which falls outside of the proposed APC assignment for HCPCS code G0563 of APC 1523 (New Technology—Level 23 ($2501–$3000)). Therefore, for CY 2027, we are finalizing the assignment of HCPCS code G0562 to APC 1517 (New Technology—Level 17 ($1501–$1600)) and of HCPCS code G0563 to APC 1524 (New Technology—Level 24 ($3001–3500)). Refer to Table 19 for the proposed CY 2027 and final CY 2027 OPPS New Technology APC and status indicator assignment for HCPCS codes G0562 and G0563. The final CY 2027 payment rates can be found in Addendum B to this final rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this final rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 19: PROPOSED AND FINAL CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BIOLOGY GUIDED RADIATION THERAPY

HCPCS Code	Long Descriptor	Proposed CY 2027 OPPS APC, SI	Final CY 2027 OPPS APC, SI
G0562	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)	1518, S	1517, S
G0563	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	1523, S	1524, S

c. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APC 5594).

Effective January 1, 2020, we assigned three CPT codes (78431, 78432, and 78433) that describe the services associated with cardiac PET/CT studies to New Technology APCs. We have explained previously that 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. In the CY 2026 OPPS/ASC final rule we noted that, over the past several years, the claims volumes for CPT codes 78431 and 78433 have increased significantly while the geometric mean costs of the codes have remained relatively stable. We explained that, although we had seen stability in the claims data for CPT codes 78431 and 78433, CPT code 78432, which is closely related to CPT codes 78431 and 78433, continued to have low claims frequency and fluctuating geometric mean costs. We explained that, due to our concerns regarding CPT code 78432 and the lack of an appropriate clinical APC for CPT codes 78431 and 78433 at the time based on resource cost similarity, we finalized maintaining CPT codes 78431 through 78433 in New Technology APCs for CY 2026 (*90 FR 53536* and *53537*). We stated that while we believe that cardiac PET/CT services, such as those described by CPT codes 78431 through 78433, are clinically similar to services assigned to the Nuclear Medicine and Related Services APC series, such as CPT codes 78429 and 78430, we previously had concerns that the resource costs for the APC series did not align with the resource costs reflected in the claims data for CPT codes 78431 through 78433. As a result, we previously maintained CPT codes 78431 through 78433 in New Technology APCs.

For CY 2027, we proposed changes to APCs 5591 through 5594 (Nuclear Medicine and Related Services) that includes the shifting of the APC assignments for several codes in that APC series. We refer readers to section III.E. Proposed APC-Specific Policies of the CY 2027 OPPS/ASC proposed rule for a discussion of the proposal (91 FR 41808). As a result of these proposed changes, the proposed geometric mean costs of the Nuclear Medicine and Related Services APC series also shifted. For the proposed rule, we believed that the new geometric mean costs of the proposed Nuclear Medicine and Related Services APC series more closely align with the costs reflected in the claims data for CPT codes 78431 through 78433. Therefore, we proposed to assign CPT codes 78431 through 78433 to APC 5594 (Level 4 Nuclear Medicine and Related Services).

Comment: Commenters were supportive of our proposal to reassign CPT codes 78431 through 78433 to APC 5594 for CY 2027. Commenters believed the proposed APC assignments were clinically and resource appropriate.

Response: We appreciate the commenters' support.

In consideration of the comments received and because the geometric mean costs of CPT codes 78431 through 78433 more closely align with the

geometric mean costs of the restructured APCs 5591 through 5594, we are finalizing as proposed. Specifically, for CY 2027, we are finalizing assignment of CPT codes 78431 through 78433 from new technology APCs to clinical APC 5594. Refer to Table 20 for the final CY 2026 and final CY 2027 APC and status indicator assignments for CPT codes 78431 through 78433. The final CY 2027 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 20: PROPOSED AND FINAL CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CARDIAC PET CT STUDIES

HCPCS Code	Long Descriptor	Final CY 2026 OPPS APC, SI	Final CY 2027 OPPS APC, SI
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	1522, S	5594, S
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability)	1517, S	5594, S
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan	1522, S	5594, S

c. Instillation of Anti-Neoplastic Pharmacologic/Biologic Agent Into Renal Pelvis (APC 1548)

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 APC 1559 (New Technology—Level 22 ($2001–$2500)), with a payment rate of $2,250.50 based on our review of the clinical and resource characteristics of this service.

For CY 2025, the OPPS payment rates were based on available CY 2023 claims data. Because we created HCPCS code C9789 effective October 1, 2023, we had limited claims data from CY 2023 available for CY 2025 rulemaking. Specifically, we only had six claims available for ratesetting, so we maintained the New Technology APC assignment of APC 1559 (New Technology—Level 22 ($2001–$2500)) with a payment of $2,250.50 for CY 2025, based on our CY 2025 policy to maintain the New Technology APC assignment for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy (89 FR 94034).

For CY 2026, the OPPS payment rates were based on available CY 2024 claims data. HCPCS code C9789 had 222 single frequency claims in CY 2024, which exceeded the 100 claims threshold generally used for the universal low volume APC policy. The geometric mean cost for HCPCS code C9789 was approximately $1,211. Therefore, for CY 2026, we assigned HCPCS code C9789 to APC 1551 (New Technology—Level 14 ($1201–$1300)) with a payment rate of $1,250.50 (90 FR 53542 and 53543).

For CY 2027, the OPPS payment rates were proposed based on available CY 2025 claims data. HCPCS code C9789 had 235 single frequency claims for the CY 2025 proposed rule and the geometric mean cost for HCPCS code was $1,173. Therefore, for CY 2027, we proposed to assign HCPCS code C9789 to APC 1550 (New Technology—Level 13 ($1101–$1200)) with a payment rate of $1,150.50 (91 FR 41796).

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A commenter supported HCPCS code C7989 remaining in a New Technology APC but expressed concern with the continued reduction in payment for C9789. The commenter requested that CMS issue additional billing guidance to HOPD billing staff regarding the use of the New Technology APC procedure code with a separately payable drug or biological HCPCS code to ensure accurate and comprehensive reporting of C9789 procedure costs. A commenter also requested that CMS carefully assess claims data associated with HCPCS code C7989 to ensure appropriate assignment. Additionally, a commenter requested that CMS expand the C–APC policy to exclude CGTs from C–APC packaging to include drugs, following expiration of New Technology APC status for the procedure code.

Response: We thank the commenters for their input. In response to the request to carefully assess claims data

associated with HCPCS code C7989, we remind interested parties that we thoroughly review, on an annual basis, the APC assignments for all items and services paid under the OPPS, including HCPCS code C9789.

Additionally, as a reminder to our readers, CMS does not provide specific coding guidance, and requests to provide coding guidance are out of scope for the OPPS/ASC final rule with comment period. We refer our readers to 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 OPPS since hospitals' assignments 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 further note that if hospitals have questions about appropriate coding that they cannot resolve on their own, the initial first step would be to review the HCPCS code descriptors or consult the appropriate Medicare Administrative Contractor (MAC) for their jurisdiction. Additionally, while CMS does not provide billing advice to hospitals, we encourage manufacturers and distributors to provide outreach to hospitals regarding billing practices that are most appropriate for their individual technologies.

Regarding the commenter's C–APC expansion request, as we stated in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53542), we again note that HCPCS code J9281 is assigned to a status indicator of 'K' (Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals; Paid under OPPS; separate APC payment) and procedures and services assigned to a New Technology APC are excluded from the C–APC packaging policy. Therefore, providers may receive separate payment for both the drug and installation procedure when providing this service (90 FR 53542). We refer readers to Addendum J for a list of exclusions to the comprehensive APC packaging policy.

As part of our review and update process, we noted that additional claims for HCPCS code C9789 have been processed since the CY 2027 OPPS/ASC proposed rule. Based on updated claims data available for this final rule with comment period, the geometric mean cost for HCPCS code C9789 is $931 based on 316 single-frequency claims. We believe that 316 single-frequency claims are adequate for ratesetting for this service. Since HCPCS code C9789 has over 100 claims, the New Technology APC assignment is based on the geometric mean cost for that code. The geometric mean cost for the APC of $931falls within APC 1548 (New Technology—Level 11 ($900–$950) with a payment rate of $950.50.

In summary, after consideration of the public comments we received and the additional processed claims, we are finalizing, with modification, a New Technology APC assignment for HCPCS code C9789 to APC 1548 (New Technology—Level 11 ($900–$950) with a payment rate of $950.50.

We refer readers to Table 21 for the final CY 2027 OPPS New Technology APC and status indicator assignment for HCPCS code C9789.

The final CY 2027 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 21: PROPOSED AND FINAL CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR HCPCS CODE C9789

HCPCS Code	Long Descriptor	Proposed CY 2027 OPPS APC, SI	Final CY 2027 OPPS APC, SI
C9789	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed	1550, T	1548, T

d. LimFlow TADV Procedure, CPT Code 0620T (APC 1580)

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-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 from a clinical APC 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. For CY 2024, the procedure was assigned to APC 1578 (New Technology—Level 41 ($25,001–$30,000)) (88 FR 81694). For CY 2025 ratesetting, there were 11 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 applied our universal low volume APC policy and used 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 and the application of the universal low volume APC policy, we assigned HCPCS code 0620T to APC 1579 (New Technology—Level 42 ($30,001–$40,000)) with a payment rate of $35,000.50 based on the median cost of approximately $36,400 (89 FR 94034 through 94036).

For CY 2026, the OPPS payment rates were proposed to be based on available CY 2024 claims data. There were 19 single frequency claims for 0620T in the CY 2024 claims data. As this is below the threshold of 100 claims for a service within a year, we proposed 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 the service to the appropriate New Technology APC. Based on our review of the available claims and the application of the universal low volume APC policy, for CY 2026 we assigned HCPCS code 0620T to APC 1580 (New Technology—Level 43 ($40,001–$50,000)) with a payment rate of $45,000.50 based on the arithmetic mean cost of approximately $43,748 (90 FR 53543 and 53544).

For CY 2027, the OPPS payment rates were proposed based on available CY 2025 claims data. There were 28 single frequency claims for 0620T in the CY 2025 proposed rule claims data. As this is below the threshold of 100 claims for a service within a year, we proposed 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 the service to the appropriate New Technology APC. Based on our review of the available claims, we determined that the arithmetic mean is approximately $51,748; the median is approximately $46,455; and the geometric mean cost is approximately $47,513. Of these, the arithmetic mean was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology falls within the cost band for APC 1581 (New Technology—Level 44 ($50,001–$60,000)). Therefore, for CY 2027, we proposed to designate this service as a low volume service under our universal low volume APC policy and to assign HCPCS code 0620T to APC 1581 (New Technology—Level 44 ($50,001–$60,000)) with a payment rate of $55,000.50 (91 FR 41797).

Comment: Two commenters supported the proposal to assign CPT code 0620T to APC 1581 (New Technology—Level 44 ($50,001–$60,000)) with a payment rate of $55,000.50 for CY 2027 based on the application of the universal low volume APC policy.

Response: We thank the commenters for their input.

Three additional claims for CY 2025 have been processed since the CY 2027 OPPS/ASC proposed rule. Our analysis of the updated claims data found that the greater of the geometric mean, arithmetic mean, or median cost calculated for CPT code 0620T is approximately $45,838 based on the arithmetic mean. This value falls within APC 1580 (New Technology—Level 43 ($40,001–$50,000)) with a payment rate of $45,000.50. Therefore, for CY 2027, we are finalizing our proposal with modification to continue to assign CPT code 0620T to APC 1580 based on the application of the universal low volume APC policy. Refer to Table 22 for the final OPPS New Technology APC and status indicator assignments for CPT code 0620T for CY 2027. The final CY 2027 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website.

TABLE 22: PROPOSED AND FINAL CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR CPT CODE 0620T

CPT Code	Long Descriptor	Proposed CY 2027 OPPS APC, SI	Final CY 2027 OPPS, SI 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	1581, S	1580, S

e. Liver Histotripsy Service (APC 1575)

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.[18] When HCPCS code 0686T was first effective, the histotripsy procedure was

[18] *ClinicalTrials.gov*. ''The HistoSonics System for Treatment of Primary and Metastatic Liver Tumors Using Histotripsy (#HOPE4LIVER) (#HOPE4LIVER).'' Accessed October 24, 2026. *https://clinicaltrials.gov/ct2/show/study/NCT04573881.*

designated as a Category A IDE clinical study (NCT04573881). Since devices in Category A IDE studies are excluded from Medicare payment, payment for CPT code 0686T only reflected the cost of the service that is performed (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 reflected payment for both the service that was performed and the device used each time it was reported on a claim. For CY 2024, we assigned CPT code 0686T to APC 1576 (New Technology—Level 39 ($15,001–$20,000)) with a payment rate of $17,500.50. For CY 2025, we continued to assign CPT code 0686T to APC 1576 (New Technology—Level 39 ($15,001–$20,000) due to our CY 2025 policy 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 were only 3 claims for CPT code 0686T in the prior 4-year period. For CY 2026, we again finalized the assignment of CPT code 0686T to APC 1576 (New Technology—Level 39 ($15,001–$20,000) using our standard ratesetting methodology.

For CY 2027, the OPPS payment rates were proposed based on available CY 2025 claims data. CPT code 0686T had 166 single frequency claims in the proposed CY 2025 claims data, which exceeds the 100 claims threshold generally used for the universal low volume APC policy. Since the total number of CY 2025 single frequency claims for CY code 0686T surpassed the 100claims threshold generally used for the universal low volume APC policy, we would use the geometric mean cost of the CY 2025 claims data to set the payment rate for CY 2027 under our standard ratesetting methodology, rather than the highest of the three statistical methodologies over a 4-year lookback period. In the proposed rule, the geometric mean cost for CPT code 0686T was $14,311. Therefore, for CY 2027, we proposed to assign CPT code 0686T to APC 1575 (New Technology—Level 38 ($10,001–$15,000)) with a payment of $12,500.50 based on the GMC ($14,311) (91 FR 41798).

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters noted that for Histotripsy of the Liver (CPT 0686T), it is standard of care to do a post-procedure diagnostic imaging procedure, and therefore they believe that CMS should utilize a J1, comprehensive status indicator, and ratesetting for this procedure should include all available claims, as opposed to the single claim. Commenters believe that utilizing the J1 status indicator would increase the GMC for CPT 0686T. Commenters also believe CMS would need to create a new APC, as they believe no clinically similar APC exists. The commenters then requested that CMS utilize our Equitable Adjustment Authority to maintain the assignment of CPT code 0686T to New Technology APC assignment APC 1576 (New Technology—Level 39 ($15,001–$20,000)), with a payment of $17,500. Commenters also requested that CPT code 0686T receive a device intensive designation.

Response: We thank the commenters for their input. We note that procedures and services assigned to a New Technology APC are excluded from the C–APC packaging policy. Providers may receive separate payment for both the procedure described by CPT code 0686T and other services or procedures integral, ancillary, or supportive to CPT code 0686T. Additionally, under the OPPS, currently only clinical procedure APCs can be assigned comprehensive status indicator ''J1''. We refer readers to section IV.B and XIII.C.4 of this final rule with comment period for our responses to comments on our device-intensive procedure policies, section II.A.2 for additional information on the C–APC packaging policy, and Addendum J for a list of exclusions to the comprehensive APC packaging policy.

Regarding commenters' reference to a newly created APC dedicated solely to Histotripsy, we do not believe it is necessary at this time; however, we will continue to consider this option in the future.

Eighteen additional single-frequency claims for CY 2025 have been processed since the CY 2027 OPPS/ASC proposed rule, bringing the total number of single-frequency claims to 184, which we believe are adequate for ratesetting for this service. Based on the updated claims data available for this final rule with comment period, the geometric mean cost for HCPCS code 0686T is approximately $14,12. After discussion with our medical officers and continued review of data available for this final rule with comment period, we are finalizing, as proposed, the assignment of HCPCS code 0686T to New Technology APC 1575 (New Technology—Level 38 ($10,001–$15,000)) with a payment rate of around $12,500.50.

We refer readers to Addendum B to this final rule with comment period for the final CY 2027 OPPS payment rate for this code. Addendum B is available via the internet on the CMS website.

f. Supervised Visits for Esketamine Self-Administration (APCs 1513 and 1517)

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 and respiratory depression caused by esketamine nasal spray administration, and the potential for abuse and misuse of the product, it is only available through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. The SPRAVATO® REMS program requires, among other requirements, that the esketamine nasal spray 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 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); see also the SPRAVATO® REMS

document and SPRAVATO® labeling available on the FDA website.[19] [20]

To facilitate prompt beneficiary access to the new, potentially life-saving treatment for TRD using esketamine, we created two new HCPCS G codes, 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*) and 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*), 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. HCPCS code G2083 describes a similar service to HCPCS code G2082 but involves the administration of more than 56 mg of esketamine.

For CY 2026, HCPCS code G2082 was assigned to APC 1512 (New Technology—Level 12 ($1001–$1100)) with a payment rate of $1,050.50 and HCPCS code G2083 was assigned to APC 1518 (New Technology—Level 18 ($1601–$1700)) with a payment rate of $1,650.50.

For CY 2027, the OPPS payment rates were proposed based on available CY 2025 claims data as the available single frequency claims exceed the 100 claims threshold generally used for our universal low volume policy. Therefore, for CY 2027, we proposed to assign HCPCS codes G2082 and G2083 to New Technology APCs based on each of the codes' geometric mean costs. Specifically, we proposed to assign HCPCS code G2082 to APC 1513 New Technology—Level 13 ($1101–$1200) with a payment rate of $1,150.50 based on its geometric mean cost of $1,181 which was calculated using the available 742 single frequency claims from CY 2025 claims data. We also proposed to maintain the APC assignment for HCPCS code G2083 to APC 1518 New Technology—Level 18 ($1601–$1700)) with a payment rate of $1,650.50 based on its geometric mean cost of $1,648, which was calculated using the available 5,741 single frequency claims from CY 2025 claims data (91 FR 41799).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the proposed APC assignments, noting that the increased reimbursement promotes patient access for behavioral health services. Commenters continue to request a clinical APC assignment for the esketamine treatment citing the uniqueness of this service justifies the establishment of a new clinical APC for these two codes and also recognizing that there does not appear to be an existing clinical APC series that are both clinically comparable and similar in resource use to these two unique codes. Clinical APCs, according to the commenters, would provide payment stability for these codes long term.

Commenters also asked us to clarify a discrepancy noted in the CY 2027 OPPS/ASC proposed rule table where we listed G2083 as having a CY 2026 APC final assignment of APC 1517, even though it should have been APC 1518.

Response: We thank the commenters for their input. As we have stated in previous rules, we have been contemplating potential clinical APC assignments for the past number of rulemaking cycles but are not convinced as to what clinical APC would be appropriate in terms of clinical and resource homogeneity, nor are we convinced that a new clinical APC with just these two codes is appropriate at this time. We appreciate the public's continued interest and support of this service and their requests for a stable long-term payment pathway. We will continue to consider potential clinical APC options for these codes through future rulemaking.

We appreciate the commenters noting the discrepancy in the CY 2027 OPPS/ASC proposed rule. In Table 19 of the CY 2027 OPPS/ASC proposed rule, we inadvertently listed the final APC assignment for G2083 as APC 1517 (New Technology—Level 17 ($1501–$1600)) for CY 2026 (91 FR 41799). G2083 was finalized to APC 1518 New Technology—Level 18 ($1601–$1700).

We note the geometric mean costs for both HCPCS codes G2082 and G2083 have changed since the CY 2027 OPPS/ASC proposed rule. Based on the updated claims data available for this final rule, the geometric mean cost for HCPCS code G2082 is around $1,146, which was calculated using the available 809 single frequency claims, and the geometric mean cost for HCPCS code G2083 is around $1,544 which was calculated using the available 6,342 single frequency claims from CY 2025 claims data. Based on this updated claims data available for this final rule with comment period, we are finalizing a New Technology APC assignment for HCPCS code G2082 to APC 1513 (New Technology—Level 13 ($1101–$1200)) with a payment rate of $1,150.50 and a New Technology APC assignment for HCPCS code G2083 to APC 1517 (New Technology—Level 17 ($1501–$1600)) with a payment of $1,550.50.

Refer to Table 23 for the CY 2027 proposed and final APC and status indicator assignments for HCPCS codes G2082 and G2083. The CY 2027 payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

[19] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/211243s016lbl.pdf.*

[20] *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/211243Orig1s021ltr.pdf.*

TABLE 23: PROPOSED AND FINAL CY 2027 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODES G2082 AND G2083

HCPCS Code	Long Descriptor	Proposed CY 2027 OPPS APC, SI	Final CY 2027 OPPS APC, SI
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	1513, S	1513, S
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	1518, S	1517, S

g. SAINT Neuromodulation System (APCs 1511 and 1525)

The SAINT Neuromodulation System is a non-invasive repetitive transcranial magnetic stimulation (rTMS) system that identifies an individualized target and delivers navigationally directed repetitive magnetic pulses to that individualized target located within the left dorsolateral prefrontal cortex to treat major depressive disorder (MDD). The patient first receives structural MRI and functional MRI scans that are analyzed by the provider to identify and localize the personalized stimulation target in the patient's dorsolateral prefrontal cortex. Once the areas targeted for treatment are identified, the patient receives non-invasive magnetic stimulation in the targeted area. The patient has 10 treatment sessions per day with each treatment session lasting 10 minutes followed by 50 minutes of rest before another treatment session occurs. The treatment is administered over five days for a total of 50 sessions of non-invasive magnetic stimulation therapy. There are four CPT codes listed below that describe the MRI scans that are used to target the treatment and describe the administration of the non-invasive magnetic stimulation therapy.

- 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.*

For CY 2025, the OPPS payment rates were proposed based on available CY 2023 claims data. However, CPT codes 0889T, 0890T, 0891T, and 0892T did not become effective until July 1, 2024, which means there were no claims data for the procedures described these CPT codes. We assigned our proposed rates for these services based on our evaluation of the resources needed to perform these services.

Because we only had a partial year of data for CY 2026 rulemaking, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the APC assignments for CPT codes 0889T, 0890T, 0891T, and 0892T.

For CY 2027, the OPPS payment rates were proposed based on available CY 2025 claims data (91 FR 41800). We proposed to assign CPT code 0889T to APC 1511 (New Technology—Level 11 ($901–$1000)) with a payment rate of $950.50 based on the median cost using 74 single frequency claims. We proposed to assign CPT code 0890T to APC 1521 (New Technology—Level 21 ($1901–$2000)) with a payment rate of $1950.50 based on the arithmetic mean using 73 single frequency claims. We proposed to assign CPT code 0891T to APC 1520 (New Technology—Level 20 ($1801–$1900)) with a payment rate of $1,850.50 based on the geometric mean cost calculated from 241 single frequency claims. We proposed to assign CPT code 0892T to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50 based on the arithmetic mean calculated from 19 single frequency claims.

The HOP Panel met on August 24, 2026, and in response to the presentation on SAINT Neuromodulation system, the Panel recommended maintaining CPT codes 0890T, 0891T, and 0892T in their current APC assignments for CY 2027.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters overwhelmingly requested that CMS maintain the current New Technology APC assignments, as the proposed rates would reduce the Medicare payment for these services by approximately 25 to 50 percent and, in their opinion, put beneficiary access to this service at risk. One of the commenters noted that providers have acknowledged incorrect

reporting of the resources needed to provide these services, and have since updated their cost reporting processes for SAINT. The updated claims data were not available for the 2025 dates of service, however, and were not reflected in the proposed rule. Many commenters shared the clinical benefits of this treatment and how it is a highly effective option for patients with Treatment Resistant Depression.

Response: We thank the commenters for their input. We agree that the proposed rates may not accurately reflect the costs for implementing, providing, and maintaining this service in the hospital outpatient setting. We acknowledge the challenges of capturing costs with a new service and appreciate the interested parties dialogue with CMS about these challenges and their effect on the claims data.

Since the CY 2027 OPPS/ASC proposed rule was published, we note that there were changes in the claims data for CPT code 0889T and 0890T. Based on this updated claims data, the median cost for CPT 0889T is $818 using 89 single frequency claims and the median cost for CPT code 0890T is $1,759 using 88 single frequency claims.

After consideration of the public comments we received, and taking into consideration the HOP Panel's recommendation, we are not finalizing our proposal for CY 2027. For CY 2027, we are using our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the current APC assignments for CPT codes 0889T, 0890T, 0891T, and 0892T. Refer to Table 24 for the proposed and final OPPS New Technology APC and status indicator assignments for CPT codes 0889T, 0890T, 0891T, and 0892T. The final CY 2027 payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 24: PROPOSED AND FINAL CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 0889T, 0890T, 0891T, AND 0892T

CPT Code	Long Descriptor	Proposed CY 2027 OPPS APC, SI	Final CY 2027 OPPS APC, SI
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	1511, S	1511, S
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	1521, S	1525, S
0891T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day	1520, S	1525, S
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	1523, S	1525, S

h. Skin Cell Suspension Autograft (SCSA) Procedures (CPT Codes 15006 Through 15009) (APC 1575)

Effective January 1, 2025, both CPT code 15013 (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 HCPCS code C8002 (Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)) describe the preparation step of a skin cell suspension autograft (SCSA) procedure to treat acute thermal burn injuries. Both codes describe the preparation step of a three-step SCSA procedure: harvesting, preparation, and application. The difference between the codes is that CPT code 15013 describes the manual preparation of the SCSA, and HCPCS code C8002 describes the automated preparation of the SCSA. Due to the similarities between the procedures, in the CY 2025 OPPS/ASC final rule with comment period, we assigned both CPT code 15013 and HCPCS code C8002 to APC 1567 (New Technology—Level 30 ($6,001–$6,500)) with a payment rate of $6,250.50 and status indicator ''T''. In the CY 2025 OPPS/ASC final rule with comment period, we noted that we believed the sum of the payment rates for the three-step process should approximate

$10,000. However, because of the effect of the multiple procedure reduction, the total payment for the skin cell suspension autograft furnished using the RECELL System would have been approximately $8,000, contrary to the intended target of $10,000 as stated in the CY 2025 OPPS/ASC final rule with comment period. To correct this error, in the CY 2025 OPPS/ASC Correction Notice, we assigned both CPT code 15013 and HCPCS code C8002 to APC 1532 (New Technology—Level 32 ($7,001–$7,500)) with a payment rate of $7,250.50 and status indicator ''S'' (Procedure or service, not discounted when multiple, paid under OPPS; separate APC payment).

For CY 2026, the OPPS payment rates were based on available CY 2024 claims data. Since CPT code 15013 and HCPCS code C8002 were not effective until January 1, 2025, we did not have any claims for either code for CY 2024. Therefore, for CY 2026, we finalized to continue to assign CPT code 15013 and HCPCS code C8002 to APC 1532 (New Technology—Level 32 ($7,001–$7,500)) with a payment rate of $7,250.50 (91 FR 41801).

Effective January 1, 2027, CPT codes 15011 through 15018 will be deleted and replaced with a bundled four code structure: CPT codes 15006–15009 (placeholder codes 15X19 through 15X22):

- CPT 15006 (placeholder CPT code 15X19): Skin cell suspension autograft (SCSA), trunk, arms, and/or legs; first 100 sq cm or less, or 1 percent of body area of infants and children
- CPT 15007 (placeholder CPT code 15X20): each additional 100 sq cm, or each additional 1 percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
- CPT 15008 (placeholder CPT code 15X21): Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1 percent of body area of infants and children
- CPT 15009 (placeholder CPT code 15X22): Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1 percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

Unlike CPT codes 15011 through 15018, which provide a three step-based coding structure with each procedural step billed separately, CPT codes 15006 through 15009 provide a simplified bundled coding structure based on anatomic size (91 FR 41801 through 41802).

In light of these coding changes, we proposed for CY 2027 to maintain overall payment rates for the SCSA procedure, as we did not believe that changes in coding structure alone warranted changes in payment for a procedure that remains clinically unchanged. Specifically, we proposed to assign CPT codes 15006 and 15008 to APC 1575 (New Technology—Level 38 ($10,001–$15,000)) with a proposed payment rate of $12,500.50 and status indicator ''S.'' We also proposed to assign add-on CPT codes 15007 and 15009 to status indicator ''N''. Due to the new bundled coding structure, for CY 2027 we also proposed to delete HCPCS code C8002 (Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)), which describes the automated preparation step of the SCSA procedure (91 FR 41802).

We received public comments on our proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposals and urged CMS to finalize the proposed APC and status indicator assignments for CPT codes 15006 through 15009 to maintain overall payment for the procedure. A commenter supported our proposal to delete HCPCS code C8002, noting that the automated preparation step is now included into the new bundled SCSA code structure. Commenters emphasized that stable and accurate payment is essential to preserving patient access to SCSA treatment, particularly for those with acute thermal burn injuries requiring treatment of large surface areas or anatomically complex sites.

Response: We thank the commenters for their support. We are finalizing the new technology APC and status indicator assignments for CPT codes 15006 through 15009 as proposed. Refer to Table 25 for the final OPPS New Technology APC and status indicator assignments for CPT codes 15006 through 15009 and HCPCS code C8002 for CY 2027. The final CY 2027 payment rates can be found in Addendum B to this final rule via the internet on the CMS website.

TABLE 25: FINAL CY 2027 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR NEW CPT CODES 15006 THROUGH 15009 AND HCPCS CODE C8002 EFFECTIVE JANUARY 1, 2027

HCPCS Code	Long Descriptor	Final CY 2027 OPPS APC, SI
15006	Skin cell suspension autograft (SCSA), trunk, arms, and/or legs; first 100 sq cm or less, or 1% of body area of infants and children	1575, S
15007	each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)	N/A, N
15008	Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children	1575, S
15009	Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)	N/A, N
C8002	Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)	N/A, D

i. Renal Histotripsy Service (APC 1575)

HCPCS code C9790 *(Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance)*) was created October 1, 2023, and was used to describe the Medicare approved Category B IDE (investigational device exemption) clinical study involving the renal histotripsy procedure associated with the use of the HistoSonics Edison System. CPT code 0888T (Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance) replaced HCPCS code C9790 effective July 1, 2024.

Renal histotripsy is a non-invasive, non-thermal, mechanical process that uses a focused beam of sonic energy to destroy solid renal tumors and is currently in a prospective, multi-center, single-arm pivotal trial designed to evaluate the effectiveness and safety of the device for the destruction of kidney tissue by treating primary solid renal tumors. Because the renal histotripsy clinical study is designated as a Category B (non-experimental/investigational) IDE study, the Medicare payment for CPT code 0888T reflects payment for both the service that is performed, and the device used each time it is reported on a claim. For CY 2025 we assigned CPT code 0888T to APC 1576 (New Technology—Level 39 ($15,001–$20,000)) with a payment rate of $17,500.50 based on the previous APC and status indicator assignments for HCPCS code C9790.

For CY 2026, the proposed OPPS payment rates were based on available CY 2024 claims data. We had identified one single frequency claim for HCPCS code C9790 and eight single frequency claims for CPT code 0888T. Given our proposal to maintain current New Technology APC assignments for CY 2026 for New Technology services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy, we finalized maintaining the APC assignment for CPT code 0888T to APC 1576 (New Technology—Level 39 ($15,001–$20,000)) with a payment rate of $17,500.50 (90 FR 53558).

For CY 2027, the proposed rates are based on available CY 2025 claims data. For the proposed rule, we identified 14 single frequency claims for CPT code 0888T, which encompassed a four year lookback. Using this claims data from the CY 2025 proposed rule, our analysis found the geometric mean cost of CPT 0888T is approximately $5,940, the median cost is approximately $6,740 and the arithmetic mean cost is approximately $8,145. The arithmetic mean is the statistical methodology that estimates the highest cost for the service. Therefore, we proposed, for CY 2027, to assign CPT code 0888T to APC 1534 (New Technology—Level 34 ($8001–$8500)) with a payment rate of $8,250.50 (91 FR 41802).

We received public comments on our proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters requested we maintain the OPPS payment and increased ASC payments.

Response: We thank the commenters for their feedback.

Since the proposed rule was published there are four additional single frequency claims available in the CY 2025 claims data. With this change in volume for CPT code 0888T, we note, the revised statistical methodologies are: geometric mean cost is approximately $6,942, the median cost is approximately $7,160, and the arithmetic mean cost is approximately $10,159. The arithmetic mean is the statistical methodology that yields the highest estimated cost of the service. This updated cost data falls outside the proposed APC assignment of APC1534 (New Technology—Level 34 ($8001–$8500); therefore, we are not finalizing as proposed. Instead, for CY 2027, we are finalizing the assignment of CPT code 0888T to APC 1575 (New Technology—Level 38 ($10,001–15,000)) with a payment rate of approximately $12,500.

The final CY 2027 payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

Refer to Table 26 for the proposed CY 2027 and final CY 2027 OPPS New

Technology APC and status indicator assignment for CPT code 0888T.

TABLE 26: PROPOSED AND FINAL CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE RENAL HISTOTRIPSY SERVICE

CPT Code	Long Descriptor	Proposed CY 2027 OPPS APC, SI	Final CY 2027 OPPS ASC, SI
0888T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance	1534, S	1575, S

j. Implantable Glucose Monitoring System (APC 1563)

Effective January 1, 2017, the AMA CPT Editorial Panel established CPT codes 0446T (*Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training*) and 0448T (*Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation*) to describe an implantable glucose sensor for patients with diabetes. These codes were used to describe sensors with a 90-day or 180-day battery life. Although these CPT codes were effective January 1, 2017, the implantable interstitial glucose sensor did not receive FDA authorization for marketing until June 6, 2019.

For CY 2021, we assigned CPT codes 0446T and 0448T to APC 5054 (Level 4 Skin Procedures) and a status indicator of ''T'' (Procedure or Service, Multiple Procedure Reduction Applies; Paid under OPPS; separate APC payment.) and maintained those APC assignments until April 1, 2025.

In the CY 2025 OPPS/ASC final rule with comment period, we created the following two HCPCS G-codes effective January 1, 2025, to describe the implantable interstitial glucose sensor with a 365-day battery life.

- G0546 (*Creation of subcutaneous pocket with insertion of 365 day implantable interstitial glucose sensor, including system activation and patient training*); and
- G0565 (*Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 365 day implantable sensor, including system activation*).

We assigned HCPCS codes G0564 and G0565 to APC 1561 (New Technology—Level 24 ($3001–$3500)) with a payment rate of $3,250.50.

For the April 1, 2025, quarterly update, we deleted HCPCS codes G0564 and G0565 and assigned 0446T and 0448T to APC 1561 (New Technology—Level 24 ($3001–$3500)) with a payment rate of $3,250.50 to describe the new implantable interstitial glucose sensor with a 365-day battery life. The 365-day glucose sensor replaced previous versions of the implantable interstitial glucose sensor with shorter battery lives. Therefore, the 365-day sensor is the only sensor on the market and can only be described by CPT codes 0446T and 0448T.

For CY 2026, we finalized maintaining the APC assignments for CPT codes 0446T and 0448T to APC 1561 (New Technology—Level 24 ($3001–$3500)) with a payment rate of $3,250.50. Because CPT codes 0446T and 0448T were assigned to New Technology APCs to describe this new sensor for the April 2025 quarterly update and the G-codes that described this service were only effective for one quarter, we did not have any claims data for the service (90 FR 53556).

For CY 2027, the OPPS payment rates were proposed based on available CY 2025 claims data. Both CPT codes 0446T and 0448T had less than 10 claims, so we proposed to maintain their current APC assignment to APC 1563 (New Technology—Level 26 ($4001–$4500)), status indicator of 'T' and a payment rate of $4,250.50.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters requested that we maintain the APC assignment for CPT codes 0446T and 0448T in a New Technology APC, stating continuous glucose monitoring is an important tool for diabetic patients, especially patients with transportation barriers, limited access to specialty care, and patients who may not be as compliant with follow-up visits. Maintaining the APC assignments, the commenters contended, would protect beneficiary access to this service while allowing CMS to gather claims data and get a better idea of the true costs of this service.

A commenter requested that CMS reassign CPT codes 0446T and 0448T to APC 1530 (New Technology—Level 30 ($6001–$6500)) with a payment of $6,250.50. The commenter cited the increased cost of the implanted 365-day glucose sensor as the reason for their request and the value of the longer sensor duration, including fewer insertion and removal procedures and better adherence to therapy. They explained that extensive research and development, along with high manufacturing costs, have contributed to the cost of the implantable continuous glucose monitoring system (iCGM system) which they state is $6,800. The commenter also requested that the OPPS payment align with the PFS payment which they state is approximately $5,800, to provide consistent payment regardless of the setting. The commenter notes that the utilization in other care settings has increased while usage in the hospital outpatient setting has been limited.

It was also noted that the continuous glucose monitoring system is under consideration for a Category I CPT code, which would allow the service to be valued through the CPT and RUC processes and support appropriate future reimbursement.

Response: We appreciate the public comment and understand the implicated value that a longer life sensor brings to Medicare beneficiaries. We agree that there would be inherently increased costs to hospitals for the new technology of a 365-day system, but as we stated last year, we do not agree that the costs to hospitals would be almost double the costs of the 180-day system. (90 FR 53556) We also remind the commenter that the OPPS pays for operational costs for hospital facilities, while the PFS pays for the professional

services. As such, we do not believe that the costs will always be aligned between the two fee schedules.

Since the CY 2027 OPPS/ASC proposed rule was published, we note that there were no changes in claims data for CPT code 0446T, but CPT 0448T now has 10 single frequency claims in the 4-year lookback period and therefore is subject to our low volume policy. Using this claims data from CY 2025, our analysis found the arithmetic mean cost is $1,779, the median cost is $1,394, and the geometric mean cost is $1,278. Because the arithmetic mean cost is the statistical methodology that estimates the highest cost for the service, we would usually assign CPT 0448T to APC 1551 (New Technology—Level 14 ($1201–$1300)), status indicator of 'T' and a payment of $1,250.50. However, we believe it is important to maintain both of these codes in their current APC assignments.

In summary, after consideration of the public comment we received, we are finalizing our proposal based on our statutory authority set out at section 1833(t)(2)(E) of the Act, to assign both CPT codes 0446T and 0448T to APC 1563 (New Technology—Level 26 ($4001–$4500)) with a payment of $4,250.50 and a status indicator of 'T'.

We remind hospitals that we review, on an annual basis, the APC assignments for all items and services paid under the OPPS. The final CY 2027 payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

k. Scalp Cooling Fitting CPT Code 97007 (APC 1516)

Scalp cooling is a service furnished during chemotherapy to prevent or minimize hair loss, a common side effect of chemotherapy treatment for cancer. Effective July 1, 2021, scalp cooling was described by CPT codes 0662T (Scalp cooling, mechanical; initial measurement and calibration of cap) and 0633T (Scalp cooling, mechanical; placement of device, monitoring, and removal of device (list separately in addition to code for primary procedure)).

However, effective January 1, 2026, CPT codes 0662T and 0663T were deleted and replaced by three Category I CPT codes:

- 97007—*Mechanical scalp cooling, including individual cap supply with head measurement, fitting, and patient education.*
- 97008—*Mechanical scalp cooling; including hair preparation, individual cap placement, therapy initiation, and precooling period).*
- 97009—*Mechanical scalp cooling; provided after discontinuation of chemotherapy, each 30 minutes (List separately in addition to code for primary procedure).*

CPT code 97007 describes the fitting and supply of the cap, which happens on a different date of service than a chemotherapy session, while CPT codes 97008 and 97009 describe the scalp cooling therapy on the same date of service as the chemotherapy session. For CY 2026, we assigned status indicator ''N'' to CPT codes 97008 and 97009 to align with our packaging policies generally, and specifically with regard to packaging of CPT code 0663T, which we believed served as a predecessor code for CPT codes 97008 and 97009 (90 FR 53597).

For CY 2027, we proposed to assign CPT code 97007 to APC 1516 (New Technology—Level 16 ($1401—$1500)) with a payment rate of $1,450.50 using the geometric mean cost of $1,425.11 based on 109 single frequency claims for the predecessor code, CPT code 0662T, that were available for the proposed rule. We refer readers to the Addendum B to the CY 2027 OPPS/ASC proposed rule for our proposals regarding CPT codes 97008 and 97009. Additionally, we refer readers to section III.E. to this final rule for preamble on our final policy for CPT code 97008.

We received a public comment on our proposal for CPT code 97007. The following is a summary of the comment we received and our response.

Comment: A commenter representing a scalp cooling device requested that we reassign CPT code 97007 to APC 1519 (New Technology—Level 19 ($1701–$1800)) with a payment rate of $1,750.50 for CY 2027. The commenter explained that because claims data for the predecessor CPT code may not have included hospital costs associated with the cap supply since the supply was not specified in the code descriptor, the claims data for CPT code 0662T should not be used to set a payment rate for CPT code 97007. Instead, the commenter asked that we use invoice data to assign CPT code 97007 to APC 1519 until there is reliable claims data upon which to base payment.

Response: We thank the commenter for their input. 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 associated with calibrating and fitting the cap, which has informed payment policy for scalp cooling.

Since Medicare began paying for scalp cooling in CY 2022, we have collected OPPS claims data on which to base payment rates for the service. For CY 2027, more than 100 single frequency claims are available to inform the payment rate for CPT code 97007. Because claims data is available here, we do not believe invoice pricing is the appropriate basis for setting the final payment rate for CPT code 97007, and we decline to adopt the commenter's suggested approach. Therefore, for CY 2027, we are finalizing our proposal to use CPT code 0662T claims data to set the APC assignment for CPT code 97007.

We note that additional claims for CPT code 97007 have been processed since the CY 2027 OPPS/ASC proposed rule. Based on updated claims data, CPT code 97007 has an updated geometric mean cost of approximately $1,401.75 based on 166 single frequency claims. Because the geometric mean cost of CPT code 97007 is within the range for APC 1516, the proposed APC assignment for CPT code 97007 for CY 2027, we are finalizing the APC assignment of CPT code 97007 as proposed. Based on the available claims data, for CY 2027, we are finalizing to assign CPT code 97007 to APC 1516 (New Technology—Level 16 ($1401–$1500)) with a payment rate of $1450.50.

Refer to Table 27 for the proposed and final CY 2027 and New Technology APC and status indicator assignment for CPT code 97007. The final CY 2027 payment rates can be found in Addendum B to this the final rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this the final rule for the status indicator definitions for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 27: PROPOSED CY 2027 AND FINAL CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR CPT CODE 97007

CPT Code	Long Descriptor	Proposed CY 2027 OPPS APC, SI	Final CY 2027 OPPS, SI APC
97007	Mechanical scalp cooling, including individual cap supply with head measurement, fitting, and patient education	1516, S	1516, S

4. Final CY 2027 Policy for SaMS Procedures Currently Assigned to New Technology APCs

We refer readers to Section X.B. for the final CY 2027 policy and payment rates for SaMS procedures assigned to New Technology APCs for CY 2026.

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 2026 OPPS/ASC proposed rule, CY 2024 claims were generally the claims used for ratesetting; and clinical and brachytherapy APCs with fewer than 100 single claims from CY 2024 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 2027 OPPS/ASC proposed rule, we proposed to designate five brachytherapy APCs and four clinical APCs as low volume APCs under the OPPS. The five brachytherapy APCs and four clinical APCs meet our criteria of having fewer than 100 single claims in the claims' year used for ratesetting (CY 2025 for the CY 2027 OPPS/ASC proposed rule). Nine of the 10 APCs were designated as low volume APCs in CY 2025. Based on data for the CY 2027 OPPS/ASC proposed rule, APC 2645 (Brachytx, non-stranded, gold-198) had 87 single claims and met our criteria to be designated as a low volume APC (91 FR 41807).

Comment: Commenters supported our proposal to continue our low volume APC policy for CY 2027.

Response: We thank commenters for their support.

After consideration of the public comments received, based on CY 2025 claims data available for this final rule with comment period, we are finalizing our proposal to designate five brachytherapy APCs and four clinical APCs as low volume APCs under the OPPS. Table 28 includes the CY 2025 claims available for ratesetting for each of the APCs we are designating as low volume APCs for CY 2027. The final cost statistics for our CY 2027 low volume APCs, such as the median, arithmetic mean, and geometric mean cost are available for download with this final rule with comment period 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 28: FINAL LOW VOLUME APCS USING COMPREHENSIVE (OPPS) RATESETTING METHODOLOGY FOR CY 2027

APC	APC Description	CY 2025 Claims Available for Ratesetting
2635	Brachytx, non-str, HA, p-103	29
2642	Brachytx, stranded, c-131	43
2643	Brachytx, non-stranded, c-131	80
2645	Brachytx, non-stranded, gold-198	92
2647	Brachytx, NS, Non-HDRIr-192	14
5244	Level 4 Blood Product Exchanges and Related Services	56
5495	Level 5 Intraocular Procedures	99
5496	Level 6 Intraocular Procedures	38
5881	Ancillary Outpatient Services When Patient Dies	49

E. APC-Specific Policies

1. Creation and/or Revisions of Clinical APCs

Neurostimulator and Related Procedures (APCs 5461 Through 5465)

In prior rulemaking, some interested parties have requested 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. We most recently responded to this request in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53584). We noted that we believed that the current 5 level APC structure for the Neurostimulator and Related Procedures series provided for an appropriate distribution of clinical and cost similarity at the different APC levels.

As discussed in the CY 2021 OPPS/ASC final rule with comment period, we reiterate 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 paid more or less than the cost of the services 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).

We continued to believe that a five-level structure for the Neurostimulator and Related Procedures APC series remained appropriate, and therefore in the CY 2027 OPPS/ASC proposed rule our proposed assignments for the structure and for many codes in the APC series remained the same as they were in the CY 2026 OPPS/ASC final rule.

Comment: A commenter supported the assignment of CPT code 61885 (Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array) to APC 5465. Commenters supported maintaining the assignment of CPT code 33276 (Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed) to New Technology APC 1580. Other commenters supported our proposal to maintain the assignment of CPT code 64568 (Open implantation of cranial nerve (*e.g.,* vagus nerve) neurostimulator electrode array and pulse generator) to New Technology APC 1580.

Some commenters noted that the claims used in modeling the estimated costs for CPT code 64568 appeared to be restricting procedure pairings to HCPCS codes C1767 (Generator, neurostimulator (implantable), non-rechargeable) and C1778 (Lead, neurostimulator (implantable)) and requested that the customary methodology be applied when evaluating CPT code 64568. Commenters also requested that CMS remove hypoglossal nerve stimulation claims for the treatment of obstructive sleep apnea from the determination of the geometric mean cost of CPT code 64568.

Response: We appreciate the commenters' support for the proposed assignments of CPT codes 33276 and 64568 to New Technology APC 1580, and of CPT code 61885 to APC 5465. We agree that it is appropriate to maintain the current temporary New Technology APC assignments for CPT codes 33276 and 64568. We will continue to monitor the claims data for the code as additional claims become available.

In reviewing the claims data for CPT code 64568, we agree that the claims were restricted to only allow specific procedure-device combinations under the device dependent APC methodology for the specific code. Based on the proposed and finalized assignment of the code to New Technology APC 1580, we note that there will not be a specific impact on the CY 2027 OPPS status indicator and APC assignment for CPT code 64568. We no longer restrict those procedure-device combinations.

We recognize the concerns commenters raised with regards to the claims data for CPT code 64568 and how they may describe varying degrees of resource complexity as a result of describing different types of nerve stimulation procedures and the associated clinical indications. However, we believe that with the assignment of CPT code 64568 to New Tech APC 1580, and the future availability of CY 2026 claims that would separate those hypoglossal nerve stimulation services based on distinct C codes, we do not believe it is necessary to update the final rule claims data and associated cost files to assume which claims describe each type of service.

Comment: Some commenters requested the creation of a Level 6 Neurostimulator and Related Procedures APC, with some requesting that specific

codes or codes with similar costs be included in that Level 6 APC. Those commenters believed that establishing the Level 6 APC would be a permanent way of addressing disparities between payment and resource costs for high-cost, low-volume neurostimulator procedures. They also noted that creating a Level 6 APC would be a way to use more claims for ratesetting based on the estimated costs of the procedures, under a comprehensive APC methodology. Commenters also noted that restructuring and creation of new clinical APCs would allow for efficient payment for services being phased out of the IPO list.

Response: We appreciate the thoughtful responses commenters have provided with regard to the Neurostimulator and Related Procedures APC series. At this time, we continue to believe the 5-level APC structure for the APC series remains appropriate and that the individual New Technology APC assignments with respect to the high-cost procedures in this evolving area resolve the concerns around procedure payment relative to cost. Finally, we note that for the CY 2027 OPPS/ASC final rule we are not removing any codes from the IPO list to the Neurostimulator and Related Procedures APC series. We will continue to monitor the claims data for these procedures as more information around their volume and estimated costs become available.

After consideration of public comments, we are finalizing the proposed assignments of CPT codes 33276 and 64568 to New Technology APC 1580, finalizing the proposed assignment of 61885 to APC 5465, and maintaining the 5-level APC structure for the Neurostimulator and Related Procedures APC series for CY 2027.

Laparoscopy and Related Services (APCs 5361 Through 5362)

As part of the CY 2016 OPPS APC restructuring process, the four level APC series for Laparoscopy and Related Services was consolidated into a 2-level APC series (80 FR 70379). Since that time, we have maintained that 2- level APC structure based on the clinical and resource homogeneity of the services assigned to those APCs.

Comment: A commenter noted that several of the codes newly proposed to be removed from the inpatient only list and assigned to the Level 2 Laparaoscopy and Related Services APC have higher geometric mean costs relative to the APC geometric mean cost for this APC, including for CPT codes 32663 (Thoracoscopy, surgical; with lobectomy (single lobe)), 32666 (Thoracoscopy, surgical; with therapeutic wedge resection (*e.g.,* mass, nodule), initial unilateral), and 32669 (Thoracoscopy, surgical; with removal of a single lung segment (segmentectomy)). The commenter requested that CMS consider whether a higher level Laparoscopy and Related Services APC is needed to establish appropriate payment for these services in the outpatient setting.

Response: While we monitor the structure of the OPPS and the various APCs, we note that some of the principles guiding the CY 2016 OPPS APC restructuring and consolidation included improved resource and clinical homogeneity, as well as reduced resource overlap in APCs within a clinical family (80 FR 70379). APC 5362 (Level 2 Laparoscopy and Related Services) has an estimated geometric mean cost of $11,401, with a range of geometric mean costs for two times rule purposes ranging from $9,347 for CPT code 58552 (Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)) to $13,534 for CPT code 55866 (Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed). While we recognize the commenter's concern around estimated costs for services removed from the IPO list being assigned to the Laparaoscopy and Related Services APC series, we note that geometric mean costs for CPT codes 32666 and 32669 fall well within that range of significant costs for the APC, and that all three codes have limited outpatient claims volume. We do not believe that there is a current need for an additional APC level for the Laparoscopy and Related Services APC series. However, we will continue to monitor the claims data as more claims become available and consider the need for additional APC levels in the future.

After consideration of the public comments, we are finalizing the 2-level APC structure for the Laparoscopy and Related Services APC series in this final rule with comment period as proposed.

Nuclear Medicine and Related Services APC Series (APC 5591 Through 5594)

The Nuclear Medicine and Related Services APC series was created as part of the broader APC restructuring and consolidation in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70392 through 70397). The APC series was developed from what were previously separate APC groupings primarily organized by anatomy and imaging modality. Since the initial establishment of the Nuclear Medicine and Related Services series in the CY 2016 OPPS/ASC final rule with comment period, we have maintained the four-level APC structure for the series.

In the CY 2025 OPPS/ASC final rule with comment period, we finalized a policy of paying separately for diagnostic radiopharmaceuticals with estimated per day costs higher than a packaging threshold specific to diagnostic radiopharmaceuticals (89 FR 93948 through 93963). Because certain diagnostic radiopharmaceuticals are paid separately under the policy, the nuclear medicine and other services these diagnostic radiopharmaceuticals would otherwise be packaged into would no longer include those costs. As a result, based on the associated changes to the ratesetting process, we observed impacts on the estimated cost of services assigned to the Nuclear Medicine and Related Services APC series such that the range of cost significant codes across the various APC levels became less distinct, in particular between Levels 3 and 4.

As part of our standard process of reviewing updated claims and cost report data, we continued to observe in the CY 2027 OPPS data that the differences between the four levels of APC geometric means were less distinct than they were previously, in part due to the policy of paying separately for diagnostic radiopharmaceuticals. Specifically, under a four-level APC structure using the 2027 NPRM claims data and maintaining the same APC assignments as in the CY 2026 OPPS/ASC final rule with comment period, the geometric mean cost of the Level 3 APC would have been $1,367.99 while the geometric mean cost of the Level 4 APC would have been $1,497.06. The range of cost significant codes in the Level 3 APC would have been from $812 to $1,404, while the range for the Level 4 APC would have been from $1,024 to $1,676; indicating a high degree of overlap in the estimated costs of the services assigned to those APC levels. Given the relative proximity of the APC geometric mean costs and the clinical and cost similarities of the services between the APCs in the Nuclear Medicine and Related Services series, we believed that it was appropriate to reorganize the Nuclear Medicine and Related Services APC series for the CY 2027 OPPS (91 FR 41808).

Additionally, we noted that CPT codes 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), 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);), and 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) had sufficient CY 2025 claims data available to be appropriately assigned to clinical APCs for CY 2027 OPPS ratesetting. We believed the restructuring of the series now made it appropriate to propose to assign these codes to APC 5594 (Level 4 Nuclear Medicine and Related Services) and we proposed to assign these three CPT codes to APC 5594 for CY 2027 (91 FR 41808).

Based on our review of the updated claims data, we proposed to reassign a number of services to revised levels in the Nuclear Medicine and Related Services APC series for CY 2027 and to assign CPT codes 78431, 78432, and 78433 to APC 5594 (Level 4 Nuclear Medicine and Related Services) in the CY 2027 OPPS. Please see the APC-sorted Two Times Listing for the proposed rule on the CMS website or Addendum B to the proposed rule to see the Nuclear Medicine APC we proposed to assign each HCPCS code in the series.

Comment: Commenters supported the proposed reorganization of the Nuclear Medicine and Related Services APC series and the proposed assignment of PET/CT procedures to APC 5594 (Level 4 Nuclear Medicine and Related Services).

Response: We appreciate the commenters' support.

Comment: Two commenters expressed concern regarding the proposed reassignment of CPT code 78830 (Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (spect) with concurrently acquired computed tomography (ct) transmission scan for anatomical review, localization and determination/detection of pathology, single area (e.g., head, neck, chest, pelvis) or acquisition, single day imaging) to APC 5592 (Level 2 Nuclear Medicine and Related Services). One of the commenters was concerned that the change would cause a move to more expensive, more invasive tests and that a phased in approach while more claims data continue to be collected.

A commenter expressed concern about the proposed assignment of CPT codes 78075 (Adrenal imaging, cortex and/or medulla), 78454 (Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection), 78811 (Positron emission tomography (pet) imaging; limited area (e.g., chest, head/neck)), and 78831 (Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (spect), minimum 2 areas (e.g., pelvis and knees, chest and abdomen) or separate acquisitions (e.g., lung ventilation and perfusion), single day imaging, or single area or acquisition over 2 or more days) to APC 5592 (Level 2 Nuclear Medicine and Related Services) and recommended assignment to APC 5593 (Level 3 Nuclear Medicine and Related Services) instead.

Response: We understand the commenter's concern. Based on the data in this final rule, the geometric mean costs for these codes range from $746.48 for CPT code 78811 to $899.39 for CPT code 78831. We believe that these codes are more appropriately placed based on their estimated costs in APC 5592, with a geometric mean cost of $591.45 rather than the Level 3 APC 5593, which has an estimated geometric mean cost $1,433.70. Additionally, in reviewing the prior year's claims data, the geometric mean cost for these codes were similarly situated. While we will continue to monitor the claims data for these codes in the future, we do not believe a phased approach is necessary, as they are appropriately assigned to APC 5592 based on the geometric mean cost of these services.

After consideration of the public comments we received, we are finalizing the HCPCS assignments for CPT codes 78075, 78454, 78811, 78830, and 78831 to APC 5592, as proposed.

Audiology and Otolaryngology

2. Cochlear Infusion of a Pharmacologic Agent, CPT Code 1056T (APC 5165)

For CY 2027, the AMA CPT Editorial Board created a new Category I CPT code 1056T (Placeholder code X565T) to describe a cochlear infusion procedure required for the administration of OTARMENI™ which is the first FDA-approved gene therapy for genetic hearing loss.

Later, the AMA CPT Editorial Board changed the effective date of the CPT code 1056T, *Cochlear infusion of pharmacologic agent (ie, gene therapy vector), including mastoidectomy, labyrinthotomy, and repair of fenestrations,* from January 1, 2027, to October 1, 2026. OTARMENI™ is an adeno-associated virus vector-based gene therapy indicated for the treatment of pediatric and adult patients with severe-to-profound and profound sensorineural hearing loss (any frequency >90 dB HL) associated with molecularly confirmed biallelic variants in the *OTOF* gene, preserved outer hair cell function, and no prior cochlear implant in the same ear.

OTARMENI™ is administered as a single dose intracochlear infusion. The recommended dose for each ear is 7.2×10^{12} vector genomes in a total volume of 0.24 ml.

In the CY 2027 OPPS/ASC proposed rule, we proposed to assign CPT code 1056T to SI ''J1'', APC 5163 (Level 3 ENT Procedures) with a proposed payment rate of $1,755.96.

We received public comments on this proposal. The following is a summary of the comments we received.

Comment: The commenters requested that CMS reassign CPT code 1056T from APC 5163 (Level 3 ENT Procedures) to APC 5165 (Level 5 ENT Procedures).

They stated that CPT code 1056T describes a highly specialized surgical procedure that requires significant operative expertise, dedicated training, substantial facility resources, and multidisciplinary coordination. The procedure includes complex otologic surgical components such as mastoidectomy and labyrinthotomy, which are more comparable to higher-acuity ENT procedures than to those typically associated with a Level 3 APC assignment. Because CPT code 1056T includes mastoidectomy as well as additional work associated with intracochlear infusion of a gene therapy vector, the commenters believe that APC 5165 better reflects the resources required to perform the cochlear infusion procedure and represents the most appropriate APC assignment for 1056T.

Commenters also noted that cochlear infusion reported with CPT code 1056T, differs substantially from the procedure described by CPT code 69801 (*Labyrinthotomy, with perfusion of vestibuloactive drug(s), transcanal),* which per our proposed rule review was

determined to be similar to CPT code 1056T and is assigned to APC 5163. CPT code 1056T describes an open surgical approach that includes mastoidectomy, labyrinthotomy, repair of fenestrations, and intracochlear infusion of a gene therapy vector, whereas CPT code 69801 describes a minimally invasive transcanal drug perfusion procedure that does not include mastoidectomy.

Response: We appreciate the commenters' feedback on this new CPT code, and we agree with the commenters' recommendation to change the APC assignment for this code. Because CPT code 1056T describes an open surgical approach that includes mastoidectomy, which differs from a minimally invasive transcanal drug perfusion procedure described by CPT code 69801, we now believe that CPT code 1056T is more appropriately assigned to APC 5165 (Level 5 ENT Procedures).

In summary, after consideration of the public comments we received, we are not adopting our proposal as final. Instead, we are assigning CPT code 1056T to APC 5165 (Level 5 ENT Procedures) for CY 2027.

Table 29 shows the finalized status indicator and APC assignment for this procedure code. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 29: FINAL CY 2027 APC AND STATUS INDICATOR ASSIGNMENT FOR CPT CODE 1056T

HCPCS Code	Long Descriptor	Final CY2027 OPPS SI	Final CY2027 OPPS APC
1056T	Cochlear infusion of pharmacologic agent (ie, gene therapy vector), including mastoidectomy, labyrinthotomy, and repair of fenestrations	J1	5165

2. Vestibular Testing Codes, CPT Codes 92513, 92514, and 92527 (APC 5721)

For CY 2027, the AMA CPT Editorial Board created 4 New Category I CPT codes 92513, 92514, 92527 and 92528 (placeholder CPT codes 92X10, 92X11, 92XX5, and 92XX6). These new codes reflect advances in vestibular testing and provide greater specificity for reporting services used by audiologists to evaluate vestibular function.

- 92513—*Video head impulse testing (vHIT), with recording, interpretation, and report; of lateral semicircular canal function;*
- 92514—*Video head impulse testing (vHIT), with recording, interpretation, and report; of lateral and vertical semicircular canal function;*
- 92527—*Rotational vestibular assessment by sinusoidal harmonic acceleration (SHA) testing with calibrated, computer-controlled chair, with interpretation and report; and*
- 92528—*Rotational vestibular assessment by sinusoidal harmonic acceleration (SHA) testing with calibrated, computer-controlled chair, with interpretation and report; with velocity step testing (VST)*

In the CY 2027 OPPS/ASC proposed rule, we proposed to assign CPT codes 92513, 92514, and 92527 to APC 5721 (Level 1 Diagnostic Tests and Related Services) with status indicator ''S'' and proposed payment rate of $146.93. We proposed to assign CPT code 92528 to status indicator ''N''.

Comment: We received one public comment on this proposal. The commenter supported our assignment of CPT codes 92513, 92514, and 92527 to APC 5721 for CY 2027; however, they were concerned with our proposed assignment of status indicator ''N'' to CPT code 92528 which would package payment for VST into payment for the base rotational vestibular assessment service (CPT code 92527). The commenter stated that the additional velocity step testing represented by CPT code 92528 requires clinical work and resources beyond those necessary to perform the base SHA testing service represented by CPT code 92527. This, according to the commenter, includes additional provider time and greater work intensity associated with CPT code 92528. The new CPT code family distinguishes the base SHA assessment from the additional VST service. The commenter also recognized our longstanding policy of packaging most procedures described by add-on codes. However, they believed that the distinct resource requirements associated with CPT code 92528 warranted reconsideration.

Response: We thank the commenter for their feedback. Our medical advisors reviewed the service described by CPT code 92528, and we do not believe that it takes significant additional time or hospital resources to perform this service. Therefore, we concluded that VST service described by an add-on CPT code 92528 is appropriately packaged into the base SHA testing service described by CPT code 92527. This is consistent with our packaging policy outlined at 42 CFR 419.2(b), which lists the types of items and services for which payment is packaged under the OPPS. Specifically, certain services described by add-on codes.

Therefore, we believe our proposed assignment of status indicator ''N'' to CPT code 92528 remains appropriate. As a result, we are finalizing our proposal without modification to assign CPT code 92528 to status indicator ''N'' for CY 2027.

We refer readers to Addendum D1 to this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda D1 is available via the internet on the CMS website.

Cardiac Related Procedures and Services

4. Cardiac Magnetic Resonance (CMR) Imaging, CPT Codes 75557, 75559, 75561, 75563 (APCs 5523, 5524, 5572, and 5573)

For CY 2027, we proposed to continue to assign the following cardiac magnetic resonance imaging (MRI) CPT codes to APC 5523 (Level 3 Imaging without Contrast), APC 5524 (Level 4 Imaging without Contrast), APC 5572 (Level 2 Imaging with Contrast), and APC 5573 (Level 3 Imaging with Contrast). The codes, long descriptors and payment assignments are listed below.

- CPT code 75557—*Cardiac magnetic resonance imaging for morphology and function without contrast material.* CPT code 75557 is currently assigned to APC 5523 (Level 3 Imaging without Contrast) and has a geometric mean cost of $305 based on 1,453 single frequency claims used for ratesetting;

• CPT code 75559—*Cardiac magnetic resonance imaging for morphology and function without contrast material; with stress imaging.* CPT code 7559 is currently assigned to APC 5524 (Level 4 Imaging without Contrast) and has a geometric mean cost of $378, based on 19 single frequency claims used for ratesetting;

• CPT code 75561—*Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences.* CPT code 75561 is assigned to APC 5572 (Level 2 Imaging with Contrast) and has a geometric mean cost of $460, based on 33,824 single frequency claims used for ratesetting; and

• CPT code 75563—*Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences; with stress imaging.* CPT code 75563 is assigned to APC 5573 (Level 3 Imaging with Contrast) and has a geometric mean cost of $783 based on 3,401 single frequency claims used for ratesetting.

We received one public comment on these codes.

Comment: The commenter states that our ''current modality-based APC structure creates a substantial and increasingly difficult-to-justify payment disparity between clinically comparable advanced cardiac imaging services.'' The commenter suggests that contrast-enhanced cardiac MRI (CMR) requires more hospital resources than single-photon emission computed tomography (SPECT) and positron emission tomography (PET) myocardial perfusion imaging and should not be placed in general imaging APCs with/without contrast APCs that also include non-cardiac related imaging examinations requiring very different resources. According to the commenter, the payment for SPECT and PET is influenced by advanced cardiac imaging while the payment for CMR is influenced by a much broader range of imaging procedures. The commenter refers to the historical placement of CPT 75563 in APC 5593 (Level 3 Nuclear Medicine and Related Services)—before the CY 2017 APC restructuring—and how there is resource and clinical homogeneity between CMR and nuclear cardiac imaging. This is especially important, the commenter continues, because these codes include contrast-enhanced imaging and pharmacologic stress. The commenter notes that these services are paid approximately 40–60 percent less despite the commenter's belief that there is comparable or greater clinical resource intensity.

The commenter requested that we reassign CPT code 75561 to APC 5593 and reassign CPT code 75563 to APC 5594. The commenter also requested that we evaluate the appropriate placement of CPT code 75557 which is currently assigned to APC 5523 and CPT code 75559 which is currently assigned to APC 5524.

Response: We thank the commenter for their thoughtful input. The OPPS payment rates were proposed based on available CY 2025 claims data. Our claims data shows that APC 5593 (Level 3 Nuclear Medicine and Related Services) has a geometric mean cost of approximately $1,433 which is significantly higher than the geometric mean costs of the cardiac MRI codes ($305 to $783).

As stated in last year's final rule (90 FR 53567), we do not believe that cardiac MRI with stress imaging is very similar to myocardial perfusion imaging just because both tests are performed under a stress protocol, and therefore should be assigned to a nuclear medicine APC. APC 5593 contains procedures that describe nuclear medicine tests, not MRI services. We continue to believe (and have stated in previous rulemaking), that MRI services should not be assigned to the nuclear medicine APCs (81 FR 79630 and 90 FR 53567).

In summary, after consideration of the public comment, we are finalizing our proposal without modification to maintain the APC assignments for the cardiac MRI codes for CY 2027. The final CY 2027 payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

5. Cardiac CT Services, CPT Codes 75572, 75573, and 75574 (APC 5572)

Cardiac computed tomography services are described by the following Category I CPT codes and have been effective since January 1, 2010:

• 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); and*

• 75574—*Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed).*

For CY 2027, the OPPS payment rates were proposed based on available CY 2025 claims data for ratesetting. We note that CPT code 75572 has a geometric mean cost of $183 calculated using 41,211 single frequency claims; CPT code 75573 has a geometric mean cost of $234 calculated using 559 claims; and CPT code 75574 has a geometric mean cost of $227 calculated using 116,963 claims. For CY 2027, we proposed to maintain these codes to APC 5572 (Level 2 Imaging with Contrast) with a payment rate of around $400.

As a reminder to readers, we reassigned these codes to APC 5572 in CY 2025 because of the assumption that facilities would have chosen the cardiology revenue code if they had been able to versus the CT scan (035X) and Radiology Diagnostic (032X) revenue codes. We became aware of an edit (that we removed in December 2024) that was prohibiting hospitals from reporting these codes with a cardiology revenue code (048X) which maps to the cardiology cost center (03140). The cardiology cost center has a higher cost-to-charge ratio (CCR) than the imaging cost centers. Utilizing cost centers with lower CCRs results in a lower OPPS payment compared to utilizing cost centers with higher CCRs. With the edit no longer in place, hospitals are able to bill for cardiac CT services with whichever revenue code they believe is appropriate for these services, including cardiology revenue code 048X. For a full discussion of this issue, we refer readers to 89 FR 94057 through 94062. We received public comments on these codes.

Comment: We received numerous comments in support of maintaining the current APC assignment. Commenters requested that we continue to maintain the APC assignment while they continue their efforts to educate their providers and hospitals to change their billing practices. They note that there is continued hesitancy surrounding the selection of appropriate revenue codes because of 'CT' in the coding descriptors. The revenue codes hospitals use to report cardiac CT

services materially affects whether OPPS payment accurately reflects the resources involved in furnishing them. Reporting cardiac CT services under cardiology revenue codes (048x) more accurately reflects the resources associated with furnishing the service. Additionally, a commenter requested that CMS issue sub-regulatory guidance and provider education confirming that cardiology revenue codes are appropriate to report for cardiac CT services, so that facility cost data and OPPS rate-setting better reflect the clinical resources used to provide the services.

Response: We appreciate the commenters' support. Once again, we agree with commenters that effectuating change in any health system can be challenging. As we stated in the CY 2025 OPPS/ASC final rule, we will continue to monitor the claims data for these services, knowing that it may take a number of years before we see changes in the claims data.

As noted previously, commenters continue to request guidance that explicitly states that it is appropriate to use the cardiology revenue codes when billing for cardiac CT services. As a reminder to our readers and as we have previously stated, we do not provide specific coding guidance. We refer our readers to 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 OPPS since hospitals' assignments 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, and 90 FR 53566).

In summary for CY 2027, we are finalizing our proposal without modification and assigning CT codes 75572, 75573, and 75574 to APC 5572 (Level 2 Imaging with Contrast). The final CY 2027 payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator definitions for all codes reported under the OPPs. Addenda B and D1 are available via the internet on the CMS website.

6. Cardiac Leadless Pacemaker Procedures, CPT Codes 0823T, 0796T, 0795T, 0801T, 0802T, and 0825T (APCs 5231 and 5232)

CPT codes 0823T and 0796T describe the insertion of a permanent single-chamber leadless pacemaker and the insertion of a permanent dual-chamber leadless pacemaker when a right ventricular single leadless pacemaker already exists. Their long descriptors and current APC and status indicators are listed below.

- CPT code 0823T—*(Transcatheter insertion of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (e.g., interrogation or programming), when performed);* assigned to APC 5224 (Level 4 Pacemaker and Similar Procedures) and status indicator 'J1'.
- CPT code 0796T—*Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual-chamber leadless pacemaker system);* assigned to APC (Level 4 Pacemaker and Similar Procedures) and status indicator 'J1'.

CPT codes 0795T and 0801T describe the insertion of a permanent dual-chamber leadless pacemaker and the removal and replacement of a permanent dual-chamber leadless pacemaker Their long descriptors and current APC and status indicators are listed below.

- 0795T—*Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; complete system (i.e., right atrial and right ventricular pacemaker components);* assigned to APC 5224 (Level 4 Pacemaker and Similar Procedures) and status indicator 'J1'.
- 0801T—*Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; dual-chamber system (i.e., right atrial and right ventricular pacemaker components);* assigned to APC 5224 (Level 4 Pacemaker and Similar Procedures) and status indicator 'J1'.

We note that CPT codes 0795T and 0801T are currently receiving device pass-through payments (approximately $15,000 in addition to the APC payment) when coded with C1605 *(Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation).* When pass-through payment expires at the end of CY 2026, the device costs are packaged into the current APC payment.

For the CY 2027 OPPS/ASC proposed rule, we proposed to make the following reassignments:

- CPT code 0823T—Reassign to APC 5231 (Level 1 ICD and Similar Procedures) with a payment rate of approximately $25,000;
- CPT code 0796T—Reassign to APC 5231 (Level 1 ICD and Similar Procedures) with a payment rate of approximately $25,000;
- CPT code 0795T—Reassign to APC 5232 (Level 2 ICD and Similar Procedures) with a proposed payment rate of approximately $35,200; and
- CPT code 0801T—Reassign to 5232 (Level 2 ICD and Similar Procedures) with a proposed payment of approximately $35,200.

We received public comments on these proposals. A summary of the comments and our responses are listed below.

Comment: We received numerous comments supporting our proposal. Several commenters noted how clinically valuable these procedures are and that the increased payment for these services will preserve beneficiary access to these procedures. A couple of commenters requested that we also reassign CPT codes 0802T and 0825T from APC 5224 to APC 5231 to establish cost-reflective payment across the full set of leadless pacemaker procedures.

Response: We thank the commenters for their support. We reviewed CPT codes 0802T *(Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; right atrial pacemaker component)* and CPT code 0825T *(Transcatheter removal and replacement of permanent single-*

chamber leadless pacemaker, right atrial, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (e.g., interrogation or programming), when performed) and note that the geometric mean cost for CPT code 0802T is $31,531 based on five single claims and the geometric mean cost for CPT code 0825T is $25,393 based on 12 single frequency claims. Even though these codes are new and there are only a few claims, we agree with the commenters that we should reassign CPT codes 0802T and 0825T to APC 5231 based on clinical and resource coherence with the other leadless pacemaker codes.

As we do every year, we will monitor the claims data and reevaluate the APC assignments for these codes in the next rulemaking cycle to determine if a more appropriate APC assignment is warranted. In summary, after consideration of the public comments we received, we are finalizing our proposal without modification, to assign CPT codes 0823T and 0796T to APC 5231 (Level 1 ICD and Similar Procedures) and to assign CPT codes 0795T and 0801T to APC 5232 (Level 2 ICD and Similar Procedures). We are also finalizing our proposal with modification to assign CPT codes 0802T and 0825T to APC 5231 (Level 1 ICD and Similar Procedures). The final CY 2027 payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website. Refer to Table 30 for the code descriptors and APC and status indicator assignments for CPT codes 0802T and 0825T for CY 2027.

TABLE 30: CY 2027 PROPOSED AND FINAL APC, SI ASSIGNMENTS FOR CPT CODES 0802T AND 0825T

CPT Code	Long Descriptor	Proposed CY 2027 APC, SI	Final CY 2027 APC, SI
0802T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component	5224, J1	5231, J1
0825T	Transcatheter removal and replacement of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (eg, interrogation or programming), when performed	5224, J1	5231, J1

7. C-Codes Describing Percutaneous Coronary Intervention With Drug-Eluting Stents

Effective January 1, 2013, CMS created several HCPCS C-codes to describe certain percutaneous coronary intervention procedures utilizing drug eluting stents to mirror those PCI CPT codes that do not utilize drug eluting stents. The AMA CPT Editorial Board deleted several of those CPT codes effective January 1, 2026. For CY 2027, we proposed to delete the following C-codes that mirrored the deleted CPT codes, specifically revising the status indicators to ''D'' (Discontinued Codes) indicating that they are no longer active codes (91 FR 41811). The C-codes and their long descriptors are listed below.

- C9601—*Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure).*
- C9603—*Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure).*
- C9605—*Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure).*
- C9608—*Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure).*

We received several comments related to this proposal.

Comments: Commenters supported the deletion of these C-codes but a couple of commenters requested that we create a new C-code to mirror CPT code 92930 (*Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed, single major coronary artery and/or its branch(es); 2 or more distinct*

coronary lesions with 2 or more coronary stents deployed in 2 or more coronary segments, or a bifurcation lesion requiring angioplasty and/or stenting in both the main artery and the side branch) when two drug eluting stents are used in two or more distinct lesions. The commenters stated that without an equivalent C-code for this scenario, there would be a CPT/HCPCS mismatch.

Response: We thank the commenters for their support to delete the previous C-codes. We disagree with commenters that a new C-code should be created to mirror CPT code 92930. The deleted C-codes were created when drug-eluting stents were novel and had significantly higher costs associated with them and we needed a mechanism to capture those costs. We believe that the gap between the costs of drug-eluting stents and bare metal stents are not as significant as they were over ten years ago when these C-codes were created.

In summary, after consideration of the public comments we received, we are finalizing our proposal without modification to delete the previous HCPCS C-codes and decline to create a C-code at this time to mirror CPT code 92930.

Cell and Gene Therapy Related Services

8. Chimeric Antigen Receptor (CAR-T) Administration, CPT Code 38228 (APC 5694)

Chimeric Antigen Receptor T-Cell (CAR T-cell) therapy is a cell-based gene therapy in which T-cells are collected and genetically engineered to express a chimeric antigen receptor that will bind to a certain protein on a patient's cancerous cells. The CAR T-cells are then administered to the patient to attack certain cancerous cells, and the individual is observed for potential serious side effects that would require medical intervention. We refer readers to previous discussions in the OPPS/ASC final rules with comment period for background regarding the specific CAR T-cell products, including the CY 2020 OPPS/ASC final rule with comment period (84 FR 61231 through 61234) and the CY 2019 OPPS/ASC final rule with comment period (83 FR 58904 through 58908). The AMA created four Category III CPT codes that are related to CAR T-cell therapy, effective January 1, 2019. We also finalized that the procedures described by CPT code 0540T would be assigned status indicator ''S'' (Procedure or Service, Not Discounted when Multiple) and APC 5694 (Level 4 Drug Administration) from CY 2019 through CY 2024 and did not propose to change the APC assignment for CY 2025 when CPT code 0540T was replaced by CPT code 38228 (Chimeric antigen receptor T-cell (CAR–T) therapy; CAR–T cell administration, autologous). For CY 2027, we proposed to maintain CPT code 38228 to APC 5694 and status indicator 'S'. We received one comment.

Comment: A commenter requested that CMS reassign CPT code 38228 (CAR T-cell administration) from APC 5694 (Level 4 Drug Administration) to APC 5242, citing closer clinical alignment with CPT 38241 (Hematopoietic progenitor cell (HPC); autologous transplantation) than with the other services currently assigned to APC 5694.

Response: We appreciate the commenter's feedback and reviewed the claims data and the clinical considerations raised. We note that in the CY 2019 OPPS/ASC final rule, CMS compared payment for CAR T-cell administration to CPT code 96413 (Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug) in the absence of available claims data. We still believe this is a clinically similar HCPCS code and the claims data for CPT code 38228 are reasonably in range with its current APC placement relative to the suggested APC 5242. We will consider this public comment in future rulemaking. After review of the service and with input from our medical advisors, we are finalizing as proposed.

The final CY 2027 payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

Diagnostic Tests

9. Syn-One Test®

The Syn-One Test® detects phosphorylated synuclein to aid clinicians in the diagnosis of a synucleinopathy, which includes Parkinson's disease, dementia with Lewy bodies, multiple system atrophy, and related neurodegenerative disorders. Three small skin biopsies are taken from the patient at different sites and sent to the CND lab for analytical processing, staining, imaging, and pathology interpretation under CND's validated laboratory procedures. CND then reports the results to the patient's provider. The hospital does not perform any of the testing.

Syn-One bills with established pathology CPT codes from the Physician Fee Schedule (PFS), including CPT codes 88305 *(Tissue exam by pathologist),* 88314 *(Special stain including interpretation and report; histochemical stain on frozen tissue block (List separately in addition to code for primary procedure)),* 88346 *(Immunofluorescence, per specimen; initial single antibody stain procedure),* 88350 *(Immunofluorescence, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure)),* and 88356 *(Morphometric analysis; nerve).* We received one public comment on this service.

Comment: A commenter requested a limited exception to the laboratory date of service (DOS) policy and our packaging rules for specialized pathology services performed after the patient's hospital outpatient encounter. The commenter also requested a G-code and an appropriate status indicator to identify the specialized pathology services that are not subject to the date of service policy. The commenter also noted that we are proposing to pay for certain algorithmic analyses performed on laboratory tests under the OPPS instead of the Clinical Laboratory Fee Schedule.

Response: We thank the commenter for their input. We are not making any changes to the DOS policy in this final rule, but we may consider this issue in future rulemaking.

The commenter is welcome to apply for a HCPCS code to describe the Syn-One Test® through the Medicare Electronic Application Request Information System (MEARIS) on the CMS website.

10. Transdermal Glomerular Filtration Rate (TGFR) System CPT Codes 0602T and 0603T (APC 5721)

The CPT Editorial Panel created CPT code 0602T (*Glomerular filtration rate (GFR) measurement(s), transdermal, including sensor placement and administration of a single dose of fluorescent pyrazine agent)* and 0603T (*Glomerular filtration rate (GFR) monitoring, transdermal, including sensor placement and administration of more than one dose of fluorescent pyrazine agent, each 24 hours),* which became effective July 1, 2020, and describes a transdermal glomerular filtration rate measurement device called the TGFR system. The device is used to monitor and assess kidney function in real time by measuring fluorescence intensity transdermal as a function of time via a reuseable sensor placed on the skin.

For CY 2027, we proposed to maintain the status indicator assignments for CPT codes 0602T and 0603T of 'Q4' (Conditionally Packaged Laboratory Tests; Paid under OPPS or CLFS). We note that we have no claims data for ratesetting purposes.

The following is a summary of the comments we received and our response.

Comment: We heard from several commenters, including the manufacturer who requested that CMS provide clarification on its treatment of CPT 0602T and 0603T and its assignment to a ''Q4'' status indicator. Commenters also requested that we assign CPT 0602T and 0603T to an appropriate APC and status indicator so that they may receive payment under OPPS.

One commenter stated that the TGFR system was approved by the FDA in December of 2025 and placed in medical centers in 2026. The commenter notes that the devices were assigned a status indicator of ''Q4'', suggesting that CPT codes 0602T and 0603T are associated with a clinical laboratory test. The commenter opines that MediBeacon® Transdermal GFR system is not regulated under 42 CFR 493 Laboratory Requirements (CLIA).

The commenter notes that the TGFR System does not require any blood, plasma, urine or other specimens outside the body to assess kidney function and as such it is an *in vivio* test and not an *in vitro* diagnostic. The commenter states the TGFR System is used on the patient themselves and no lab is required.

Response: We thank the commenters for their input. After further evaluation and discussion with our medical officers, we believe that it is appropriate for the procedure described by CPT codes 0602T and 0603T to be paid separately. Therefore, we are reassigning CPT codes 0602T and 0603T to APC 5721 (Level 1 Diagnostic Tests and Services) and status indicator 'S' (Procedure or Service, Not Discounted When Multiple; Paid under OPPS; separate APC payment).

In summary, after consideration of the public comments, we are finalizing with modification the APC and status indicator assignment for CPT codes 0602T and 0603T. Specifically, we are finalizing the assignment of CPT codes 0602T and 0603T to APC 5721 (Level 1 Diagnostic Tests and Services) and we are revising the status indicator for CPT codes 0602T and 0603T to 'S' indicating that these services are separately payable. Refer to Table 31 for the long descriptors, APC assignments, and status indicator assignments for CPT codes 0602T and 0603T for CY 2027.

The final CY 2027 payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 31: PROPOSED AND FINAL CY 2027 APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 0602T AND 0603T

CPT Code	Long Descriptor	Proposed CY 2027 APC, SI	Final CY 2027 APC, SI
0602T	Glomerular filtration rate (GFR) measurement(s), transdermal, including sensor placement and administration of a single dose of fluorescent pyrazine agent	Q4	5721, S
0603T	Glomerular filtration rate (GFR) monitoring, transdermal, including sensor placement and administration of more than one dose of fluorescent pyrazine agent, each 24 hours	Q4	5721, S

Dialysis Related Services and Technologies

11. Dialysis-Related Amyloidosis (DRA) Treatment With LIXELLE® Apheresis Columns and Dialysis Technologies

LIXELLE® b2-microglobulinApheresis Column is indicated for use in the treatment of dialysis-related amyloidosis (DRA), a disease that affects people with end-stage renal disease (ESRD). DRA is a metabolic disorder from the failure of the kidney to filter and remove b2 microglobulin, typically from chronic hemodialysis (typically 5 years or longer). The LIXELLE® device is used in an apheresis procedure that selectively removes b2-microglobulin from circulating blood and is used in accordance with a physician prescription in conjunction with hemodialysis. It is intended to be used at each hemodialysis session (that is, frequency of treatment is expected to be 3 times per week). In March 2015, FDA approved a Humanitarian Device Exemption (HDE) application for LIXELLE® a Class III Humanitarian Use Device (HUD).

For CY 2027, there are currently no specific HCPCS or CPT codes that represent the service performed with the LIXELLE® apheresis device. We received public comments on this topic. The following is a summary of the comments we received and our responses.

Comment: A commenter notes that access to LIXELLE® has been limited by the lack of a clear reimbursement pathway, and they urge CMS to clarify coverage in the OPPS Final Rule for the benefit of the small number of patients with DRA. The commenter states that the FDA recognizes that there continues to be no feasible alternative treatments for DRA in the United States, and that extensive clinical evidence supports LIXELLE® as reasonable and necessary for the treatment of DRA.

The commenter understands that CMS continues to evaluate how to facilitate Medicare reimbursement for treatments of medical devices that are administered during dialysis procedures but that are not ''renal dialysis services'' and supports a CMS policy clarification that such treatments and dialysis procedures that accompany them are appropriately reimbursed through OPPS benefit. The commenter reminded CMS

that the FDA further clarified that ''qualified health care professionals such as physician assistants, nurse practitioner or registered nurses are qualified to supervise hemodialysis procedures'' to alleviate previous clinical supervision concerns.

Another commenter supported the payment of dialysis technologies not included in the End Stage Renal Disease (ESRD) bundle through the OPPS and urged CMS to assign an appropriate APC to facilitate payment for the apheresis procedure with LIXELLE® in the OPPS.

Response: We appreciate the comments and continued interest regarding coverage and payment for medical device technologies used in conjunction with dialysis services, such as LIXELLE® for the treatment of DRA. We understand that DRA represents a serious complication for long-term dialysis patients and the need for effective treatment options. We continue to contemplate coverage pathways for innovative treatments that address unmet medical needs in the ESRD population and note this complex, ongoing issue is still under consideration.

We remind commenters that routine outpatient maintenance dialysis for End-Stage Renal Disease (ESRD) is not paid under the OPPS and because the treatment with Lixelle is used at each hemodialysis session (*e.g.,* routine maintenance dialysis), we do not believe that the OPPS is a viable option for payment for the DRA treatment with LIXELLE® at this time. We also recognize the challenges of ensuring appropriate payment pathways for innovative treatments that may be administered during dialysis but fall outside the definition of a renal dialysis service under § 413.171 and thus are not paid for under the ESRD PPS.

We will continue to evaluate the appropriate payment mechanisms for such technologies for future rulemaking.

Endoscopy Procedures

12. Esophagogastroduodenoscopy, Flexible, Transoral; With Optical Endomicroscopy, CPT Code 43252 (APC 5302)

CPT code 43252 describes an upper gastrointestinal endoscopy that includes real-time, microscopic tissue analysis using optical endomicroscopy.

In the CY 2027 OPPS/ASC proposed rule, we proposed to continue assigning CPT code 43252 to APC 5302 (Level 2 Upper GI Procedures) with status indicator ''J1'', and a proposed payment rate of $2,185.75 for CY 2027.

Comments: We received one public comment related to this code.

The manufacturer requested that we use CMS's equitable adjustment authority under section 1833(t)(2)(E) of the Social Security Act to reassign CPT 43252 to APC 5303 (Level 3 Upper GI Procedures) for CY 2027 or assign CPT 43252 to an appropriate New Technology APC to stabilize payment while representative cost data accumulate. They further asked that CMS issue guidance on how hospitals should report per-use costs for reposable devices.

They described an ongoing underreporting issue that some hospitals reported starting in 2024 and noted that even though the number of hospitals that reported CPT code 43252 had declined from sixteen to fifteen, the geometric mean cost of CPT code had risen from $1,727.65 to $2,343.31 (an increase of $615.66, or approximately 36 percent) between the CY 2026 final rule and this proposed rule. According to the manufacturer, this is underreporting correcting itself because a shrinking group of hospitals started to slowly correct chargemaster practices for reposable device costs, and measured costs climbed toward the true cost of the procedure.

Response: As we have stated regularly over the history of the OPPS, it is the responsibility of providers and other interested parties, not CMS, to resolve potential claims and cost reporting issues for individual CPT codes and medical services payable by Medicare. In the claims available for OPPS ratesetting for this final rule, CPT code 43252 has an estimated geometric mean cost of $2,323.30 based on 176 single claims. The geometric mean cost of APC 5302 (Level 2 Upper GI Procedures) is $2,034.07. We believe that the proposed placement of CPT code 43252 in APC 5302 remains appropriate based on its geometric mean cost relative to that of the APC.

Therefore, we are finalizing our proposal, without modification, to continue to assign CPT code 43252 to APC 5302 for CY 2027. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website. We will continue to monitor the claims data and adjust the APC placement for CPT code 43252 based on the claims data in future rulemaking.

13. Endoscopic Submucosal Dissection, CPT 43498 and 45991 (APC 5303 and 5313)

Effective January 1, 2027, the AMA CPT Editorial Panel created CPT codes 43498 (Endoscopic submucosal dissection (ESD) of upper gastrointestinal tract, including mucosal closure, when performed) and 45991 (Endoscopic submucosal dissection (ESD) of lower gastrointestinal tract, including mucosal closure, when performed), previously described by placeholder CPT codes 4XX01 and 4XX02 respectively. For CY 2027, we proposed to assign CPT codes 43498 to APC 5303 (Level 3 Upper GI Procedures) with a proposed payment rate of around $4,306. We also proposed to assign CPT code 45991 to APC 5313 (Level 4 Lower GI Procedures). Additionally, we proposed to delete HCPCS code C9779 (Endoscopic submucosal dissection (esd), including endoscopy or colonoscopy, mucosal closure, when performed), which served as the predecessor code for CPT codes 43498 and 45991. For CY 2026, HCPCS code C9779 was assigned to APC 5303.

We received public comments on this proposal. The following is a summary of the comments we received and our response.

Comment: Six commenters requested that we reassign CPT codes 43498 and 45991 to APC 5331 (Complex GI Procedures), which had a proposed payment rate of around $7,141. Commenters stated that the procedures described by CPT codes 43498 and 45991 are clinically similar to the CPT code 43497 (Lower esophageal myotomy, transoral (*i.e.,* peroral endoscopic myotomy [POEM])).

Response: We thank the commenters for their input. After further review, we agree with the commenters that CPT codes 43498 and 45991 are clinically similar to the POEM procedure described by CPT code 43497. Additionally, our updated claims data shows that the predecessor code C9779 had a geometric mean cost of around $5,278, showing that the cost of the procedure may be higher than the payment for its previously assigned APC. Therefore, we are finalizing our proposal with modification to assign CPT codes 43498 and 45991 to APC 5331 (Complex GI Procedures), as reflected in Table 32. The final CY 2027 payment rate for the code can be found in Addendum B to this final rule with comment period. We also refer readers to Addendum D1 to this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 32: PROPOSED AND FINAL CY 2027 OPPS APC AND SI ASSIGNMENTS FOR CPT CODES 43498 AND 45991

CPT Code	Long Descriptor	Proposed CY 2027 SI	Proposed CY 2027 APC	Final CY 2027 SI	Final CY 2027 APC
43498	Endoscopic submucosal dissection (ESD) of upper gastrointestinal tract, including mucosal closure, when performed	J1	5303	J1	5331
45991	Endoscopic submucosal dissection (ESD) of lower gastrointestinal tract, including mucosal closure, when performed	J1	5313	J1	5331

Endovascular and Vascular Procedures

14. Permanent Placement of Common Carotid Artery Filters, CPT Code 1091T (APC 1576)

Effective April 1, 2026, we created HCPCS code C8010 *(Percutaneous placement of permanent common carotid embolic protection device, including all system components and imaging guidance; bilateral)* as a result of a New Technology APC application. This code is associated with Javelin Medical's clinical study that was approved by CMS for Medicare coverage on July 30, 2024, as a Category B IDE study.[21] Because the clinical study is conducted in the hospital outpatient setting, we created HCPCS code C8010 and initially assigned it to APC 1575 (New Technology—Level 38 ($10,001–$15,000)) with a payment rate of $12,500.50. The study information is listed below in Table 33.

TABLE 33: Permanent Placement of Common Carotid Artery Filters Category B Investigational Device Exemption (IDE) Study

Study Title	Sponsor Name	NCT Number	IDE Number	CMS Approval Date	Category
Carotid Implants for PreveNtion of STrokE ReCurrEnce From Large Vessel Occlusion in Atrial Fibrillation Patients Treated With Oral Anticoagulation	Javelin Medical	NCT05723926	G220272	07/30/2024	B

We then heard from the interested parties informing us that the APC assignment does not cover all of the costs associated with the procedure and care when the implants alone each cost $5,000. After review of the additional information provided and input from our medical advisors, we reassigned HCPCS code 8010 to APC 1576 (New Technology—Level 39 ($15,001–$20,000)) with a payment of $17,500.50 effective July 1, 2026.

At the beginning of August, the AMA announced that the Category III codes that were released in July with an effective date of January 1, 2027, have a new effective date of October 1, 2027. We note that the AMA Editorial Panel created CPT placeholder code X626T (permanent code 1091T) to describe the placement of bilateral carotid artery filters. The long descriptor is as follows:

- CPT 1091T—*Placement of permanent common carotid artery filter, percutaneous, bilateral, including ultrasound guidance, when performed.*

For the October quarterly update, we deleted the predecessor HCPCS code C8010 and assigned CPT code 1091T to APC 1576 (New Technology—Level 39 ($15,001–$20,000)) with a status indicator (SI) of 'S' effective October 1, 2026, because CPT code 1091T describes the same procedure that HCPCS code C8010 did.

For CY 2027, we proposed to assign CPT code 1091T to APC 1576 (New Technology—Level 39 ($15,001–$20,000)) and delete HCPCS code C8010.

Comment: We received a comment requesting that we finalize the APC assignment for the placement of the permanent carotid filters under the auspices of the new Category III CPT code.

Response: We appreciate the comment and agree with the commenter.

In summary, after consideration of the public comment we received, we are finalizing our proposal to delete HCPCS C8010 and assign CPT code 1091T to APC 1576 (New Technology—Level 39 ($15,001–$20,000)). The final CY 2027 payment rates for this code can be found in Addendum B to this final rule with

[21] *https://www.cms.gov/medicare/coverage/investigational-device-exemption-ide-studies/approved/g220272-nct05723926.*

comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

15. Venous Mechanical Thrombectomy, CPT Code 37187 (APC 5193)

CPT code 37187 (Percutaneous transluminal mechanical thrombectomy, vein(s), including intraprocedural pharmacological thrombolytic injections and fluoroscopic guidance) was made effective January 1, 2006 and discussed in the CY 2007 OPPS final rule. Since the CY 2018 OPPS, this code has been assigned to the Endovascular Procedures APC series and has been assigned to APC 5193 since the CY 2021 OPPS (85 FR 85987).

Comment: A commenter requested that CMS reconsider the current methodology used to determine claims for ratesetting for CPT code 37187 and the proposed assignment of the code to APC 5193. The commenter opined that the current rate does not adequately reflect the reported geometric mean cost for the procedure and variation in the costs at the claim level. The commenter, using the growth in Medicare usage of venous thrombectomy and increased utilization of the hospital outpatient setting, asked CMS to consider whether the rate-setting claims adequately reflect current practice patterns and the adoption of technology, variation in coding, complexity of patients, and site-of-service trends, and to consider whether additional data or a different methodology would better determine accurate payments.

Response: We appreciate the commenter's concerns regarding payment for CPT code 37187. CMS previously reassigned CPT 37187 from APC 5192 to APC 5193 for CY 2021 after finding that its geometric mean cost was comparable to other clinically related thrombectomy and endovascular services in APC 5193 (85 FR 85987). We reviewed the most updated claims data available for CY 2027 rate setting and continue to believe that APC 5193 appropriately reflects the clinical characteristics and relative resource costs of CPT code 37187. Under the OPPS, payment rates are established at the APC level based on the geometric mean cost of all applicable services assigned to the APC based on clinical and cost similarity. The number of claims used to calculate the geometric mean cost for CPT code 37187 represents claims remaining after application of the comprehensive APC rate-setting methodology and should not be interpreted as total Medicare utilization. Under that methodology, qualifying higher-cost combinations involving CPT code 37187 receive a complexity adjustment and are reassigned to the next higher-level endovascular APC. Consequently, those complexity-adjusted claims are removed from the cost calculation for CPT code 37187 in APC 5193 and included separately in APC 5194. We further note that most claims containing CPT code 37187 that were available were used for OPPS ratesetting purposes, whether for the code itself or as part of a code combination qualifying for complexity adjustment.

Although the commenter identified variation among CPT code 37187 claims, this variation does not, by itself, demonstrate that the claims are inaccurate or that the service is inappropriately assigned. Moreover, we believe that some of that variation is a reflection of the varying practice patterns in the claims containing codes, most of which we are using in our OPPS ratesetting process. Therefore, we are finalizing the assignment of CPT code 37187 to APC 5193.

16. Simulation Angiogram for Radioembolization of Tumors, HCPCS Code C8004 (APC 5194)

CMS created HCPCS code C9797 (*Vascular embolization or occlusion procedure with use of a pressure-generating catheter (e.g., one-way valve or occlusion balloon, intermittently or temporarily occluding), inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction*) to describe a vascular embolization or occlusion procedure with use of a pressure-generating catheter effective April 1, 2024. We assigned C9797 to APC 5194 (Level 4 Endovascular Procedures) and a status indicator of 'J1'.

CMS then created HCPCS C8004 *(Simulation angiogram with use of a pressure-generating catheter (e.g., one-way valve or occlusion balloon, intermittently or temporarily occluding), inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the angiogram, for subsequent therapeutic radioembolization of tumors)* to describe the simulation angiogram service using a pressure-generating catheter effective April 1, 2025. We assigned HCPCS code C8004 to APC 5193 (Level 3 Endovascular Procedures) and status indicator 'J1'. The simulation procedure has a nearly identical workflow to the embolization procedure, including the use of the same pressure-generating catheter, and allows delivery of the diagnostic radioactive tracer to maximize the radiation dose to the tumor and avoid the normal liver tissue. The simulation procedure is followed by the embolization procedure usually 3 to 14 days later.

HCPCS code C1982 *(Catheter, pressure-generating, (e.g., one-way valve or occlusion balloon, intermittently or temporarily occluding)* describes the type of catheter used with these procedures. The device code is currently assigned to status indicator 'N' which means it is packaged with the procedure code.

For CY 2027, we proposed to maintain the payment assignments for all three HCPCS codes. We did, however, update the long descriptors for all three HCPCS codes for the October 2026 OPPS update to broaden the definition of pressure-generating catheter. We are also aware of the new HCPCS G-code G0577 *(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 performed in the non-facility setting)* that was created for the non-facility setting and is retroactive to July 1, 2026. HCPCS G-code G0577 is assigned to status indicator B and is not payable in the OPPS.

We received one public comment on HCPCS code C8004.

Comment: We received one comment requesting that we reassign HCPCS code C8004 to APC 5194 (Level 4 Endovascular Procedures) because of the clinical and resource similarities between C8004 and C9797. The commenter states that these two procedures are the same except that C8004 uses a diagnostic radiopharmaceutical for the simulation angiogram and C9797 uses a brachytherapy source for the embolization treatment. The commenter also pointed to the geometric mean cost (GMC) of C8004 and how it is within the range of significant procedures assigned to APC 5194.

Response: We appreciate the commenter's input. First, we note that the GMC for APC 5193 (Level 3 Endovascular Procedures) is $12,304 and the GMC for APC 5194 (Level 4 Endovascular Procedures) is $19,661.

Second, the GMC for C8004 is $22,076, and the GMC for C9797 is $21,910. We agree with the commenter and believe that APC 5194 is a more appropriate assignment for C8004 based on clinical and resource homogeneity.

In summary, after consideration of the public comment we received, we are modifying our proposal and finalizing assignment of HCPCS code C8004 to APC 5194 (Level 4 Endovascular Procedures). While we did not receive public comment on the OPPS proposed rule on the coding descriptors for these codes, we will review the coding descriptors for these codes, including the new G-code, for the January 2027 quarterly update to determine if further coding/descriptor refinements are necessary. Refer to Table 34 for the code descriptor, APC assignment, and status indicator assignment for HCPCS code C8004 for CY 2027.

The final CY 2027 payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator (SI) definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 34: PROPOSED AND FINAL CY 2027 APC AND STATUS INDICATOR ASSIGNMENT FOR HCPCS CODE C8004

HCPCS Code	Long Descriptor	Proposed CY 2027 APC, SI	Final CY 2027 APC, SI
C8004	Simulation angiogram 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 angiogram, for subsequent therapeutic radioembolization of tumors	5193, J1	5194, J1

Gastrointestinal Related Procedures

17. Colorectal Anastomosis (Colovac), CPT Code 0967T

The CPT Editorial Panel created CPT code 0967T (Transanal insertion of endoluminal temporary colorectal anastomosis protection device, including vacuum anchoring component and flexible sheath connected to external vacuum source and monitoring system) which became effective July 1, 2025, and describes the insertion of a device called the Colovac. The device is used following colorectal surgery to protect the anastomotic site from contact with fecal matter.

For CY 2027, we proposed to maintain the APC assignment to 5312 (Level 2 Lower GI Procedures) and status indicator 'T'. We note that we have zero claims for ratesetting purposes. The following is a summary of the comments we received and our response.

Comment: We heard from several commenters, including the manufacturer who requested that we reassign CPT code 0967T to a status indicator of 'E1' while the Colovac device is still investigational. Commenters also requested that we remove CPT code 0967T from the ASC Covered Procedures List.

Response: We thank the commenters for their input. We are unable to determine if the Colovac device has received marketing authorization by the FDA. Services with devices that lack FDA marketing authorization are assigned to status indicator 'E1' (Not covered by any Medicare outpatient benefit category; Statutorily excluded by Medicare, Not reasonable and necessary; Not paid by Medicare when submitted on outpatient claims) and are not payable in HOPDs or in ASCs. We look forward to hearing from the manufacturer when FDA marketing authorization has been obtained.

In summary, after consideration of the public comments that we received, we are finalizing our proposal with modification. We are assigning CPT code 0967T to status indicator 'E1' and removing this code from the ASC Covered Procedures List. We refer readers to Addendum D1 to this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website.

18. Gastrointestinal Myoelectrical Activity Study (Stomach Through Colon), CPT Code 0779T (APC 5723)

Effective January 1, 2023, CPT code 0779T (Gastrointestinal myoelectrical activity study, stomach through colon, with interpretation and report) is often associated with abdominal patches, that records myoelectric signals of the gastrointestinal tract from the stomach, small and large intestines, over multiple days, such as the G-Tech Medical's GutTracker Wireless Patch System. Since CPT code 0779T became effective January 1, 2023, we have had no claims and therefore have maintained its initial APC assignment to APC 5723 (Level 3 Diagnostic Tests and Related Services).

For CY 2027, the OPPS payment rates were based on available CY 2025 claims data. CPT code 0779T does not currently have any single claims. Because we did not have any available claims data, we proposed to continue to assign CPT code 0779T to APC 5723 for CY 2027.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A commenter, the manufacturer, requested reassignment of 0779T from APC 5723 (Level 3 Diagnostic Tests and Related Services) to APC 5724 (Level 4 Diagnostic Tests and Related Services). The commenter stated that APC 5723 is inadequate to cover the costs of the hospital's supplies, equipment, and staff needed to provide this service. The commenter cited the acquisition of continuous physiologic data across three gastrointestinal organ regions for up to six days and the required post-acquisition processing for CPT 0779T as justification for the higher-level APC assignment. The commenter claimed clinical and resource coherence to CPT code 91035 (Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH

electrode placement, recording, analysis and interpretation) as a multi-day, multi-organ ambulatory diagnostic.

Response: We thank the commenter for their comment. After further review and additional discussion with our medical officers, we are finalizing our proposal without modification to continue to assign CPT code 0779T to APC 5723 for CY 2027. CMS continues to believe that assigning CPT code 0779T to APC 5723 is supported. More specifically, CMS believes CPT code 0779T shares more clinical and resource similarities with the services assigned to APC 5723 than those assigned to APC 5724, which are generally more complicated and invasive services. In regard to the commenter's reference to similarities to CPT code 91035, we note that while CPT code 0779T and CPT code 91035 are both diagnostic gastroenterology tests used to track physiological activity inside the digestive tract, we believe the invasiveness of the upper endoscopy included in CPT code 91035 requires more resources than an external wearable patch system described by CPT code 0779T. We will continue to monitor the claims data and update the payment rate in future rulemaking based on the available claims.

The final CY 2027 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

19. Gastric Electrophysiology Mapping With Simultaneously Validated Patient System Profiling (GEMS) Service, CPT Code 0868T (APC 5724)

Effective July 1, 2023, based on a New Technology application received by CMS for the GEMS service, CMS established HCPCS code C9787 (Gastric electrophysiology mapping with simultaneous patient symptom profiling) and assigned it to APC 5723 (Level 3 Diagnostic Tests and Related Services) based on a crosswalk to CPT code 0779T. Effective July 1, 2024, HCPCS code C9787 was deleted and replaced by CPT code 0868T (High-resolution gastric electrophysiology mapping with simultaneous patient symptom profiling, with interpretation and report). CMS assigned CPT code 0868T to APC 5723, the same APC to which its predecessor code, HCPCS code C9787, was assigned. For CY 2026, CMS maintained the APC assignment for CPT code 0868T.

For CY 2027, CMS proposed to continue to assign CPT code 0868T to APC 5723 with a proposed payment rate of $435.61. For CY 2027 ratesetting, there are 37 single frequency claims available for CPT code 0868T, with a geometric mean cost of $2,497.78.

The manufacturer of the GEMS service presented at the August 2026 meeting of the Advisory Panel on Outpatient Payment (HOP Panel). The HOP Panel recommended to reassign CPT code 0868T to APC 5724 (Level 4 Diagnostic Tests and Related Services) for CY 2027.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: We received several comments requesting that we reassign CPT code 0868T from APC 5723 to APC 5724 consistent with the HOP Panel's August 2026 recommendation. Commenters pointed to the cost disparity between CPT code 0868T's geometric mean cost and APC 5723's proposed payment rate. Commenters explained that the current payment provided for the service is inadequate to cover the costs and requested that CMS set payment at a level that allows hospitals to continue to furnish the service.

Response: We thank the commenters for their input. We agree with commenters and the HOP Panel's August 2026 recommendation that the proposed APC assignment for CPT code 0868T is inappropriate at this time based on a review of the available claims data. Additionally, we believe that CPT code 0868T shares similarities with CPT code 91035 (Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation) and is proposed to be assigned to APC 5724 with status indicator ''S''.

Therefore, based on the comments received, we are not finalizing the APC assignment for CPT code 0868T as proposed. For CY 2027, we are finalizing assigning CPT code 0868T to APC 5724 (Level 4 Diagnostic Tests and Related Services). Refer to Table 35 for the code descriptor, APC assignment, and status indicator assignment for CPT code 0868T.

The final CY 2027 payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator (SI) definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 35: PROPOSED AND FINAL CY 2027 OPPS APC AND SI ASSIGNMENT FOR CPT CODE 0868T

HCPCS Code	Long Descriptor	Proposed CY 2027 OPPS APC, SI	Final CY 2027 OPPS APC, SI
0868T	High-resolution gastric electrophysiology mapping with simultaneous patient symptom profiling, with interpretation and report	5723, S	5724, S

Imaging Services

20. Duplex Scan of Hemodialysis Fistula, CPT Code 0876T

The AMA CPT Editorial Panel established CPT code 0876T *(Duplex scan of hemodialysis fistula, computer-aided, limited (volume flow, diameter, and depth, including only body of fistula))* effective July 1, 2024. We assigned CPT code 0876T to status indicator 'E1' for July 1, 2024, based on our belief that the implantable marker used with this procedure did not have FDA marketing authorization.

For CY 2026, we proposed to continue to assign CPT code 0876T to E1 (Not covered by any Medicare outpatient

benefit category; Statutorily excluded by Medicare, Not reasonable and necessary; Not paid by Medicare when submitted on outpatient claims) because we had not been notified by interested parties regarding an updated FDA status. We received public comments on this proposal (90 FR 53577). The following is a summary of the comment we received and our response.

Comment: We received one comment requesting that we assign CPT code 0876T to an APC and a payable status indicator (SI). The commenter noted that a significant number of end-stage renal disease admissions are for access complications, but repeated interventions to salvage an existing fistula are more cost-effective than replacing access.

Response: We thank the commenter for their input. We are unable to determine if FDA-regulated devices used in this service have all received marketing authorization from the FDA and therefore are maintaining the status indicator assignment of ''E1''. We look forward to hearing from the manufacturer when FDA marketing authorization has been obtained.

In summary, after consideration of the public comment that we received, we are finalizing the status indicator assignment for CPT code 0876T without modification. We refer readers to Addendum D1 to this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website.

21. Computed Tomographic Colonography, CPT Code 74263 (APC 5523)

For CY 2025, we finalized assigning CPT code 74263 to APC 5523 (Level 3 Imaging without Contrast) using CPT code 74176 (Computed tomography, abdomen and pelvis; without contrast material) as a crosswalk code because of the coverage changes for colorectal cancer screening services. (See 89 FR 94287 through 94290 for a full discussion of the coverage changes for colorectal cancer screening services.)

For the CY 2026 OPPS/ASC proposed rule, we proposed to maintain the APC assignment for CPT code 74263 in APC 5523 (Level 3 Imaging without Contrast) with a proposed payment of around $245 and a status indicator of 'S' (Procedure or Service, Not Discounted When Multiple; Paid under OPPS) (90 FR 53575).

For CY 2027, we proposed to continue to assign CPT code 74263 to APC 5523 (Level 3 Imaging without Contrast) and a status indicator of 'S' (Procedure or Service, Not Discounted When Multiple; Paid under OPPS).

We received one comment on this proposal. The following is a summary of the comment we received and our response.

Comment: A commenter requested that CMS reassign CPT code 74263 from APC 5523 (Level 3 Imaging without contrast) to APC 5524 (Level 4 Imaging without Contrast). The commenter notes that reimbursement for Computed Tomographic Colonography (CTC) remains substantially lower than payment for comparable CT imaging services. They state that unlike other imaging services assigned to non-contrast imaging APC's, CTC requires significant radiologist and technologist involvement, as well as increased resource costs, and an APC assignment to 5524 (Level 4 Imaging without Contrast) would better align payment with complexity and recourse costs. They state that the current payment rate may discourage hospitals and imaging practices from offering billing of CTC, which in turn limits beneficiary access and suppresses utilization. The commenter urges CMS to account for service-specific resource differences and avoid treating all non-contrast imaging services as comparable in complexity or cost. They encourage CMS to consider exceptions, safeguards, or transition policies for preventive screenings, which will ensure that payment changes do not reduce beneficiary access or discourage adherence to recommended screening guidelines.

Response: We thank the commenter for the information regarding the clinical and operational resources associated with the CT colonography (CTC). We recognize that CTC involves bowel preparation, oral contrast administration, insufflation, multiple image acquisitions, image postprocessing and technologist involvement. However, we do not agree that these considerations support reassignment of CPT code 74263 to APC 5524. The OPPS payment rates were proposed based on available 2025 claims data. Our claims data shows that APC 5523 (Level 3 Imaging without contrast) has a geometric mean cost (GMC) of $250, and APC 5524 (Level 4 Imaging without contrast) has a GMC of $577. We reviewed CPT code 74263 and noted that the GMC is $88 based on 692 single frequency claims.

While we understand the commenter's rationale, we believe that reassigning CPT code 74263 to APC 5524 would result in overpayments based on the GMC for the code of $88, compared to the GMC of APC 5524 which is $577.

In summary, after consideration of the public comment we received, we are finalizing our proposal without modification to assign CPT code 74263 to APC 5523 (Level 3 Imaging without Contrast).

The final CY 2027 payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

22. Breast Imaging Service Performed With QT Scanner, CPT Code 1079T (APC 5522)

Effective October 1, 2026, CPT code 1079T (placeholder code X579T) *(3D quantitative transmission water bath volumetric ultrasound tomography, breast, with augmentative algorithmic derivation of breast tissue composition (ie, fibroglandular volume), bilateral, with physician or other qualified health care professional interpretation and report)* describes the breast imaging service performed with QT Scanner. The device uses a 360-degree moving transducer to generate quantitative 3D breast images. The QT Scanner 2000 Model A is indicated to provide reflection-mode and transmission-mode breast images and calculates fibroglandular tissue volume (breast density), and is ''not intended to be used as a replacement for screening mammography.''

For CY 2027, we proposed to assign CPT code 1079T to status indicator ''E1'' because we did not believe the QT Scanner service would fall under an existing benefit category.

We received a public comment on this proposal. The following is a summary of the comment we received and our response.

Comment: A commenter, the manufacturer of QT Scanner, requested that we revise the proposed ''E1'' status indicator to status indicator ''S'' for CPT code 1079T and assign the code to a new technology APC. Per the commenter, physician-ordered diagnostic use of the QT Scanner falls within an existing Medicare benefit category under section 1861(s)(3) and section 1861(s)(2)(B) of the Social Security Act, and NCD 220.5 (Ultrasound Diagnostic Procedures (Effective May 22, 2007)) provides coverage either as breast sonography under Category I or as an unenumerated diagnostic ultrasound procedure subject to local MAC discretion under Section D. The commenter also cited FDA clearance of the QT Scanner 2000 Model

A (K253898) and CPT's creation of the Category III CPT code as support for the existence of a diagnostic use distinct from screening.

Response: After reviewing the comment, we agree, on a narrow basis, that assignment of status indicator E1 is not appropriate for CPT code 1079T. We agree that physician-ordered use of a QT Scanner to evaluate a specific clinical finding could be capable of falling within the existing diagnostic ultrasound benefit category described in NCD 220.5 Ultrasound Diagnostic Procedures, consistent with CMS's treatment of other forms of breast sonography. In the event this code is covered, and determined to be reasonable and necessary, we believe an appropriate APC assignment for CPT code 1079T is APC 5522 (Level 2 Imaging without Contrast), based on similar codes in that APC series, for example CPT code 76641 *(Ultrasound, breast, unilateral or bilateral, real-time with image documentation, complete).* Therefore, for CY 2027, in response to the commenter, we are revising our proposal in this final rule and assigning CPT code 1079T to APC 5522 with status indicator ''S.''

As we have consistently stated in past OPPS/ASC final rules with comment period (see, for example, *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. Coverage of a claim where the QT Scanner is used would require an independent showing, made at the time the claim is adjudicated, that the service was reasonable and necessary for the individual beneficiary under section 1862(a)(1)(A) of the Act, ordered by a physician to address a specific diagnostic question.

While our decision to finalize payment rests on the plausible diagnostic use of this technology within the existing framework of NCD 220.5, under current rules, use of the QT Scanner would not be covered by Medicare as a screening service. Coverage of breast ultrasonography as a screening service would require either a statutory change or a qualifying recommendation from the United States Preventive Services Task Force under section 1861(ddd) of the Act. Neither condition currently exists. Therefore, claims for QT Scanner where the service is furnished for routine screening of asymptomatic beneficiaries would not currently be covered. Additionally, we clarify that the indication for the FDA-cleared device, itself, does not support the use of the QT Scanner device for breast cancer screening.

In summary, we are not finalizing our proposal to assign CPT code 1079T to status indicator ''E1'' as proposed. In response to the commenter, for CY 2027, we are assigning CPT code 1079T to APC 5522 and status indicator ''S.'' Refer to Table 36 for the final CY 2027 OPPS APC and status indicator assignments for CPT code 1079T. The final CY 2027 payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 36: PROPOSED AND FINAL CY 2027 OPPS APC AND SI ASSIGNMENT FOR CPT CODE 1079T

HCPCS Code	Long Descriptor	Proposed OPPS CY 2027 APC, SI	Final OPPS CY 2027 APC, SI
1079T	3D quantitative transmission water bath volumetric ultrasound tomography, breast, with augmentative algorithmic derivation of breast tissue composition (ie, fibroglandular volume), bilateral, with physician or other qualified health care professional interpretation and report	E1	5522, S

Maternity Care Services

23. Maternity Care Services, CPT Codes 59081–59083, 59431, 59432, 59502–59504 (APCs 5414 through 5416)

Effective January 1, 2027, the AMA created several new codes describing maternity care provided during the antepartum, labor management, and postpartum periods.

Listed below are the CPT codes (and placeholder codes), long descriptors, and their proposed APC assignments.

- 59081 (59XX2)—Initial day labor management; complex, per day; proposed APC assignment 5414.
- 59082 (59XX3)—Subsequent day labor management; straightforward, per day; proposed APC assignment 5414.
- 59083 (59XX4)—Subsequent day labor management; complex, per day; proposed APC assignment 5414.
- 59431 (59XX5)—Vaginal delivery only (with or without episiotomy and/or forceps); proposed APC assignment 5414.
- 59432 (59XX6)—Vaginal delivery, with or without episiotomy; after previous cesarean delivery; proposed APC assignment 5414.
- 59502 (59XX7)—Cesarean delivery; primary; proposed APC assignment 5416.
- 59503 (59XX8)—Cesarean delivery; repeat; proposed APC assignment 5416.
- 59504 (59XX9)—Subtotal or total hysterectomy after cesarean delivery; proposed APC assignment 5416.

We received comments regarding the CY 2027 proposed assignments. The following is a summary of the comments we received and our responses.

Comment: Commenters offered appreciation for the OPPS inclusion of APC assignments for the new code and expressed concern that the proposed APC assignments do not adequately distinguish between certain maternity services in terms of clinical and resource requirements. Commenters encouraged CMS to ensure that the upper levels of the Gynecologic Procedures APC family maintain appropriate clinical and resource homogeneity and sufficient payment differentiation for exceptionally

resource-intensive gynecologic and obstetric procedures. Commenters noted that complex labor management can involve greater monitoring, staffing, clinical intervention, and other hospital resources than straightforward labor management. Commenters stated that assigning both services to the same APC effectively eliminates resource distinctions for hospital outpatient payment purposes. Commenters stated that it would be more appropriate to assign complex labor management codes to APC 5415, Level 5 Gynecologic Procedures.

Additionally, commenters claimed that the vaginal delivery codes better align with APC 5416, Level 6 Gynecologic Procedures, based on the instrumentation, complexity, and time of a vaginal delivery and the similarities of the codes existing in APC 5416. They also stated that the abdominal surgical procedure of cesarean deliveries requires an operating room, a surgical, sterile environment, and the necessary equipment for an abdominal incision and closure, not dissimilar to the requirements in APC 5342, Level 2 Abdominal/Peritoneal/Biliary and Related Procedures, or APC 5361, Level 1 Laparoscopy and Related Services. Commenters further stated that payment for cesarean hysterectomy at the same APC level as primary and repeat cesarean delivery does not adequately recognize these significant differences in hospital resource requirements.

Response: We thank the commenters for their comments and support in ensuring appropriate assignment of the newly established codes related to maternity care services. After consideration of the public comments we received, and discussion and input from our Medical Officers, and where applicable, a review of claims data for related predecessor codes, we believe that CPT code 59432 (59XX6) shares greater resource cohesion with several services and procedures included in APC 5415. However, we continue to believe that CPT codes 59081, 59082, 59083, 59431, 59502, 59503, and 59504 are appropriately assigned. We note that we will continue to monitor the APC series as more claims data are available for the procedures assigned to this series and remain interested in suggestions and supporting materials regarding changes to those assignments for future years.

In summary, for CY 2027, CMS will finalize the maternity care service codes as proposed, with the modification of assigning CPT code 59432 to APC 5415. The final CY 2027 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 37: PROPOSED AND FINAL CY 2027 OPPS APC AND STATUS INDICATOR ASSIGNMENT FOR CPT CODE 59432

HCPCS Code	Long Descriptor	CY 2027 Proposed APC Assignment	CY 2027 Final APC Assignment
59432	Vaginal delivery, with or without episiotomy; after previous cesarean delivery	5414	5415

Neuro and Nerve Related Procedures

24. Transcutaneous Magnetic Peripheral Nerve Stimulation CPT Codes 0766T and 0767T (APC 5722)

Transcutaneous Magnetic Peripheral Nerve Stimulation is intended to stimulate peripheral nerves for relief of chronic intractable pain, post-traumatic pain, post-surgical pain and/or for relief of chronic painful diabetic peripheral neuropathy in the lower extremities for patients 18 and older. CPT code 0766T (Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve) became effective January 1, 2023. For CY 2025, CPT code 0766T was reassigned to APC 5722 (Level 2 Diagnostic Tests and Related Services) with the status indicator ''S'' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment). There are no claims available for CPT code 0766T in CY 2025. For CY 2027, we proposed to continue assigning CPT code 0766T to APC 5722.

CPT code 0767T (Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (list separately in addition to code for primary procedure)) became effective January 1, 2023 and assigned status indicator ''N'' (packaged). CPT code 0767T is an add-on code and we proposed to continue assignment of status indicator ''N'' for this code for CY 2026 (90 FR 53583).

We note that at the August 24, 2026, HOP Panel Meeting, a presentation was made requesting (1) the reassignment of 0766T from APC 5722 to APC 5724 (Level 4 Diagnostic Tests and Related Services) and (2) reassignment of the status indicator for 0767T from ''N'' to ''S'' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment). The Panel made no recommendations on these requests.

We received 4 comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: All commenters requested CPT code 0766T be reassigned to APC 5724 (Level 4 Diagnostic Tests and Related Services), claiming that CPT code 0766T is not clinically similar and does not use comparable resources to other services in APC 5722. All commenters also stated that it is necessary to change the status indicator from ''N'' to ''S'' for CPT code 0767T because the additional nerve stimulations require the physician to reposition the device, identify and map a separate nerve target, establish appropriate stimulation parameters, and deliver treatment to that additional anatomical target. All commenters requested that CMS follow the 2025 HOP Panel recommendations to reassign 0766T to APC 5724 and reassign the 0767T status indicator to ''S'' (Significant Procedures, Not Discounted

when Multiple. Paid under OPPS; separate APC payment).

Response: We disagree that CPT code 0766T is comparable, clinically and in resource costs, to the services assigned to APC 5724. We continue to believe CPT code 0766T is more comparable, clinically and from a resource cost perspective, to CPT code 90867 (Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; initial, including cortical mapping, motor threshold determination, delivery and management), and CPT code 90868 (Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent delivery and management, per session), which are assigned to APC 5722 (Level 2 Diagnostic Tests and Related Services), because these services share similar magnetic stimulation and nerve localization processes.

We note that CPT code 0767T is an add-on code. Add-on codes are always performed in addition to the primary service or procedure and not reported as a stand-alone code. As specified under regulation 42 CFR 419.2(b)(18), add-on codes are generally packaged under the OPPS, and payment for the codes are bundled with the primary codes. Consequently, CPT code 0767T is not paid separately under the OPPS and its payment is packaged into payment for the primary code.

After consideration of the public comments we received, we are finalizing our proposed APC assignment and status indicators for CPT codes 0766T and 0767T without modification.

We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

25. BioWavePENS, CPT 1088T (APC 5721)

Effective October 1, 2026, the AMA CPT Editorial Panel created CPT code 1088T (*Percutaneous application of high-frequency neuromodulation signals using microneedle electrode array for the treatment of nociceptive or neuropathic pain, including electrode placement and patient training, per day)* to describe the procedure for percutaneous electrical nerve stimulation using microneedle electrode arrays for the treatment of pain. Beginning on October 1, 2026, we assigned CPT code 1088T to APC 5721 (Level 1 Diagnostic Tests and Related Services) with a proposed payment rate of around $147.

We received one public comment on this proposal. The following is a summary of the comment we received and our response.

Comment: A commenter requested that CMS assign CPT code 1088T to APC 5443 (Level 3 Nerve Injections), which had a proposed payment rate of around $1,019, due to clinical similarity to other percutaneous nerve interventions in APC 5443.

Response: We thank the commenter for their input. We note that since is a new code and became effective on October 1, 2026, we do not currently have any claims data for this procedure. After further review, we continue to believe that CPT code 1088T is appropriately assigned to APC 5721. Therefore, we are finalizing our proposal to assign CPT code 1088T to APC 5721 (Level 1 Diagnostic Tests and Related Services). We note that we will continue to monitor the claims data and update the payment rate in future rulemaking based on the available claims. The final CY 2027 payment rate for the code can be found in Addendum B to this final rule with comment period. We also refer readers to Addendum D1 to this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

26. Hypoglossal Nerve Neurostimulator (HGNS) Procedures, C8007–C8009 and C8011–C8013, (APCs 5465, 5463, and 5432)

Effective January 1, 2022, the AMA's CPT Editorial Panel created three new codes to describe the open implantation of hypoglossal nerve neurostimulator (HGNS) array with an implanted pulse generator and a separate distal respiratory sensor, the revision or replacement of the HGNS, and the removal of the HGNS for the treatment of obstructive sleep apnea (OSA). The codes, their long descriptors, and APC and status indicators are listed below.

- 64582—*Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array.* CPT code 64582 is assigned to APC 5465 (Level 5 Neurostimulator and Related Procedures) and status indicator ''J1'' (Hospital Part B Services Paid Through a Comprehensive APC).
- 64583—*Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator.* CPT code 64583 is assigned to APC 5463 (Level 3 Neurostimulator and Related Procedures) and status indicator ''J1'' (Hospital Part B Services Paid Through a Comprehensive APC).
- 64584—*Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array.* CPT code 64584 is assigned to APC 5432 (Level 2 Nerve Procedures) and status indicator ''Q2'' (T-Packaged Codes).

As the technology has evolved, we realized that the current HGNS CPT codes did not accurately describe the newer hypoglossal nerve neurostimulators that are on the market. As a result, some providers utilized CPT code 64568 (*Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator*) to describe the implantation of hypoglossal nerve neurostimulators that are not described by the current hypoglossal nerve neurostimulator implantation code.

As a result of the questions and concerns regarding coding and billing for the implantation, revision or replacement, or removal of hypoglossal nerve neurostimulators that are not described by existing coding, we created six new C-codes (91 FR 41809). These new C-codes describe the implantation, revision or replacement, and removal of hypoglossal nerve neurostimulators that do not contain a separate implantable respiratory sensor electrode or electrode array, and systems that do not contain an implanted battery or pulse generator. The C-codes and their long descriptors and payment assignments are listed below.

- C8007—*Open implantation of hypoglossal nerve neurostimulator array and pulse generator, not requiring insertion of a separate distal respiratory sensor electrode or electrode array.* C8007 is assigned to APC 5465 (Level 5 Neurostimulators and Related Procedures) and status indicator ''J1'' (Hospital Part B Services Paid Through a Comprehensive APC).
- C8008—*Revision or replacement of hypoglossal nerve neurostimulator array including connection to existing pulse generator.* C8008 is assigned to APC 5463 (Level 3 Neurostimulators and Related Procedures) and status indicator ''J1'' (Hospital Part B Services Paid Through a Comprehensive APC).
- C8009—*Removal of hypoglossal nerve neurostimulator array and pulse generator.* C8009 is assigned to APC 5432 (Level 2 Nerve Procedures) and status indicator ''Q2'' (T-Packaged Codes; Paid under OPPS).
- C8011—*Open implantation of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver, including external power source and all system components.* C8011 is assigned to APC 5465 (Level 5 Neurostimulators and Related Procedures) and status

indicator ''J1'' (Hospital Part B Services Paid Through a Comprehensive APC).

• C8012—*Revision or replacement of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver.* C8012 is assigned to APC 5463 (Level 3 Neurostimulators and Related Procedures) and status indicator ''J1'' (Hospital Part B Services Paid Through a Comprehensive APC).

• C8013—*Removal of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver.* C8013 is assigned to APC 5432 (Level 2 Nerve Procedures) and status indicator ''Q2'' (T-Packaged Codes; Paid under OPPS).

We used the current HGNS CPT codes as the crosswalk codes for making payment assignments for these new C-codes. These new C-codes and their APC and status indicator assignments were published in the April 2026 quarterly update CR (Transmittal 13686, Change Request 14380, dated March 13, 2026), and are retroactive to January 1, 2026.

Comment: We received two comments supporting the creation of these codes, their APC assignments, and the fact that we made them effective retroactive to January 1, 2026. A commenter suggested that CMS delay finalizing these codes, as they believe that the AMA CPT Editorial Panel is creating new HGNS codes. Another commenter requested that we reassign C-code C8011 to a New Technology APC suggesting that APC 5465 (Level 5 Neurostimulator and Related Procedures) does not adequately account for the device costs and hospital resources required to perform this procedure.

Response: We thank the commenters for their input and support for the creation of these codes. We appreciate the fact that a commenter has suggested that we wait to finalize the HCPCS C-codes we created that describe the HGNS procedures; however, we want to address the coding and billing issues that surround these newer technologies that are not described by existing codes. If and when new CPT codes are created that describe these newer HGNS procedures, we will review the new codes and determine if maintaining the HCPCS C-codes are necessary. Regarding the APC assignments for these C-codes, we believe that the proposed APC assignments are appropriate, as we crosswalked the new C-codes to the existing coding for the HGNS procedures. We do not believe that it is appropriate to assign C8011 to a New Technology APC at this time without having adequate claims data to support the reassignment. We review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data and review of the clinical characteristics of the procedure.

In summary, after consideration of the public comments we received, we are finalizing the proposed APC assignments for the C-codes noted previously without modification. The final CY 2027 payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

27. IB-Stim, CPT Code 64567 (APC 5301)

Effective January 1, 2026, the AMA CPT Editorial Panel created CPT code 64567 (*Percutaneous electrical nerve field stimulation, cranial nerves, without implantation*). This code describes a neuromodulation therapy for the treatment of functional gastrointestinal disorders. CPT code 64567 replaced the predecessor CPT code 0720T (Percutaneous electrical nerve field stimulation, cranial nerves, without implantation). For CY 2027, we proposed to continue to assign CPT code 64567 to APC 5301 (Level 1 Upper GI Procedures).

We received one public comment on this proposal. The following is a summary of the comment we received and our response.

Comment: A commenter requested that CMS reassign CPT code 64567 to APC 5312 (Level 2 Lower GI Procedures). The commenter stated that APC 5312 would better align payment with the clinical and resource cost of CPT code 64567.

Response: We thank the commenter for their input. Since CPT code 64567 was new for CY 2026, we note that we will not have any claims data for this code until CY 2028 rulemaking. Additionally, there were no claims data for the predecessor CPT code 0720T.

After further review of the commenter's request, we are reassigning CPT code 64567 to APC 5311 (Level 1 Lower GI Procedures) to better align the procedure clinically, as reflected in Table 38. We note that we will continue to monitor the claims data and update the payment rate in future rulemaking based on the available claims. The final CY 2027 payment rate for the code can be found in Addendum B to this final rule with comment period. We also refer readers to Addendum D1 to this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 38: PROPOSED AND FINAL CY 2027 OPPS APC AND SI ASSIGNMENTS FOR CPT CODE 64567

CPT Code	Long Descriptor	Proposed CY 2027 APC, SI	Final CY 2027 APC, SI
64567	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation	5301, T	5311, T

28. ReneuRX™ System, CPT Code 1096T (APC 5442)

Effective October 1, 2026, the AMA CPT Editorial Panel created CPT code 1096T (Injection(s) of thermoregulated multiphase suspension to demyelinate nerves innervating the knee joint, including imaging guidance, when performed). Because the technology associated with the procedure had not received FDA marketing authorization at the time of its assignment, we assigned CPT code 1096T to status indicator ''E1'' (Not covered by any Medicare outpatient benefit category; Statutorily excluded by Medicare; Not reasonable and necessary; Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) for the October 2026 quarterly update.

We received one public comment on this proposal. The following is a summary of the comment we received and our response.

Comment: A commenter stated that this device received FDA approval on

August 21, 2026. Therefore, they requested that CMS reassign CPT code 1096T to APC 5431 (Level 1 Nerve Procedures) with a proposed payment rate of around $2,270. The commenter stated that this assignment was appropriate due to the clinical similarity to other procedures in this APC.

Response: We thank the commenter for their input. We agree with the commenter that CPT code 1096T should be reassigned to a clinical APC since the technology associated with the procedure has received FDA authorization. However, we disagree with the commenter's recommendation to assign the procedure to APC 5431. After careful review, we believe that this procedure has similar clinical and resource utilization to procedures in APC 5442 (Level 2 Nerve Injections). Therefore, we are finalizing our proposal with modification to assign CPT code 1096T to APC 5442 (Level 2 Nerve Injections) retroactive to October 1, 2026. We note that we will monitor the claims data and update the payment rate in future rulemaking based on the available claims. The final CY 2027 payment rate for the code can be found in Addendum B to this final rule with comment period. We also refer readers to Addendum D1 to this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 39: PROPOSED AND FINAL CY 2027 APC AND SI ASSIGNMENT FOR CPT CODE 1096T

CPT Code	Long Descriptor	Proposed CY 2027 APC, SI	Final CY 2027 APC, SI
1096T	Injection(s) of thermoregulated multiphase suspension to demyelinate nerves innervating the knee joint, including imaging guidance, when performed	E1	5442, T

Oncology Related Services

29. Radiation Oncology Treatment Delivery, CPT Codes 77402, 77407, 77412 (APCs 5621 and 5623)

At the September 2024 CPT Editorial Panel meeting, the Panel approved the revision of radiation therapy CPT codes 77402, 77407 and 77412 to establish a technique-agnostic family of codes and bundle imaging into the three CPT codes. In addition, Intensity Modulated Radiation Therapy (IMRT) treatment delivery codes 77385 and 77386 and CT guidance code 77014 were deleted and consolidated into this new code structure:

Revised CPT code 77402 *(Radiation treatment delivery; Level 1 (e.g., single electron field, multiple electron fields, or 2D photons), including imaging guidance, when performed)* describes the delivery of a low-complexity form of radiation to a cancer or tumor and includes any imaging that is used during the session to ensure the radiation beam is accurately targeting the cancer.

Revised CPT code 77407 *(Radiation treatment delivery; Level 2, single isocenter (e.g., 3D or IMRT), photons, including imaging guidance, when performed)* describes the delivery of a more complex form of radiation using a single central point of radiation (isocenter) with high-energy photons which may be delivered through 3D conformal radiation therapy (3D–CRT) or Intensity-Modulated Radiation Therapy (IMRT) and includes any imaging that is used during the session.

Revised CPT code 77412 *(Radiation treatment delivery; Level 3, multiple isocenters with photon therapy (e.g., 2D, 3D, or IMRT) OR a single isocenter photon therapy (e.g., 3D or IMRT) with active motion management, OR total skin electrons, OR mixed electron/photon field(s), including imaging guidance, when performed)* describes the most complex radiation treatment delivery where multiple points of focus (isocenters) are used with photon therapy (2D, 3D, or IMRT) or a single isocenter is used but with active motion management or specialized techniques like total skin electrons or mixed electron/photon beams are performed and includes any imaging that is used during the session.

For the CY 2026 OPPS/ASC final rule with comment period, we used the following crosswalk methodology to make assignments for these codes. For CPT code 77407, we imputed all CY 2024 claims in CPT code 77407, the bottom 50 percent (with respect to total estimated cost) of single claims from CPT code 77412, and all of the claims from CPT code 77385 (90 FR 53595 through 53596).

For CPT code 77412, we imputed the highest 50 percent (with respect to total estimated cost) of claims in 77412, and all of the claims from 77386. As a result of this crosswalking of claims, we continued to assign CPT code 77407 to APC 5622 (Level 2 Radiation Therapy), which currently has a geometric mean cost of around $423 and reassigned CPT code 77412 to APC 5623 (Level 3 Radiation Therapy), which currently has a geometric mean cost of around $592 (90 FR 53595 through 53596).

For the CY 2027 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 77402 to APC 5621 (Level 1 Radiation Therapy), status indicator 'S', CPT code 77407 to APC 5622 (Level 2 Radiation Therapy), status indicator 'S', and CPT code 77412 to APC 5623 (Level 3 Radiation Therapy), status indicator 'S'.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed concern that CMS's proposed APC assignments for these codes do not adequately reflect the procedures described by the revised codes and does not provide sufficient payment. Commenters reminded us that these revised codes include 3D conformal and IMRT treatment delivery that were previously described by deleted CPT codes 77385 and 77386.

A commenter suggested that we reassign 77402, 77407, and 77412 to the next highest APC, with many additional commenters requesting that, at a minimum, we reassign CPT code 77407 to APC 5623 (Level 3 Radiation Therapy). Another commenter suggested that we delete 77407 altogether so there is a two tier structure for radiation therapy versus the current three tier structure. This commenter stated CPT code 77402 can remain the lower-level treatment delivery code and 77412 can serve as the principal code for external-beam treatment delivery.

A number of commenters expressed concern about the methodology used to crosswalk historical claims data to the revised CPT codes and asked us to revise the methodology we used in the CY 2026 OPPS/ASC final rule with comment period. A commenter provided an example of an alternative methodology of crosswalking the historical claims data to the revised codes stating that their example reflects real world data. They went on to state that if we were not inclined to update the crosswalking methodology that we used in last year's rule, we should consider reassigning CPT 77407 to a higher APC because the costs associated with this service (since it includes IMRT delivery) is much higher than the current payment. Commenters are concerned that the proposed APC assignment for CPT codes 77407 and 77412 undervalue these services.

A commenter requested a retroactive payment correction for 2026 claims by reprocessing claims and issuing lump sum payments to facilities and providers.

Response: We thank the commenters for their input. We are not persuaded by the comments to revise our crosswalking methodology that we articulated in the CY 2026 OPPS/ASC final rule with comment period. We note that for CY 2027, we use CY 2025 claims data for ratesetting so the impact of our crosswalking methodology will not be evident in the claims data until the CY 2028 rule. We reviewed the claims data for these codes and noted the following:

- CPT code 77402 has geometric mean cost of approximately $169 based on 5,169 single frequency claims;
- CPT code 77407 has a geometric mean cost of approximately $423 based on 1,165,573 single frequency claims; and
- CPT code 77412 has a geometric mean cost of approximately $592 based on 1,235,088 single frequency claims.

We are persuaded by the commenters that we should reassign CPT code 77407 to APC 5623 (Level 3 Radiation Therapy). We believe that since the revised CPT code 77407 includes the deleted IMRT services (which both had geometric mean costs of over $500), it is appropriate to reassign 77407 to APC 5623. We believe CPT codes 77402 and 77412 are in the appropriate APCs.

We are not able to provide payments to recoup the difference between a prior APC payment rate and the one that will be in effect beginning January 1, 2027.

We note that we review the APC assignments for all items and services paid under the OPPS on an annual basis. We will continue to reevaluate the APC assignments for CPT codes 77402, 77407 and 77412 in the next rulemaking cycle.

In summary, after consideration of the public comments we received, we are finalizing our proposal with modification, to assign CPT code 77407 to APC 5623 (Level 3 Radiation Therapy). Table 40 shows the finalized APC assignment and status indicator for these procedure codes. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reportable under the OPPS. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 40: PROPOSED AND FINAL CY 2027 APC AND SI ASSIGNMENTS FOR CPT CODES 77402, 77407, AND 77412

CPT Code	Long Descriptor	CY 2027 Proposed OPPS APC, SI	CY 2027 Final OPPS APC, SI
77402	Radiation treatment delivery; Level 1 (eg, single-electron field, multiple-electron fields, single isocenter 2D photons), including imaging guidance, when performed	5621, S	5621, S
77407	Radiation treatment delivery; Level 2, single-isocenter (eg, 3D or IMRT), photons, including imaging guidance, when performed	5622, S	5623, S
77412	Radiation treatment delivery; Level 3, multiple isocenters with photon therapy (eg, 2D, 3D, or IMRT) or a single-isocenter photon therapy (eg, 3D or IMRT) with active motion management, or total skin electrons, or mixed-electron/photon field(s), including imaging guidance, when performed	5623, S	5623, S

30. Radiation Treatment Planning Software (MAXPOINT), CPT Code 1025T (APC 5612)

Effective January 1, 2026, CPT code 1025T *(Alternating electric fields dosimetry and delivery-simulation modeling, creation and selection of patient-specific array layouts, and placement verification)* describes a 3D treatment planning software that is used to aid in electrode placement for Tumor Treatment Fields (TTFields) therapy utilization called MAXPOINT. The service creates individualized transducer array layouts for the treatment of various cancers using TTFields. For CY 2027, we proposed to assign CPT code 1025T to APC 5611 (Level 1 Therapeutic Radiation and Treatment Preparation) with a proposed payment rate of $137.32. Since the code was made effective in 2026, we do not currently have available claims data to use for ratesetting.

MAXPOINT presented at the August 2026 meeting of the Advisory Panel on Outpatient Payment (HOP Panel). The HOP Panel recommended to reassign CPT code 1025T to APC 5612 (Level 2

Therapeutic Radiation and Treatment Preparation) for CY 2027.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters asked CMS to reconsider the proposed APC 5611 assignment for the CPT code 1025T and requested we reassign the code to APC 5613 (Level 3 Therapeutic Radiation Treatment Preparation). The commenters stated that the proposed APC assignment for CPT code 1025T does not accurately describe the MAXPOINT technology and that the planning software's mechanism of action involves advanced computational analysis, which is similar to other codes assigned to APC 5613. Commenters explained that there are similarities between codes in APC 5613 and the MAXPOINT technology, including services assigned to APC 5613 that generate 3D maps and provide complex computational analysis.

Response: We thank the commenters for their input. At this time, we do not have claims data to provide additional information to assess the appropriate APC assignment for CPT code 1025T. However, we agree with commenters, and the HOP Panel, that APC 5611 may not be an appropriate APC assignment for CPT code 1025T at this time. We see similarities between CPT code 1025T and other more complex services in APC 5612, including CPT code 77285. Therefore, we are not finalizing our proposal to assign CPT code 1025T to APC 5611 as proposed. For CY 2027, we are finalizing an APC assignment for CPT code 1025T to APC 5612 in line with the HOP Panel's recommendation. We will continue to evaluate, on an annual basis, additional data as it becomes available to inform future decisions regarding the APC assignment and payment rate for CPT code 1025T. Refer to Table 41 for the code descriptor, APC assignment, and status indicator assignment for CPT code 1025T.

The final CY 2027 payment rates for CPT code 1025T can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator (SI) definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 41: PROPOSED AND FINAL CY 2027 OPPS APC AND SI ASSIGNMENT FOR CPT CODE 1025T

HCPCS Code	Long Descriptor	Proposed CY 2027 APC, SI	Final CY 2027 APC, SI
1025T	Alternating electric fields dosimetry and delivery-simulation modeling, creation and selection of patient-specific array layouts, and placement verification	5611, S	5612, S

31. Scalp Cooling Preparation and Pre-Cooling Service, CPT 97007–97009 (APC 1494)

Scalp cooling is a service furnished during chemotherapy to prevent or minimize hair loss, a common side effect of chemotherapy treatment for cancer. The service is furnished in two parts. On a different date of service than the chemotherapy session, the patient's head is measured and a scalp cooling cap is individually fitted to the patient. On the day of chemotherapy administration, the service includes a precooling and preparation period of approximately 30 minutes prior to chemotherapy initiation, placement and maintenance of the cooling cap during chemotherapy infusion, and a post-infusion cooling period following discontinuation of chemotherapy, as clinically appropriate.

Effective January 1, 2026, the scalp cooling service is described by three Category I CPT codes:

- 97007—Mechanical scalp cooling, including individual cap supply with head measurement, fitting, and patient education.
- 97008—Mechanical scalp cooling; including hair preparation, individual cap placement, therapy initiation, and precooling period).
- 97009—Mechanical scalp cooling; provided after discontinuation of chemotherapy, each 30 minutes (List separately in addition to code for primary procedure).

For CY 2026, we assigned the initial cap supply and fitting service, described by CPT code 97007, to APC 1516 (New Technology—Level 16 ($1,401–$1,500) with a payment rate of $1,450.50 and status indicator ''S.'' We assigned CPT codes 97008 and 97009 to status indicator ''N'' for CY 2026. As provided in the CY 2026 OPPS FR, we explained that we believed the costs associated with the scalp cooling service are appropriately captured within the packaged payment for chemotherapy treatment. Therefore, we packaged payment for CPT codes 97008 and 97009 with the primary chemotherapy service performed at the same time (90 FR 53597).

However, for CY 2027, we acknowledged that the resources required to furnish CPT code 97008 may not be fully captured when packaged. Specifically, we recognized that there is an additional 30 minutes of chair and nursing time, prior to the initiation of chemotherapy, when CPT code 97008 is furnished. Therefore, we proposed to assign CPT code 97008 to APC 1495 (New Technology—Level 1D ($31–$40)) with a status indicator of ''S'' for CY 2027.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters stated that the proposed APC assignment for CPT code 97008 does not fully capture the costs of the preparation and pre-cooling portion of the scalp cooling service. Commenters estimated the actual cost of the service at approximately $500, compared to the proposed payment rate of $35.50. Commenters noted that scalp cooling must be furnished by a specialized oncology nurse and described the associated resources, including room preparation, filling the coolant reservoir, hair preparation, administration of pre-service medications, operation of the device, period patient monitoring, and ongoing patient support.

Response: We thank the commenters for their input. Having reviewed the described resources submitted by commenters in consultation with our medical officers for this supportive service, we do not believe it would be appropriate for Medicare to compensate the 30 minute period during which the patient and device are prepared for scalp cooling at approximately $500 per

session. The resources described by commenters, including setting up the room and device, preparing the patient's hair, periodic monitoring and patient support, are consistent in clinical intensity with other short-duration, nursing-supported services paid for under the OPPS. In determining the proposed payment rate for CPT code 97008, we looked to chemotherapy infusion services (including CPT code 96415), which reflect hourly resource costs for comparable clinical monitoring and support activities furnished by specialized oncology staff. Applying that hourly rate on a pro-rated basis to the 30 minute duration of CPT code 97008 yields a resource valuation consistent with our proposed rate. Accordingly, we continue to believe it is appropriate to assign CPT code 97008 to APC 1495 (New Technology—Level 1D ($31–$40)) with a status indicator of ''S'' for CY 2027. Therefore, we are finalizing the APC and status indicator assignments for CPT code 97008 as proposed.

We refer readers to section III.C. and addendum B to this final rule for the payments regarding CPT code 97007 for CY 2027. The final CY 2027 OPPS payment rate for all codes payable under the OPPS can be found in Addendum B to this proposed rule. In addition, we refer readers to Addendum D1 to this final rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 Is available via the internet on the CMS website.

Ophthalmology Related Services

32. Administration of Lacrimal Ophthalmic Insert Into Lacrimal Canaliculus, CPT Code 68841 (APC 5503)

HCPCS code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*), describes the drug Dextenza, which is a drug indicated for ''the treatment of ocular inflammation and pain following ophthalmic surgery'' and for ''the treatment of ocular itching associated with allergic conjunctivitis.'' [22] Dextenza is administered via a natural opening in the eyelid (called the punctum) and delivers a tapered dose of dexamethasone to the ocular surface for up to 30 days. CPT code 68841 (*Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each*) describes the insertion of the implant to administer Dextenza.

For CY 2026, we assigned CPT code 68841 to APC 5503 with OPPS status indicator of 'Q1' (STV Packaged Codes), which typically means there is a packaged APC payment if this code is billed on the same claims as a HCPCS code assigned to status indicator 'S', 'T', or 'V' (90 FR 53592).

For CY 2027, we proposed to continue to assign CPT code 68841 to APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures) and status indicator 'Q1' (STV-Packaged Codes; Paid under OPPS).

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: We heard from several commenters, who requested that we assign CPT code 68841 to APC 5503 with a different status indicator that allows for separate payment in the ASC setting. Commenters requested that CMS revise the status indicator to 'J1' (Hospital Part B Services Paid Through a Comprehensive APC; Paid under OPPS) to allow for separate ASC payment. A commenter opined that Dextenza replaces the use of self-administered eye drops, which carry adherence and administration challenges—particularly among older patients with dexterity, vision, or mobility limitations. The commenter also stated for cost-sensitive ASCs, the lack of payment for the procedure is a disincentive to use Dextenza and requires beneficiaries to use alternatives such as eye drops.

The commenters did not agree with CMS that the fact that CPT code 68841 was performed as a standalone procedure a small percentage of the time was adequate justification for assigning a 'Q1' status indicator. A commenter stated that CMS is treating this procedure (CPT 68841) differently than about 75 other procedures, such as CPT codes 66030 (*Injection, anterior chamber of eye (separate procedure); medication*) and 0699T (*Injection, posterior chamber of eye, medication*) that are assigned to APC 5503, which have 'J1' status indicators. The commenter further states that not making CPT code 68841 separately payable due to a low level of single frequency claims, treats this code differently than similar situations. The commenter also used Exparel (described by HCPCS code J0666) as an example of a non-opioid post-surgical treatment for which the insertion procedure (CPT code 64415) has as low a frequency claim rate as CPT code 68841 and has a status indicator 'T' that allows for separate payment in the ASC setting. The commenters requested that we revise the status indicator to 'J1' to allow separate payment in the ASC setting and facilitate better treatment of ocular pain and itching.

Response: We thank the commenters for their input but disagree regarding the appropriate status indicator for this service. For CY 2027, the OPPS payment rates were proposed based on available CY 2025 claims data. We note that CPT code 68841 does not have any single frequency claims out of the 4,619 total frequency claims. We believe this data, combined with the clinical nature of this procedure, once again reinforces our belief that CPT code 68841, the administration of Dextenza, is not furnished independently of a surgical procedure and should be packaged into the primary ophthalmic procedure with which the drug and the drug administration procedure are associated.

In summary, after consideration of the public comments we received, we are finalizing our proposal without modification to assign CPT code 68841 to APC 5503 (Level 3 Extraocular, Repair, and Plastic Eye Procedures) and 'Q1'. In addition, based on the OPPS assignments, we are finalizing an ASC payment indicator of 'N1' (Packaged service/item; no separate payment made) for CPT code 68841 for CY 2027.

The final CY 2027 payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

33. Implantation of Drug-Releasing Device, CPT Codes 0660T, 0661T (APC 5492)

Trabecular bypass procedures are used for the treatment of glaucoma and may be performed along with cataract surgery or as a stand-alone procedure. Another glaucoma treatment involves the implantation of a device that releases a drug into the eye. CPT codes 0660T and 0661T describe the implantation of a device that releases a drug into the eye.

CPT code 0660T (*Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach*) and CPT code 0661T (*Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant*) became effective July 1, 2021. These codes became payable in OPPS in 2024 after the implantable articles used in each

[22] See Package Insert. *https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=7514e6b8-c33f-4fbf-8810-ef520e1eb4bd.*

procedure received FDA marketing authorization.

For CY 2027, we proposed to maintain their current payment assignments to APC 5492 (Level 2 Intraocular Procedures) and status indicator of 'J1'. We received one public comment on these codes.

Comment: The commenter supported the APC assignment for both CPT codes 0660T and 0661T but requested that we revise the status indicator assignment to 'S' (Procedure or Service, Not Discounted When Multiple; Paid under OPPS; separate APC payment) for both codes noting that the drug used with this procedure (iDose TR® (travoprost intracameral implant)) will be coming off of pass-through July 1, 2027. Upon the expiration of pass-through, HCPCS code J7355 would no longer be paid separately, and the drug would be packaged with the procedure subject to the OPPS comprehensive packaging policy. The commenter states that the cost of iDose TR® is greater than the payment rate for APC 5492 and lack of adequate payment will likely lead to reduced access for beneficiaries.

Response: We appreciate the commenter's input. We note that CPT code 0660T has a geometric mean cost of $10,545 based on 165 single frequency claims and also has 165 multiple frequency claims. CPT code 0661T has a geometric mean cost of $7,237 based on one single frequency claim and has one additional multiple frequency claim. We believe that this procedure is often done with another ophthalmic procedure and do not believe that we should revise the status indicator from 'J1' to an 'S' so as to avoid our packaging policy under OPPS.

After consideration of the public comment, we are finalizing our proposal, without modification, to maintain the APC and status indicator assignments for CPT codes 0660T and 0661T to APC 5492 (Level 2 Intraocular Procedures) and status indicator of 'J1'. The final CY 2027 payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

34. Implantation of Scaffolding Allograft, CPT 1084T

The AMA CPT Editorial created CPT code 1084T *(Implantation of scaffolding allograft to reinforce the suprachoroidal space)* to replace CPT X588T. We note that this code initially was to be effective January 1, 2027, and was included in Addendum B of the CY 2027 OPPS/ASC proposed rule; however, the AMA revised its 'release and effective date' schedule for Category III CPT codes, and the new effective date is October 1, 2026.

This new code describes an ophthalmic procedure that enhances aqueous outflow with scaffolding allografts in the uveoscleral space to lower intraocular pressure using the alloflo™ uveo device. For CY 2027, we proposed to assign 1084T to APC 5492 (Level 2 Intraocular Procedures) and status indicator 'J1'. We received a public comment on this APC assignment.

Comment: We received one comment from the manufacturer requesting that we reassign CPT code 1084T to APC 5493 (Level 3 Intraocular Procedures) using CPT codes 0671T *(Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more)* and 0449T *(Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device)* as crosswalk codes. The manufacturer also requested that we designate CPT code 1084T as a device-intensive procedure in the ASC and assign a HCPCS-specific device offset of $4,485 or in the alternative, apply the applicable APC-level device offset.

The procedure uses the alloflo™ uveo platform, which consists of two to three permanently implanted scleral allograft bio-tissue implants and the single-use AlloSert™ micro-interventional uveoscleral system used to access the outflow space and to insert the implants. The commenter states the implantables and the delivery-device cost is approximately 78 percent of the geometric mean cost of APC 5493.

The commenter cites clinical and resource similarities to other services that are assigned to APC 5493, including 0617T and 0449T, noting that these procedures are ab-interno, clear-cornea implant procedures that treat open-angle glaucoma by placing one or more implants into an aqueous-outflow pathway to lower intraocular pressure. The commenter also states that CPT code 1084T is more resource-intensive than the two suggested crosswalk codes, noting that the intraservice time is longer than that of the other two procedures.

Response: We appreciate the commenter's input. In determining the appropriate APC placement for new CPT codes, we rely on input from a variety of sources, including, but not limited to, review of the resource costs and clinical similarity of the service to existing procedures, input from CMS medical advisors, as well as information from interested parties. Based on our review of the clinical characteristics of the procedure, we believe that CPT code 1084T is more similar clinically and in terms of resource requirements and procedure costs to the procedures assigned to APC 5492 (Level 2 Intraocular Procedures). For the device-intensive request and our response, we refer readers to section IV.B and XIII.C.4 of this final rule with comment period.

We remind readers that we review, on an annual basis, the APC assignments for all items and services paid under the OPPS and we will continue to monitor the claims data as it becomes available.

In summary, after consideration of the public comments we received, we are finalizing our proposal without modification, to assign CPT code 1084T to APC 5492 (Level 2 Intraocular Procedures). The final CY 2027 payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

35. Patient-Initiated Remote Retinal Optical Coherence Tomography (OCT) Scans, CPT Codes 0604T–0606T

CPT codes 0604T–0606T describe patient-initiated remote retinal optical coherence tomography (OCT) scans.

In the CY 2027 OPPS/ASC proposed rule, we proposed to continue to assign CPT codes 0604T–0606T to status indicator ''E1''.

We received one public comment on this proposal.

Comment: The commenter requested that CMS change the status indicators for each of these codes from ''E1'' to ''B'' for 2027. The home OCT services described by CPT codes 0604T and 0605T are only furnished through an independent diagnostic testing facility (IDTF), while the service described by CPT code 0606T is only furnished in the physician office, and these services are not furnished in the hospital outpatient department.

The commenter stated that status indicator ''E1'' has been erroneously interpreted by some Medicare administrative contractors (MACs) as meaning that the service is non-payable in any outpatient site of service, including the physician office. According to the commenter, this interpretation is incorrect. The commenter believes that the best way to

clear up this misunderstanding would be to assign status indicator ''B'' (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)) to each of CPT codes 0604T, 0605T, and 0606T in the 2027 OPPS/ASC final rule.

Response: We thank the commenter for their input, and we agree with the commenter. We have received several MAC inquiries earlier and in response to these inquiries, we are changing the status indicator for CPT codes 0604T, 0605T and 0606T from status indicator ''E1'' to ''B'' in the October 2026 update of the Integrated Outpatient Coding Editor (I/OCE) and in the October 2026 Update of the Addendum B that was posted to the CMS website.

For this final rule with the comment period, we are finalizing our proposal with modification and are assigning CPT codes 0604T, 0605T and 0606T to status indicator ''B''.

Table 42 shows the finalized status indicator for the procedure codes.

We refer readers to Addendum D1 of this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 42: FINAL CY 2027 OPPS STATUS INDICATOR ASSIGNMENT FOR CPT CODES 0604T, 0605T AND 0606T

CPT Code	Long Descriptor	Final CY 2027 OPPS SI
0604T	Optical coherence tomography (oct) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center, unilateral or bilateral; initial device provision, set-up and patient education on use of equipment	B
0605T	Optical coherence tomography (oct) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center, unilateral or bilateral; remote surveillance center technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days	B
0606T	Optical coherence tomography (oct) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center, unilateral or bilateral; review, interpretation and report by the prescribing physician or other qualified health care professional of remote surveillance center data analyses, each 30 days	B

36. Evacuation of Meibomian Glands, Using Heat Delivered Through Wearable, Open-Eye Eyelid Treatment Devices and Manual Gland Expression, Bilateral CPT 0563T (APC 5501)

CPT code 0563T describes evacuation of meibomian glands, using heat delivered through wearable, open-eye eyelid treatment devices and manual gland expression, bilateral. TearCare® is a technology-enabled interventional therapy for meibomian gland disease (MGD) and dry eye disease (DED) that continuously heats all four eyelids to a therapeutic temperature to melt or liquefy hardened oil obstructions in the meibomian glands, followed by physician-performed manual evacuation of the glands.

DED is a chronic affliction of the ocular surface. In the human eye, meibum, aqueous, and mucus form the three layers of tear film, which is the fluid that keeps the eye moist and serves the critical function of protecting the cornea. Meibomian glands are important oil producing glands located within each of the four eyelids. When healthy, these glands produce a clear liquid oil called meibum, which is expressed with every blink, coats the tear with oil, and prevents the tear from evaporating prematurely and exposing the cornea. In patients with MGD, the meibomian glands become diseased and inflamed and the meibum hardens. Obstructed meibomian glands cannot produce healthy new liquid meibum, leaving the tear uncoated and resulting in accelerated tear evaporation and an exposed cornea. This evaporative cascade is the leading cause of dry eye disease.

In the 2027 ASC/OPPS proposed rule, we proposed to continue to assign CPT code 0563T to status indicator ''Q1'' and APC 5733 (Level 3 Minor Procedures) with proposed payment rate of $66.91.

We received several public comments related to our proposal. The following is a summary of the comments we received.

Comments: The commenters requested that we reassign CPT code 0563T from APC 5733 to APC 5503 (Level 3 Extraocular, Repair and Plastic Eye Procedures) with status indicator ''J1'' and proposed payment rate of $2,808.31. They stated that they do not believe that the current assignment appropriately reflects either the clinical nature of the procedure or the resources required to furnish it. TearCare® requires specialized capital equipment, single-use bilateral treatment components, treatment of all four eyelids, clinical staff and treatment-room resources, followed by physician-performed manual evacuation of the meibomian glands. The single-use treatment components alone have a cost

that substantially exceeds the proposed APC 5733 payment.

They also pointed out that TearCare® is performed predominantly in the physician-office setting, where utilization does not generate an OPPS facility claim. Therefore, the limited HOPD claims reflect where TearCare® is currently performed rather than the resources required to furnish the procedure. They stated they do not believe these limited claims provide a representative basis for determining the appropriate APC assignment for CPT 0563T and those limited claims could have been filed in error. This is particularly important because the current APC payment, in their opinion, does not adequately recognize the resources required to furnish the procedure in the HOPD and may create a barrier for providers seeking to offer TearCare® to Medicare beneficiaries in other settings of care.

According to one of the commenters, the procedure requires dedicated equipment (SmartHub); bilateral, single-use Smartlid devices, a tool to clear glands, and additional supplies; in addition to clinical labor time for pre-service, intraservice, and post-service activities involving approximately 60 minutes. Based on these costs, the estimated hospital resource costs to perform the procedure will exceed $1,800 per procedure.

Response: We appreciate the commenters' input. We agree with the commenters that a family of APCs that describe Extraocular Procedures is more clinically appropriate for CPT code 0563T. However, because there has only been minimal claims data since CY 2020, (only 2 single claims in CY 2023 and CY 2025 final rules) and there are only 2 single claims and 3 total claims for this procedure in the claims available for ratesetting in this final rule, we concluded that the data doesn't support a payment increase of around $2,520.00. Therefore, we are assigning CPT code 0563T to Level 1 Extraocular, Repair and Plastic Eye Procedures for CY 2027.

In summary, after consideration of the public comments we received, we are not adopting our proposal as final. Instead, we are adopting a final APC assignment for CPT code 0563T to APC 5501 (Level 1 Extraocular, Repair and Plastic Eye Procedures) with status indicator ''T'' for CY 2027 as reflected in Table 43 of this final rule with comment period.

We reiterate that we analyze our claims data on an annual basis to establish the annual OPPS payment rates. Once we have data, we will reevaluate and, if necessary, reassign the code to appropriate APC based on the latest claims data.

Finally, the final payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 43: FINAL CY 2027 APC AND STATUS INDICATOR ASSIGNMENT FOR CPT CODE 0563T

HCPCS Code	Long Descriptor	Final CY2027 OPPS APC, SI
0563T	Evacuation of meibomian glands, using heat delivered through wearable, open-eye eyelid treatment devices and manual gland expression, bilateral	5501, T

Orthopedic Related Services

37. Application of Rigid Total Contact Leg Cast, CPT Code 29445 (APC 5102)

CPT code 29445 describes a procedure of applying a Total Contact Leg Cast. Total contact casting (''TCC''—which is pressure offloading) is an integral part of the standard of care for diabetic foot ulcer (DFU) management, alongside with vascular management, infection management, and sharp debridement, deemed as the ''VIPS'' of DFU care. The use of TCC is often associated with higher healing rates, faster healing times, lower infection rates, and fewer amputations.

TCC is commonly applied after a debridement or grafting procedure during the same office or clinic visit to protect the wound site from ongoing pressure, which could further delay healing.

In the CY 2027 ASC/OPPS proposed rule, we proposed to continue to assign CPT code 29445 to status indicator ''T'' (Procedure or service, multiple procedure reduction applies; with a separate APC payment under OPPS) and APC 5102 (Level 2 Strapping and Cast Application) with proposed payment rate of $331.21.

At the August 24, 2026, HOP Panel Meeting, a presenter advised the Panel to request that CMS reassign CPT code 29445 (*Application of rigid total contact leg cast*) to status indicator ''S'' (Procedure or Service, Not Discounted When Multiple; with a separate APC payment under OPPS). Based on the information presented at the meeting, the Panel recommended that CMS make that reassignment.

We received one comment related to CPT code 29445.

Comment: The commenter stated that CPT coding guidance allows for debridement (CPT codes 11042–11047, 97597–97598) as well as the application of CTPs (CPT codes 15271–15278) on the same date of service as the application of TCC (CPT code 29445). The cast improves the ability of the wound to heal. If a wound debridement is performed (CPT codes 11042–11047, 97597–97598), any primary or secondary dressing materials used to cover the wound would be included in the debridement and would not be separately reported. However, a TCC is not considered a wound dressing and is not included in the debridement procedure. Therefore, the cast application should be coded in addition to the code for the appropriate level of debridement, if performed, and should be assigned to status indicator ''S'' because the application of a TCC is labor intensive and the cost of the product is not insignificant.

Response: We thank the commenter for their input. Per our evaluation of the service and an input from our medical advisors, we determined that there are other clinical procedures that involve an application of cast, such as an application of short leg cast, described by CPT code 29405 or an Unna boot that

is also used for leg ulcer treatment, that is described by CPT code 29580, that are assigned to status indicator ''T''. Therefore, we believe that status indicator ''T'' is appropriately assigned to TCC. As a result, we are maintaining our status indicator assignment as proposed for CY 2027.

We refer readers to Addendum D1 to this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website.

38. Arthrocentesis, Aspiration, and/or Injection of Joint, CPT Codes 20604 and 20611 (APC 5441)

CPT codes 20604, 20606, and 20611 describe arthrocentesis, aspiration, and/or injections of small, intermediate, or major joints with ultrasound guidance. The long descriptors are listed below along with their proposed APC and status indicator assignments.

- 20604—*Arthrocentesis, aspiration and/or injection, small joint or bursa (e.g., fingers, toes); with ultrasound guidance, with permanent recording and reporting.* CPT code 20604 is assigned to APC 5441 (Level 1 Nerve Injections) and status indicator 'T'.
- 20606—*Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (e.g., temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting.* CPT code 20606 is assigned to APC 5442 (Level 2 Nerve Injections) and status indicator 'T'.
- 20611—*Arthrocentesis, aspiration and/or injection, major joint or bursa (e.g., shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting.* CPT code 20611 is assigned to APC 5441 (Level 1 Nerve Injections) and status indicator of 'T'.

For CY 2027, we proposed to maintain the APC and status indicator assignments for these codes. Below is a summary of the comment and our response.

Comment: We received one comment requesting that we reassign CPT codes 20604 and 20611 to APC 5442 (Level 2 Nerve Injections). The commenter noted that there are three CPT codes in this series that include ultrasound guidance and two of those codes (CPT codes 20604 and 20611) are assigned to APC 5441 (Level 1 Nerve Injections), but the third code (CPT code 20606) is assigned to APC 5442 (Level 2 Nerve Injections). The commenter stated that they would expect the CPT codes ''with ultrasound guidance'' to be assigned to the higher APC.

Response: We thank the commenter for their input. The OPPS payment rates were proposed based on available 2025 claims data. Our claims data shows that APC 5441 (Level 1 Nerve Injections) has a geometric mean cost (GMC) of $320 and APC 5442 (Level 2 Nerve Injections) has a geometric mean cost of $748. We reviewed each of the three CPT codes and note that CPT 20604 has a GMC of $415 based on 1,883 single frequency claims; CPT 20606 has GMC of $506 based on 2,455 single frequency claims; and CPT code 20611 has a GMC of $362 based on 41,333 claims.

While we understand the commenter's rationale to assign all three codes that include ultrasound guidance to the same APC, we believe that reassigning CPT codes 20604 and 20611 to APC 5442 (Level 2 Nerve Injections) would result in overpayments based on the codes GMCs—$415 and $362 respectively, compared to the GMC of APC 5442 which is $748. We believe that CPT codes 20604 and 20611 are assigned to an appropriate APC.

As a reminder, we review on an annual basis, the APC items and services paid under OPPS. If we believe that a code or codes are more appropriately paid under a different APC, we will propose a reassignment during the next rulemaking cycle.

After consideration of the public comment we received, we are finalizing our proposal without modification to continue to assign CPT codes 20604 and 20611 to APC 5441. The final CY 2027 payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

39. Arthroscopy, Knee, Surgical; With Meniscus Repair (Medial or Lateral), CPT Code 29882 (APC 5113)

CPT code 29882 describes an arthroscopic surgical procedure of the knee used to repair a torn meniscus in either the medial (inner) or lateral (outer) compartment.

For CY 2027, we proposed to continue to assign CPT code 29882 to APC 5113 (Level 3 Musculoskeletal Procedures) with a proposed payment rate of $3,855.98 and status indicator ''J1''.

We received several public comments related to CPT code 29882. The following is a summary of the comments we received.

Comments: Commenters recommended moving CPT code 29882 from APC 5113 to APC 5114, as this would be a better fit for this arthroscopic meniscal repair procedure, separating these repairs from less costly debridement or meniscectomy procedures grouped in APC 5113. They stated that geometric mean costs of CPT code 29882 are $6,612, which is significantly closer to the geometric mean cost ($8,004) of APC 5114. CPT code 29882 costs are $3,000 higher than the geometric mean costs of APC 5113, where this code currently resides.

Response: We thank the commenters for their input; however, we respectfully disagree with the information presented. Given that any claims data in CY 2025 would be from before the service was payable in the OPPS, it would be difficult to rely on the claims data to determine the APC assignment for this code.

After clinical review and input from our CMS Medical Officers, we continue to believe that CPT code 29882 is appropriately assigned to APC 5113 based on clinical and resource similarity with other codes in that APC.

We remind readers that we review, on an annual basis, the APC assignments for all items and services paid under the OPPS. In summary, after consideration of the public comments we received, we are finalizing our proposal without modification. The final CY 2027 payment rate for this code can be found in Addendum B to this final rule with comment period. Addendum B is available via the internet on the CMS website.

40. Fusion of Foot Bones, CPT Code 28740 (APC 5114)

CPT code 28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint) describes the fusion of foot bones. In the CY 2027 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 28740 to APC 5114 (Level 4 Musculoskeletal Procedures) with a status indicator of ''J1'' (Hospital Part B Services Paid Through a Comprehensive APC; Paid under OPPS) and proposed payment rate of $8,566.15.

We received a public comment on this proposal. The following is a summary of the comment we received and our response.

Comment: A commenter stated that the assignment of CPT code 28740 to APC 5114 may represent a violation of the 2 times rule, which may impede access to care for beneficiaries. The commenter recommended that CMS consider a volume threshold of 500 single major claims (or the existing greater or equal to 99 claims that

constitute greater than or equal to the 2 percent criterion) as the standard for designating an item or service ''significant'' for purposes of the 2 times rule. The commenter requested that we reassign CPT code 28740 to APC 5114 (Level 5 Musculoskeletal Procedures) to resolve the alleged 2 times rule violation.

Response: We appreciate the commenter's input. As discussed in section III.B. of this final rule with comment period, for purposes of reviewing APCs for determining violations of the two-times rule, we consider a procedure code cost significant when it has more than 1,000 single-major claims or when it has more than 99 single major claims and accounts for at least 2 percent of the single major claims used to establish the APC cost.

Based on our review of the updated claims data available for this final rule with comment period, CPT code 28740 has a geometric mean cost of approximately $12,571 based on 549 single claims. However, these claims do not meet the 2 percent threshold of claims used to establish ratesetting for APC 5114. Therefore, CPT code 28740 does not meet the significance threshold used in our evaluation of the two-times rule. The lowest-cost significant procedure in APC 5114 has a geometric mean cost of approximately $5,862.49, while the highest-cost significant procedure has a geometric mean cost of approximately $10,510.96. Consequently, we did not identify a violation of the two-times rule for APC 5114.

After consideration of the public comment, we are finalizing our proposal without modification to assign CPT code 28740 to APC 5114 with status indicator ''J1'' for CY 2027. The final CY 2027 payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

41. Hip Arthroplasty Revision Procedures, CPT Codes 27134, 27137, and 27138 (APC 5115)

For CY 2026, CMS removed the revision of hip arthroplasty procedures described by CPT code 27134 (Revision of total hip arthroplasty; both components, with or without autograft or allograft), CPT code 27137 (Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft), and CPT code 27138 (Revision of total hip arthroplasty; femoral component only, with or without allograft) from the IPO list as part of the first phase of the elimination of the list. For CY 2026, we assigned CPT codes 27134, 27137, and 27138 to APC 5115 (Level 5 Musculoskeletal Procedures). For CY 2027, we proposed to continue to assign these codes to APC 5115, with a proposed payment rate of around $14,629.

We received one public comment on this proposal. The following is a summary of the comment we received and our response.

Comment: A commenter requested that we reassign CPT codes 27134, 27137, and 27138 to APC 5116 (Level 6 Musculoskeletal Procedures) with a proposed payment rate of $20,224. The commenter stated that hospital inpatient knee and hip revision procedures are more resource-intensive and are assigned to a higher MS–DRG payment than the primary procedure in the hospital inpatient setting.

Response: We thank the commenter for their input. Our updated claims data shows that CPT codes CPT codes 27134, 27137, and 27138 have geometric mean costs of $14,967, $13,206, and $12,279 respectively. Additionally, we believe that these procedures are appropriately assigned to APC 5115, as hip arthroplasty and other revision procedures are currently in this APC. Therefore, due to the available claims data and clinical similarity to other procedures in APC 5115, we are finalizing our proposal to continue to assign CPT codes 27134, 27137, and 27138 to APC 5115 for CY 2027.

We note that we will monitor the claims data and update the payment rate in future rulemaking based on the available claims, as these codes were previously on the IPO list. The final CY 2027 payment rate for the code can be found in Addendum B to this final rule with comment period. We also refer readers to Addendum D1 to this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

42. Limb Cryocompression Therapy, APCs 1069T and 1070T

CPT Codes 1069T (placeholder code X601T) *(Initial fitting, measurement, therapy education, glove/boot supplies))* and 1070T (placeholder code X602T) *(Cryocompression treatment setup, coolant/supplies, oncology nurse time))* describe a supportive care service that combines cooling and intermittent pneumatic compression of the limbs during chemotherapy to reduce the incidence and severity of chemotherapy-induced peripheral neuropathy. Both codes will become effective January 1, 2027.

For CY 2027, CMS proposed to assign CPT code 1069T to status indicator ''S'' and APC 5735 (Level 5 Minor Procedures) with a proposed payment rate of $487.07. CMS proposed to assign CPT code 1070T to status indicator ''S'' APC 5732 (Level 2 Minor Procedures) with a proposed payment rate of $41.98.

We received a public comment on this proposal. The following is a summary of the comment we received and our response.

Comment: We received a comment from the manufacturer of the Limb Cryocompression System, which is used to furnish the fitting and cooling service described by CPT codes 1069T and 1070T, requesting that we finalize alternative APC assignments for both codes that more closely align with the resources used to furnish the service. Specifically, the commenter requested that we reassign CPT code 1069T to APC 1561 (New Technology—Level 24 ($3,001–$3,500)) with a proposed payment rate of $3,250.50 or APC 1562 (New Technology—Level 25 ($3,501–$4,000)) with a proposed payment rate of $3,750.50, and that we reassign CPT 1070T to APC 5734 (Level 4 Minor Procedures) with a proposed payment rate of $152.43.

Response: We thank the commenter for their input. At this time, we do not believe that the device utilized to furnish the service has FDA marketing authorization. Therefore, we are not finalizing our proposal at this time. For CY 2027, we are finalizing to assign CPT codes 1069T and 1070T to status indicator ''E1'' until such time that we are able to confirm that the device has FDA marketing authorization. Refer to Table 44 for the code descriptors and status indicator assignments for CPT codes 1069T and 1070T.

In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator (SI) definitions for all codes reported under the OPPS. Addendum D1 is available via the internet on the CMS website.

TABLE 44: PROPOSED AND FINAL CY 2027 OPPS APC AND SI ASSIGNMENTS FOR CPT CODES 1069T AND 1070T

HCPCS Code	Long Descriptor	Proposed CY 2027 APC, SI	Final CY 2027 SI
1069T	Initial fitting, measurement, therapy education, glove/boot supplies	5735, S	E1
1070T	Cryocompression treatment setup, coolant/supplies, oncology nurse time	5735, S	E1

43. Revision of Total Knee Arthroplasty, With or Without Allograft; 1 Component, CPT Code 27486 (APC 5115)

CPT code 27486 describes a revision, repair, or reconstruction of a total knee replacement involving one component (with or without an allograft). In the 2027 ASC/OPPS proposed rule, we proposed to continue assigning CPT code 27486 to APC 5115 (Level 5 Musculoskeletal Procedures) with status indicator ''J1'' and a proposed payment rate of $14,628.91 for CY 2027. We received one public comment related to CPT code 27486.

Comment: The commenter was concerned that an assignment to APC 5115 does not account for the significant resource demands of the revision of total joint arthroplasty procedures and they believed that the geometric mean cost associated with CPT code 27486 is more closely aligned with APC 5116 (Level 6 Musculoskeletal Procedures) than with the currently proposed assignment to APC 5115. Therefore, the commenter urged CMS to assign total knee revision procedure to the more appropriate APC 5116.

Response: We thank the commenter for their input. CPT code 27486 has an updated geometric mean cost of $9,014.40 in the final rule data, which is less than half than the geometric mean cost of $18,825.67 of APC 5116. The geometric mean cost of APC 5115 is $13,545.46. Even though any claims data in CY 2025 would be from before the service was payable in the OPPS, and it would be difficult to rely on the claims data to determine the APC assignment for this code, we still continue to believe that CPT 27486 is more closely aligned with APC 5115. Additionally, there are other clinically similar revision procedure codes assigned to APC 5115. Therefore, we think that our proposal to assign CPT code 27486 to APC 5115 is appropriate for CY 2027 and we are finalizing it without modification.

The final CY 2027 payment rate for the code can be found in Addendum B to this final rule with comment period. Addendum B is available via the internet on the CMS website.

44. TOPS System, CPT Code 0202T (APC 5117)

For CY 2026, CMS removed CPT code 0202T (*Posterior vertebral joint(s) arthroplasty (e.g., facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine*) from the IPO list. This procedure was assigned to APC 5115 (Level 5 Musculoskeletal Procedures) based on clinical and resource utilization.

We received one public comment on this proposal. The following is a summary of the comment we received and our response.

Comment: One commenter requested that CMS reassign CPT code 0202T to APC 5117 (Level 7 Musculoskeletal Procedures) based on its claims data and clinical similarity to CPT codes 22630 (*Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar*) and 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*).

Response: We thank the commenter for their input. After further review, we agree with the commenter that CPT code 0202T does share clinical similarity to CPT codes 22630 and 22633. We also note that our available claims CPT code 0202T showed 6 claims with a geometric mean cost of around $32,538. While this is a very low number of claims, it could show that the resource cost of CPT code 0202T may better align with the payment for APC 5117. Therefore, due to its clinical and resource similarity, we are finalizing our proposal with modification to reassign CPT code 0202T from APC 5115 to APC 5117, as reflected in Table 45 below. The final CY 2027 payment rate for the code can be found in Addendum B to this final rule with comment period. We also refer readers to Addendum D1 to this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 45: PROPOSED AND FINAL CY 2027 OPPS APC AND SI ASSIGNMENTS FOR CPT CODE 0202T

CPT Code	Long Descriptor	Proposed CY 2027 APC, SI	Final CY 2027 APC, SI
0202T	Posterior vertebral joint(s) arthroplasty (eg, facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine	5115, J1	5117, J1

Pulmonary Related Services

45. Insertion of Endobronchial Valves, CPT Code 31647 (APC 5155)

CPT code 31647 (*Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe*) describes a procedure used for conditions such as severe emphysema or persistent bronchopleural air leaks, where a device is placed to control airflow into a portion of the lung. For the CY 2027 OPPS/ASC proposed rule, we proposed to continue to assign the procedure to APC 5155 (Level 5 Airway Endoscopy) and status indicator J1, which has a payment rate of around $7,710.

We note that at the August 24, 2026, HOP Panel Meeting, a presentation was made requesting the reassignment of CPT code 31647 from APC 5155 to New Technology APC 1575 (New Technology—Level 38 ($10,001–$15,000) with a payment rate of $12,500.50. Based on the information presented at the meeting, the Panel recommended CMS create a new Level 6 Airway Endoscopy APC.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters recommended that CMS reassign CPT code 31647 from APC 5155 to New Technology APC 1575 (New Technology—Level 38 ($10,001–$15,000)). The commenters noted that the cost of the procedure exceeds the payment by approximately $3,000 and expressed concern that this discrepancy would result in patient access to the procedure being limited, particularly considering that the alternatives for severe emphysema patients involve much more invasive and expensive treatment options. The commenter stated that the reassignment to a New Technology APC was necessary because the APC assignment 5155 does not appropriately account for the resources involved as reflected by CMS data.

One commenter claimed that the geometric mean costs for CPT code 31647 remains consistent and well above the geometric mean cost for the APC into which it maps (APC 5155). While acknowledging that there is not a 2-times rule violation (given the number of single frequency claims for the procedure), the commenter noted that the GMC for CPT code 31647 is significantly above the GMC of the other procedures assigned to APC 5155 and more than double for many procedures in the APC 5155.

The commenter also stated that they considered an alternative clinical APC but could not identify a clinically and resource cohesive clinical APC into which to move it. The commenter stated that with no appropriate or higher clinical APC to use as an alternative, CMS should assign the procedure to a new technology APC that more closely aligns with its GMC. The commenter concluded that APC 1575 is the appropriate new technology APC for the service given that the GMC for CPT code 31647 has been in the $11,000–$12,000 range for the past 4 plus years and the GMC is $11,456 in the 2025 claims data that CMS released. Another commenter stated that the GMC for 31647 has remained consistently high over multiple years and outpatient claims are likely to remain steady, ranging from 72 to 88 claims. The commenter noted that the concern is underscored by the fact that the lowest geometric mean cost of a significant procedure in APC 5155 for CY 2027 is $5,481. The commenter stated that CMS previously received a recommendation from the HOP panel suggesting reassignment of CPT 31647 to New Tech APC 1575 and the commenter supports that recommendation as an interim measure until a permanent APC solution can be established.

Response: As recognized by one of the commenters, APC 5155 does not currently have a 2 times rule violation in the final rule data, and APC 5155 appears to be the best clinical fit for CPT code 31647 of any existing clinical APC.

After consideration of the public comments we received and discussion and input from our Medical Officers, we are finalizing our proposal without modification to assign CPT code 31647 to APC 5155. We examined the HOP panel recommendation and decided not to create a new APC (Level 6 Airway Endoscopy). We note that a new APC Level 6 would have less than 1000 claims and claims for CPT code 31647 have been stable from year to year and have 95 single frequency claims.

We acknowledge the commenters' concerns and rationale for reassigning CPT code 31647 to New Tech APC 1575 (New Technology Level 38), but we disagree with the reassignment. In part, we do not believe that an assignment to a new technology APC is an appropriate crosswalk because this is not a new technology.

We review the APC assignments for all items and services paid under the OPPS on an annual basis. We will reevaluate the APC assignment for CPT code 31647 in the next rulemaking cycle.

In summary, after consideration of the public comments we received, we are finalizing our proposal without modification to assign CPT code 31647 to APC 5 (Level 5 Airway Endoscopy).

The final CY 2027 payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer to Addendum D1 to this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

46. RejuvenAir System, CPT Code 1040T

CPT code 1040T (Bronchoscopy, flexible, with bronchial cryotherapy, 1 lung, including trachea, when performed) describes flexible bronchoscopy with bronchial cryotherapy of one lung, including the trachea, when performed. For CY 2027, we proposed to assign CPT code 1040T to status indicator ''E1'' (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)).

We received a public comment on this proposal. The following is a summary of the comment we received and our response.

Comment: A commenter discussed the appropriate OPPS payment classification for CPT code 1040T. The commenter stated that the RejuvenAir system, which is used to furnish the service described by CPT code 1040T, has received FDA Breakthrough Device Designation and that a Premarket Approval application was submitted to FDA in January 2026, but the device has not yet received FDA approval. The commenter acknowledged CMS's proposed assignment of status indicator ''E1'' and stated that, once FDA approval is obtained, the commenter intends to notify CMS so that CMS can assign an appropriate payable status indicator and APC. The commenter emphasized the importance of establishing an appropriate APC assignment following FDA approval to support hospital payment and beneficiary access to the service.

Response: We thank the commenter for its input. Because the medical device associated with CPT code 1040T has not received marketing authorization from the FDA, we are unable to determine the appropriate APC assignment for the service at this time. Therefore, we are maintaining the status indicator assignment of ''E1'' for CPT code 1040T. We look forward to hearing from the manufacturer when FDA marketing authorization has been obtained. At that time, we will evaluate the appropriate

status indicator and APC assignment for CPT code 1040T.

In summary, after consideration of the public comment that we received, we are finalizing the status indicator assignment of ''E1'' for CPT code 1040T without modification. The final CY 2027 status indicator for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

Skin Related Procedures

47. Electromagnetic Therapy for Ulcers, HCPCS Code G0329

HCPCS code G0329 (Electromagnetic therapy, to one or more areas for chronic stage iii and stage iv pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care) was created in Transmittal 124, dated March 19, 2004, CR 3149), and made effective on July 1, 2004. HCPCS code G0329 was assigned to status indicator ''A'' in the CY 2005 OPPS final rule (69 FR 66135) and has continued to be assigned that status indicator under the OPPS since that time.

Comment: A commenter requested that CMS make available data on the claims and cost data used to develop the geometric mean cost for G0329 and to evaluate whether the APC the code is assigned to meets the criteria for the universal low volume APC policy.

Response: As we noted earlier in this section, HCPCS code G0329 was proposed to continue to be assigned a status indicator of ''A'', indicating that the code is paid under a fee schedule or payment system other than the OPPS. Under that designation, there would not be an OPPS APC assignment, and therefore OPPS ratesetting for developing OPPS payment weights for that code and associated policies like the universal low volume policy would not be applicable. Further, we note that HCPCS code G0329 is included on the list of therapy services at *https://www.cms.gov/medicare/coding-billing/therapy-services/annual-therapy-update.*

We continue to believe that the assignment of status indicator ''A'' for HCPCS code G0329 is appropriate and therefore are finalizing the assignment for the CY 2027 OPPS.

After consideration of the public comments received, we are finalizing the assignment of status indicator of ''A'' for HCPCS code G0329 in the CY 2027 OPPS.

48. UltraMIST System Wound Care Service, CPT Code 97610 (APC 5051)

CPT code 97610 *(Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day)* first became effective January 1, 2014, and describes a wound care service using ultrasound. For CY 2027, we proposed to assign CPT code 97610 to APC 5051 (Level 1 Skin Procedures) and status indicator ''Q1.'' For CY 2027, CPT code 97610 has a geometric mean cost of $221.36 based on 2,013 single frequency claims. CPT code 97610 has 4,378 total frequency claims for CY 2027.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters requested that we not finalize the proposed APC and status indicator assignments for CPT code 97610. The manufacturer of the UltraMIST System, which may be described by CPT code 97610, requested that CMS revise the status indicator from ''Q1'' to ''T'' and the APC assignment from APC 5051 (Level 1 Skin Procedures) to APC 5052 (Level 2 Skin Procedures). The UltraMIST System consists of a wand that delivers low-frequency ultrasound energy through a fine, sterile saline mist without touching the wound directly. Regarding the status indicator request, the manufacturer requested that we revise the status indicator to ''T'' for CY 2027 based on a crosswalk to CPT code 97597, which the commenter claimed was the closest clinical sibling of CPT code 97610. The commenter explained that the proposed status indicator assignment of Q1 would exclude most of the code's claims for ratesetting, since 54 percent of the claims for CPT code 97610 are total frequency claims, and therefore represent claims where the CPT code 97610 is billed alongside another service. Another commenter requested that assign CPT code 97610 to status indicator ''S'' to allow for more accurate claims collection specific to the service.

Regarding the proposed APC assignment, commenters requested that we revise the APC assignment for CPT code 97610 from APC 5051 to APC 5052 to better align resource use and costs to more comparable wound treatment codes, like CPT codes 97610 (Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters) and 97608 (Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters), which we proposed to assign to APC 5052.

Response: We thank the commenters for their feedback. Regarding the status indicator for CPT code 97610, we believe that a crosswalk to the status indicator for a debridement service as recommended by commenters (*e.g.* CPT code 97597, which is assigned to status indicator ''T''), is appropriate in terms of clinical and resource similarity. Regarding the APC assignment for CPT code 97610, while we acknowledge that the service is often provided at the same time as other procedures, we note that the $196.40 geometric mean cost based on the 3,778 single frequency claims aligns closely with the geometric mean cost of the proposed APC 5051, which is approximately $221. Therefore, we are declining to finalize a revised APC assignment for CPT code 97610 and will continue to evaluate the claims data in future years.

In summary, after consideration of the public comments we received, we are finalizing our proposals with modifications. Specifically, we are finalizing a revised status indicator of ''T'' for CPT code 97610 and finalizing assignment of CPT code 97610 to APC 5051 as proposed. Refer to Table 46 for the code descriptor, APC assignment, and status indicator assignment for CPT code 97610 for CY 2027.

The final CY 2027 payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator (SI) definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 46: PROPOSED AND FINAL CY 2027 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR ULTRAMIST SYSTEM WOUND CARE SERVICE

HCPCS Code	Long Descriptor	Proposed CY 2027 APC, SI	Final CY 2027 APC, SI
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day	5051, Q1	5051, T

Sleep Studies

49. Unattended Sleep Study, CPT Code 95846, (APC 5723)

CPT code 95846 (placeholder code 95X20) (Unattended sleep study, set-up, data acquisition and technical analysis; high complexity, 11 or more channels) describes a high-complexity unattended sleep study. CPT code 95846 is currently assigned to APC 5722 (Level 2 Diagnostic Tests and Related Services) with a proposed payment of around $247, and a status indicator of 'S' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment).

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters requested that CMS reassign CPT code 95846 from APC 5722 (Level 2 Diagnostic Tests and Related Services) to a higher-level APC. Commenters stated that CPT code 95846, which describes a high-complexity unattended sleep study involving 11 or more channels, requires greater resources than CPT code 95844 (95X19) and is also assigned to APC 5722, which describes a moderate-complexity unattended sleep study involving 5 to 10 channels. Commenters stated that the high-complexity service requires more sophisticated equipment and supplies, additional physiologic sensors and channels, greater software and data processing capabilities, and additional technical resources.

Commenters stated that because CPT codes 95844 and 95846 are new for CY 2027, historical claims data for predecessor sleep study codes may not adequately reflect the resource differences between the newly established complexity levels. Commenters requested that CMS assign CPT codes 95844 and 95846 to separate APCs and consider available cost information and other supporting evidence in determining the appropriate APC assignments. A commenter specifically requested that CMS reassign CPT code 95846 to APC 5723 (Level 3 Diagnostic Tests and Related Services), while maintaining CPT code 95844 in APC 5722. The commenter further stated that APC 5723 would better reflect the clinical and resource characteristics of the high-complexity unattended sleep study and provided information regarding the costs associated with furnishing the service in support of the requested reassignment.

Response: We thank the commenters for their input. After consideration of the public comments and further review of the clinical and resource characteristics of CPT code 95486, we agree with the commenters that CPT code 95486 should be assigned to a higher-level APC than CPT code 95844. We believe that the greater number of channels and physiologic parameters associated with the high-complexity unattended sleep study described by CPT code 95486, as well as the additional equipment, supplies, and technical resources associated with furnishing the service, support assignment to APC 5723 (Level 3 Diagnostic Tests and Related Services). We believe that APC 5723 more appropriately reflects the clinical and resource characteristics of the service.

Therefore, after consideration of the public comments we received, we are finalizing with modification our proposal and assigning CPT code 95846 to APC 5723 (Level 3 Diagnostic Tests and Related Services) with status indicator ''S'' for CY 2027. We will continue to monitor the claims data for these new codes as the data become available and reevaluate their APC assignments in future rulemaking, as appropriate.

The final CY 2027 payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

TABLE 47: PROPOSED AND FINAL CY 2027 OPPS APC AND SI ASSIGNMENT FOR CPT CODE 95846

CPT Code	Long Descriptor	Proposed CY 2027 APC, SI	Final CY 2027 APC, SI
95846	Unattended sleep study, set-up, data acquisition and technical analysis; high complexity, 11 or more channels that generate at least 9 parameter categories	5722, S	5723, S

Spinal and Brain Procedures

Spinal and Brain Procedures

50. Central Nervous System and Spinal Services, CPT Codes 62350, 61720, 63741, and 63744 (APCs 5432 Through 5433)

For CY 2027 ASC/OPPS proposed rule, we proposed to continue to assign CPT code 63744—*Replacement, irrigation or revision of lumbosubarachnoid shunt* to APC 5432 (Level 2 Nerve Procedures) with status indicator ''J1'' and proposed payment rate of $3,934.73.

We proposed to continue assigning the following CPT codes to APC 5433 (Level 3 Nerve Procedures) with status indicator ''J1'' and proposed payment rate of $9,926.55:

- 61720—*Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus.*
- 62230—*Replacement or revision of cerebrospinal fluid shunt, obstructed valve, or distal catheter in shunt system.*
- 62350—*Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; without laminectomy.*
- 63741—*Creation of shunt, lumbar, subarachnoid-peritoneal, -pleural, or other; percutaneous, not requiring laminectomy.*

We received public comments related to our proposal.

Comment: The following is a summary of the comments we received. The commenters recommended that we reassign CPT code 62350 to APC 5114 (Level 4 Musculoskeletal Procedures). They also recommended reassigning CPT code 61720 to APC 5461 (Level 1 Neurostimulator and Related Procedures) and the following CPT codes to APC 5462 (Level 2 Neurostimulator and Related Procedures): 62230, 63741 and 63744.

Some commenters stated that this APC reassignment would place these services with procedures that share more comparable anatomy, technology, workflow, and hospital resource requirements. Other commenters pointed out that these changes would strengthen APC integrity and better align payment classifications with the actual services furnished in the hospital outpatient setting. They urged CMS to perform the APC reassignments to prevent central nervous system and spinal services from diluting the clinical integrity of APCs 5432 and 5433. One of the commenters has conducted the following analysis that according to the commenter demonstrated that:

- CPT 62350 aligns exceptionally well with APC 5114. It falls near the center of the APC cost distribution and demonstrates excellent resource homogeneity.
- CPT 61720 demonstrates strong alignment with APC 5461. The CPT geometric mean cost is only 13.2 percent above the APC 5461 benchmark and dramatically closer than its current APC assignment.
- CPT 63744 aligns closely with APC 5462 and is positioned near the center of the APC cost distribution.
- CPT 63741 demonstrates improved alignment with APC 5462 and falls within the established APC cost range, although this is a low-volume service.
- CPT 62230 falls comfortably within the APC 5462 cost distribution and exhibits cost characteristics consistent with procedures currently assigned to APC 5462.

Response: We wanted to thank the commenters for their input. Based on our review of the claims data, and recommendations from CMS's Medical Officers, we don't believe that these procedures should be reassigned to other clinical APC families or moved to other Nerve Procedure APC Levels.

We reviewed each code individually. In the claims available for OPPS ratesetting for this final rule, CPT code 62350 has an estimated geometric mean cost of $8,025.50 based on 271 single claims. The geometric mean cost of APC 5433 (Level 3 Nerve Procedures) is $9,156.83. We believe that the proposed placement of CPT code 62350 in APC 5433 remains appropriate based on its geometric mean cost relative to that of the APC. Therefore, we are finalizing our proposal without modification to assign CPT code 62350 to APC 5433 for CY 2027.

In the claims available for OPPS ratesetting for this final rule, CPT code 61720 has an estimated geometric mean cost of $4,318.70 based on 7 single claims. The geometric mean cost of APC 5433 is $9,156.83. Because of such a low volume of claims for this service, we believe that CPT code 61720 is appropriately placed in APC 5433 for CY 2027 and will continue to monitor claims data as more claims become available in future years. As a result, we are finalizing assignment of CPT code 61720 to APC 5433 for CY 2027.

In the claims available for OPPS ratesetting for this final rule, CPT code 62230 has an estimated geometric mean cost of $8,310.25 based on 339 single claims. The geometric mean cost of APC 5433 is $9,156.83. Therefore, we believe that the proposed placement of CPT code 62230 in APC 5433 is still appropriate for CY 2027 and are finalizing our proposal to assign CPT code 62230 to APC 5433 for CY 2027.

In the claims available for OPPS ratesetting for this final rule, CPT code 63741 has an estimated geometric mean cost of $10,755.50 based on 9 single claims. The geometric mean cost of APC 5433 is $9,156.83. Because we only have 9 single claims, we think that CPT code 63741 is in line with the geometric mean cost of APC 5433 for CY 2027 but will continue to monitor claims data as more updated claims become available. As a result, we are finalizing our proposed assignment of CPT code 63741 to APC 5433 for CY 2027.

In the claims available for OPPS ratesetting for this final rule, CPT code 63744 has an estimated geometric mean cost of $8,471.68 based on 12 single claims. The geometric mean cost of APC 5432 (Level 2 Nerve Procedures) is $4,248.97. Since we only have 12 claims, we believe that APC 5432 remains a good fit for CPT code 63744 for CY 2027 based on clinical coherence and will monitor claims data as more updated claims become available in future years.

Therefore, we are finalizing without modification our proposal to assign CPT code 63744 to APC 5432 for CY 2027.

We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reported under the OPPS. Addendum B is available via the internet on the CMS website.

Surgical Procedures

51. Diaphragmatic Hernia Repair, CPT Code 39542 (APC 5342)

Effective January 1, 2027, the AMA CPT Editorial Panel created CPT code 39542 (Repair of nontraumatic diaphragmatic hernia via laparotomy), which was previously described by placeholder code 39XX3. CPT code 39542 describes the procedure for nontraumatic diaphragmatic hernia repair via a laparotomy approach. For CY 2027, we proposed to assign CPT code 39542 to APC 5342 (Level 2 Abdominal/Peritoneal/Biliary and Related Procedures), with a proposed payment rate of around $7,715.

We received one public comment on this proposal. The following is a summary of the comment we received and our response.

Comment: One commenter requested that we reassign CPT code 39542 to APC 5362 (Level 1 Laparoscopy and Related Services), which had a proposed payment rate of around $12,300. The commenter stated that this procedure had similar clinical and resource utilization as other diaphragmatic procedures assigned to APC 5362.

Response: We thank the commenter for their input. After careful review, we continue to believe that assignment of CPT code 39542 to APC 5342 is appropriate due to its similarity to other laparotomy procedures in this APC. We note that since this is a new code, we will not have claims data available until CY 2029 rulemaking. We will monitor the claims data and update the payment rate in future rulemaking based on the available claims.

The final CY 2027 payment rate for the code can be found in Addendum B to this final rule with comment period. We also refer readers to Addendum D1 to this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

52. Radiofrequency Ablation of Lumpectomy Cavity, CPT Code 1955T

Effective October 1, 2026, the AMA CPT Editorial Panel created CPT code 1055T (Intraoperative radiofrequency ablation of lumpectomy cavity, unilateral, including applicator placement and removal (List separately in addition to code for primary procedure)). Based on the OPPS packaging policy, we assigned CPT code 1055T to status indicator ''N'' (packaged) for in the October 2026 quarterly update.

We received one public comment on this proposal. The following is a summary of the comment we received and our response.

Comment: A commenter requested that CMS assign CPT code 1055T to APC 1575 (New Technology—Level 38 ($10,001–$15,000)) and status indicator ''S''. The commenter stated that this assignment would ensure beneficiary access to the procedure and allow CMS to obtain hospital claims data for the procedure.

Response: We thank the commenter for their input. We note that CPT code 1055T is an add-on code. Add-on codes are always performed in addition to the primary service or procedure, not reported as a stand-alone code. As specified under regulation 42 CFR 419.2(b)(18), add-on codes are generally packaged under the OPPS, and payment for the codes are bundled with the primary codes. Consequently, CPT code 1055T is not paid separately under the OPPS and its payment is packaged into payment for the primary code. Therefore, we are finalizing our proposal to assign CPT code to status indicator ''N'' for CY 2027.

We refer readers to Addendum D1 to this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda D1 is available via the internet on the CMS website.

Technology-Enabled Care

53. Digital Mental Health Treatment (DMHT) Services, HCPCS Code G0552 (APC 5012)

HCPCS code G0552 (Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan) describes the supply of a digital mental health treatment device and initial patient education and onboarding. HCPCS code G0552 is currently assigned to APC 5012 (Clinic Visits and Related Services), with a proposed CY 2027 payment of approximately $148, and a status indicator of 'V' (Clinic or Emergency Department Visit).

We received public comments on this proposal. The following is a summary of the comments we received and our response.

Comment: Commenters requested that CMS reconsider the proposed assignment of HCPCS code G0552 (Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan) to APC 5012 (Clinic Visits and Related Services). Commenters stated that the assignment of HCPCS code G0552 to APC 5012 does not appropriately reflect the clinical characteristics or hospital resources associated with furnishing a DMHT device.

Commenters stated that HCPCS code G0552 differs from remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM) services assigned to APC 5012 because HCPCS code G0552 includes the supply of an FDA-authorized digital treatment device in addition to initial education and onboarding. Commenters explained that DMHT devices deliver a therapeutic intervention to treat or alleviate a mental health condition, whereas RPM and RTM devices generally monitor a patient's status or response to treatment. Commenters also stated that the device supply for HCPCS code G0552 is furnished for an entire course of treatment, rather than being separately reported on a recurring basis.

Commenters further stated that the hospital costs associated with furnishing DMHT devices substantially exceed the payment rate for APC 5012. Commenters also stated that CMS's proposed payment policy for Software as a Medical Service (SaMS) supports recognizing hospital expenditures for access to proprietary software as a resource cost under the OPPS, even though DMHT devices are not included within the proposed definition of SaMS.

Commenters recommended that CMS reassign HCPCS code G0552 to a higher-paying APC that more appropriately reflects the clinical and resource characteristics of the service. One commenter suggested APC 5735 (Level 5 Minor Procedures) or APC 5723 (Level 3 Diagnostic Tests and Related Services), or, alternatively, the establishment of a new Level 4 Health and Behavioral Services APC 5824.

Response: We thank the commenters for their recommendations and the information provided regarding the clinical characteristics and costs associated with furnishing DMHT devices. We continue to believe that APC 5012 (Clinic Visits and Related Services) is the most appropriate APC assignment for HCPCS code G0552 at this time. As discussed in in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94087 through 94088), we believe that the DMHT services described by HCPCS codes G0552, G0553, and G0554 are clinically similar to other services assigned to APC 5012, and we believe that maintaining these services within the same APC continues to be appropriate based on the information currently available to us.

We acknowledge the commenters' concerns regarding the costs associated with the DMHT device included in HCPCS code G0552 and appreciate the additional cost information submitted by the commenters. However, we do not believe that the information submitted provides a sufficient basis at this time to reassign HCPCS code G0552 to APC 5723 or APC 5735, or to establish a new Level 4 Health and Behavioral Services APC.

As additional claims data become available for HCPCS code G0552, we will continue to evaluate the clinical and resource characteristics of the service and consider whether a different APC assignment may be appropriate in future rulemaking. Therefore, after consideration of the public comments, we are finalizing our proposal to continue to assign HCPCS code G0552 to APC 5012 (Clinic Visits and Related Services) for CY 2027.

Urology Related Services

54. Clearance of Renal Calculi by Ultrasonic Propulsion, CPT Code 1054T (APC 5373)

The CPT Editorial Panel created CPT code X559T (now replaced with CPT code 1054T) to describe a new

procedure to clear residual fragments of kidney stones out of the kidney by delivering low amplitude, low frequency focused ultrasound that pushes and propels the fragments towards the uretero-pelvic junction post-lithotripsy. The long descriptor for CPT code 1054T is below.

• 1054T—*Focused non-shock wave ultrasonic propulsion of residual stone fragment(s) post-lithotripsy, unilateral, including ultrasound guidance, fragment(s) less than or equal to 5 mm.*

For CY 2027, we proposed to assign CPT code 1054T to APC 5373 (Level 3 Urology and Related Services). Since the CY 2027 OPPS/ASC proposed rule was published, the AMA revised the effective date for this code to October 1, 2026. We received public comment on this service.

Comment: The commenter requested that we assign CPT code 1054T to APC 5374 (Level 4 Urology and Related Services) stating that the total resource costs are $3,765 citing the intra-operative overhead costs are $3,720 based on 60 minutes of procedure time. The commenter notes the geometric mean cost for APC 5374 is $3,797 and CPT code 1054T should therefore, be assigned to APC 5374.

Response: We thank the commenter for their input. We note that this procedure is performed after the lithotripsy has already been completed and question the amount of intraoperative time cited for clearing stone fragments. Based on our review of the service, as well as input from our medical advisors, we believe CPT code 1054T is appropriately assigned to APC 5373.

As we do every year, we will monitor the claims data and reevaluate the APC assignment for this code in the next rulemaking cycle to determine if a more appropriate APC assignment is warranted.

In summary, after consideration of the public comment we received, we are finalizing our proposal without modification, to assign CPT code 1054T to APC 5373 (Level 3 Urology and Related Services) and a status indicator of J1. The final CY 2027 payment rates for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

55. Cystourethroscopy With Lithotripsy and Vacuum Aspiration of Kidney, HCPCS Codes C9761 and C0814 (APCs 5375 and 5376)

HCPCS code C9761 (*Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, and ureteral catheterization for steerable vacuum aspiration of the kidney, collecting system, ureter, bladder, and urethra if necessary, with use of steerable ureteral catheter or suction-integrated ureteroscope*) became effective October 1, 2020 and describes a minimally invasive procedure used to break up and remove kidney stone fragments and dust by use of a continuous irrigation and vacuum system. The long descriptor was revised in CY 2023 to include ''must use a steerable ureteral catheter'' and we further revised the long descriptor to include ''suction-integrated ureteroscope'' effective July 1, 2026, after meeting with the specialty society.

We also established HCPCS code C8014 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, including use of a suction enabled ureteral access sheath, with irrigation (if performed) effective July 1, 2026, to describe these cystourethroscopy procedures where a suction-enabled ureteral access sheath is used to vacuum kidney stone fragments. We assigned HCPCS code C8014 to APC 5375 (Level 5 Urology and Related Procedures) and status indicator 'J1' as we believe this procedure with this device has clinical and resource similarities to other procedures assigned to APC 5375.

For CY 2027, the OPPS payment rates are proposed based on available CY 2025 claims data. For the CY 2027 proposed rule, we found a total of 3,516 single frequency claims and a geometric mean cost of approximately $9,472 for HCPCS code C9761. For CY 2027, we proposed to maintain the APC assignment of 5376 (Level 6 Urology and Related Procedures) and status indicator of 'J1' for HCPCS code C9761.

For CY 2027, we proposed to maintain the APC and status indicator assignment for HCPCS code C8014. We currently have no claims data for ratesetting purposes as this is a new code.

We received public comments on these two HCPCS codes. Below is a summary of the comments and our responses.

Comment: A commenter suggested that we consolidate both C-codes into one single technology-neutral code to describe suction-assisted ureteroscopic and/or pyeloscopic lithotripsy and if we did not consolidate the two C-codes, provide exclusive coding instructions for each of these HCPCS codes. The commenter explained that both of these C-codes describe suction-assisted stone-fragment evacuation during cystourethroscopy with ureteroscopy and/or pyeloscopy with lithotripsy and are furnished during the same procedure, through the same anatomic pathway, and for the same purpose. The commenter believes the device distinction is not enough of a meaningful difference to require separate HCPCS codes or have a different APC assignment. The commenter cites studies supporting their position that the performance between a flexible and navigable suction access sheath (FANS) and the CVAC system described by C9761. The commenter then went on to say that if CMS continues to maintain both HCPCS codes, C9761 and C8014 should be assigned to the same APC. The commenter requested that CMS publish clear coding instructions with illustrative examples distinguishing between the three types of devices: (1) a suction-enabled ureteral access sheath (*i.e.,* FANS); (2) a steerable vacuum-aspiration ureteral catheter (*i.e.,* CVAC system); and (3) a suction-integrated ureteroscope noting that additional coding guidance would support accurate coding and reduce claims denials.

Another commenter requested that we reassign C8014 to APC 5376 (Level 6 Urology and Related Services stating that the reassignment would be more appropriate, both clinically and based on resource utilization. The commenter noted that there are a number of complex kidney stone procedures in APC 5376, including HCPCS code C9761. The commenter believes that because we do not yet have claims data available for C8014 for our standard geometric mean cost (GMC) methodology, clinical coherence with existing APC assignments should receive significant consideration in evaluating the appropriate APC placement, such as C9761 as a crosswalk. In addition, the commenter provided their analysis of claims data to support their belief that C8014 would be more appropriately assigned to APC 5376.

Another commenter supported the creation of HCPCS code C8014 and its APC assignment to APC 5375 (Level 5 Urology and Related Services). They believe that the creation of this code will help CMS measure utilization, resources, and costs separately from the service described by HCPCS code C9761

and refine payment as we begin to have claims data.

The commenter expressed concerns regarding the revised long descriptor for C9761 stating that the revised language causes some further confusion with cases involving a suction-capable ureteroscope (also commonly referred to as a direct in-scope suction (DISS) ureteroscope), with or without a suction-enabled ureteral access sheath. The commenter requested clarification regarding the term ''integrated'' and suggested that there be a documentation-based framework that articulates three different care pathways to distinguish the type of technology used (or not used), including (1) the standard ureteroscopy/lithotripsy pathway; (2) the suction-enabled access sheath pathway; and (3) the steerable-vacuum aspiration pathway. The commenter states that the clinical literature does not support the equivalency of suction-capable ureteroscopes and suction-enabled access sheaths are equivalent to the steerable renal vacuum-aspiration service represented by HCPCS code C9761.

This commenter believes that our coding clarification should distinguish the device predicate from the service predicate and further clarification is necessary for payment accuracy, beneficiary protection, and program integrity. The commenter suggests that HCPCS C9761 is coded when the services actually provided are less resource intensive. To remedy these concerns, the commenter requested that CMS issue provider communication explaining the three types of care pathways to distinguish the types of technology used and define ''suction-integrated ureteroscope'' in functional terms, or in the alternative, revise the current long descriptors to provide clarity regarding the service described by the code.

Response: We appreciate the input and recommendations from the interested parties. Over the years we have heard from interested parties regarding concerns about providers utilizing HCPCS code C9761 to describe the ureteroscopy/lithotripsy procedure with a suction-enabled ureteral access sheath and the potential program integrity concerns that raises when C9761 is assigned to a higher APC because of the underlying device costs. To remedy these concerns, we created C8014 to specifically describe the ureteroscopy/lithotripsy procedures with suction-enabled sheaths and assigned it to what we believe is an appropriate APC. We then heard from the American Urological Association who then informed us that there is a third type of device (suction-integrated ureteroscope) that is used to vacuum stone fragments during ureteroscopy/lithotripsy procedures. As a result, we revised the descriptor language to include this device in the descriptor for C9761.

We do not believe that we should at this time consolidate these two HCPCS codes into one single technology neutral code and assign it to APC 5376. While we understand the rationale, we do not want to create further coding confusion since we just created C8014 to distinguish suction-enabled sheaths from steerable vacuum catheters and suction-integrated ureteroscopes. We believe the descriptor language is clear and that there is enough of a difference in costs that warrants separate coding. In addition, we do not believe both HCPCS codes should be assigned to the same APC.

In response to the comments regarding coding guidance and MLN education, we have stated in past rules that we do not provide coding guidance, as it is out of scope for the OPPS/ASC final rule with comment period (89 FR 94122) and if hospitals have questions about appropriate coding that they cannot resolve on their own, the appropriate first step would be to review the HCPCS codes or consult their Medicare Administrative Contractor (MAC) for their jurisdiction. We refer readers to MLN Matters MM14477 (OPPS July 2026 Update) for information regarding the creation of C8014 and the descriptor revision for C9761.

In summary, after consideration of the public comments we received, we are finalizing our proposal without modification, to assign HCPCS code C9761 to APC 5376 (Level 6 Urology and Related Procedures) and a status indicator of 'J1' and HCPCS code C8014 to APC 5375 (Level 5 Urology and Related Procedures) and a status indicator of 'J1'. As we do every year, we will monitor the claims data and reevaluate the APC assignments for these codes in the next rulemaking cycle to determine if more appropriate APC assignments are warranted.

The final CY 2027 payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

56. Optilume BPH Catheter System, CPT Code 52443 (APC 5376)

Effective January 1, 2026, the AMA CPT Editorial Panel created CPT code 52443 (Cystourethroscopy with initial transurethral anterior prostate commissurotomy with a nondrug-coated balloon catheter followed by therapeutic drug delivery into the prostate by a drug-coated balloon catheter, including transrectal ultrasound and fluoroscopy, when performed). For CY 2027, we proposed to continue to assign CPT code 52443 to APC 5376 (Level 6 Urology and Related Services) with a proposed payment rate of around $10,797.

We received one public comments on this proposal. The following is a summary of the comment we received and our response.

Comment: A commenter requested that CMS reassign CPT code 52443 to APC 5377 (Level 7 Urology and Related Services). The commenter stated that CPT code 52443 would better align with procedures assigned to APC 5377. Additionally, the commenter stated that claims data showed that CPT code 52443 had a geometric mean cost of around $12,712.

Response: We thank the commenter for their input. Since CPT code 52443 was new for CY 2026, we note that we will not have any claims data for this code until CY 2028 rulemaking and we are unable to confirm the claims data stated by the commenter. After further review, we believe that CPT code 52443 is appropriately assigned to APC 5376. Therefore, we are finalizing our proposal to assign CPT code 52443 to APC 5376 (Level 6 Urology and Related Services) for CY 2027.

We note that we will monitor the claims data and update the payment rate in future rulemaking based on the available claims. The final CY 2027 payment rate for the code can be found in Addendum B to this final rule with comment period. We also refer readers to Addendum D1 to this final rule with comment period for the SI meanings for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

57. Permanent Prostatic Urethral Stent, CPT Code 52282 (APC 5375)

The ProVee® System is indicated to treat obstructive lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) in men with prostatic urethral lengths greater than or equal to 3.75 cm and prostatic volumes between 30 cc and 80 cc. The insertion of a permanent prostatic urethral stent procedure, represented by CPT code

52282 (Cystourethroscopy, with insertion of permanent urethral stent), became effective January 1, 1998, and describes the insertion of a permanent urethra stent using an endoscope. This procedure offers another therapy option for select patients with lower urinary tract symptoms (LUTS) secondary to BPH.

For CY 2026, we assigned CPT code 52282 to APC 5374 (Level 4 Urology and Related Services) with a payment rate of $3,601.33 based on its geometric mean cost of approximately $3,775, which was calculated using the available 115 single frequency claims from the CY 2024 claims data.

For the CY 2027 OPPS/ASC proposed rule, we reviewed the CY 2025 claims submitted between January 1, 2025 through December 31, 2025, that were processed on or before December 31, 2025, for CPT code 52282 and found 109 single frequency claims available for ratesetting, with a resulting geometric mean cost of $4,005 (91 FR 41810). We noted that there has not been an FDA authorized permanent prostatic urethral stent on the US market for approximately 9 years until a permanent prostatic urethral stent received their FDA PMA approval in late 2025. Therefore, we believed the report claims for CPT code 52282 did not accurately represent the device and service cost associated with inserting a permanent prostatic urethral stent. Based on our examination of device and service costs associated with a permanent prostatic urethral stent, we believed it was appropriate to move CPT code 52282 to APC 5375 (Level 5 Urology and Related Services) from APC 5374 (Level 4 Urology and Related Services) because CPT code 52282 shares more resource cost and clinical homogeneity with procedures in APC 5375. Specifically, we believed CPT code 52282 shares resource and clinical homogeneity with HCPCS code C9739 (Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants). Therefore, for CY 2027, we proposed to reassign CPT code 52282 from APC 5374 (Level 4 Urology and Related Services) to APC 5375 (Level 5 Urology and Related Services) (91 FR 41810).

Comment: We received twelve comments on our proposal. Two commenters supported our proposal to move CPT code 52282 from APC 5374 to 5375. 10 commenters requested that we move CPT code 52282 to APC 5376 (Level 6 Urology and Related Services). Some of these commenters additionally requested device-intensive status for CPT 52282. The commenters requesting reassignment of CPT code 52282 from APC 5374 to 5376 state that C9739 (Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants) is not the appropriate comparator because fewer than 4 implants is not how the ProVee therapy is performed. They state that the appropriate comparators are CPT code 53865 for the iTIND stent, CPT code 0941T for the Zenflow Stent/Scaffold and HCPC code C9740 for the UroLift procedure which are assigned to 5376. These commenters state that 52282 and these procedures share the same indication—lower urinary tract symptoms secondary to BPH—the same anatomic target, the same cystoscopic transurethral access, the same facility footprint, and the same recovery and follow-up pattern.

Response: We thank the commenters for their detailed analysis and recommendation. As we indicated in the proposed rule, prior to the permanent prostatic urethral stent that received FDA authorization in late 2025, there had not been an FDA authorized permanent prostatic urethral stent on the US market for approximately 9 years. Consequently, we do not believe that the reported claims for CPT code 52282 accurately represent the device and service cost associated with inserting a permanent prostatic urethral stent. Given the uncertainty of the existing claims data, we think we should wait for additional, more representative data before adjusting the payment rate for CPT code 52282 beyond APC 5375.

Regarding the commenters that requested device-intensive status for CPT 52282. We refer readers to sections IV.B and XIII.C.4 of this final rule with comment period for our response those requests.

After consideration of the public comments we received and discussion and input from our Medical Officers, we are finalizing our proposal without modification for the APC assignment for CPT code 52282. We note that we review the APC assignments for all items and services paid under the OPPS on an annual basis. We will reevaluate the APC assignments for CPT code 52282 in the next rulemaking cycle.

We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

58. Transperineal Laser Ablation of Prostate, CPT Codes 0714T and 0867T (APC 5375)

Both CPT codes 0714T (*Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume less than 50 mL*) and CPT code 0867T (*Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume greater or equal to 50 mL*) describe the destruction of benign prostate tissue using laser ablation.

For CY 2027, we proposed to maintain the APC assignments for CPT codes 0714T and 0867T to APC 5375 (Level 5 Urology and Related Services). We received public comment on these codes.

Comment: We received one comment requesting that we reassign CPT codes 0714T and 0867T to APC 5376 (Level 6 Urology and Related Services) because these codes have clinical and resource homogeneity with CPT code 55873 (*Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)*) which is assigned to APC 5376.

Response: We thank the commenter for the input. We note that the current geometric mean cost for CPT code 0714T is $5,234 based on two single frequency claims and we have no claims data for CPT code 0867T. After evaluation of the service, as well as input from our medical advisors, we are not persuaded that CPT code 55873 is a more appropriate crosswalk code for CPT codes 0714T and 0867T. We do not believe that CPT codes 0714T and 0867T should be reassigned to APC 5376. As we do every year, we will monitor the claims data and reevaluate the APC assignments for these codes in the next rulemaking cycle to determine if a more appropriate APC is warranted.

In summary, after consideration of the public comments we received, we are finalizing our proposal without modification to assign CPT codes 0714T and 0867T to APC 5375 (Level 5 Urology and Related Services).

The final CY 2027 payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for the SI definitions for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

Miscellaneous Issues

59. APC Assignments for Devices Coming Off of Transitional Payment Pathways

For CY 2027, we proposed to continue our device pass-through and new technology APC policies unchanged from CY 2026. We note that these are meant to serve as temporary, transitional payment pathways prior to permanent payment through assignments to clinical APCs.

Comment: We received comments requesting that CMS take a comprehensive view to determine appropriate APC assignments for services with expiring pass-through status or following assignments to new technology APCs. Commenters requested that CMS define a transition pathway from pass-through or new technology APC status to permanent payment, including clearer criteria, timelines, data requirements and advance notice. Regarding new technology APCs, we received comments requesting that initial assign to new technology APCs should be based on the best available information, and that services should remain assigned to new technology APCs until there is sufficient cost information to support a reassignment to a clinical APC. Commenters believe this period may be longer than 3 years. Commenters requested that Medicare teams collaborate to determine appropriate payment and to collect accurate claims data for services with expiring passthrough. Commenters asked us to evaluate the effect of expiration of transitional device pass-through payment on total resources of the service before making an APC assignment.

Response: We thank the commenters for sharing their perspectives. We are considering whether changes are necessary to ensure that our payment methodologies appropriately account for services coming off of a transitional payment pathway, like new technology APCs and pass-through. We will consider the commenters' suggestions for future rulemaking.

60. Bone Mass Measurement: Biomechanical Computed Tomography (BCT) Analysis

There are five existing CPT codes (0554T, 0555T, 0556T, 0557T, and 0558T) that describe biomechanical computed tomography (BCT) analysis. These codes became effective July 1, 2019, and have not been covered by Medicare as a preventive service until recently. On May 26, 2026, CMS issued Transmittal 13752 announcing the BCT codes (when used for diagnostic purposes) are now covered by National Coverage Determination (NCD) 150.3 Bone (Mineral) Density Studies with a retroactive date of January 1, 2024. Beneficiary copays are waived with most preventive services. We received one comment.

Comment: The commenter noted that Transmittal 13752 indicated a waiver of patient copays for the BCT services, but the proposed CY 2027 Addendum B file did not indicate that the patient copays were waived.

Response: We appreciate the comment. This error has been corrected. We refer readers to the October 2027 Addendum B which can be found on the CMS website for the payment rates for these codes. This change is also reflected in the addenda to this final rule with comment period.

61. Nerve Repair Procedure (APC 5433)

CPT code 64910 (*Nerve repair; with synthetic conduit or vein allograft (eg, nerve tube), each nerve*) describes a type of nerve repair procedure with a graft. This CPT code was created by the AMA and became effective January 1, 2007. CPT code 64910 is currently assigned to APC 5433 (Level 3 Nerve Procedures) with a status indicator of 'J1'. For CY 2027, we proposed to maintain the payment assignments for CPT code 64910.

Comment: We received one comment on this code requesting that we revise the short descriptor to read ''Nerve repair w/conduit'' to more accurately reflect the conduit-focused nature of the procedure.

Response: We appreciate the commenter's input; however, CPT code descriptors are owned and copyrighted by the AMA and therefore this comment is out of scope for OPPS. We refer the reader to the AMA for the process on submitting a formal CPT Code Change Application to request a descriptor revision.

62. Suggested Drug-Intensive Procedure Policy

Comment: We received two comments requesting that CMS evaluate the impact of implementing a drug-intensive procedure policy, analogous to the current device-intensive procedure policy, for ASC payment purposes. Commenters stated that this suggested drug-intensive procedure policy would allow ASC rates to accurately reflect costly drugs that are packaged into procedures, when drug cost is a large share of the procedure's cost but is not separately paid. The commenter further suggested that CMS could compute ASC rates by holding the drug portion neutral, similar to how devices are held neutral, which would maintain consistency and fairness in payment policy, preserve ASC access, and avoid site-of-service shifts driven by underpayment.

Response: We thank the commenters for this suggestion and will consider it in future rulemaking.

63. APC Specific Comments That Support the Proposed APC Assignment

Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As a result of our annual review of the services and the APC assignments, we may reassign some services to another APC or maintain the current APC assignment.

Comment: Commenters supported the following proposed CY 2027 assignments for various HCPCS and CPT codes and requested that CMS finalize the payment assignments for CY 2027 as proposed.

Response: We thank the commenters for their input.

Therefore, for CY 2027, we are finalizing without modification the APCs and status indicators for the HCPCS codes listed in Table 48. The final CY 2027 payment rates for the codes listed below can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 to this final rule with comment period for all codes reported under the OPPS. Addenda B and D1 are available via the internet on the CMS website.

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TABLE 48: FINAL CY 2027 APC AND STATUS INDICATOR ASSIGNMENTS FOR VARIOUS CPT AND HCPCS CODES

HCPCS/CPT Code	Long Descriptor	Final CY 2027 SI	Final CY 2027 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	S	1580
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more	J1	5493
0730T	Trabeculotomy by laser, including optical coherence tomography (OCT) guidance	J1	5493
0786T	Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed	J1	5464

HCPCS/CPT Code	Long Descriptor	Final CY 2027 SI	Final CY 2027 APC
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	J1	5331
0930T	Electrophysiologic evaluation of cardiac contractility modulation-defibrillator leads, including defibrillation-threshold evaluation (induction of arrhythmia, evaluation of sensing and therapy for arrhythmia termination), at time of initial implantation or replacement with testing of cardiac contractility modulation-defibrillator pulse generator	N	n/a
C9781	Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (e.g., balloon), includes debridement (e.g., limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed	J1	5115
G0460	Autologous platelet rich plasma or other blood-derived product for non-diabetic chronic wounds/ulcers, including as applicable phlebotomy, centrifugation or mixing, and all other preparatory procedures, administration and dressings, per treatment	T	5054
G0465	Autologous platelet rich plasma (prp) or other blood-derived product for diabetic chronic wounds/ulcers, using an fda-cleared device for this indication, (includes as applicable administration, dressings, phlebotomy, centrifugation or mixing, and all other preparatory procedures, per treatment)	T	5054
G0574	Management of new patient with dementia residing in an eligible residential care community, for use only in a medicare-approved cmmi model (services must be furnished within a patient's eligible residential care community, including assisted living facilities, board and care homes, or other qualifying residential settings where dementia care services are provided)	M	n/a
G0575	Management of established patient with dementia residing in an eligible residential care community, for use only in a medicare-approved cmmi model (services must be furnished within a patient's eligible residential care community, including assisted living facilities, board and care homes, or other qualifying residential settings where dementia care services are provided)	M	n/a
52284	Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed	J1	5375
55882	Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducer for delivery of thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed	J1	5377
61715	Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation of target, intracranial, including stereotactic navigation and frame placement, when performed	J1	5463

HCPCS/CPT Code	Long Descriptor	Final CY 2027 SI	Final CY 2027 APC
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array	J1	5465
64568	Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator	S	1580
66711	Ciliary body destruction; cyclophotocoagulation, endoscopic, without concomitant removal of crystalline lens	J1	5491
66987	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation	J1	5492
66988	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation	J1	5492
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	J1	5493
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	J1	5493
76978	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion	S	5572

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IV. OPPS Payment for Devices

A. Pass-Through Payment for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

The intent of transitional device pass-through payment, as implemented at 42 CFR 419.66, is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to include the costs for these devices into the procedure APC rate (66 FR 55861). Under section 1833(t)(6)(B)(iii) of the Act, OPPS transitional pass-through payment status for a device category are limited to a period of not less than 2 years but not more than 3 years.

In the CY 2017 OPPS/ASC final rule with comment period, 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 (81

FR 79654). In addition, in the CY 2017 OPPS/ASC final rule with comment period, we finalized a policy to allow for quarterly expiration of pass-through payment status for devices to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices (81 FR 79655). We also established a 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.[23]

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, 21 device categories are eligible for pass-through payment. These devices are listed in Table 49, previously published as Table 29 of the CY 2027 OPPS/ASC proposed rule (91 FR 41815 through 41816), where we detail the expiration dates of pass-through payment status for each of the 21 devices currently receiving device pass-through payment.

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TABLE 49: DEVICES WITH PASS-THROUGH STATUS EXPIRING IN 2026, IN 2027, IN 2028, OR IN 2029

HCPCS Code	Long Descriptor	Pass-Through Effective Date	Pass-Through Expiration Date
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
C8000	Support device, extravascular, for arteriovenous fistula (implantable)	10/01/2024	09/30/2027
C1735	Catheter(s), intravascular for renal denervation, radiofrequency, including all single use system components	01/01/2025	12/31/2027

[23] 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 collection (CMS–10052) has an OMB control number of 0938–0857 and an expiration date of June 30, 2029.

HCPCS Code	Long Descriptor	Pass-Through Effective Date	Pass-Through Expiration Date
C1736	Catheter(s), intravascular for renal denervation, ultrasound, including all single use system components	01/01/2025	12/31/2027
C1737	Joint fusion and fixation device(s), sacroiliac and pelvis, including all system components (implantable)	01/01/2025	12/31/2027
C1738	Powered, single-use (i.e. disposable) endoscopic ultrasound-guided biopsy device	01/01/2025	12/31/2027
C1739	Tissue marker, uniquely detectable and identifiable with probe/sensor, any method (implantable), with delivery system	01/01/2025	12/31/2027
C9610	Catheter, transluminal drug delivery with or without angioplasty, coronary, non-laser (insertable)	01/01/2025	12/31/2027
C1740	Leadless electrode, transmitter, battery (all implantable), for sequential left ventricular pacing	10/01/2025	09/30/2028
C1741	Anchor/screw for bone fixation, absorbable (implantable)	10/01/2025	09/30/2028
C1742	Pressure monitoring system, compartmental intramuscular (implantable), continuous, including all components (e.g., introducer, sensor), excludes mobile (wireless) software application	10/01/2025	09/30/2028
C1607	Neurostimulator, integrated (implantable), rechargeable with all implantable and external components including charging system	01/01/2026	12/31/2028
C1608	Prosthesis, total, dual mobility, first carpometacarpal joint (implantable)	01/01/2026	12/31/2028
C1743	Scaffold, endovascular non-coronary, resorbable drug eluting, with delivery system (implantable)	04/01/2026	03/31/2029
C1609	Vertebral device, motion-preserving, with screw fixation	07/01/2026	06/30/2029

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2. New Device Pass-Through Applications for CY 2027

a. Background

Section 1833(t)(6) of the Act provides pass-through payments for devices, and section 1833(t)(6)(B) of the Act requires CMS to use categories to determine the eligibility of devices for pass-through payments. As part of implementing the statute through regulations, we continue to believe that pass-through payments for devices that offer substantial clinical improvement are important to ensure that hospitals can provide Medicare beneficiaries with access 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 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 (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.

As finalized in CY 2026 OPPS/ASC final rule with comment period, skin substitutes with an approved Biologics License Application (BLA) will be considered under transitional drug pass-through payment status, and skin substitutes with FDA Premarket approval (PMA) or FDA 510(k) clearance will continue to be evaluated under transitional device pass-through payment status (90 FR 53636).

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 depreciable 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, 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)).

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. We 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 (69 FR 65775), and we calculate the device offset amount at the HCPCS/CPT code level (81 FR 79657); and

- Demonstrate a substantial clinical improvement, that is, the device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment, or, 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.

In the CY 2016 OPPS/ASC final rule with comment period, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to CMS through the quarterly process, but the applications are subject to notice and comment rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications preliminarily approved during quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while applicants whose submissions are not approved during 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 2023 OPPS/ASC final rule with comment period, we finalized our policy to publicly post online OPPS device pass-through applications received on or after March 1, 2023, beginning with the issuance of the CY 2025 OPPS/ASC 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.

In the CY 2020 OPPS/ASC final rule with comment period, 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.

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19457 through 19459), we proposed to repeal the alternative pathway for new technology add-on payment and OPPS device pass-through applications and require all applicants for new technology add-on payments and OPPS device pass-through payments to demonstrate that they meet the same eligibility requirements to receive add-on payments and/or pass-through payments. Specifically, we proposed that all applications received for OPPS device pass-through payment status on or after October 1, 2026, including all applications received through the remainder of the CY 2028 OPPS application cycle ending on March 1, 2027, and applications received for subsequent calendar years would have to demonstrate that the technology met the requirements currently reflected at § 419.66(c)(2)(i). OPPS device pass-through payment applications submitted as of September 30, 2026, for devices that are part of the FDA's Breakthrough Devices Program and received FDA marketing authorization for the indication covered by the Breakthrough Device designation would be evaluated and could be approved under the alternative pathway, provided that all other criteria have been met. Existing device category codes established based on the approval, either preliminary or via a final determination made in an OPPS/ASC final rule, including any device category codes established for approved alternative pathway applications received as of September 30, 2026, would continue to be eligible for device pass-through payment status and would remain in effect for at least 2 years, but no more than 3 years, consistent with § 419.66(g). Previously existing device category codes that were no longer eligible for device pass-through payment status would remain unchanged. We proposed to revise paragraph § 419.66(c)(2)(ii) to reflect this proposed policy. If finalized as proposed, the change would go into effect on October 1, 2026 (91 FR 19458).

In the FY 2027 IPPS/LTCH PPS final rule (91 FR 49767 through 49789; 91 FR 50346 through 50347), we finalized our policy, with modification, that, unless specifically exempted, all applications received for device pass-through payment status on or after October 1, 2026, including all applications received through the remainder of the CY 2028 application cycle ending on March 1, 2027, and applications received for subsequent calendar years will have to demonstrate that the technology met the requirements currently reflected at § 419.66(c)(2)(i).

We also finalized our policy that device pass-through payment applications submitted to CMS as of September 30, 2026, for devices that are part of the FDA's Breakthrough Devices Program that received FDA marketing authorization for the indication covered by the Breakthrough Device designation will be evaluated and could be approved under the alternative pathway, provided that all other criteria have been met. In addition, we finalized a limited exception for a new device that had received FDA Breakthrough Device designation as of September 30, 2026, and has received marketing authorization for the indication covered by the Breakthrough Device designation. Such devices will remain eligible to apply for device pass-through payment under the alternative pathway, which will continue to accept applications for CYs 2028 and 2029. As such, in order to be considered for the limited exception, CMS must receive a complete application for eligible devices under the limited exception no later than March 1, 2028.

In the FY 2027 IPPS/LTCH PPS final rule, we also finalized that existing device category codes established based on the approval, either preliminary or via a final determination made in an OPPS/ASC final rule, including any device category codes established for approved alternative pathway applications received as of September 30, 2026, will continue to be eligible for device pass-through payment status and would remain in effect for at least 2 years, but no more than 3 years, consistent with § 419.66(g). We stated that previously existing device category codes that were no longer eligible for device pass-through payment status would remain unchanged.

We finalized revisions, with modifications, to paragraph § 419.66(c)(2)(ii) to reflect the finalized policy, effective October 1, 2026.

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.

b. Applications Received for Device Pass-Through Status for CY 2027

We received 19 applications by the March 2, 2026, quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in the CY 2027 OPPS/ASC proposed rule. Of the applications, we received five in the second quarter of 2025, eight in the third quarter of 2025, one in the fourth quarter of 2025, and five in the first quarter of 2026. Six applications subsequently withdrew.

We discussed the 13 complete applications, 10 under the alternative pathway and 3 under the traditional pathway, that we received by the March 2, 2026 deadline (as set out in section IV.2.b. of CY 2027 OPPS/ASC proposed rule (91 FR 41818 through 41846)), including seven applications that were preliminarily approved for device pass-through payment status during the quarterly review process. We are addressing these 13 applications in this final rule with comment period. We do not include in this final rule with comment period the description and discussion of new device category for transitional pass-through payment status applications that were withdrawn or ineligible for CY 2027, nor do we summarize or respond to public comments received regarding these applications. We are finalizing pass-through payment status for all seven preliminary approvals in this final rule, and we are approving two additional applications.

Applications received after the March 2026 deadline for the remaining 2027 quarters (the quarters beginning June 1, September 1, and December 1 of 2026) through March 1, 2027, if any, will be discussed in the CY 2028 OPPS/ASC proposed rule. We note that the quarterly application process and requirements have not changed because of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment application are included on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf.*

(1) Preliminary Approvals

Seven applications were preliminarily approved for device pass-through payment status during the quarterly review process for CY 2027: The MY01 Continuous Compartmental Pressure Monitor, RemeOs™ Screw LAG Solid, WiSE® CRT System, SetPoint System, TOUCH® CMC 1 Prosthesis, Esprit™

BTK Everolimus Eluting Resorbable Scaffold System, and TOPS™ System. We refer readers to the CY 2027 OPPS/ASC proposed rule cited in Table 50 in this section for a complete summary of each of these device pass-through applications. As discussed in section IV.2.b.1. of the CY 2027 OPPS/ASC proposed rule (91 FR 41818 through 41835), we invited public comment on whether we should finalize approval for device pass-through payment status for these seven applications.

Comment: Several commenters expressed their support for approval of device pass-through payment for one or multiple of the preliminarily approved device pass-through applications, including the MY01 Continuous Compartmental Pressure Monitor, RemeOs™ Screw LAG Solid, WiSE® CRT System, SetPoint System, TOUCH® CMC 1 Prosthesis, Esprit™ BTK Everolimus Eluting Resorbable Scaffold System, and TOPS™ System.

Response: We appreciate the commenters' input and recognize their support for the approval of the MY01 Continuous Compartmental Pressure Monitor, RemeOs™ Screw LAG Solid, WiSE® CRT System, SetPoint System, TOUCH® CMC 1 Prosthesis, Esprit™ BTK Everolimus Eluting Resorbable Scaffold System, and TOPS™ System. We have taken these comments into consideration in our final determination of pass-through payment status for the device pass-through applications.

After consideration of the public comments we received and our review of the device pass-through applications, we have determined the MY01 Continuous Compartmental Pressure Monitor, RemeOs™ Screw LAG Solid, WiSE® CRT System, SetPoint System, TOUCH® CMC 1 Prosthesis, Esprit™ BTK Everolimus Eluting Resorbable Scaffold System, and TOPS™ System meet the requirements for device pass-through status described at § 419.66. We are finalizing our approvals for device pass-through payment status for these seven applications under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

TABLE 50: FINAL STATUS FOR DEVICES PRELIMINARILY APPROVED FOR DEVICE PASS-THROUGH PAYMENT STATUS DURING THE QUARTERLY REVIEW PROCESS FOR CY 2027

Devices	CY 2027 OPPS/ASC Proposed Rule Citation	Final Status	Pass-through Effective Date
MY01 Continuous Compartmental Pressure Monitor	91 FR 41822 through 41823	Approved	10/01/2025
RemeOs™ Screw LAG Solid	91 FR 41826 through 41827	Approved	10/01/2025
WiSE® CRT System	91 FR 41832 through 41835	Approved	10/01/2025
SetPoint System	91 FR 41827 through 41827	Approved	01/01/2026
TOUCH® CMC 1 Prosthesis	91 FR 41831 through 41832	Approved	01/01/2026
Esprit™ BTK Everolimus Eluting Resorbable Scaffold System	91 FR 41820 through 41821	Approved	04/01/2026
TOPS™ System	91 FR 41820 through 41831	Approved	07/01/2026

(2) Alternative Pathway Device Pass-Through Applications

(a) Altius® Direct Electrical Nerve Stimulation System

Neuros® Medical, Inc. submitted an application for a new device category for transitional pass-through payment status for the Altius® Direct Electrical Nerve Stimulation System (the Altius® System) for CY 2027. According to the applicant, the Altius® System is an implantable neuromodulation system that provides continuous, high frequency, high amplitude nerve stimulation to either the sciatic nerve or both the tibial and common peroneal nerves by directly stimulating targeted nerves via implanted cuff electrode leads that are wrapped circumferentially around target nerves in the amputated leg. The applicant stated that the Altius® System consists of the (1) Altius® Implantable Pulse Generator (IPG), which is implanted in the abdomen; (2) Altius® Cuff Electrode Leads; (3) Altius® Battery Charger and alternating current (AC) adapter; (4) Altius® Patient Controller, which allows the patient to activate the IPG to initiate therapy; (5) Programming Wand, which is used by the provider to program and set stimulus therapy parameters; and (6) Programmer Application Personal Computer (PAPC), which includes physician programming software. The applicant is seeking a new device category for transitional pass-through payment status for only the Altius® IPG and the Altius® Cuff Electrode Lead components of the Altius® System. The applicant stated that the Altius® IPG is a rechargeable neurotransmitter device that is implanted in the abdomen and when activated, generates a continuous high frequency, high amplitude alternating current electrical stimulus (5kHz and 10kHz) via the Altius® Cuff Electrode Leads, which are circumferentially wrapped, anchored, and implanted around the nerve(s). Per the applicant, the ''alternating'' nature of the delivered electrical stimulus refers to the direct electrical stimulation of the circumferential electrodes within a lead distributed in an alternating fashion across these electrodes.

Table 51 provides an overview of the transitional device pass-through payment status application for the Altius® System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP250530FMCYD.*

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TABLE 51: ALTIUS® SYSTEM APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization:* PMA approval - August 26, 2024 *Application submitted to CMS:* May 30, 2025	No concerns.
Breakthrough Device Designation	*FDA Indication:* Altius® System is an aid in the management of chronic intractable phantom and residual lower limb post-amputation pain in adult amputees. *Breakthrough Device designation:* Altius® System is an aid in the management of chronic intractable pain of the lower limb of adult amputees. This device received FDA Breakthrough Device designation under the trade name Altius® High Frequency Nerve Block System. The trade name was later updated to the Altius® Direct Electrical Nerve Stimulation System.	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with human tissue, and is surgically implanted.	No concerns.

§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	No concerns.
Device Category	Device category codes C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), C1778 (Lead, neurostimulator (implantable)), C1767 (Generator, neurostimulator (implantable), non-rechargeable), C1787 (Patient programmer, neurostimulator), C1816 (Receiver and/or transmitter, neurostimulator (implantable)), C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system), C1823 (Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads), C1825 (Generator, neurostimulator (implantable), non-rechargeable, with carotid sinus baroreceptor stimulation lead(s)), C1826 (Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system), C1827 (Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller), and C1883 (Adapter/extension, pacing lead or neurostimulator lead (implantable) do not describe the device.	See following discussion.
Cost Criteria	The cost for eligible device components of Altius® System (the Altius® IPG and Altius® Cuff Electrode Lead(s)) is $41,000.00 or $52,000.00, depending on whether the patient requires one or two cuff electrodes.[1] The cost of the Altius® IPG is $30,000.00 and the cost of each Altius® Cuff Electrode Lead is $11,000.00. For cost significance requirements:[2] HCPCS code: 64575 APC code: 5463 CY 2026 device offset amount: $7,697.89 CY 2026 APC payment rate: $11,384.04 The Altius® IPG with one Altius® Cuff Electrode Lead: Requirement #1: ($41,000.00 / $11,384.04) x 100 = 360.15%. Requirement #2: ($41,000.00 / $7,697.89) x 100 = 532.61% Requirement #3: (($41,000.00 - $7,697.89) / $11,384.04) x 100 = 292.53% The Altius® IPG with two Altius® Cuff Electrode Leads: Requirement #1: ($52,000.00 / $11,384.04) x 100 = 456.78%. Requirement #2: ($52,000.00 / $7,697.89) x 100 = 675.51% Requirement #3: (($52,000.00 - $7,697.89) / $11,384.04) x 100 = 389.16%	No concerns.

1. The applicant conducted cost calculations for both the Altius® IPG with one Altius® Cuff Electrode Lead ($41,000.00) and the Altius® IPG with two Altius® Cuff Electrode Leads ($52,000.00). We considered both costs as the estimated reasonable cost to assess whether the Altius® System meets the cost significance requirements.
2. For its cost calculations, the applicant selected HCPCS code 64590 in APC 5464 and based its calculations on CY 2026 data. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). For our calculations, we used APC 5463, which we believe has the lowest applicable APC payment rate ($11,384.04) related to the HCPCS codes provided by the applicant, and HCPCS code 64575 in APC 5463, which has a device offset amount of $7,697.89, at the time the application was received. Based on our initial assessment for the CY 2027 OPPS/ASC proposed rule, we stated using the APC payment rate of $11,384.04 and the device offset amount of $7,697.89 would result in the Altius® System meeting the cost significance requirements.

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We invited public comment on whether the Altius® System meets the newness criterion at § 419.66(b)(1) and whether the Altius® IPG and the Altius® Cuff Electrode Lead components meet the eligibility criteria at § 419.66(b)(3) and (4).

We did not receive public comments regarding whether the Altius® System meets the newness criterion at § 419.66(b)(1) or whether the Altius® IPG and the Altius® Cuff Electrode Lead components meet the eligibility criteria at § 419.66(b)(3) and (4).

We received the application for device pass-through payment status for the Altius® System within 3 years of the date of FDA PMA approval. Based on our review of the application, we have determined that the Altius® System meets the newness criterion at § 419.66(b)(1) and that the Altius® IPG and the Altius® Cuff Electrode Lead components meet the eligibility criteria at § 419.66(b)(3) and (4).

In the CY 2027 OPPS/ASC proposed rule, we noted regarding the device category eligibility criterion at § 419.66(c)(1), with respect to the Altius® IPG and Altius® Cuff Electrode Lead components, that the applicant stated that no existing (current or previous) device pass-through payment categories appropriately describe the nominated device components. Per the applicant, the existing pass-through codes C1778 (Lead, neurostimulator (implantable)) and C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system) do not describe the Altius® IPG and the Altius® Cuff Electrode Lead components because these codes (1) are not specifically indicated for treating chronic intractable lower limb amputation pain; (2) are not capable of delivering continuous, high amplitude, high frequency alternating current; (3) do not use circumferentially wrapped and anchored cuff electrode leads to provide direct energy delivery to the targeted nerves; and (4) do not allow for physician-pre-programmed therapy delivery controlled by the patient using the patient stimulation controller. The applicant also stated that devices described by C1778 do not make direct contact with the target nerve; instead, they deliver stimulation to the general region of the pain, unlike the Altius® Cuff Electrode Leads. The applicant added that existing devices described by C1822 deliver low-amplitude, rectangular pulses per second to general or peripheral areas to increase nerve activity and produce pain relief, whereas the Altius® IPG provides continuous, high-amplitude sinusoidal waveform stimulation to decrease target nerve activity and produce on-demand pain relief. The applicant stated that the Altius® System, including the Altius® IPG and Altius® Cuff Electrode Lead components, is the only FDA-authorized neuromodulation system indicated as an aid in the management of chronic intractable phantom and residual lower limb post-amputation pain in adult amputees.

Based on the description the applicant provided, we stated that the Altius® IPG is a rechargeable neurotransmitter device that generates a continuous high frequency, high amplitude alternating electrical stimulus (5kHz and 10kHz) via the Altius® Cuff Electrode Leads, which are circumferentially wrapped, anchored, and implanted around the nerve(s), and therefore, could be appropriately described by C1778 (Lead, neurostimulator (implantable)) and C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), respectively. Specifically, we stated our belief that the pass-through payment category C1778 may appropriately describe the Altius® Cuff Electrode Lead component because the pass-through payment category describes any device that is an implantable neurostimulator lead. Additionally, we stated our belief that the pass-through payment category C1822 may appropriately describe the Altius® IPG because the category includes implantable neurostimulator pulse generators that deliver high-frequency stimulation (including approximately 10 kHz) and are rechargeable using an external charging system. Further, we stated that C1822 does not describe the amplitude, pulse frequency, or waveform of the stimulation generated by the device. We noted that CMS does not establish pass-through device categories for the purpose of describing specific devices, but rather, device categories are intended to encompass all devices that can be appropriately described by a category. In this context, we stated that we believed that the Altius® IPG and the Altius® Cuff Electrode Lead components may be appropriately described by C1778 and C1822. We also stated that, after reviewing the information provided by the applicant, we were unable to determine that the Altius® System, inclusive of the Altius® IPG and the Altius® Cuff Electrode Lead components, meets the device category eligibility criteria, and therefore, we proposed to deny transitional pass-through payment status for CY 2027.

We invited public comment on whether the Altius® IPG and the Altius® Cuff Electrode Lead components meet the device category eligibility criterion at § 419.66(c)(1). We also invited public comments on our proposal to deny transitional pass-through payment status for the Altius® System, inclusive of the Altius® IPG and the Altius® Cuff Electrode Lead components for CY 2027.

Comment: A few commenters expressed their support for the denial of device pass-through payment for the Altius® System, stating that the nominated device does not meet all the criteria needed to qualify for transitional pass-through payment.

Response: We appreciate the commenters' input. We have taken these comments into consideration in our final determination for pass-through payment status for the Altius® System.

Comment: The applicant and many commenters requested that CMS approve device pass-through payment for the Altius® System. The applicant and these commenters stated that denying pass-through payment for the Altius® System would create major financial barriers for hospitals and surgical centers, resulting in fewer offering the device, and therefore, limiting Medicare patients' access to a proven, non-opioid treatment for severe post-amputation pain. In addition, the applicant and commenters stated that the Altius® System offers a meaningful safety and quality-of-life benefit, as well as directly supporting CMS and the broader public health system's ongoing priorities to expand non-opioid pain therapies.

The applicant and commenters stated that they believe there are no existing device categories or categories previously in effect that appropriately describe the Altius® System. In response to our concerns that the Altius® IPG and the Altius® Cuff Electrode Lead components may be appropriately described by C1778 and C1822, the applicant and commenters stated that, in the proposed rule, CMS misclassified the Altius® System under C codes for legacy spinal cord stimulation (SCS) and peripheral nerve stimulation (PNS) devices, specifically C1778 (Lead, neurostimulator implantable) and C1822 (generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system). The applicant and commenters stated that neither C1778 and C1822, nor any existing neurostimulator codes, adequately describe the Altius® System because it is a fundamentally new type of device. The applicant and commenters

reiterated that the Altius® System is an FDA Breakthrough-designated therapy engineered specifically to deliver an on-demand, high-frequency, high-amplitude alternating current and circumferential electric nerve conduction block.

The applicant and several commenters stated that the Altius® System represents a distinct technology class defined by a unique mechanism of action (neurostimulation that results in a complete electrical nerve block), a unique electrode design (360° circumferential cuff surgically wrapped around the sciatic nerve or its main branches through a dedicated open surgical implant), and a unique energy delivery profile (high blocking amplitude in a continuous alternating current (5–10k Hz) in 30 minute). The applicant and commenters compared the Altius® System's mechanism of action to that of legacy SCS and PNS devices which rely on percutaneous leads placed near a nerve that stimulate the nerve at a low amplitude and frequency (10–100 Hz) in discrete pulses using a field effect to produce paresthesia intended to mask pain. The applicant and commenters stated that paresthesia cannot override the constant, high-frequency ectopic firing of a damaged peripheral neuroma, eventually rendering these legacy devices ineffective. The applicant and commenters stated that the Altius® System deadens nerve endings in a completely different way than current peripheral and spinal cord stimulators, and, as a result, no existing device categories describe the nominated device and its novel therapy. The applicant and commenters further explained that implanting the Altius® Cuff Electrode Lead, a full circumferential cuff, requires an open surgical procedure under general anesthesia in an ambulatory surgical center or hospital outpatient department, rather than the quick needle-based placement used for standard leads done in office.

In addition, the applicant stated that existing OPPS Ambulatory Payment Classifications (APCs) for general neurostimulators reflect low-cost, percutaneously-inserted needle lead systems and do not cover the additional expenses associated with the Altius® System. The applicant stated that, by stating C1822 appropriately describes the Altius® IPG, CMS is equating high-frequency spinal cord generators that deliver low-amplitude pulsed direct current into the epidural space to alter central gating without blocking nerve conduction with the Altius® IPG's high-amplitude alternating current generator that produces a true peripheral nerve conduction block. According to the applicant, by stating that C1778 appropriately describes the Altius® Cuff Electrode Lead components, CMS is also equating percutaneous lead wires place adjacent to tissues with the Altius® Cuff Electrode Lead's 360-degree cuff electrode that is surgically wrapped around the sciatic nerve. The applicant concluded that grouping the Altius® IPG and the Altius® Cuff Electrode Lead components under legacy SCS and PNS codes (C1822 and C1778) mischaracterizes the Altius® System's physics, biology, and clinical reality. The applicant further suggested that CMS create the following new device category code that would appropriately describe the Altius® System: neurostimulator system, peripheral, circumferential nerve block, includes an implanted rechargeable pulse generator (high frequency, high amplitude, alternating current), implanted cuff electrode(s) (wrapped around nerve), and patient controller.

Another commenter stated that the existing HCPCS device categories, including C1778 and C1822 appropriately describe the Altius® System and its components. The commenter stated that, as CMS noted, C1822 does not describe a specific amplitude, pulse frequency, or waveform generated by a device. The commenter stated that rather, HCPCS device categories are intended to encompass all devices that share the relevant functional and technological characteristics, not to distinguish among individual products based on proprietary design features. Further, the commenter stated that the Altius® System's lead design does not appear to be sufficiently unique to warrant creation of a new device category. Per the commenter, other commercially available neurostimulation systems utilize leads that wrap around and anchor to a target nerve. The commenter stated, for example, that LivaNova's VNS Therapy™ System employs a helical lead that coils around the vagus nerve and is secured in place, demonstrating that circumferential nerve-wrapping lead designs are already present in the market and can be appropriately accommodated within existing neurostimulator lead categories. The commenter concluded that distinctions resting on a device's approved indication, electrode geometry, stimulation parameters, control interface, or the physiologic direction of its effect do not identify anything absent from the current HCPCS framework nor is the analysis altered by Breakthrough Device Designation, which affects only the requirement to demonstrate substantial clinical improvement and does not displace the pass-through requirement at § 419.66(c)(1).

Response: We appreciate the applicant's and commenters' input. After consideration of the public comments we received and further review of the application, we agree with the applicant that there is no existing device category, or category previously in effect, that appropriately describes a neurostimulator system that uses high-frequency, alternating current.

In the proposed rule, we also invited public comment on whether the Altius® IPG and the Altius® Cuff Electrode Lead components meet the cost criterion at § 419.66(d).

We did not receive any comments regarding whether the Altius® IPG and the Altius® Cuff Electrode Lead components meet the cost significance criteria as described at § 419.66(d). Based on our findings from the first, second, and third cost significant tests, we continue to believe the Altius® IPG and the Altius® Cuff Electrode Lead components meet the cost significance criteria specified at § 419.66(d).

After consideration of the public comments we received and our review of the device pass-through application, we have determined that the Altius® System, inclusive of the Altius® IPG and the Altius® Cuff Electrode Lead components, meets the requirements for device pass-through status described at § 419.66. Therefore, we are approving the Altius® System for device pass-through payment status effective January 1, 2027, under the alternative pathway for devices that have an FDA Breakthrough Device designation and FDA marketing authorization for the indication covered by the Breakthrough Device designation.

(b) ProSense® Cryoablation System

IceCure™ Medical Ltd. submitted an application for a new device category for transitional pass-through payment status for the ProSense® Cryoablation System for CY 2027. According to the applicant, the ProSense® Cryoablation System is designed to destroy tissue by the application of extreme cold temperatures utilizing liquid nitrogen for the treatment of breast cancer for patients with low-risk tumors. The applicant stated that the ProSense® Cryoablation System is comprised of (1) the ProSense® Chassis, (2) an adjustable touch screen, and (3) external accessories, including introducers, liquid nitrogen dewar, holder, foot pedal, and Prosense® Cryoprobes. The

applicant is seeking a new device category for transitional pass-through payment status for only the ProSense® Cryoprobe component of the ProSense® Cryoablation System. Per the applicant, the ProSense® Cryoprobe is a rigid probe with a tip that creates ice balls to destroy target tissue through cycles of freezing and thawing.

Table 52 provides an overview of the transitional pass-through payment status application for the ProSense® Cryoablation System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP251226K6A1C.*

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TABLE 52: PROSENSE® CRYOABLATION SYSTEM APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization:* De Novo authorization - October 3, 2025 *Application submitted to CMS:* December 26, 2025	See following discussion.
Breakthrough Device Designation	*FDA Indication:* The ProSense® Cryoablation System is indicated for the local treatment of breast cancer in patients ≥70 years of age with biologically low-risk tumors ≤1.5 cm in size and treated with adjuvant endocrine therapy, including patients not suitable for surgery for breast cancer treatment. Biologically low-risk breast cancer is defined as unifocal tumor, size ≤1.5 cm, estrogen receptor (ER)-positive, progesterone receptor (PR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, Ki-67<15%, and/or genomic testing indicative of low-risk breast cancer, infiltrating ductal carcinoma (excluding lobular carcinoma, extensive intraductal component, or evidence of lymphovascular invasion), and clinically negative lymph node (N0). *Breakthrough Device designation:* The IceCure ProSense® Cryoablation System is intended for cryogenic destruction of tissue during surgical procedures by the application of extreme cold temperatures. It is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ear, nose, and throat (ENT), gynecology, oncology, proctology, and urology. The system is designed to destroy tissue by the application of extreme cold temperatures including breast cancer, prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts. The system has the following specific indications: • Urology (ablate prostate tissue in cases of prostate cancer and benign prostatic hyperplasia (BPH). • Oncology (ablation of cancerous or malignant tissue and benign tumors and palliative intervention). • Dermatology (ablation or freezing of skin cancers and other cutaneous disorders. Palliation of tumors of the skin. Destruction of warts or lesions). • Gynecology (ablation of malignant neoplasia or benign dysplasia of the female genitalia). ENT (Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth). General Surgery (ablation of leukoplakia of mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions. • Palliation of tumors of the rectum, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions. Destruction of warts or lesions. Palliation of tumors of the oral cavity, rectum, and skin). • Thoracic Surgery (ablation of arrhythmic cardiac tissue and cancerous lesions). • Proctology (ablation of benign or malignant growths of the anus and rectum and hemorrhoids). • Breast Cancer: The ProSense® is indicated for use in the treatment of patients with T1 invasive breast cancer and/or	No concerns.

	patients not suitable for surgical alternatives for the treatment of breast cancer.	
§ 419.66(b)(3)	Device is single-use, is an integral part of the cryoablation procedure, is used in one patient only, is surgically inserted, and comes into contact with human tissue.	No concerns.
§ 419.66(b)(4)	Device is not equipment for which depreciation and financing expenses are recovered as depreciable assets and is not a supply furnished incident to the service.	No concerns.
Device Category	Device category code C2618 (Probe, cryoablation) does not describe the ProSense® Cryoprobe.	See following discussion.
Cost Criteria	The cost of the ProSense® Cryoprobe is $2,550.00. For cost significance requirements: HCPCS code: 0581T APC code: 5091 CY 2025 device offset amount: $1,816.99 CY 2025 APC payment rate: $3,829.28 Requirement #1: ($2,550.00 / $3,829.28) x 100 = 66.59%. Requirement #2: ($2,550.00/ $1,816.99) x 100 = 140.34%. Requirement #3: (($2,550.00 - $1,816.99) / $3,829.28) x 100 = 19.14%.	No concerns.

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We stated in the CY 2027 OPPS/ASC proposed rule that, as stated previously, with respect to the newness criterion at § 419.66(b)(1), the device must have received FDA approval or clearance (that is, FDA marketing authorization), and the pass-through payment application must be submitted within 3 years from the date of the initial FDA marketing authorization. We noted that in the CY 2016 OPPS/ASC final rule with comment period, we clarified that we intended to convey that the 3-year timeframe for submitting a device pass-through payment application would be triggered by the initial FDA approval or clearance, and not by any subsequent FDA approvals or clearances. We specified ''initial'' FDA clearance or approval in § 419.66(b)(1) because, in some cases, FDA will provide supplemental approvals or new clearances for a device lineage after the initial approval or clearance (80 FR 70420). We further stated in the proposed rule that we received a pass-through payment status application for the ProSense® Cryoablation System on December 26, 2025, which we did not believe was within 3 years of the initial FDA marketing authorization.

We also stated in the proposed rule (91 FR 41825) that the ProSense® Cryoablation System, inclusive of the ProSense® Cryoprobe, was previously cleared on December 20, 2019, in K183213, the 510(k) clearance for the IceCure Family Cryoablation System (IceSense™3, ProSense®, MultiSense).[24] We also noted that the predicate device described in K183213, the IceSense™3 System, was previously cleared on November 29, 2010, in K102360,[25] and the preceding predicate device, the Galil Medical SeedNet Family, was cleared on November 18, 2005, in K052530.[26] We noted that according to K183213, cryoablation is the fundamental technological principle for both the subject IceCure Family of cryotherapy devices and the predicate IceSense™3 System cleared in K102360 and the Galil Medical SeedNet Family cleared in K052530. Finally, we noted that according to K183213, the ProSense® Cryoablation System is a mere rebranding of the cleared IceSense™3 single-probe system cleared in K102360, and the ProSense® Cryoablation System has the same hardware and software components as the IceSense™3 System. We also noted that per K183213, the hardware and software changes introduced since the device was originally cleared on November 29, 2010, in K102360, were analyzed and determined not to require new 510(k) premarket notifications and that the K183213 submission includes the current configuration of the system.

We noted in the CY 2027 OPPS/ASC proposed rule that the October 3, 2025, FDA decision summary for De Novo classification for the ProSense® Cryoablation System includes a new indication for use in the treatment of patients with T1 invasive breast cancer and/or patients not suitable for surgical alternatives for the treatment of breast cancer. We stated that based on the information in K183213, we believed that the initial FDA marketing authorization date for the ProSense® Cryoablation System, inclusive of the nominated ProSense® Cryoprobe component, may be as early as November 18, 2005, or as recent as December 20, 2019. We stated that the applicant submitted the pass-through payment application on December 26, 2025, which was more than 3 years after either November 18, 2005, or December 20, 2019; therefore, we stated we did not believe that the ProSense® Cryoablation System, inclusive of the nominated ProSense® Cryoprobe, meets the newness criterion.

We invited public comment on whether the ProSense® Cryoablation System meets the newness criterion at § 419.66(b)(1).

Comment: A commenter expressed its support for the denial of device pass-through payment for the ProSense® Cryoablation System.

[24] U.S. Food and Drug Administration. (2019, December 20). *Decision Summary for K183213 [IceCure Family Cryoablation System (IceSense™3, ProSense®, MultiSense)].* U.S. Department of Health and Human Services.*https://www.accessdata.fda.gov/cdrh_docs/pdf18/K183213.pdf.*

[25] U.S. Food and Drug Administration. (2010, November 29). *510(k) Summary for K102360 [IceCure's IceSense™3 device].* U.S. Department of Health and Human Services. *https://www.accessdata.fda.gov/cdrh_docs/pdf10/K102360.pdf.*

[26] U.S. Food and Drug Administration. (2005, November 18). *510(k) Summary for K052530 [SeedNet Family].* U.S. Department of Health and Human Services. *https://www.accessdata.fda.gov/cdrh_docs/pdf5/K052530.pdf.*

Response: We appreciate the commenter's input.

Comment: The applicant submitted a public comment in support of device pass-through payments for the ProSense® Cryoablation System, noting that the nominated device meets all the transitional device pass-through payment criteria. The applicant also stated that transitional pass-through payment is intended to reduce financial disincentives and for new technology to be adopted so that it provides a substantial clinical improvement to Medicare beneficiaries. The applicant stated that the population for which FDA authorized the ProSense® Cryoablation System is primarily the Medicare population, and without transitional pass-through payment, hospitals face a disincentive to adopt the only FDA-authorized, non-surgical local treatment for low-risk breast cancer, particularly for women for whom surgery is an unsuitable option. In addition, the applicant stated that CMS establishing a device category effective January 1, 2027, would allow Medicare beneficiaries access to the ProSense® Cryoablation System while hospitals are making adoption decisions.

With respect to the newness criterion at § 419.66(b)(1), the applicant requested that CMS recognize October 3, 2025, as the initial date of FDA marketing authorization and the beginning of the newness period for the ProSense® Cryoablation System. The applicant reiterated that FDA granted the ProSense® Cryoablation System De Novo classification on October 3, 2025, and maintained that this is the initial date of FDA authorization for purposes of device pass-through payment status. The applicant also noted that it submitted its application for transitional pass-through payment on December 26, 2025, within three years of this date. The applicant stated that FDA classified the ProSense® Cryoablation System as a new generic device type under a newly created classification regulation (21 CFR 878.4355): cryoablation device for local treatment of low-risk breast cancer. The applicant added that FDA assigned this device type a new product code, QXW (DEN220077), consistent with section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act which states that the classification shall be the initial classification of the device.

According to the applicant, federal regulations (21 CFR 860.200(a)) state that the purpose of the De Novo process is to classify devices for which there is no legally marketed device on which to base a review of substantial equivalence. The applicant stated that because FDA granted the ProSense® Cryoablation System De Novo authorization, rather than 510(k) clearance, FDA has already determined that there is no legally marketed predicate device for the nominated device. The applicant further stated that FDA's De Novo order created a device type, a classification regulation, and a product code that did not previously exist, and it imposed special controls, including a 400-patient, 30-site post-market surveillance study, that apply to no prior cryoablation clearance. Additionally, the applicant stated that it is inappropriate for CMS to extrapolate to previous 510(k) devices when FDA has already determined that the device qualifies for De Novo classification. The applicant concluded that CMS should use October 3, 2025, as the initial date of FDA marketing authorization, and recognize that the ProSense® Cryoablation System meets the criteria for the transitional pass-through payment.

Response: We appreciate the applicant's input. After consideration of the public comments we received and our review of the application, we continue to believe that the ProSense® Cryoablation System, including the nominated Prosense® Cryoprobe, received FDA marketing authorization prior to the October 3, 2025 De Novo classification. As previously discussed, the current ProSense® Cryoablation System was included in K183213, cleared on December 20, 2019, and that clearance identified the previously cleared IceSense™3 System in K102360 as its predicate. As we stated in the proposed rule, in the K183213 clearance, FDA stated that the ProSense® Cryoablation System is a rebranding of the IceSense™3 single-probe system in K102360, with the same hardware and software components. Additionally, FDA stated that it analyzed and determined that the hardware and software changes introduced since the IceSense™3 System clearance on November 29, 2010 did not require new 510(k) premarket notifications. The current system and cryoablation technology are traceable through FDA clearances issued on November 18, 2005 (K052530), November 29, 2010 (K102360), and December 20, 2019 (K183213). Therefore, the ProSense® Cryoablation System does not meet the newness criterion described at § 419.66(b)(1) because we received the ProSense® Cryoablation System application for device pass-through payment on December 26, 2025, which is not within 3 years of these prior FDA marketing authorizations.

While the applicant stated that the ProSense® Cryoablation System De Novo classification on October 3, 2025 established a new device type, classification regulation, and product code, and that FDA's order states that the classification is the initial classification of the device, it appears that this De Novo authorization established a new FDA classification for the device when used for the treatment of certain patients with low-risk breast cancer. Therefore, it does not constitute the initial FDA marketing authorization of this device technology for the purposes of § 419.66(b)(1), because this device technology, including the nominated cryoprobe, had previously received FDA marketing authorization with different indications for use. Although we recognize FDA's regulatory responsibility for determining the appropriate pathway for marketing authorization, CMS applies the requirements at § 419.66(b)(1) in determining whether a device technology meets the newness criterion for device pass-through payment, which does not depend on the type of FDA marketing authorization.

Because we have not received information demonstrating that the device itself is sufficiently different from the previously cleared ProSense® Cryoablation System such that October 3, 2025 should not be considered its initial FDA marketing authorization for purposes of § 419.66(b)(1), we continue to believe that the October 3, 2025, De Novo classification does not restart the newness period.

After consideration of the public comments we received and our review of the application, the ProSense® Cryoablation System does not meet the newness criterion to be considered for device pass-through payment. Therefore, in this final rule with comment period, we will not address whether the technology meets the remaining criteria required for device pass-through payment. We are not approving the ProSense® Cryoablation System for device pass-through payment status for CY 2027 because the technology does not meet the newness criterion at § 419.66(b)(1).

(c) TIDAL™ Fusion Cage System (Ossera™ AFX)

Restor3d submitted an application for a new device category for transitional pass-through payment status for the TIDAL™ Fusion Cage System for CY 2027. According to the applicant, the TIDAL™ Fusion Cage is a single, continuous, porous piece of titanium alloy containing a circular window for an intramedullary nail used during

salvage procedures to restore bone length due to bone void, absent bone or surgical resection. The TIDAL™ Fusion Cage System is composed of the TIDAL™ Fusion Cage and a Disposable Instrument Kit, which includes size trials, cannulated reamers, and inserters. The applicant stated that the TIDAL™ Fusion System is not for standalone use and is intended for use as an accessory to the DynaNail® TTC Fusion System and with an autograft and/or allogenic bone graft.

Table 53 provides an overview of the device category for transitional pass-through payment status application for TIDAL™ Fusion Cage System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP250529B0B27.*

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TABLE 53: TIDAL™ FUSION CAGE SYSTEM APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization:* 510(k) clearance - March 24, 2025 *Application submitted to CMS:* May 29, 2025	No concerns.
Breakthrough Device Designation	*FDA Indication:* The TIDAL™ Fusion Cage System is intended for use as part of a tibiotalocalcaneal fusion construct in a salvage procedure following failed ankle arthrodesis or failed ankle arthroplasty for patients at risk of limb loss. The TIDAL™ Fusion Cage System is intended for use as an accessory to the DynaNail® TTC Fusion System. The TIDAL™ Fusion Cage System is not intended for standalone use. The TIDAL™ Fusion Cage System is intended for use with autograft and/or allogenic bone graft. *Breakthrough Device designation:* The restor3d Fusion Cage System is intended for tibiotalocalcaneal arthrodesis (fusion) to provide stabilization of the hindfoot and ankle with critical size bone defect, in lieu of bulk allograft in procedures such as: post-traumatic and degenerative arthritis; post-traumatic or primary arthrosis involving both ankle and subtalar joints; revision after failed ankle arthrodesis with subtalar involvement; failed total ankle arthroplasty; non-union ankle arthrodesis; rheumatoid hindfoot; talectomy; avascular necrosis of the talus; neuroarthropathy; neuromuscular disease and severe deformity; osteoarthritis; Charcot foot; and previously infected arthrosis, second degree. The restor3d Fusion Cage System is intended to provide stabilization in long bones of skeletally mature patients, including tibia, femur and humerus, in the presence of critical sized bone defects in lieu of bulk allograft, bone transport or other treatment for segmental defects in procedures such as: stabilization of fractures of the diaphyseal or metaphyseal regions of long bones; malunions and nonunion; osteomyelitis; and periprosthetic fractures. Note: FDA granted Breakthrough Device designation to this device under the trade name restor3d Fusion Cage System, which the applicant later changed to TIDAL™ Fusion Cage System (Ossera™ AFX).	See following discussion.
§ 419.66(b)(3)	Device is integral to the service furnished, used for one patient only, comes in contact with human tissue, and is surgically implanted into the ankle joint for permanent implantation.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	No concerns.
Device Category	Device category codes C1776 (Joint device (implantable)) and C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) do not describe the device.	See following discussion.

Cost Criteria	The TIDAL™ Fusion Cage System's total device cost is $32,995.00, consisting of a Fusion Cage ($27,995.00) and a Disposable Instrument Kit ($5,000.00). For cost significance requirements: HCPCS code: 27871 APC code: 5115 CY 2026 device offset amount: $5,973.37 CY 2026 APC payment rate: $13,116.76 Requirement #1: ($27,995 / $13,116.76) x 100 = 213.43%. Requirement #2: ($27,995 / $5,973.37) x 100 = 468.66%. Requirement #3: (($27,995 - $5,973.37) / $13,116.76) x 100 = 167.89%.	See following discussion.

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Regarding the Breakthrough Device designation, we noted in the CY 2027 OPPS/ASC proposed rule that restor3d submitted a new technology add-on payment application for FY 2026 for the TIDAL™ Fusion Cage under the alternative pathway, as discussed in the FY 2026 IPPS/LTCH PPS proposed and final rules (90 FR 18200 through 18202; 36817 through 36819). In that final rule, we stated that because the Disposable Instrument Kit was not included in the Breakthrough Device designation, only the TIDAL™ Fusion Cage was eligible for new technology add-on payments under the alternative pathway. We stated, consistent with our decision regarding new technology add-on payment eligibility, we would not consider the Disposable Instrument Kit for transitional pass-through payment status under the alternative pathway because it is not included in the Breakthrough Device designation. We further noted that we would only be discussing the TIDAL™ Fusion Cage in the following paragraphs.

We invited public comment on whether the TIDAL™ Fusion Cage meets the newness criterion at § 419.66(b)(1).

Comment: The applicant submitted a public comment regarding the newness criterion at § 419.66(b)(1) and confirmed that only the TIDAL™ Fusion Cage received both Breakthrough Device designation and marketing authorization from FDA and reiterated that the TIDAL™ Fusion Cage meets the newness requirement for device pass-through payment.

Response: We appreciate the applicant's input. We received the application for device pass-through payment status for the TIDAL™ Fusion Cage within 3 years of the date of FDA 510(k) clearance. After consideration of the public comments we received and our review of the application, we have determined that the TIDAL™ Fusion Cage meets the newness criterion at § 419.66(b)(1).

In the proposed rule, we also invited public comment on whether the TIDAL™ Fusion Cage meets the eligibility criteria at § 419.66(b)(3) and (4).

We did not receive public comments regarding whether the TIDAL™ Fusion Cage meets the eligibility criteria at § 419.66(b)(3) and (4). Based on our review of the application, we agree with the applicant and have determined that the TIDAL™ Fusion Cage meets the eligibility criteria at § 419.66(b)(3) and (4).

In the CY 2027 OPPS/ASC proposed rule, we noted regarding the device category eligibility criterion at § 419.66(c)(1) that the applicant stated that no existing (current or previous) device pass-through payment categories appropriately describe the TIDAL™ Fusion Cage. Per the applicant, the existing pass-through code C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) does not appropriately describe the TIDAL™ Fusion Cage because C1713 is typically used to represent fixation components, such as an intramedullary nail or other fixation screws, but does not represent the TIDAL™ Fusion Cage.

Based on the description the applicant provided, we stated in the proposed rule that the TIDAL™ Fusion Cage is a porous cage used as part of a limb salvage arthrodesis construct to bridge bone loss or a critical bone defect in the ankle and restore length due to bone void, absent bone, or surgical resection and therefore, could be described by C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)). Specifically, we stated our belief that the pass-through payment category C1713 may appropriately describe the TIDAL™ Fusion Cage because C1713 is defined as implantable pins and/or screws inserted or drilled into bone, principally with the intent to facilitate stabilization or oppose bone-to-bone contact and may include orthopedic plates with accompanying washers or nuts as well as synthetic bone substitutes that may be used to fill bony voids or gaps.[27] In this context, we stated our belief that the TIDAL™ Fusion Cage may be appropriately described by C1713. We also stated that, after reviewing the information provided by the applicant, we were unable to determine that the TIDAL™ Fusion Cage meets the device category eligibility criteria, and therefore, we proposed to deny transitional pass-through payment status for CY 2027.

We invited public comment on whether the TIDAL™ Fusion Cage meets the device category eligibility criterion at § 419.66(c)(1). We also invited public comments on our proposal to deny transitional pass-through payment status for the TIDAL™ Fusion Cage for CY 2027.

Comment: A commenter expressed its support for the denial of device pass-through payment for the TIDAL™ Fusion Cage.

Response: We appreciate the commenter's input.

Comment: The applicant and a few commenters submitted public comments urging CMS to approve device pass-through payments for the TIDAL™ Fusion Cage. A few commenters stated that the TIDAL™ Fusion Cage provides an alternative treatment to certain patients who are at risk of limb loss and without other good

[27] Centers for Medicare & Medicaid Services. (2024). *Medicare Claims Processing Manual* (CMS Pub. 100–04), Chapter 4: Part B Hospital (including inpatient hospital part B and OPPS). U.S. Department of Health and Human Services. *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c04.pdf.*

treatment options. The commenters added that denying the TIDAL™ Fusion Cage device pass-through payment would limit patients' access to this treatment option. One of these commenters also stated that when a patient loses their leg, besides the physical and mental anguish, the cost for the prosthetic is ever increasing.

With respect to whether the TIDAL™ Fusion Cage may be appropriately described by C1713, the applicant stated that there are no existing categories or categories previously in effect that appropriately describe the TIDAL™ Fusion Cage. Specifically, the applicant stated that C1713 describes fixation hardware such as anchors, screws, pins, plates, washers, and nuts used to facilitate stabilization or oppose bone-to-bone contact as well as certain conventional synthetic bone substitutes used to fill voids or gaps. The applicant compared this description to the TIDAL™ Fusion Cage, which it stated is an FDA-cleared ankle fusion cage that is a permanent, porous, load-bearing structural spacer used with a tibiotalocalcaneal (TTC) intramedullary rod to reconstruct a critical-size ankle/hindfoot bone defect, restore limb length, and enable salvage fusion in patients at risk of limb loss. The applicant also stated that CMS's preliminary conclusion relies on an overly broad interpretation of C1713 that stretches the device category beyond its natural scope of fixation hardware and void-filling substitutes. The applicant stated that CMS's interpretation of C1713 includes any implant associated with stabilization, fusion, or a bone defect and would result in the device category code inappropriately including a broad range of musculoskeletal reconstructive implants. The applicant stated that this would be inconsistent with the device category eligibility criterion, which asks whether an existing pass-through category appropriately describes the nominated device. According to the applicant, the appropriate question is not whether C1713 can be stretched to cover a device that touches bone or participates in fusion, but rather, whether C1713 appropriately describes the TIDAL™ Fusion Cage. The applicant reiterated that C1713 does not describe the TIDAL™ Fusion Cage because the device is a structural, porous, titanium ankle fusion cage with a central window for an intramedullary nail, used to replace absent bone and restore limb length in limb-salvage TTC fusion and not an anchor, screw, pin, plate, washer, nut, or conventional synthetic bone substitute.

The applicant stated that the TIDAL™ Fusion Cage is not an anchor, screw, pin, or plate. Per the applicant, C1713 describes an anchor/screw for opposing bone-to-bone or soft tissue-to-bone with the defining function of fixation by anchoring, screwing, pinning, drilling, or opposing tissue or bone surfaces. The applicant stated that, by contrast, the TIDAL™ Fusion Cage is not drilled into bone like a screw or pin, does not attach tendon or soft tissue to bone, and is not a plate, washer, nut, or fixation assembly. The applicant reiterated that the TIDAL™ Fusion Cage is a porous titanium cage with a circular window to contain an intramedullary nail and is used to restore length due to bone void, absent bone, or surgical resection during TTC fusion procedures in patients at risk of limb loss. The applicant stated that the TIDAL™ Fusion Cage's function is categorically different from opposing two tissues or two bone surfaces. The applicant stated that the nominated device is an interpositional, load-bearing reconstructive implant placed where bone is missing, and the intramedullary nail provides the primary internal fixation pathway through the construct while the cage replaces the segmental defect and provides a porous osseointegrative scaffold around the rod.

Furthermore, the applicant stated that CMS should not treat the TIDAL™ Fusion Cage as a conventional synthetic bone substitute used to fill bony voids or gaps under C1713. The applicant stated that CMS uses synthetic bone substitutes to collapse every device used in or around a bone defect into C1713. The applicant further stated that conventional bone void fillers are typically indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure, and many are resorbable materials that are replaced by bone over time.

The applicant noted that FDA's product code for this device is directly relevant to CMS's analysis of C1713 and confirms that a conventional synthetic bone graft or bone-void filler is a different type of device. The applicant stated that FDA classified the TIDAL™ Fusion Cage under product code SAI, Ankle Fusion Cage, under regulation 21 CFR 888.3020. The applicant further stated that FDA's product-code for an ankle fusion cage describes a permanent metal structure that acts as a structural spacer where the defect is intrinsic to stability and limb length. The applicant compared this ankle fusion cage product-code to FDA's separate product classification MQV for Filler, Bone Void, Calcium Compound, regulated under 21 CFR 888.3045, which is defined as a resorbable implant intended to fill bony voids or gaps caused by trauma or surgery that are not intrinsic to the stability of the bony structure. The applicant stated that treating the TIDAL™ Fusion Cage as a synthetic bone substitute would disregard the separate regulatory identities FDA assigned to these materially different device types. The applicant further explained that the TIDAL™ Fusion Cage is used precisely where the defect is intrinsic to stability, limb length, and salvage reconstruction and that FDA's product classification likewise describes the device as a metal open-space structure that acts as a structural spacer as part of a TTC fusion construct. Additionally, the applicant stated that, although the TIDAL™ Fusion Cage may be packed with autograft or allogenic bone graft, this does not make the cage itself a bone substitute. The applicant noted that labeling for the nominated FDA-cleared device indicates that it is intended for use with autograft and/or allogenic bone graft, confirming, per the applicant, that the cage is the structural implant and the graft is the biologic fusion material.

In addition, the applicant contended that CMS should give substantial weight to FDA's classification because FDA's product-code framework directly addresses devices' technological and clinical identity. The applicant reiterated that the SAI product code for ankle fusion cage describes the device type as a metal cylinder, spherical, or rectangular-box physical state with open space throughout that is used as a structural spacer and an accessory to a TTC intramedullary rod. The applicant explained that it believes this regulatory identity is materially distinct from screws, anchors, pins, plates, washers, nuts, and conventional synthetic bone substitutes. The applicant requested that CMS not deny transitional pass-through payment status for the TIDAL™ Fusion Cage on the basis that it is described by C1713. The applicant stated that a more accurate category would be a new ankle joint fusion device category, such as joint fusion device, ankle, including all system components (implantable).

Other commenters also stated that the nominated device is different from the types of anchors, screws, plates, or bone void fillers classified in existing device categories because it is a structural ankle fusion cage that sits in place of missing bone and permits the leg to carry weight while it heals in. A commenter further described the TIDAL™ Fusion Cage as a porous titanium spacer and stated that the nominated device restores leg length.

Response: We appreciate the applicant and commenters' input. After consideration of the public comments we received and our review of the application, we agree there is no existing category or category previously in effect that appropriately describes the TIDAL™ Fusion Cage because no pass-through category describes a device that is a structural component used to replace absent bone and restore limb length in an ankle fusion, and not an anchor, screw, pin, plate, washer, nut, or conventional synthetic bone substitute. Based on this information, we have determined that the TIDAL™ Fusion Cage meets the device category eligibility criterion at § 419.66(c)(1).

We also invited public comment on whether the TIDAL™ Fusion Cage meets the cost criterion at § 419.66(d)(3).

Comment: With respect to cost significance criteria, the applicant reiterated that the TIDAL™ Fusion Cage meets all three of the cost significance criteria.

Response: We appreciate the applicant's input. After consideration of the public comments we received and our findings from the first, second, and third cost significant tests, we agree that the TIDAL™ Fusion Cage meets the cost significance criteria specified at § 419.66(d).

After consideration of the public comments we received and our review of the device pass-through application, we have determined that the TIDAL™ Fusion Cage meets the requirements for device pass-through status described at § 419.66. We are approving the TIDAL™ Fusion Cage for device pass-through payment status effective January 1, 2027, under the alternative pathway for devices that have an FDA Breakthrough Device designation and FDA marketing authorization for the indication covered by the Breakthrough Device designation.

(3) Traditional Device Pass-Through Applications

(a) EndoForce™ Connector for Endovascular Venous Anastomosis

Phraxis Inc. submitted an application for a new device category for transitional pass-through payment status for the EndoForce™ Connector for Endovascular Venous Anastomosis (the EndoForce™ System) for CY 2027. According to the applicant, the EndoForce™ System provides an endovascular method for attachment of a non-autogenous arteriovenous graft (AVG) to a vein in the upper arm in patients with end stage renal disease (ESRD) requiring hemodialysis. Per the applicant, the EndoForce™ System is provided as a sterile, single-use EndoForce™ Connector Delivery System with a pre-mounted EndoForce™ Connector that is attached endovascularly at the venous anastomosis, in conjunction with a standard 6mm expanded polytetrafluoroethylene (ePTFE) vascular access graft, to establish an end-to-end endovascular anastomotic conduit designed to help absorb the shear forces of blood flow at the AVG-vein junction and to provide a physical barrier to the ingress of neointimal hyperplasia.

Table 54 provides an overview of the transitional pass-through payment status application for the EndoForce™ System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP260228AHPFT.*

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TABLE 54: ENDOFORCE™ SYSTEM APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization*: PMA approval - May 15, 2025. *Application submitted to CMS*: February 28, 2026.	No concerns.
FDA Indication	The EndoForce™ System is indicated to provide an endovascular method for attachment of an AVG to a vein in the upper arm in patients with ESRD requiring hemodialysis. The EndoForce™ Connector is used together with conventional suturing of the graft to the artery during the implantation procedure. The graft is then used for vascular access during hemodialysis.	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with human tissue, and is surgically inserted.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	No concerns.
Device Category	Device category codes C1768 (Graft, vascular), C1874 (Stent, coated/covered, with delivery system), C1875 (Stent, coated/covered, without delivery system), C1876 (Stent, non-coated/non-covered, with delivery system), C1877 (Stent, non-coated/non-covered, without delivery system), and C8000 (Support	No concern.

	device, extravascular, for arteriovenous fistula (implantable)) do not describe the device.	
Cost Criteria	The cost of the EndoForce™ System is $5,000.00. For cost significance requirements: HCPCS code: 36830 APC code: 5184 CY 2026 device offset amount: $1,474.69 CY 2026 APC payment rate: $5,685.01 Requirement #1: ($5,000.00 / $5,685.01) x 100 = 87.95%. Requirement #2: ($5,000.00 / $1,474.69) x 100 = 339.05%. Requirement #3: (($5,000.00 - $1,474.69) / $5,685.01) x 100 = 62.01%.	No concerns.
Substantial Clinical Improvement Criterion	Claim #1: Improved Patency, Reduced Intervention Burden, and Reduced AVG Abandonment at 6 months. Claim #2: Improved Patency and Reduced AVG Abandonment. Claim #3: Sustained Patency and Fewer Interventions to Maintain Patency. Claim #4: Improved Cumulative (Secondary Patency) Compared to Sutured AVGs. Claim #5: Improved Cumulative (Secondary Patency) Compared to Mature AV Fistulas. Claim #6: Improved Cumulative Patency Compared to WaveLinQ™. Claim #7: Improved Cumulative Patency Compared to Ellipsys™. Claim #8: Reduced Interventions Compared to Traditional AVGs. Applicant provided one published study assessing the technology, two unpublished studies assessing the technology, and six background documents.	See following discussion.

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In the CY 2027 OPPS/ASC proposed rule, we invited public comments on whether the EndoForce™ System meets the newness criterion at § 419.66(b)(1), the eligibility criteria at § 419.66(b)(3) and (4), and the device category eligibility criterion at § 419.66(c)(1).

Comment: The applicant submitted a public comment reiterating that the EndoForce™ System meets the newness, eligibility, and device category eligibility criteria for device pass-through payment.

Response: We appreciate the applicant's input. We received the application for device pass-through payment status for the EndoForce™ System within 3 years of the date of FDA premarket approval. We also agree with the applicant that the EndoForce™ System is an integral part of the service furnished, used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted or applied in or on a wound or other skin lesion. Additionally, we agree with the applicant that the EndoForce™ System is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, or a material or supply furnished incident to a service. We believe that there is no existing category or category previously in effect that appropriately describes the EndoForce™ System. Therefore, after consideration of the public comments we received and our review of the application, we have determined that the EndoForce™ System meets the newness criterion at § 419.66(b)(1), the eligibility criteria at § 419.66(b)(3) and (4), and the device category eligibility criterion at § 419.66(c)(1).

Regarding the substantial clinical improvement criterion at § 419.66(c)(2), after reviewing the information provided by the applicant, we stated in the CY 2027 OPPS/ASC proposed rule that we had the following concerns regarding whether the EndoForce™ System meets the substantial clinical improvement criterion.

In support of claims one through four and eight, the applicant submitted three studies evaluating the EndoForce™ System: Burgess et al. (2024), Kramer et al. (2026), and Astor et al. (2026), and three background studies: Halbert et al. (2020), Harms et al. (2016), and Woodside et al. (2021), which did not assess the nominated device.[28] In

[28] In its application, the applicant submitted unpublished versions of Kramer et al. (2026) and Astor et al. (2026), which we reviewed. Accordingly, we cited these studies in the proposed rule as Kramer et al. (n.d.) and Astor et al. (n.d.).

Continued

support of claims five through seven, the applicant submitted three background articles (Pisoni et al., 2021; Berland et al., 2019; Hull et al., 2018) which did not assess the nominated device.[29] [30] [31]

We noted that the Burgess et al. (2024) study is a single-arm, non-randomized study that analyzed the use of the EndoForce™ System in 158 patients aged 18 and older diagnosed with ESRD scheduled to have an AVG for hemodialysis placed in their upper arm in 10 U.S. institutions between 2018 and 2021 after a 6-month follow-up period.[32] We stated we had several concerns with this study.

Firstly, we stated we were concerned that the study does not provide a comparison to a control group, such as patients treated with standard graft-to-vein sutured anastomosis. Without a comparison to currently available treatments, particularly in the clinical setting where it is most likely to be used, we stated we were unable to assess whether the EndoForce™ System demonstrates substantial clinical improvement over currently available treatments. To demonstrate substantial clinical improvement, we stated we consider supporting evidence, preferably 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 other currently available treatments.

Secondly, we were concerned that the smaller patient population and study design of Burgess et al. (2024), and the lack of stratification by key clinical factors known to affect AVG outcomes, may limit both the reliability of the cumulative patency findings and the generalizability of results to the Medicare population. We stated that stratification factors, such as coronary artery disease, hypertension status, and ipsilateral access placement, which have all been shown to be associated with thrombosis, need for intervention, and cumulative patency would be helpful to assess the outcomes.

In addition, we stated it was unclear to what extent any improvement in cumulative patency is due to use of the EndoForce™ Connector versus the less invasive endovascular procedure used for implantation. We stated we would welcome additional information on differentiating how the EndoForce™ System's connection to AVG versus the less invasive nature of the endovascular procedure leads to improvements in cumulative patency.

Furthermore, we noted that, in Burgess et al. (2024), the authors compared results to three background studies, Halbert et al. (2020) (submitted in support of claim 4), Harms et al. (2016) (submitted in support of claim 8), and Woodside et al. (2021) (submitted in support of claim 8), none of which directly address the EndoForce™ System.[33] [34] [35] We questioned the appropriateness of comparing cumulative patency, intervention rates, and AVG abandonment in Burgess et al. (2024) to outcomes reported in the three background studies, as observed differences may be influenced by variations in study design, study location, patient population and characteristics, and study period. Specifically, we stated that Burgess et al. (2024) reports a 6-month cumulative patency of 92 percent in its patient population and compares it to the 80 percent rate reported in Halbert et al. (2020). However, we noted that Halbert et al. (2020) is a meta-analysis of 32 studies conducted across 14 countries between 2007 and 2019, representing 3,381 AVGs placed in patients with chronic kidney disease or ESRD undergoing or preparing for hemodialysis using ePTFE grafts. In contrast, we stated that Burgess et al. (2024) analyzed ESRD patients between 2018 and 2021. Thus, we questioned whether the results in Halbert et al. (2020), which included studies dating back more than a decade, reflect current operative techniques and perioperative care in the U.S. and therefore whether they are an appropriate comparator to Burgess et al. (2024). Similarly, we stated that Harms et al. (2016) is a retrospective study of 599 patients treated between January 2006 and December 2011, and Woodside et al. (2021) is an observational cohort study of 73,027 patients using data from July 2012 to December 2014. We noted that these studies reflect earlier clinical practices and patient populations that differ from those in Burgess et al. (2024), which evaluated patients between 2018 and 2021. We stated that Burgess et al. (2024) compared its reported intervention rate of 1.22 per patient-year to higher rates reported in Harms et al. (2016) and Woodside et al. (2021), 1.58 and 1.87 respectively; however, these comparisons may not be appropriate given the significant differences in study design, time periods and patient populations. We also stated that these earlier studies do not adequately account for changes in clinical practice over time and any observed differences in outcomes are likely confounded by these factors rather than attributable to the technology itself. As such, we stated that these studies may not provide a valid basis for comparison to Burgess et al. (2024).

Moreover, we noted patient populations varied across studies, and it is unclear how these differences may have affected intervention rates per patient-year. We stated, for example, Burgess et al. (2024) included patients with two or fewer previous vascular accesses in the treatment arm, while Woodside et al. (2021) included patients undergoing a first-time AVG placement between dialysis initiation and 1 year. We noted that patients who have had previous hemodialysis access points experience damage to the blood vessels regardless of whether the access point is a central venous catheter, AVG, or

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In its public comment discussed later in this section, the applicant cited published versions of these studies and indicated that the published versions did not contain material changes.

[29] Pisoni, R. L., Zepel, L., Zhao, J., Burke, S., Lok, C. E., Woodside, K. J., Wasse, H., Kawanishi, H., Schaubel, D. E., Zee, J., & Robinson, B. M. (2021). International Comparisons of Native Arteriovenous Fistula Patency and Time to Becoming Catheter-Free: Findings From the Dialysis Outcomes and Practice Patterns Study (DOPPS). *American journal of kidney diseases: the official journal of the National Kidney Foundation, 77*(2), 245–254. *https://doi.org/10.1053/j.ajkd.2020.06.020.*

[30] Berland, T. L., Clement, J., Griffin, J., Westin, G. G., & Ebner, A. (2019). Endovascular Creation of Arteriovenous Fistulae for Hemodialysis Access with a 4 Fr Device: Clinical Experience from the EASE Study. *Annals of vascular surgery, 60,* 182–192. *https://doi.org/10.1016/j.avsg.2019.02.023.*

[31] Hull, J. E., Jennings, W. C., Cooper, R. I., Waheed, U., Schaefer, M. E., & Narayan, R. (2018). The Pivotal Multicenter Trial of Ultrasound-Guided Percutaneous Arteriovenous Fistula Creation for Hemodialysis Access. *Journal of vascular and interventional radiology: JVIR,* 29(2), 149–158.e5. *https://doi.org/10.1016/j.jvir.2017.10.015.*

[32] Burgess, J. S., Beaver, J. D., London, M., Rohan, V., Orland, P., Yevzlin, A., Setum, C., Ross, J., & InterGraft Study Investigators. (2024). Prospective multicenter study of a novel endovascular venous anastomotic procedure and device for implantation of an arteriovenous graft for hemodialysis. *The Journal of Vascular Access, 25*(4), 1244–1251. *https://doi.org/10.1177/11297298231159691.*

[33] Halbert, R. J., Nicholson, G., Nordyke, R. J., Pilgrim, A., & Niklason, L. (2020). Patency of ePTFE Arteriovenous Graft Placements in Hemodialysis Patients: Systematic Literature Review and Meta-Analysis. *Kidney360, 1*(12), 1437–1446. *https://doi.org/10.34067/kid.0003502020.*

[34] Harms, J. C., Rangarajan, S., Young, C. J., Barker-Finkel, J., & Allon, M. (2016). Outcomes of arteriovenous fistulas and grafts with or without intervention prior to successful use. *Journal of Vascular Surgery, 64*(1), 155–162. *https://doi.org/10.1016/j.jvs.2016.02.033.*

[35] Woodside, K. J., Repeck, K. J., Mukhopadhyay, P., Schaubel, D. E., Shahinian, V. B., Saran, R., & Pisoni, R. L. (2021). Arteriovenous Vascular Access–Related Procedural Burden Among Incident Hemodialysis Patients in the United States. *American Journal of Kidney Diseases, 78*(3), 369–379.e1. *https://doi.org/10.1053/j.ajkd.2021.01.019.*

AVF.[36] [37] Further, we stated having prior vascular access points in the ipsilateral arm has been shown to decrease cumulative patency in Harms et al. (2016). We stated that we would welcome additional studies that control for patients with comparable vascular access placement histories, to more accurately quantify the contributions of the EndoForce™ System to improvements in interventions per patient-year.

Finally, we stated that we were concerned that differences in vascular location for patients in the Burgess et al. (2024) compared to patients in the background studies may influence outcomes and adversely impact comparability of results. Specifically, while Burgess et al. (2024) evaluated patients with upper arm AVGs consistent with the EndoForce™ System's FDA approved indication, we stated that this varied across the comparator studies: Halbert et al. (2020) excluded studies that exclusively assessed lower extremity AVGs, Harms et al. (2016) included patients who had AVGs in the chest and thigh in addition to the upper extremity, and Woodside et al. (2021) did not specify the anatomical location of AVGs. We noted that it was unclear whether some of the studies included patient populations with upper extremity, lower extremity, and chest AVGs. As discussed in greater detail later in this section for the second claim, we stated that it was unclear whether upper extremity and upper arm are used interchangeably. We questioned whether vascular access location influences clinical outcomes, and as such, the results in these background studies may be confounded by inclusion of patients with additional graft locations that could adversely impact the comparability of the results to Burgess et al. (2024).

With regard to the second claim that the EndoForce™ System improves patency and reduces AVG abandonment, the applicant submitted a study by Astor et al. (2026) that compared the primary patency (defined as the time interval from initial implantation until first intervention) and cumulative patency (defined as the time interval between implantation of the graft to abandonment) results from Burgess et al. (2024) to pooled results from a meta-analysis of 34 studies of AVGs implanted using traditional surgical techniques.[38] We expressed concern that Astor et al. (2026) may not demonstrate that the EndoForce™ System substantially improves the diagnosis or treatment of an illness when compared to the benefits of other available treatments. We stated that Astor et al. (2026) reported a high degree of variability among the comparator studies included in the meta-analysis (primary patency I^2 = 99.44; cumulative patency I^2 = 99.36), many of which showed similar or higher primary patency (60.21 percent; 95 percent confidence interval (CI): 50.84, 69.59) and cumulative patency (92.08 percent; 95 percent CI: 86.98, 97.18) compared to results from Burgess et al. (2024). We noted that 19 of the 31 studies that provided data on cumulative patency in Astor et al. (2026) did not specifically report 6-month patency outcomes in tables or text; the studies only provided data in survival curves from which the authors of Astor et al. (2026) derived 6-month patency measurements. We stated that the estimated 6-month cumulative patency including all 31 studies was 83.23 percent (95 percent CI: 80.18, 86.28), whereas the 6-month cumulative patency estimated from the 12 studies reporting numerical values was 86 percent (95 percent CI: 81.78, 90.22). We noted that Astor et al. (2026) did not state whether the difference between the 6-month cumulative patency rates of 92 percent in Burgess et al. (2024) and 86 percent was statistically significant. However, we noted the lower 95 percent CI bound reported in Burgess et al. (2024) was 86.98 percent, lower than the upper 95 percent CI bound of 90.22 percent for the 12 studies in Astor et al. (2026) providing numerical data. We also noted that Astor et al. (2026) states that the primary patency for the EndoForce™ System is similar to pooled results from comparator studies (60.21 percent vs 60.35 percent; p = 0.75). Additionally, we noted that the 20 percent AVG abandonment rate used as a baseline by Astor et al. (2026) which they report was reduced to 8 percent, comes from a single meta-analysis (Halbert) based on 32 studies from 14 countries conducted between 2007 and 2019. We questioned whether this is an appropriate comparator to the 158 patients treated between 2018 and 2021 in 10 U.S. institutions reported in Burgess et al. (2024).

We also noted that the criteria for comparator studies included in the meta-analysis in Astor et al. (2026) excluded those studies which only assessed lower extremity or chest AVGs. However, we questioned whether some of the studies included patient populations with upper extremity AVGs as well as lower extremity and chest AVGs. We stated that, as previously discussed, vascular access location may influence outcomes, therefore, the results in these background studies may be confounded by inclusion of patients with additional graft locations that could adversely impact the comparability of the results to Burgess et al. (2024). Additionally, because of the EndoForce™ System's FDA approved indication for use in the upper arm, we questioned whether the comparison is appropriate. Further, we noted it is unclear in the application whether the upper arm means the entire upper extremity, including the forearm (distal to the elbow) or only a portion of the arm (proximal to the elbow). We stated that we would be interested in additional information clarifying the meaning of upper arm to help us evaluate the evidence provided in support of substantial clinical improvement and determine if it is applicable.

With regard to the third claim that the EndoForce™ System sustains patency and requires fewer interventions to maintain patency, the applicant submitted one extended follow-up study (Kramer et al. (2026)) of 37 patients from Burgess et al. (2024), that evaluates the number of interventions performed to achieve cumulative patency for an additional 6 months beyond the most recent intervention.[39] We stated, similar to our concerns regarding Burgess et al. (2024), we were concerned that Kramer et al. (2026) does not provide a control group for comparison. We noted that the authors in Kramer et al. (2026) stated that, since both the EndoForce™ System's pivotal trial (Burgess et al, 2024) as well as this extended follow-up study do not directly compare outcomes

[36] Harms, J. C., Rangarajan, S., Young, C. J., Barker-Finkel, J., & Allon, M. (2016). Outcomes of arteriovenous fistulas and grafts with or without intervention prior to successful use. *Journal of Vascular Surgery, 64*(1), 155–162. *https://doi.org/10.1016/j.jvs.2016.02.033.*

[37] Lok, C. E., Huber, T. S., Orchanian-Cheff, A., & Rajan, D. K. (2024). Arteriovenous access for hemodialysis: A review. *Journal of American Medical Association,* 331(15), 1307–1317. *https://doi.org/10.1001/jama.2024.0535.*

[38] Astor, B. C., KMLST Moorthi, Grant, L., & Litchfield, T. (2026). Endovascular AVG venous anastomosis improves cumulative patency compared to traditional sutured anastomosis: a meta-analysis. *Journal of Interventional Nephrology,* 9(1), 427–434. *https://www.openaccessjournals.com/articles/endovascular-avg-venous-anastomosis-improves-cumulative-patency-compared-to-traditional-sutured-anastomosis-a-metaanalysis-18782.html.*

[39] Kramer, A., KMLST Moorthi, Grant, L., & Litchfield, T. (2026). Extended Follow-Up of an Endovascular Venous Anastomotic Connector for Arteriovenous Graft Creation in Hemodialysis: A Multicenter Study. *Journal of Interventional Nephrology, 9*(1), 418–426. *https://www.openaccessjournals.com/articles/extended-followup-of-an-endovascular-venous-anastomotic-connector-for-arteriovenous-graft-creation-in-hemodialysis-a-multicenter-s-18760.html.*

to sutured AVGs, a meta-analytic approach to compare endovascular anastomosis of an AVG with a traditional sutured anastomosis may be warranted. We stated that we would welcome additional information directly comparing endovascular anastomosis of an AVG with a traditional sutured anastomosis.

We noted that, like Burgess et al. (2024), the authors of Kramer et al. (2026) compared results to two background studies, Harms et al. (2016) and Woodside et al. (2021), neither of which directly address the EndoForce™ System. As mentioned previously, we questioned whether the comparison of rates of interventions per patient-year in Kramer et al. (2026) to Harms et al. (2016) and Woodside et al. (2021) are appropriate and reflect true improvements or are attributable to differences in study design, patient population, and study period. We noted that Kramer et al. (2026) reported a rate of 1.32 interventions per patient-year in its patient population using the nominated technology and compared it to rates of 1.58 and 1.87 reported in Harms et al. (2016) and Woodside et al. (2021). We stated, however, as previously noted in our discussion of the first claim that the EndoForce™ System improves patency, reduces intervention burden, and reduces AVG abandonment at 6 months, due to the differences in study periods between Kramer et al. (2026) and Harms et al. (2016) and Woodside et al. (2021), we questioned whether the results in the comparator studies, some of which are over a decade old, reflect current operative techniques and latest perioperative care in the U.S. We also stated that, as previously noted in our discussion of the first claim, the extent of variance in vascular access locations of the patient populations assessed in these three studies was unclear. As such, we stated our concern that the results in these background studies may be confounded by inclusion of patients with additional graft locations which could adversely impact the comparability of the results to Kramer et al. (2026).

We also expressed concern about whether the patient population in Kramer et al. (2026), which included 29 active patients at the end of the study period from the 37 patients initially assessed, is powered sufficiently to assess statistical significance, especially compared to Burgess et al. (2024), which included 134 active patients at the end of the study period from the 158 patients initially assessed. We noted that when a study is not adequately powered for the statistical analysis, the statistics may appear artificially inflated and do not reflect confounding effects. We also expressed concern that the cohort in Kramer et al. (2026) was selected and analyzed post-hoc, rather than identified as a variable of interest at the initiation of Burgess et al. (2024) and questioned whether quality of the study was diminished due to selection bias.

Additionally, we questioned whether Kramer et al. (2026) conclusively demonstrates that the EndoForce™ System provides a substantial clinical improvement compared to other available treatments. We noted that Kramer et al. (2026) estimated a cumulative patency of 78.4 percent at 180 days into the extended follow-up period (12 months from AVG implant at the start of Burgess et al. (2024)). We stated that, in comparison, Halbert et al. (2020) reported a 12-month cumulative patency of 70 percent (95 percent CI: 64, 75). We also noted the high degree of variability ($I^2 = 91$) among the comparator studies in Halbert et al. (2020), many of which showed similar or higher cumulative patency compared to Kramer et al. (2026). Therefore, we stated we were unable to conclusively attribute the difference in outcomes to the nominated device.

Lastly, we questioned the appropriateness of comparing measures of cumulative patency that are not equally defined. Kramer et al. (2026) compared cumulative patency between participants with and without graft interventions within the 6-month study period discussed in Burgess et al. (2024) and stated that the cumulative patency at 6 months was nearly identical (91.79 percent versus 91.80 percent, respectively). We stated that, in Kramer et al. (2026), for patients without an intervention, time to loss of patency was measured from the date of implant, while for patients with interventions, time to loss of patency was measured from the date of first intervention. We questioned the appropriateness of comparing cumulative patency between AVGs used at first hemodialysis without intervention and those that required intervention prior to first hemodialysis use. We stated, as Harms et al. (2016) notes, intervention prior to first hemodialysis use is associated with a shortened cumulative patency. As such, we questioned if making such comparisons could be potentially misleading.

In support of claims five through seven, that the EndoForce™ System improves cumulative (secondary) patency compared to mature AV fistulas (AVFs), and devices used for AVF creation, including WaveLinQ™, and Ellipsys™, the applicant submitted three background articles (Pisoni et al. (2021); Berland et al. (2019); Hull et al. (2018)) which did not assess the nominated device. The applicant stated that improvement in AVG patency is comparable to the 6-month cumulative patency associated with mature AVFs (71 to 93 percent) (Liu, P. et al. (2023)). However, we noted that the EndoForce™ System is indicated for attachment of an AVG to a vein, not for the creation of an AVF. We also noted that an AVF involves a direct anastomosis between an artery and a vein, whereas an AVG uses a graft as a conduit between the artery and the vein. Therefore, we questioned whether it is clinically appropriate to compare the EndoForce™ System, a device used for AVG attachment, to mature AVFs and devices used for AVF creation, including WaveLinQ™ and Ellipsys™. Given these fundamental differences in mechanism and clinical use, we questioned whether these claims demonstrate a substantial clinical improvement over existing technologies.

We invited public comment on whether the EndoForce™ System meets the device category criterion at § 419.66(c)(2) and the cost criterion at § 419.66(d)(3).

Comment: A commenter expressed its support for the denial of device pass-through payment for the EndoForce™ System due to their belief that it does not meet all criteria for approval.

Response: We appreciate the commenter's input.

Comment: The applicant and several commenters recommended that CMS approve of device pass-through payment for the EndoForce™ System. These commenters stated that the EndoForce™ System exhibits a genuinely different technological approach to an important and persistent problem in dialysis vascular access compared to traditional hand-sewn venous anastomosis, and therefore, offers a promising opportunity to improve the durability and preservation of permanent dialysis access via an AVG. Commenters stated that, without approval, hospitals may face a financial disincentive or be unable to offer the EndoForce™ System even when the surgeon believes it is the best option for a patient for whom an AVG is the appropriate permanent-access strategy. Commenters expressed concern that this would thereby limit physicians' ability to gain experience with a new technology, restrict patient access, and impede generation of the broader real-world clinical evidence CMS seeks and is necessary to determine the technology's long-term value. The

commenters also stated that, given that important dialysis vascular access and management innovations are slow-developing and infrequent, device pass-through payment status would create disciplined adoption that can allow appropriate Medicare beneficiaries to receive an innovative technology while physicians, investigators, and other interested parties continue to develop evidence regarding its clinical performance and value. In addition, a few commenters stated that approving transitional pass-through payment for the EndoForce™ System would not end the evidence discussion and does not require CMS to conclude that this technology has already established all its potential long-term clinical or economic benefits.

A few commenters stated that, for patients requiring an AVG, preserving a usable graft with fewer interventions per patient-year and avoiding a catheter is not marginal improvement, but rather, is the difference between stable dialysis and another cycle of access failure. These commenters also stated that the EndoForce™ System will reduce disruptions in dialysis care and caregiver burden, while also decreasing frequency of invasive procedures that expose patients to procedural risks; pain, anxiety, and recovery; and additional demands on limited vascular anatomy.

A few commenters stated that the EndoForce™ System is particularly important for Medicare beneficiaries who are unsuitable candidates for a usable AVF and for whom an AVG may be the most appropriate, as it is the most likely to become promptly usable and shortens catheter exposure. Moreover, a commenter stated that providers embrace new technologies, such as the EndoForce™ System, which has the potential to reduce catheter dependence and improve AVG patency, and that beneficiaries deserve the choice of innovations that could improve their access care.

A few commenters agreed with some of CMS's concerns in the CY 2027 OPPS/ASC proposed rule (91 FR 41837 through 41839), specifically regarding the absence of a concurrent control group, differences among comparator populations and treatment periods, variation in vascular-access history and graft location, and uncertainty regarding the source of the observed clinical benefit, further agreeing that they warrant appropriate caution. However, the commenters stated that the concerns alone do not warrant a negative determination of substantial clinical improvement. The commenters stated that CMS should evaluate the evidence in the clinical context of patients who actually received an AVG and the persistent clinical problem that the EndoForce™ System intends to address. The commenters stated that, in evaluating the evidence for substantial clinical improvement, the available statistical comparisons have recognized limitations, and therefore, CMS should consider the totality of the circumstances, including the nature of the patient population, the historical difficulty of maintaining dialysis vascular access, the burden imposed by repeated access procedures, and the potential significance of reducing those interventions.

Additionally, the commenters suggested that CMS also consider the potential downstream consequences of denying transitional pass-through payment status, including the need for repeated interventions, vascular access-related hospital and outpatient encounters, vascular access failure, catheter exposure, and the cumulative burden these events impose on Medicare beneficiaries and the Medicare program. These commenters also stated that CMS's substantial clinical improvement standard recognizes long-term catheter use and decreased rate of subsequent diagnostic or therapeutic interventions as a clinically important outcome and, from a dialysis patient's perspective, they may be the most important outcomes CMS can consider.

A commenter emphasized the clinical challenges of dialysis vascular access, such as their path-dependent nature and how a functioning graft's loss may consume additional vascular territory, require another access procedure, and return a patient to catheter dependence, and that this patient population has limited options available. The commenter stated that transitional pass-through payment status for the EndoForce™ System would enable its availability for appropriately selected patients while its additional cost is not yet included into payment rates. Additionally, the commenter stated that device pass-through payment status would not imply that the EndoForce™ System should replace conventional AVG in every patient, but it would permit physicians to consider the technology in the select patients for whom its clinical advantages justify use.

Response: We thank the applicant and commenters for their comments. We have taken these comments into consideration in our final determination for pass-through payment status for the EndoForce™ System.

Comment: In response to our concerns regarding Burgess et al.'s (2024) lack of a control group and differences from the available comparator populations, the applicant commented that, while a study comparing the EndoForce™ System to a control group would be a useful addition to the available evidence, no such study exists at this time. The applicant explained that because of this, its evidence strategy was to rely on comparison to other studies through systematic reviews and meta-analyses. The applicant stated that it provided sufficient information to support an apt and revealing comparison, enabling a reasonable judgement about a complicated issue. Citing a publication on randomized control trials (RCTs), the applicant added that the most rigorous form of a study with a control group is a RCT, and that while RCTs are generally regarded as a methodological gold standard, they can be subject to several forms of bias that are not necessarily defeated by randomization.[40]

The applicant further stated that when meta-analyses are well-specified and review high-quality studies, methodologists place them at the top of the evidence hierarchy and consider them to be likely superior to even randomized clinical trials when well conducted.[41] [42] As a result, the applicant stated that CMS should not readily dismiss the evidence available from the comparative studies provided in its application. The applicant noted that Burgess et al. (2024) included patients fitted with sutured AVGs by Halbert et al. (2020) and that Halbert et al. (2020) only included studies in which patients had newly created AVGs, as opposed to graft revisions.

The applicant further stated that the patient population in Halbert et al. (2020) aligns with Burgess et al. (2024) and that the Burgess et al. (2024) study design deliberately enables comparison to previously published studies to provide a meaningful historical comparison. The applicant also stated that it specifically intended for Astor et al. (2026) to provide a direct comparison to Burgess et al. (2024). The applicant reiterated comparisons of 6-month cumulative patency between Burgess et al. (2024) and Halbert et al. (2020), and

[40] Msaouel, P. (2021). Impervious to Randomness: Confounding and Selection Biases in Randomized Clinical Trials. *Cancer Investigation,* 1–6. *https://doi.org/10.1080/07357907.2021.1974030.*

[41] Vatkar, A. (2025). Understanding the Levels of Evidence in Medical Research. *J. Orthop. Case Rep.,* 15(5):6–9. doi: 10.13107/jocr.2025.v15.i05.5534 *https://pubmed.ncbi.nlm.nih.gov/40351623/.*

[42] Cazzola, M., Stolz, D., Bafadhel, M., & Rogliani, P. (2024). Understanding evidence from randomised controlled trials and meta-analyses: a comparative overview. *European Respiratory Journal, 63*(5), 2400694–2400694. *https://doi.org/10.1183/13993003.00694-024.*

Burgess et al. (2024) and Astor et al. (2026), which CMS discussed in the CY 2027 OPPS/ASC proposed rule (91 FR 41837 and 41838, respectively).

Additionally, a commenter stated that while differences among comparator populations are important, those differences reflect the clinical reality of AVG recipients, who are a highly heterogeneous population. The commenter added that factors, including prior catheters and accesses, remaining vasculature condition, ipsilateral access history, anatomical location, and comorbidities, can affect both the decision to place a graft and its subsequent performance. The commenter stated that contemporary literature demonstrates the difficulty of consistently accounting for these variables. The commenter cited a 2026 systematic review and meta-analysis of 63 studies and 357,333 patients (Yang et al.),[43] which found substantial clinical and methodological heterogeneity along with inconsistent reporting of variables such as prior AVF or AVG use, first-access status, and prior catheter use. The commenter noted that Yang et al. (2026) could not include several of these clinically important variables into its meta-regression because they are inconsistently reported. The commenter stated that the same variables CMS identified as necessary for comparability (*e.g.,* prior access history, anatomical location, ipsilateral vascular history, and relevant comorbidities) are both clinically consequential and inconsistently reported in contemporary vascular-access literature. The commenter stated that the absence of a study comparing the EndoForce™ System to a concurrent control group remains a meaningful limitation and reduces strong causal inference, but this limitation should not be interpreted to mean that existing conventional-AVG experience has little comparative value or that the submitted evidence is clinically uninformative. Instead, the commenter stated that the lack of a perfect contemporary comparator should affect the weight and certainty assigned to the available evidence.

In response to our concerns about the small patient population in Burgess et al. (2024), the applicant stated that the reliability of the study's findings was not compromised by the patient population's size and that the study team selected the sample size to support FDA premarket approval and intended to provide adequate statistical power to demonstrate that AVG placement with the EndoForce™ System met a pre-specified performance goal of 75 percent cumulative patency at 6 months ($p<0.001$).

Regarding our concerns about lack of stratification in Burgess et al. (2024), the applicant stated that the study's generalizability to the Medicare population is unlikely to be a practical problem as the preponderance of patients requiring vascular access are eligible for Medicare and, while the study did not report patients' insurance status, the provided demographic information comports with the Medicare population. The applicant also stated that the possible stratifications in which CMS expressed interest are among the factors clinicians wrestle with daily in developing patients' treatment plans. The applicant added that the 2019 Kidney Disease Outcomes Quality Initiative (KDOQI) guideline do not specify in detail how physicians should handle such factors but defer to clinicians' judgement to take these factors, among others, into account when dealing with the complex specifics of cases before them.[44] The applicant stated that although Burgess et al. (2024) includes information about the extent of a number of diseases and other factors, stratified analysis within the study would have been of questionable value given the sample size. Lastly, the applicant stated its interest in investigating some of these clinical aspects in future research, recognizing that additional reliable studies could help improve clinical practice, but questioned CMS's concern that the available information at present is inadequate to find the EndoForce™ Connector represents substantial clinical improvement relative to other available technologies.

In response to our concern about whether the EndoForce™ Connector is the cause of any cumulative patency improvement or if it can be contributed to the less invasive endovascular procedure used for implantation, the applicant stated that it does not see how these two aspects can be meaningfully separated for investigation because it is the EndoForce™ Connector itself that enables the endovascular approach and no purely endovascular AVG placement procedure, with or without an additional device, is available. A commenter stated that while this is a legitimate causal question, the distinction should not obscure how the EndoForce™ Connector functions in clinical use. The commenter stated that the endovascular implantation method is not a separate, unrelated co-intervention, but the means by which the EndoForce™ Connector performs its FDA-approved function of creating the venous graft attachment. The commenter further stated that the available evidence may not establish whether any observed benefit predominantly results from reduced surgical trauma, altered geometry or hemodynamics, the EndoForce™ Connector's physical characteristics, or some combination of those effects, but the remaining mechanistic uncertainty does not require CMS to treat the EndoForce™ Connector and the procedure as clinically unrelated. The commenter stated that the clinically relevant comparison is between the EndoForce™ System as used according to its FDA indication and the conventional sutured venous anastomosis it replaces.

In response to our concern about the appropriateness of comparing Burgess et al. (2024) to the three provided background studies (Halbert et al., 2020; Harms et al., 2016; and Woodside et al., 2021) due to differences in study design, study location, and patient population, the applicant stated that Burgess et al. (2024) and Halbert et al. (2020) have very similar population characteristics, outcomes, and other factors, noting that detailed information about the patient populations and other aspects of the studies included in Halbert et al. (2020) are provided in a set of Supplemental Tables available on the journal's website. Further, the applicant stated that Halbert et al. (2020) showed no statistically significant difference across average outcomes in U.S. studies versus those conducted overseas; type of AVG used; observational studies versus randomized controlled trials; and sex, race, or presence of diabetes. The applicant also stated that Halbert et al. (2020) reviewed studies using a bias risk assessment procedure and found no statistically significant difference in bias between the studies.

Moreover, the applicant provided additional information about the population characteristics of studies included in the Astor et al. (2026) meta-analysis and compared them to Burgess et al. (2024), noting that patients included in Burgess et al. (2024) were older (mean age: 58.24 years vs. 62.6 years); had higher rates of diabetes

[43] Yang, C., Yang, W., Xiao, L., Zhu, R., Li, X., Xiang, E., Wang, H., Lou, J., & Gao, Z. (2026). Comparative outcomes of arteriovenous fistulas and grafts in haemodialysis: meta-analysis with subgroup analysis by fistula type and transposition status. *BJS Open, 10*(2). *https://doi.org/10.1093/bjsopen/zraf165.*

[44] Lok, C. E., Huber, T. S., Lee, T., Shenoy, S., Yevzlin, A. S., Abreo, K., Allon, M., Asif, A., Astor, B. C., Glickman, M. H., Graham, J., Moist, L. M., Rajan, D. K., Roberts, C., Vachharajani, T. J., & Valentini, R. P. (2020). KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update. *American Journal of Kidney Diseases, 75*(4), S1–S164. *https://doi.org/10.1053/j.ajkd.2019.12.001.*

(51.99 percent vs. 62.0 percent, p = 0.013), higher rates of cardiovascular disease (16.05 percent vs. 49.4 percent, p<0.001), higher tobacco use (10.63 percent vs. 14.6 percent, p = 0.12); and lower rates of hypertension (75.96 percent vs. 56.3 percent, p<0.001). In addition, the applicant stated that Burgess et al. (2024), Halbert et al. (2020), and Astor et al. (2026) had patient populations similar in a number of key characteristics that are generally thought to influence patency and compared them to values reported in the United States Renal Data System (age: 62.6 years, 61.0 years, 58.24 years, and 63.21 years respectively; sex (percent male/female): 39/61, 45/55, 42/58, and 58.6/41.4, respectively; and diabetes prevalence: 62 percent, 48 percent, 52 percent, and 45 percent, respectively). The applicant stated that the patient population characteristics, such as age, sex, and prevalence of diabetes, in Burgess et al. (2024) are more closely associated with worse outcomes for cumulative patency, and insofar as these variables might affect cumulative patency, they would tend to depress rather than elevate the cumulative patency results relative to those in the other studies; however, the EndoForce™ System showed a clinically significant improvement.

In response to our concern that results in Halbert et al. (2020), Harms et al. (2016), and Woodside et al. (2021) may be inappropriate comparators to Burgess et al. (2024) as older studies may not reflect current operative techniques and perioperative care in the U.S., the applicant stated that basic procedures and technology related to AVGs have not materially changed in the last 20 years. The applicant added that further analysis of studies in Halbert et al. (2020) illustrate slightly higher (69.5 percent vs. 68.8 percent), but not statistically significant, 12-month cumulative patency results in the older cohort of studies (published pre-2014) compared to the more recent cohort (published between 2014 and 2019). The applicant also noted that, in Burgess et al. (2024) and Halbert et al. (2020), included studies' time periods overlap (2018 to 2021 compared to 2007 to 2019, respectively). The applicant stated that this suggests that no meaningful improvement in AVG vascular access outcomes occurred and that the studies in question are all comparable regardless of publication date. The applicant stated that the EndoForce™ System represents a meaningful technological advance in AVG, because it directly targets the longstanding failure point through a sutureless endovascular venous anastomosis. Another commenter stated that although the concern warrants consideration, the significance of a study's age should depend on whether the treatment being compared has materially changed. The commenter stated that although imaging, graft materials, perioperative management, surveillance, and techniques used to treat failing access have advanced, the basic surgical method for creating venous anastomosis in a conventional AVG has remained largely the same for decades. The commenter added that the EndoForce™ System's design avoids the conventional sutured graft-to-vein junction by creating an end-to-end endovascular venous anastomosis, reduces local vessel trauma and adverse flow conditions, and may lessen the drivers of neointimal hyperplasia. The commenter concluded that older studies comparing ePTFE grafts with conventional surgical anastomosis are still relevant if that comparator and its underlying failure mechanism remain a cause of graft failure, even if the study predates Burgess et al. (2024). Lastly, the commenter stated that older evidence may warrant less weight than a contemporary controlled comparison, but this does not negate the older evidence's value when the conventional treatment remains materially similar and the failure mechanism under study remains clinically relevant.

In response to our concern that differences in vascular access location for the patients in the Burgess et al. (2024), Halbert et al. (2020), Harms et al. (2016), and Woodside et al. (2021) studies may be confounding factors that influence patency and adversely impact comparability of results, the applicant stated that the most important difference that might matter for the outcomes of interest is the size of the vessels: the major veins and arteries in the upper arm being larger than in those the lower arm. The applicant cited a study stating this difference is more pertinent for AVFs, which generally appear to work best when vessels have a larger diameter.[45] The applicant stated that for AVGs, vessels as small as two millimeters in diameter generally work well and such vessels are available in the lower arms of most individuals. In addition, the applicant cited another study that investigated AVGs' optimal location (upper arm versus forearm) and concluded that upper arm AVGs have similar graft patency and access-related complications compared with forearm AVGs despite the fact that [upper arm AVGs] are assumed to be constructed based on larger outflow veins.[46] Further, the applicant cited a study that reviewed records of over 52,000 accesses placed between 2021 and 2022 and found that only 9.7 percent of AVGs were placed in forearms and that this percentage had declined over time.[47] Based on these studies, the applicant stated that although the comparator studies may include lower-arm cases while Burgess et al. (2024) does not, any confounding effect on the outcomes of interest may be minimal.

In response to our concern regarding differences in vascular access locations in Burgess et al. (2024), which evaluated upper arm AVGs, compared to the background studies' (Halbert et al., 2020; Harms et al., 2016; and Woodside et al., 2021), which had various access locations, and our concern that comparator studies included in the Astor et al. (2026) excluded studies which only assessed lower extremity or chest AVGs, the applicant stated that lower extremity AVGs have generally been regarded as a last resort for patients who have exhausted their upper extremity access possibilities. The applicant added that, although good estimates of the extent of use in the dialysis population are unavailable, a few studies suggest the number may be less than two percent of patients. Additionally, the applicant cited a study that found recent case studies show cumulative patency rates at 6 months for leg (thigh) grafts and arm (upper extremity) AVGs are generally comparable, ranging between 75 and 85 percent. The applicant further stated that this study found that leg AVGs may exhibit slightly superior or equal cumulative patency compared to arm grafts due to femoral vessels' larger diameter.[48] Based on this information,

[45] Van Vliet, L.V, Zonnebeld, N., Tordoir, J. H., Huberts, W., Bouwman, L. H., Cuypers, P. W., Heinen, S. G., Huisman, L. C., Lemson, S., Mees, B. M., Schlösser, F. J., de, A., Toorop, R. J., Tammo Delhaas, & Snoeijs, M. G. (2023). Guideline recommendations on minimal blood vessel diameters and arteriovenous fistula outcomes. *The Journal of Vascular Access, 25*(5), 1584–1592. *https://doi.org/10.1177/11297298231180627.*

[46] Farber, A., Tan, T.-W., Hu, B., Dember, L. M., Beck, G. J., Dixon, B. S., Kusek, J. W., & Feldman, H. I. (2015). The effect of location and configuration on forearm and upper arm hemodialysis arteriovenous grafts. *Journal of Vascular Surgery, 62*(5), 1258–1265. *https://doi.org/10.1016/j.jvs.2015.06.132.*

[47] Fitzgibbon, J. J., Heindel, P., Appah-Sampong, A., Holden-Wingate, C., Hentschel, D. M., Mamdani, M., Ozaki, C. K., & Hussain, M. A. (2024). Temporal trends in hemodialysis access creation during the fistula first era. *Journal of Vascular Surgery* (Vol. 79, Issue 6, pp. 1483–1492.e3). *https://doi.org/10.1016/j.jvs.2024.02.020.*

[48] Han, S., Song, D., & Yun, S. (2016). Long Term Outcomes of Arteriovenous Grafts for Hemodialysis in Lower Extremities. *Vascular Specialist*

Continued

the applicant stated that, if the comparator studies did include patients with lower extremity AVGs, the net effect would likely be a higher cumulative patency, which in turn would understate the EndoForce™ System's comparative advantage.

Finally, with regard to our concern about the potential inclusion of chest AVGs in the comparative data, the applicant stated that chest AVGs appear to only be used in an exceedingly small number of cases. The applicant also cited one medical center's case-series, which reported chest AVGs in only 0.56 percent of 1,192 patients between 2007 and 2012.[49] The applicant stated that the possibility of cases with AVGs in the legs or chest does not appear to be a major concern, and specific to chest AVGs, the possibility of the comparator studies' results being affected is remote enough to be negligible.

A commenter stated that, taken together, the Burgess et al. (2024), Kramer et al. (2026), and Astor et al. (2026) studies support substantial clinical improvement for the EndoForce™ System. The commenter also stated that, while the studies are not randomized, concurrent comparisons, and have identified limitations, they provide prospective, multicenter evidence in the specific upper-arm AVG population for which the EndoForce™ System is indicated. The commenter added that these limitations affect the precision of attributing outcomes solely to the EndoForce™ System, but they do not negate the clinical significance of the observed results or justify CMS disregarding the comparative evidence altogether.

In response to the totality of our concerns regarding Burgess et al. (2024), a commenter stated that experienced, specialized dialysis-access physicians prospectively designed Burgess et al. (2024) to support FDA review and understood the difference between a statistically attractive endpoint and an access that remains useful to a real patient, and therefore, the consistency of the patency findings across the pivotal study, systematic reviews, and the Astor et al. (2026) meta-analysis should be given meaningful weight.

In response to our concerns about Astor et al.'s (2026) comparison of primary patency results, a commenter agreed that the evidence does not suggest that the EndoForce™ System improves every AVG performance measure but stated that primary patency and cumulative patency measure different clinical outcomes. Per the commenter, primary patency measures how long an access remains functional before the first intervention, and cumulative or secondary patency concerns whether the access can ultimately be preserved rather than abandoned. The commenter stated that, therefore, an AVG that requires an intervention but remains available for dialysis is not clinically equivalent to an AVG that is lost. The commenter added that it believes the available evidence suggests that the EndoForce™ System may be more beneficial for preserving AVG access than for preventing all subsequent interventions. Additionally, the commenter stated that this distinction is particularly important for patients whose permanent-access options are already limited, because AVG preservation is a clinically meaningful outcome and can prevent loss of a functioning AVG, use of additional vascular territory, interruptions in reliable dialysis access, and a patient returning to catheter dependence. The commenter concluded that substantial clinical improvement should be based on whether the EndoForce™ System improves the ability to maintain durable permanent access and avoid graft abandonment, not by measures of primary patency.

In response to our note that Astor et al. (2026) derived 6-month patency measurements from studies that did not specifically report 6-month patency outcomes, the applicant stated that 6-month patency outcomes in Burgess et al. (2024) were higher than both cohorts of studies. The applicant further stated that Astor et al. (2026) provided comparison information indicating little difference between studies that relied on survival curves versus other studies. The applicant also stated that relying on information in survival curves where such information is not reported in text or tables is methodologically appropriate. The applicant further stated that Astor et al. (2026) used commercial software specifically designed to extract numerical data from plots and that these studies, among many others, have found excellent accuracy and no differential bias in estimates abstracted using such tools. The applicant concluded that there is, therefore, no reason to suspect that this effect is considerable or would manifestly affect results' reliability to the extent that they should be excluded from the analysis. Lastly, the applicant noted that a peer-reviewed journal accepted the study which included this methodology after publication of the CY 2027 OPPS/ASC proposed rule.

In response to our concern about whether Halbert et al. (2020)'s 20 percent AVG abandonment rate is an appropriate comparator to Astor et al. (2026)'s 8 percent AVG abandonment rate due to varied study locations and time periods, the applicant stated that the Astor et al. (2026) meta-analysis summarized 30 of the 32 studies published in the last 10 years and that studies conducted in the U.S. and outside the U.S. reflect no significant difference based on supplemental tables for Halbert et al. (2020).

In response to our interest in additional information clarifying the meaning of upper arm, the applicant stated that the term upper arm in the EndoForce™ System's FDA approval refers to the portion of the arm above the elbow.

In response to our concern that Kramer et al. (2026) lacked sufficient power to assess statistical significance, the applicant stated that the study authors do not claim the results are statistically significant. The applicant stated that Kramer et al.'s observed number of interventions per patient-year (1.32), while somewhat higher than the rate of 1.22 reported for the larger sample in Burgess et al. (2024), does compare favorably with the rates of 1.58 and 1.87 shown in Halbert et al. (2020) and Woodside et al. (2021), respectively. The applicant further stated that Kramer et al. (2026) is an extension of Burgess et al. (2024), capturing up to an additional 6 months of data for a subset of Burgess et al. (2024) patients who were high risk due to their experience of early interventions, were not lost to follow-up, and consented to additional evaluation. Additionally, the applicant noted that Kramer et al. (2026) is an intentional sub-group analysis with some additional observations on patients treated with the EndoForce™ System, and therefore, the sample size was ipso facto limited by the number of Burgess et al. (2024) patients that received at least 1 intervention in 6 months, were available for further study, and consented to extended follow up; however, the characteristics of the patient groups in both studies are very similar.

In response to our concerns regarding Kramer et al.'s (2026) insufficiently-sized patient population, inconclusive results, and differences from the available comparator populations, a commenter stated that although the study was not a randomized efficacy

International, 32(4), 180–185. *https://doi.org/10.5758/vsi.2016.32.4.180.*

[49] Liechty, J. M., Fisher, T., Davis, W., Oglesby, W. C., Bennett, M., Grimsley, B., & Shutze, W. (2015). Experience with chest wall arteriovenous grafts in hemodialysis patients. In *Annals of Vascular Surgery* (Vol. 29, Issue 4, pp. 690–697). *https://doi.org/10.1016/j.avsg.2014.11.014.*

trial and had a small sample, it should be viewed as an assessment of durability and procedural burden in a particularly challenging subgroup from the pivotal cohort, including patients who required early maintenance. The commenter also stated that Kramer et al.'s (2026) lower intervention rates are clinically meaningful because each potential avoided intervention reduces procedural risk, preserves veins, protects future options, and reduces the likelihood that a patient will experience access failure and return to catheter dependence.

In response to our concern about whether the strength of evidence of Kramer et al. (2026) may have been impacted by selection bias, as the patient cohort was selected and analyzed post-hoc, rather than identified as a variable of interest at the Burgess et al. (2024) initiation, the applicant explained that it selected and analyzed the Kramer et al. (2026) cohort post-hoc because, during the Burgess et al. (2024) study with input from FDA, it realized that durability results may be skewed if the patients in Burgess et al. (2024) received more maintenance services than normal. The applicant stated that it sponsored Kramer et al. (2026) to examine whether patients with an AVG and the EndoForce™ System received more maintenance procedures than normally expected and that the study determined the patients received fewer interventions than comparator studies.

In response to our concern about the appropriateness of comparing measures of cumulative patency in Burgess et al. (2024) and Kramer et al. (2026) that are not equally defined, the applicant stated the measure of cumulative patency for both studies was identical with respect to whether those who received an intervention before first cannulation were included, and how patency was measured did not differ between the studies, though obviously the measurement periods were different. The applicant stated the design of Kramer et al. (2026) was intended to capture 6 months of patient experience after either a first intervention (if the patient experienced 1 within the first 6 months) or after an implant (in the case of those who received no maintenance interventions during the 6 months). The applicant further stated a patient who received a first intervention on day 179 after implant would then be followed for an additional 6 months for a total of 1 year less a day (in the absence of some other censoring event), and investigation of a patient with no interventions by day 180 would be censored on that day. Per the applicant, how patency was measured did not differ between the Burgess et al. (2024) and Kramer et al. (2026) studies, though obviously the measurement periods were different.

In response to our concern that it is clinically inappropriate to compare the EndoForce™ System to devices used for AVF creation to demonstrate substantial clinical improvement over existing technologies, the applicant stated AVFs and AVGs are indisputably different, but it objects to CMS's dismissal of the comparison. The applicant stated its claim that the improvement in AVG patency means that an AVG with the EndoForce™ System would exhibit patency comparable to mature AVFs is important because greater patency has been recognized as one advantage of AVFs over AVGs, and therefore, impacts clinical decision making relating to choice of vascular access for a particular patient at a particular time. The applicant additionally stated that comparison of AVGs with the EndoForce™ System to AVFs is entirely pertinent as reviewing a technology as it compares to other relevant clinical choices should be an important point of examining substantial clinical improvement. The applicant further stated that patients and their physicians are frequently able to choose between AVFs and AVGs where both would be anatomically and otherwise suitable, and speed to maturity for dialysis (on which AVGs dominate), cumulative patency (on which AVFs have dominated), extent of maintenance procedures required, and risk of infection are among the factors taken into consideration. Lastly, the applicant stated that achieving comparable cumulative patency to that reported for AVFs, including the two percutaneous AVF devices (WavelinQ™ and Ellipsys™), would thus improve AVGs' clinical attractiveness in comparison to an existing, widely used therapeutic option for the dialysis population and that this improvement could be particularly important for patients that may be marginal as candidates for an AVF (*e.g.,* those with smaller vessels, such as many females).

In contrast to the applicant, a commenter stated that because the EndoForce™ System creates an AVG in such patients, the relevant comparator for assessing substantial clinical improvement is the conventional surgically-created graft-to-vein anastomosis, not mature AVFs and devices used to create AVFs as these technologies involve fundamentally different mechanisms and clinical uses. The commenter also agreed with CMS that AVFs and AVGs differ in mechanism and use and noted that AVF creation may be unsuccessful or inappropriate for some patients, making an AVG the more appropriate permanent-access option.[50] The commenter further stated that for patients who are appropriate candidates for permanent AVG access, maintaining this access can help avoid prolonged catheter dependence, its greater infection risk, and other associated clinical risks.

Further, the commenter stated that CMS's prior application of the substantial clinical improvement standard supports granting the EndoForce™ System transitional pass-through payment status despite meaningful evidentiary limitations because overall the evidence supports the technology producing a clinically important benefit. The commenter cited three precedents it believes support evaluating the limitations in the provided evidence as factors affecting weight and certainty, rather than as categorical barriers to approval. The commenter cited CMS's approval of the Hemospray® Endoscopic Hemostat in the CY 2021 OPPS/ASC final rule (85 FR 85997 through 86003), in which CMS considered concerns including single-arm studies, selection bias, and differences in study populations but approved transitional pass-through payment status; the AUGMENT Bone Graft in the CY 2020 OPPS/ASC final rule (84 FR 61292 through 61294) after initially questioning the evidence's adequacy, the appropriate comparator, and the duration of follow-up; and the Tablo System in the CY 2022 ESRD PPS final rule (86 FR 61889 through 61906), in which CMS stated that randomized controlled trials are not required to demonstrate substantial clinical improvement.

Response: We appreciate the applicant's and commenters' input. We agree with the applicant and commenters that the EndoForce™ System and the endovascular procedure should be assessed together for the purposes of evaluating substantial clinical improvement. However, we continue to have several of the concerns listed in the CY 2027 OPPS/ASC proposed rule. In particular, we are concerned about the lack of comparative evidence based on matched patient data. We note that imbalance in baseline patient characteristics could confound the association between EndoForce™ and patency. We acknowledge the comments from the applicant and a

[50] *CMS ESRD Measures Manual for the 2026 Performance Period.* (2026). *https://www.cms.gov/files/document/esrd-measures-manual-v11-2.pdf.*

commenter regarding vascular access location and the time periods, or ages, of different studies, but remain concerned about the extent to which the findings of the Burgess et al. (2024), Astor et al. (2026), and Kramer et al. (2026) studies might have been biased by measured and unmeasured confounders. We expressed concern in the CY 2027 OPPS/ASC proposed rule that Burgess et al. (2024) lacked stratification by key clinical factors known to affect AVG outcomes, and therefore, there are insufficient data to rule out the possibility that factors other than EndoForce™ may also have impacted cumulative and primary unassisted patency. We acknowledge the comparison provided by the applicant, in its comments, of the average age and body mass index (kg/m2) of the patients in the Burgess et al.(2024) and Astor et al. (2026) studies, and the percentages of those who were male, white, diabetic, with hypertension, cardiovascular disease, or current tobacco use. However, we note that other risk factors, such as prior catheter use, low albumin, an elevated high-sensitivity C-reactive protein (hsCRP) level, low fetuin-A, low diastolic blood pressure, hemoglobin <10 g/dL, peripheral artery disease, and low initial intra-access blood flow (< 650 mL/min), have also been associated with decreased patency.[51] [52] [53] [54] [55] Although the applicant noted that the sample size would have limited the value of stratified analyses within the Burgess et al. study (2024), this limitation does not resolve our concerns about differences across studies in patients' baseline characteristics, inclusion and exclusion criteria, and study designs. These differences could increase the uncertainty [56] around the estimates for the endpoints.[57] [58]

While we agree with the commenter who stated that cumulative patency is a clinically relevant endpoint for evaluating the EndoForce™ System, we continue to have concerns about the high degree of variability, or heterogeneity, among the comparison studies in the two meta-analyses, Astor et al. (2026) and Halbert et al. (2020). Although commenters discussed several potential sources of heterogeneity, we did not receive sufficient information or analyses to determine the extent to which those factors account for the high degree of variability among the included studies. We note that the values of the I^2 statistic in Astor et al. (2026) (I^2=99.36 percent for cumulative patency at 6 months; I^2=99.44 percent for primary unassisted patency at 6 months) and Halbert et al. (2020) (I^2=91 percent for cumulative patency at 12 months) indicated considerable heterogeneity among included studies. We remain uncertain whether the pooled estimates of 83.23 percent and 60.35 percent in the Astor et al. study (2026) accurately represented the 6-month cumulative and primary unassisted patency, respectively, of AVGs with a sutured venous anastomosis. Similarly, we remain concerned about the reliability and validity of the patency rates reported by Halbert et al. (2020) and whether these serve as an appropriate standard for comparison. While we acknowledge that heterogeneity can be difficult to avoid when comparing the results of different studies, we remain concerned that substantial variability may affect the extent to which generalizable conclusions can be formed about EndoForce™'s impact on patency relative to existing technologies.[59] As a result, we remain concerned that the comparisons between EndoForce™ and existing treatments for those endpoints may not be reliable indicators of EndoForce™'s substantive clinical improvements.

In addition, we note that the primary endpoint of Burgess et al. (2024), cumulative patency at 6 months, was compared to the pre-specified 6-month performance goal of 75 percent. Per Burgess et al. (2024), this performance goal was based on five published studies.[60] However, we note that these studies reported cumulative and primary unassisted patency at different time points, ranging from 6 to 22.5 months. We also note that while three of the studies reported patency at 12 months, only one [61] reported patency at 6 months. As a result, we are unable to determine whether the 75 percent performance goal was a valid indicator of the 6-month performance of existing technologies, or the extent to which comparing EndoForce™'s effects on cumulative patency against the 75 percent performance goal could reliably indicate whether EndoForce™ performs better than existing technologies in maintaining patency.

In addition, we remain concerned about the use of a digitization tool by Astor et al. (2026) and Halbert et al. (2020) to abstract data on 6-month patency measurements from Kaplan-Meier survival curves from studies that did not specifically report 6-month patency outcomes. We note that the 6-month patency rates from more than half of the studies in Astor et al.'s (2026) meta-analysis were abstracted using DigitizeIt software, a digitization tool.[62] We note that studies validating abstracted data have found DigitizeIt

[51] Monroy-Cuadros M. Yilmaz S, Salazar-Bauelos AS, et al. (2012). Independent prediction factors for primary patency loss in arteriovenous grafts within six months. *The Journal of Vascular Access.* Jan-Mar; 13(1):28–35. doi: 10.5301/JVA.2011.8425 *https://pubmed.ncbi.nlm.nih.gov/21688243/.*

[52] Ocak, G., Rotmans, J.I., Vossen, C.Y. et al. Type of arteriovenous vascular access and association with patency and mortality. *BMC Nephrol* 14, 79(2013). *https://doi.org/10.1186/1471-2369-14-79.*

[53] Trivedi PS, Lind KE, Ray CE, et al. (2018). Race and sex disparities in outcomes of dialysis access maintenance interventions. *Journal of Vascular and Interventional Radiology* 2018 Apr;29(4):476–481.e1. doi: 10.1016/j.jvir.2017.10.018 *https://pubmed.ncbi.nlm.nih.gov/29373244/.*

[54] Park J, Kim J, Hwang S, et al. (2018). Arteriovenous graft patency outcomes and prognostic factors. *Vascular* DOI: 10.1177/1708538118807844 *https://pubmed.ncbi.nlm.nih.gov/30360702/.*

[55] Hamouda M, Rahgozar S, Rogers UH, et al. (2026). Progression of peripheral arterial disease predicts worse outcomes after dialysis access surgery. *Journal of Vascular Surgery.* 84(2): p. 510–518. DOI: 10.1016/j.jvs.2026.04.00 *https://pubmed.ncbi.nlm.nih.gov/42268171/.*

[56] International Council for Harmonization (ICH) (2000). ICH Harmonized Tripartite Guideline. E10—Choice of Control Group and Related Issues in Clinical Trials. Step 4 version (*https://www.ich.org/page/efficacy-guidelines,* accessed September 15, 2026).

[57] Hatswell A, Freemantle N, Baio G, et al. (2020). Summarizing salient information on historical controls: A structured assessment of validity and comparability across studies. *Clinical Trials.* Vol. 17(6) 607–616 *https://doi.org/10.1177/1740774520944855.*

[58] Collignon O, Schritz A, Spezia R, et al. (2021). Implementing historical controls in oncology trials. *The Oncologist.* 26:e859-e862 *https://doi.org/10.1002/onco.13696.*

[59] Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, et al, editor(s). *Cochrane Handbook for Systematic Reviews of Interventions* version 6.5 (updated August 2024). Cochrane, 2024. Available from *www.cochrane.org/handbook.* (*https://www.cochrane.org/authors/handbooks-and-manuals/handbook/current,* accessed September 15, 2026).

[60] Those 5 publications included Huber TS, Carter JW, Carter RL, et al. Patency of autogenous and polytetrafluoroethylene upper extremity arteriovenous hemodialysis accesses: A systematic review. *Journal of Vascular Surgery* 2003: 38:1005–1011; Glickman MH, Burgess J, Cull D, et al. Prospective multi-center study with a 1-year analysis of a new vascular graft used for early cannulation in patients undergoing hemodialysis. *Journal of Vascular Surgery.* 2015: 62:434–441; Dixon BS, Beck GJ, Vazquez MA, et al. Effect of dipyridamole plus aspirin on hemodialysis graft patency. *New England Journal of Medicine.* 2009: 360: 2191–2201; Miller PE, Carlton D, Deierhoi MH, et al. Natural history of arteriovenous grafts in hemodialysis patients. *American Journal of Kidney Disease* 2000; 36:68–74; and Cnat ME, Hopkins J and Wilson SE. A prospective evaluation of PTFE graft patency and surveillance techniques in hemodialysis access. *Annals of Vascular Surgery* 1999; 13: 191–198.

[61] Huber 2003, *op.cit.*

[62] Figure 2 of the Astor study (2026) showed that data were abstracted from 24 (53 percent) of the 45 studies in its meta-analysis of 6-month cumulative patency. Figure 3 of the same study showed that data were abstracted from 25 (N=54 percent) of the 46 studies in its meta-analysis of 6-month primary unassisted patency.

and similar software in general to be highly accurate.[63] However, we also note that the reliability and validity of the abstracted data have been found to be independent of the specific software program, but are dependent on the properties of the figure being digitized.[64] In particular, the reliability of the abstracted data depends on the quality of the initial input and the level of information provided by the publication.[65] Published figures, like low-quality or rasterized images, rather than the abstraction, were a major source of errors.[66] Halbert et al (2020) reported that some survival curves could not be digitized because of the poor quality of the original publication graphics.[67] A recent study found that digitization tools like DigitizeIt could be limited by operator precision and image resolution.[68] Even tools developed using automated image-based approaches remain constrained by figure quality and rasterization artifacts. Errors introduced during digitization can propagate and affect downstream analyses, such as treatment effect estimation and meta-analysis. Another recent study found that pixelation and color blending could degrade coordinate accuracy, introducing noise during digitization.[69] The study also found visual representations of censoring to be another common source of errors. Specifically, when censoring ticks are missing or poorly resolved, algorithms may misplace event timings, leading to biased survival estimates. Dense clustering of early censoring marks can obscure later events or make digitization unreliable. Because a 6-month patency point sits exactly in this early, censoring-dense region, we are concerned that these limitations may have important implications for the Astor et al. (2026) and Halbert et al. (2020) meta-analyses. We remain concerned about the quality of these abstracted data and the potential impact on the pooled 6-month patency among currently available AVGs, and uncertain whether the results reported by Astor et al. (2026) and Halbert et al. (2020) indicate that EndoForce™ produced better clinical outcomes than the AVGs with a standard sutured venous anastomosis. Regarding Astor et al. (2026), it also remains unclear whether the difference between the 6-month cumulative patency rates of 92 percent in Burgess et al. (2024) and 86 percent in the 12 studies reporting numerical values was statistically significant.

We continue to have concerns about the appropriateness of comparing EndoForce™'s effects on patency with those of AVFs. We agree with the commenter who stated that AVF is not a viable permanent-access strategy for some patients, that current KDOQI guidance [70] emphasizes a patient-centered approach based on vessel characteristics, comorbidities, anticipated dialysis needs, and patient circumstances rather than an absolute 'fistula first' approach, and that the substantial clinical improvement inquiry should ask whether EndoForce™ improves treatment relative to the conventional, surgically created graft-to-vein anastomosis it replaces, not whether an AVG created with EndoForce™ is superior to an AVF in a patient for whom an AVF is otherwise appropriate. Accordingly, comparisons between EndoForce™ and AVFs do not directly address whether EndoForce™ provides substantial clinical improvement over existing technologies.

In response to our concern that Kramer et al. (2026) was not sufficiently powered to assess patency at 180 days post-implantation among patients with ESRD who needed hemodialysis, the applicant stated that the study did not claim that its results were statistically significant and a commenter noted that CMS should nevertheless treat the results as clinically meaningful. However, we maintain our concern that a comparison of the results from Kramer et al. (2026) to other studies could be confounded by differences between the studies, and we remain uncertain whether any difference in intervention rates or patency can be attributed to the use of EndoForce™ alone.

A commenter noted that CMS's prior application of the substantial clinical improvement standard supports granting the EndoForce™ System transitional pass-through payment status despite meaningful evidentiary limitations, because the evidence supports the technology producing a clinically important benefit. We disagree that the prior approvals cited by the commenter establish that EndoForce™ System meets the substantial clinical improvement criterion. We note that we assess each application on its own merits based on the evidence submitted. Our concerns regarding the evidence supporting this application are discussed previously. We refer to the full details of our rationale regarding other applications in the respective final rules.

After consideration of the public comments we received and our review of the application, the EndoForce™ System does not meet the substantial clinical improvement criterion to be considered for device pass-through payment. Therefore, in this final rule with comment period, we will not address whether the technology meets the remaining criterion required for device pass-through payment. We are not approving the EndoForce™ System for device pass-through payment status for CY 2027 because the technology does not meet the substantial clinical improvement criterion at § 419.66(c)(2).

(b) LINK™ External Fixator

Metric Medical Devices, Inc. submitted an application for a new device category for transitional pass-through payment status for the LINK™ External Fixator for CY 2027. According to the applicant, the LINK™ External Fixator is a dynamic percutaneous bone external fixator that provides continuous compression during the healing of bony fractures, fusions, and osteotomies. The applicant stated that the LINK™ External Fixator is composed of the (1) LINK™, a stainless steel box-shaped spring that applies forces to wires or pins inserted in the bone to either actively pull together and compress or distract the bones; (2) LINK™ Cover, a silicone cap that covers the bone pins or wire; and (3) LINK™ Bone Pins, which are inserted in a patient's bones and to which the LINK™ attaches.

Table 55 provides an overview of the transitional pass-through payment status application for the LINK™ External Fixator and CMS's preliminary

[63] Rakap S, Rakap S, Evran D, et al. (2016). Comparative evaluation of the reliability and validity of three data extraction programs: UnGraph, Graphclick, and DigitizeIt. *Computers in Human Behavior* 55:159–166.

[64] Moeyaert M, Maggin D, Verkulen J, et al. (2016). Reliability, validity, and usability of data extraction programs for single-case research designs. *Behavior Modification* Vol 40, Issue 6 *https://doi.org/10.1177/014544551664.*

[65] Guyot P, Ades AE, Ouwens MJNM, et al. (2012). Enhanced secondary analysis of survival data: reconstructing the data from published Kaplan-Meier survival curves. *BMC Medical Research Methodology.* 12:9 *https://doi.org/10.1186/1471-2288-12-9.*

[66] Wojtyniak JG, Britz H, Selzer D, et al. (2020). Data digitizing: Accurate and precise data extraction for quantitative systems pharmacology and physiologically-based pharmacokinetic modeling. *Pharmacometrics & Systems Pharmacology https://doi.org/10.1002/psp4.12511.*

[67] Halbert et al, 2020, *op.cit.,* p. 1439.

[68] Lang L, Gao Q, Zhao Y, et al. (2026). RESOLVE–IPD: High-Fidelity Individual Patient Data Reconstruction and Uncertainty—Aware Subgroup Meta-Analysis. arXiv:2511.01785v2 [stat.ME] *https://arxiv.org/html/2511.01785.*

[69] Tong G, and Li F (2026). Reconstructing Pseudo Individual Patient-Level Data From Published Survival Curves in Cardiovascular Trials. *Journal of American College of Cardiology* 87(5): 530–532. doi: *10.1016/j.jacc.2025.12.060.*

[70] Lok CE, Huber TS, Lee T, et al; KDOQI Vascular Access Guideline Work Group. KDOQI clinical practice guideline for vascular access: 2019 update. *American Journal for Kidney Disease.* 2020; 75(4) (suppl 2):S1–S164.

assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP250902M814F.*

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TABLE 55: LINK™ EXTERNAL FIXATOR APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization:* 510(k) clearance - May 29, 2024 *Application submitted to CMS*: September 2, 2025	No concerns.
FDA Indication	Indications for use: 1) hand and foot bone fragment and osteotomy fixation and joint arthrodesis, 2) fixation of proximal tibial metaphysis osteotomy and 3) adjunctive fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude LINK™ bone pin placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bones such as the pelvis, scapula and sternum.	No concerns.
§ 419.66(b)(3)	Device is integral to the service(s) furnished, used for one patient only, comes in contact with human tissue, and is surgically inserted/implanted/applied in or on a wound or other skin lesion.	See following discussion.

§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	See following discussion.
Device Category	Device category code C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) does not describe the device.	See following discussion.
Cost Criteria	The cost of the LINK™ External Fixator is $4,800. This cost includes the 4-pin LINK™ and the corresponding LINK™ Cover ($4,500) as well as two LINK™ Bone Pin packages (2 pins in each package) ($300).[1] For cost significance requirements:[2] HCPCS code: 28899 APC code: 5111 CY 2025 device offset amount: $50.18 CY 2025 APC payment rate: $239.88 Requirement #1: ($4,800 / $239.88) x 100 = 2,001.00%. Requirement #2: ($4,800 / $50.18) x 100 = 9,565.56%. Requirement #3: (($4,800 - $50.18) / $239.88) x 100 = 1,980.08%.	No concerns.
Substantial Clinical Improvement Criterion	Claim #1: The LINK™ External Fixator offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, such as those patients with infected sites, metal allergies, anesthesia sensitivity, skin pathology, or other co-morbidities such as diabetes, neuropathy or immunocompromised patients, due to the minimally invasive nature of the bone fixation the LINK™ External Fixator provides. Claim #2: The LINK™ External Fixator significantly improves clinical outcomes for a patient population as compared to currently available treatments because of its ability to percutaneously fixate fractures, osteotomies, or arthrodesis, thus protecting the soft tissue envelope, vascular, and neural structures, which historically result in a more robust healing response and a shorter time to function. Two documents describing the nominated technology and its fundamental principles were provided. No published or unpublished studies assessing the technology were provided.	See following discussion.

[1.] Per the applicant, the LINK™ is the shape changing force creating bridging element between bone pin implants with the fracture or site of fusion between the pins. The cost and components listed in the table are for a 4-pin LINK™ External Fixator. According to the applicant, a 2-pin LINK™ External Fixator is available and would cost $3,650 for the 2-pin LINK™ and LINK™ Cover ($3,500) as well as one LINK™ Bone Pin package (2 pins in each package) ($150). Each LINK™ package includes a cover to protect it from the environment. Additional LINK™ Covers can be purchased in a separate package if a replacement cover is needed ($300 for a 2-pin cover or $350 for a 4-pin cover). Per the applicant, all components (LINK™, LINK™ Bone Pins, and LINK™ Cover) are required, and there are no partial systems. The applicant stated that multiple LINK™ units may be used for higher level musculoskeletal procedures, such as five LINK™ units for a Lisfranc dislocation, complex fractures, or Charcot foot fixation.

[2.] In the CY 2027 OPPS/ASC proposed rule, we noted that the applicant selected the APC level device offset amount of $0.19 for APC 5111 found in CY 2025 NFRM APC Offset File. Beginning in CY 2017, we calculate the device offset amount at the HCPCS code level instead of the APC level (81 FR 79657). We noted the HCPCS code level device offset amounts for the HCPCS codes provided by the applicant are available in Addendum P to the CY 2025 OPPS/ASC final rule with comment period (89 FR 93912). For our calculation, we selected the HCPCS level device offset amount of $50.18 related to HCPCS 28899 in APC 5111 found in Addendum P. Based on our initial assessment for the CY 2027 OPPS/ASC proposed rule, we stated using the device offset amount of $50.18 would result in the LINK™ External Fixator meeting the cost significance requirements.

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We invited public comment on whether the LINK™ External Fixator meets the newness criterion at § 419.66(b)(1).

Comment: With respect to the newness criterion at § 419.66(b)(1), the applicant reiterated that the LINK™ External Fixator meets the newness requirement for device pass-through payment.

Response: We appreciate the applicant's input. We received the application for device pass-through payment status for the LINK™ External Fixator within 3 years of the date of FDA 510(k) clearance. After consideration of the public comments we received and our review of the application, we have determined that the LINK™ External Fixator meets the newness criterion at § 419.66(b)(1).

Regarding the eligibility criterion at § 419.66(b)(3), we stated in the CY 2027 OPPS/ASC proposed rule that we were concerned that the LINK™ External Fixator components may not be integral to the service furnished, come in contact with human tissue, or be surgically inserted or implanted.

With respect to whether the LINK™ Bone Pins and LINK™ Cover are integral to the service furnished, based on the information provided by the applicant, we questioned whether the components are necessary to furnish or deliver the primary procedure with which it is used. We noted that, in the CY 2014 OPPS/ASC 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. We stated, for example, a pacemaker is integral to the procedure of implantation of a pacemaker. We noted that according to the applicant, the LINK™ uses a single- use external fixator consisting of a stainless-steel bridge spring formed into a box shape, with holes that are held in alignment by surgical needle drivers during pin placement. We stated that per the applicant, when released, the bridge shortens to apply forces and the side elements swing outward to create moments on bone fixation pins or wires embedded in bone, pulling together and compressing or distracting bony structures. We stated, while the LINK™ External Fixator may include LINK™ Bone Pins, per the applicant, other commercially available bone pins, k-wires, or Steinmann pins (hereinafter referred to collectively as ''bone fixation pins or wires'') may be compatible with the LINK™ External Fixator, and we therefore questioned whether the LINK™ Bone Pins are integral to the service furnished as they may be replaced with other commercially available bone fixation pins or wires. We further questioned whether the LINK™ Bone Pins are integral to the service furnished as it is unclear, based on the information provided in the application, whether any LINK™ Bone Pins are included in the LINK™ External Fixator packaging, or if they are packaged and sold separately from the LINK™ External Fixator. With respect to the LINK™ Cover, because the applicant stated that the LINK™ Cover is a separate removable silicon elastomer cover that protects the LINK™ and the patient from the pin and wire ends and does not play a role in providing compression, as such, we also questioned if the LINK™ Cover is integral to the service furnished. We stated that we would be interested in additional information about these components of the LINK™ External Fixator, including whether the components are required to furnish or deliver the primary procedure with which it is used and if the components can be substituted with other commercially available products.

With respect to whether the LINK™ External Fixator comes in contact with human tissue and is surgically inserted or implanted, we noted that, per the applicant, the LINK™ Bone Pins (or other bone pins or wires) are the only components that come in contact with human tissue and are surgically implanted or inserted into the patient. We stated, per the applicant, the LINK™ component remains outside the body and acts like a spring on skin penetrating bone fixation pins to reduce and provide continuous compression at the bone healing interface. We further noted that, according to the applicant, the LINK™ Cover is a separate, removable cover that does not come in contact with and is not surgically implanted or inserted into the patient. Therefore, we stated our belief that the LINK™ and the LINK™ Cover components of the LINK™ External Fixator do not come into contact with human tissue and are not surgically inserted or implanted as required by § 419.66(b)(3).

We invited public comment on whether the LINK™ External Fixator meets the eligibility criterion at § 419.66(b)(3).

Comment: In response to our concerns that the LINK™ External Fixator is not integral to the services furnished because the LINK™ and the LINK™ Cover components do not come into contact with human tissue and are not surgically inserted or implanted, the applicant and a few commenters stated that the LINK™ and the LINK™ Bone Pins and Cover are integral for performing bone fixation. The applicant reiterated that an assembled LINK™ External Fixator consists of the LINK™, LINK™ Bone Pins with locking mechanism (sharp or flat groove), and the LINK™ Cover that protects the LINK™, limits forces by limiting expansion of the LINK™, restricts shape change, and provides the first layer of wound coverage.

The applicant commented that the LINK™ Bone Pins have sharp or flat grooves that lock into the LINK™ bridge, so that they operate as a single unit when implanted or inserted or applied to the wound. The applicant further stated it offers the LINK™ External Fixator under one part number as a bundled product offering consisting of the LINK™, two LINK™ Bone Pins with locking mechanism, and the LINK™ Cover. The applicant added that it offers three types of LINK™ Bone Pins, all with sharp or flat grooves to lock into the LINK™, so that the physician has the option of choosing which LINK™ Bone Pin type is best for the condition being treated and for the style of LINK™ selected. The applicant concluded that the LINK™, the LINK™ Bone Pins, and the LINK™ Cover are consequently an integral part of the bone fixation service provided, and thus, the LINK™ External Fixator meets the requirements of § 419.66(b)(3).

The applicant stated it does not offer k-wires or Steinman pins for use with the LINK™ External Fixator, although these wires or pins are compatible as they are stainless steel and 2.0 mm in diameter. The applicant and a few other commenters stated that although physicians may choose another vendor's pins or k-wires to use with the LINK™, this is not recommended because these pins or wires have not been adequately tested with the LINK™ External Fixator and may be unable to withstand the forces created. The applicant and a commenter specifically noted that use of other bone pins would not have the advantage of locking to the LINK™ to prevent moving or shifting, which could potentially alter a surgeon's positioning of bones and the preferred force profile generated. The applicant added that k-wires and Steinman pins will not retain the LINK™ nor have the strength of the LINK™ Bone Pins.

A commenter stated that the pins are integral to the functioning of the LINK™ External Fixator as the nominated device's bone stabilization and compression improves outcomes versus other devices on the market. The commenter stated that due to the spring-like quality of the LINK™ External

Fixator, the device locks onto the bone pins once compression is realized by releasing the needle drivers from the compressing tab. The commenter explained that this converts the separate components of the LINK™ and each LINK™ Bone Pin into a solid dynamic construct, where any force applied to the LINK™ Bone Pins is transferred to the LINK™ and vice versa. The commenter expressed its belief that the LINK™ Bone Pins and LINK™ are essential to one another to function as intended.

Another commenter explained that the applicant packages the LINK™ Bone Pins separately to allow physicians to choose which pin type to use during surgery. The commenter stated that combining both types of pins into the same box would force a physician to open multiple packages and increase waste in the case the physician needs larger pins than originally expected or a mix of sizes due to anatomical challenges.

In response to our concerns that the LINK™ External Fixator does not come in contact with human tissue and may not be surgically inserted or implanted or applied in or on a wound or other skin lesion, the applicant commented that, in patients with complex, open Grade III fractures, the LINK™, the LINK™ Bone Pins, and the LINK™ Cover are surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound. The applicant stated that, while inserting, implanting, or applying the LINK™ and a LINK™ Bone Pin, the LINK™ is placed in contact with the bone, wound, or skin while guiding the LINK™ Bone Pins and steading the placement. According to the applicant, once stable, the LINK™ Bone Pin is advanced deeper into bone and additional bone pins are placed prior to lifting the LINK™ from the bone or wound to adjust the bone fixation forces. The applicant further stated and provided images to show that the LINK™ Cover is commonly in contact with the skin or wound to seal the site from contamination, and that after removal, the LINK™ Cover leaves a visible impression in the skin from long-term contact. The applicant stated that this clinical use shows the placement of the LINK™ on the wound, skin closure around the LINK™ Bone Pins, and evidence of the LINK™ Cover in long-term contact with the skin. The applicant further explained that the LINK™ Bone Pins are always implanted in bone while the LINK™ and the LINK™ Cover can be placed in direct contact with the osseous and soft tissue structures in an open wound (such as a grade III fracture) to apply the greatest forces to bone, then adjusted upward to optimize bone applied forces.

The applicant stated that an example of implantation of the LINK™, the LINK™ Bone Pins, and the LINK™ Cover occur when an open, often infected bone fracture requires a multi-step surgical procedure to close it. According to the applicant, in these fractures, the LINK™ External Fixator is used differently than in the office. Specifically, the applicant stated that in an open wound, the physician can move the LINK™ on the LINK™ Bone Pins from bony cortex to above the skin. The applicant stated that the LINK™ can lie in an open wound and be covered with skin flaps or dressing to support immediate bony reconstruction while limiting bacterial colonization, as physicians commonly do not immediately close infected or heavily contaminated wounds because sealing bacteria inside causes severe complications like osteomyelitis. Per the applicant, treatment relies on thorough cleaning, antibiotics, and delayed closure. The applicant further explained that screw, plate, staple, or rod type internal fixation hardware is contraindicated because it will often harbor the infection. The applicant stated that an unsolved healthcare problem exists during this treatment period when internal fixation cannot be used, because dynamic compression's enhanced bone healing effects are unavailable in external fixators other than the LINK™ External Fixator. The applicant stated that in this population, the LINK™ External Fixator is the only available bone fixation option, because if it becomes colonized by bacteria, the LINK™ External Fixator can be easily removed and replaced with a new sterile LINK™ system. The applicant stated that this permits immediate bone fixation and supports an optimized bone-healing response while still allowing the physician to perform staged wound closure. The applicant stated that together, this allows the treated bone to achieve fusion while managing the infection with repeated debridement, covering and uncovering, force adjustment, and closure.

In addition, the applicant stated that when a wound is not traumatically opened, a physician either sutures the LINK™ Bone Pin within an incision or inserts it percutaneously. Specifically, the applicant stated that, prior to incision closure, the LINK™ is brought into contact with bone then raised to its optimal force height. The applicant stated that this step optimizes the dynamic compression forces the LINK™ applies to fixate bone and promote healing. The applicant further noted that, in both open and closed fractures, the LINK™ External Fixator is in contact with skin or surgically implanted. According to the applicant, the LINK™ cannot operate independently of the bone pins as it is assembled by inserting a bone pin through it and then bringing both the bone pin and the LINK™ into the wound such that they contact bone, subcutaneous tissues, fascia, or skin. The applicant stated that the bone being fixated is effectively part of the LINK™ External Fixator system, because the device cannot be assembled and function without bone being the final member in the construct. The applicant concluded that in patients suffering from an open fracture or bone-communicating skin ulcer, the LINK™ and the LINK™ Cover components of the LINK™ External Fixator do come into contact with human tissue, and thus, are surgically inserted or implanted as required by § 419.66(b)(3).

Response: We appreciate the applicant and commenters' input. Although we remain uncertain for reasons described in our consideration of the § 419.66(b)(4) criterion, we believe that the LINK™ External Fixator, including the LINK™ Cover and the LINK™ Bone Pin components, may be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically implanted or inserted or applied in or on a wound or other skin lesion. After consideration of the public comments we received and our review of the application, we believe that the LINK™ External Fixator may meet the eligibility criterion at § 419.66(b)(3), unless the LINK™ Bone Pins may be considered a supply, as discussed in greater detail later in this section.

In the CY 2027 OPPS/ASC proposed rule, regarding the eligibility criterion at § 419.66(b)(4), we questioned whether the LINK™ Bone Pins could be considered a supply furnished incident to a service, based on the applicant's description. First, we questioned the role of LINK™ Bone Pins in creating surgical openings for access to bone to accomplish the fixation provided by the LINK™. In the CY 2001 OPPS interim final rule (65 FR 67804 through 67805), we stated that 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. Based on the information in the application, we stated we were unclear if the LINK™ Bone Pins (or

other bone fixation pins or wires) are placed through a previously created surgical opening or if they are directly inserted through skin and soft tissue to access bone. We stated we would welcome information regarding whether, when, and how an incision is created during placement of the LINK™ External Fixator. Second, as discussed previously with respect to criteria at § 419.66(b)(3), we noted that it is unclear whether the LINK™ Bone Pins may be replaced with other commercially available bone fixation pins or wires. We stated that we would be interested in clarification about whether the LINK™ Bone Pins can be substituted with other commercially available products. We questioned whether LINK™ Bone Pins 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).

We invited public comment on whether the LINK™ External Fixator meets the eligibility criterion at § 419.66(b)(4).

Comment: The applicant submitted a public comment reiterating its belief that the LINK™ External Fixator is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, or a material or supply furnished incident to a service. As previously mentioned, the applicant stated that it would not recommend the use of k-wires or Steinman pins with the LINK™ because they would not lock into the LINK™. The applicant stated that the LINK™ Bone Pin's locking system is unique to the LINK™ External Fixator and novel, as described in U.S. patents 11,944,352 and 12,690,890. The applicant stated that LINK™ Bone Pins are incompatible with general use as a pin or wire, and thus, are not a general supply incidental to the bone fixation procedure. A commenter also stated that other bone pins could possibly be used, although they were not tested with the LINK™ during the 510(k) clearance process. The commenter added that using non- LINK™ bone pins may present concerns because it is unclear whether they would lock into the LINK™ without moving, sliding, or shifting, potentially altering the surgeon's positioning of bones and the preferred force profile set.

In response to whether the LINK™ Bone Pins are used to create surgical openings during placement of the LINK™ External Fixator, the applicant stated that the LINK™ Bone Pins could not be considered a supply furnished incident to a service due to their unique locking feature design, use in open fractures, and within an incision, and in these cases, the LINK™ Bone Pins are not used to create a surgical opening for access to fixate in bone. The applicant stated that the LINK™ Bone Pins are, consequently, outside the scope of CY 2001 OPPS interim final rule (65 FR 67804 through 67805).

Response: We appreciate the applicant and commenter's input. With respect to the eligibility criterion at § 419.66(b)(4), in the CY 2001 OPPS interim final rule (65 FR 67804 through 67805), we stated that 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.

While the applicant stated that the LINK™ Bone Pins are not used to create a surgical opening when used in open fractures and within an incision, the applicant also stated that when the wound is not traumatically opened, the LINK™ Bone Pin may be inserted percutaneously. In these cases, it is unclear if the LINK™ Bone Pins are being inserted directly through the skin. In addition, while the LINK™ Bone Pins' locking feature is specific to the LINK™ External Fixator and not interchangeable with commonly available fixation pins or wires, which distinguishes the LINK™ Bone Pins from certain generally available supplies, we do not believe it resolves our concern regarding whether the LINK™ Bone Pins may constitute a supply, particularly when inserted percutaneously. Therefore, after consideration of the public comments we received and our review of the application, it remains unclear whether the LINK™ Bone Pins may be considered a supply or material furnished incident to a service. In addition, if the LINK™ Bone Pins may sometimes be considered a supply and therefore potentially ineligible for pass-through under § 419.66(b)(4), then the LINK™ External Fixator, considered as a whole device, may be ineligible. Considering the components separately, we remain concerned that the LINK™ and the LINK™ Cover components of the LINK™ External Fixator do not appear to be surgically implanted or inserted as required by § 419.66(b)(3) in cases where the LINK™ Bone Pins may be considered a supply.

We stated in the CY 2027 OPPS/ASC proposed rule, regarding the device category eligibility criterion at § 419.66(c)(1), that the applicant stated that the existing pass-through code of C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) does not appropriately describe the LINK™ External Fixator because the category does not include fixators with the LINK™'s shape-changing, spring-like design that stores elastic mechanical energy allowing it to provide continuous dynamic compression, which pulls bones together and closes gaps formed by bone resorption or inadvertent mechanical loading and stimulates mesenchymal stem cells (MSC) to differentiate along an osteogenic pathway to form bone and cartilage. In contrast, the applicant stated that traditional external fixators included in C1713 are static, and therefore, do not readjust or impart compression or distraction forces to enhance bone healing as the LINK™ does.

We also stated in the CY 2027 OPPS/ASC proposed rule that, based on the description the applicant provided, the LINK™ External Fixator is an external fixator that attaches to pins inserted into the bone principally with the intent to facilitate stabilization or oppose bone-to-bone contact, and therefore, could be appropriately described by C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)). Further, we stated that C1713 does not describe the type of fixation or specify the type of compression created by the device. Specifically, we stated our belief that the pass-through payment category C1713 may appropriately describe the LINK™ External Fixator because C1713 describes implantable pins and/or screws inserted or drilled into bone, principally with the intent to facilitate stabilization or oppose bone-to-bone contact, which is consistent with the LINK™ External Fixator description. We noted that we do not establish pass-through device categories for the purpose of describing specific devices, rather, device categories are intended to encompass all devices that can be appropriately described by a given category. In this context, we stated our belief that the LINK™ External Fixator may be appropriately described by C1713. We also stated that, after reviewing the information provided by the applicant, we were unable to determine that the LINK™ External Fixator meets the device category eligibility criteria, and therefore, we proposed to deny transitional pass-through payment status for CY 2027.

We invited public comment on whether the LINK™ External Fixator meets the device category eligibility criterion at § 419.66(c)(1). We also invited public comments on our

proposal to deny transitional pass-through payment status for the LINK™ External Fixator for CY 2027.

Comment: Several commenters expressed general support for the approval of device pass-through payment for the LINK™ External Fixator. Another commenter expressed its support for the denial of device pass-through payment for the LINK™ External Fixator because it does not meet the criteria for device pass-through payment.

Response: We appreciate the applicant and commenters' input. We have taken these comments into consideration in our final determination for pass-through payment status for the LINK™ External Fixator.

Comment: The applicant and a commenter commented that the LINK™ External Fixator is not appropriately described by C1713, because the C1713 category includes static devices such as implantable pins and/or screws to oppose bone-to-bone or soft tissue-to-bone whereas the LINK™ External Fixator uses elastic energy. Specifically, the applicant stated that the device category C1713 does not describe the LINK™ External Fixator because the LINK™ External Fixator applies elastic mechanical energy to bone creating electrical current flow to stimulate healing. The applicant stated this is dramatically different from those devices in the C1713 category which describes static devices such as implantable pins and/or screws to oppose bone-to-bone or soft tissue-to-bone. The applicant commented that in effect, the elastic nature of the LINK™ bridge acts as an energy source to deform the bone matrix causing it to create current flow that recruits MSC to the site and then deforms the MSC nucleus causing it to differentiate along an osteogenic pathway. The applicant stated the use of elastic energy to create current versus implanted electrodes or pulsed magnetic fields used in bone stimulators is a significantly different mode of operation than the static pins and screws in the C1713 category and that thus the LINK™ meets the device category eligibility criterion at § 419.66(c)(1).

A commenter stated the compressive force created by the LINK™ External Fixator is dynamic and continuously closes gap formation forcing the body into the primary bone healing state. According to the commenter, without this important feature of continuous dynamic compression, gaps can form due to bone resorption, micromovements and non-compliant patients, leading to higher chances of non-union.

Response: We appreciate the applicant and commenter's input. After consideration of the public comments we received and our review of the application, we continue to believe that C1713 appropriately describes the LINK™ External Fixator because the device category code does not differentiate between static external fixators and those that use elastic mechanical energy. We do not believe that the LINK™ External Fixator's dynamic compression mechanism, by itself, places the device outside C1713, because the category encompasses devices used to facilitate stabilization or oppose bone-to-bone or soft tissue-to-bone. Therefore, we have determined that the LINK™ External Fixator does not meet the device category eligibility criterion at § 419.66(c)(1), because it is appropriately described by an existing category or a category previously in effect.

After consideration of the public comments we received and our review of the application, the LINK™ External Fixator does not meet the device category eligibility criterion to be considered for device pass-through payment. Therefore, in this final rule with comment period, we will not address whether the technology meets the remaining criteria required for device pass-through payment. We are not approving the LINK™ External Fixator for device pass-through payment status for CY 2027 because the technology does not meet the device category eligibility criterion at § 419.66(c)(1).

(c) Santreva™-ATK Endovascular Revascularization Catheter

AngioSafe®, Inc. submitted an application for a new device category for transitional pass-through payment status for the Santreva™-ATK Endovascular Revascularization Catheter (Santreva™-ATK Catheter) for CY 2027. According to the applicant, the Santreva™-ATK Catheter is an energy and wire-free platform for simultaneous intraplaque crossing and revascularization of complex occlusive peripheral artery disease, intended for facilitating intraluminal placement of guidewires beyond stenotic lesions.

Table 56 provides an overview of the device category for the transitional pass-through payment status application for the Santreva™-ATK Catheter and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP260302QH9AE.*

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TABLE 56: SANTREVA™-ATK CATHETER APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization:* 510(k) clearance - September 22, 2025 *Application submitted to CMS*: March 2, 2026	No concerns.
FDA Indication	The Santreva™-ATK Endovascular Revascularization Catheter is intended to facilitate the intraluminal placement of guidewires beyond stenotic lesions, including Chronic Total Occlusions (CTOs), in the femoropopliteal (arterial) peripheral vasculature.	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with human tissue, and is percutaneously inserted.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	No concerns.
Device Category	Device category code C1887 (catheter, guiding (may include infusion/perfusion capability)) does not describe the device.	See following discussion.
Cost Criteria	The cost of the Santreva™-ATK Catheter is $3,000.00. For cost significance requirements: HCPCS code: 37263 APC code: 5192 CY 2026 device offset amount: $2,314.89 CY 2026 APC payment rate: $5,814.84 Requirement #1: ($3,000.00 / $5,814.84) x 100 = 51.59%. Requirement #2: ($3,000.00 / $2,314.89) x 100 = 129.60%. Requirement #3: (($3,000.00 - $2,314.89) / $5,814.84) x 100 = 11.78%.	No concerns.
Substantial Clinical Improvement Criterion	Claim #1: Substantially improved mechanism; simultaneous crossing and revascularization Claim #2: Substantially improved safety: no periprocedural injury and reduced need for adjunctive plaque modification interventions with known adverse events Claim #3: Substantially improved complex lesion crossing Claim #4: Substantially improved crossing success in severely calcified lesions Claim #5: Substantial lumen gain while crossing complex lesions, delivering positive outcomes of multiple currently reimbursed maneuvers Claim #6: Predominantly intraplaque crossing and recanalization, preserving vessel wall integrity Claim #7: Substantial improvement in clinical condition and quality of life of patients Claim #8: Substantial improvement for physicians in day-to-day clinical practice Provided 1 published study assessing the technology, 19 published studies and articles assessing comparator technologies, and 31 background documents.	See following discussion.

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We invited public comment on whether the Santreva™-ATK Catheter meets the newness criterion at § 419.66(b)(1) and the eligibility criteria at § 419.66(b)(3) and (4).

Comment: An applicant and another commenter submitted public comments regarding the newness criterion at § 419.66(b)(1). They reiterated that the Santreva™-ATK Catheter meets the newness requirement for device pass-through payment, and is an integral part of the service furnished, used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted, or applied in or on a wound or other skin lesion. They also reiterated that the Santreva™-ATK Catheter is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, or a material or supply furnished incident to a service.

Response: We appreciate the applicant's and commenters' input. We received the application for device pass-through payment status for the Santreva™-ATK Catheter within 3 years of the date of FDA 510(k) clearance. After consideration of the public comments we received and our review of the application, we have determined that the Santreva™-ATK Catheter meets the newness criterion at § 419.66(b)(1).

We agree with the applicant and commenter that the Santreva™-ATK Catheter is an integral part of the service furnished, used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted or applied in or on a wound or other skin lesion. We also agree that the Santreva™-ATK Catheter is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, or a material or supply furnished incident to a service. After consideration of the public comments we received and our review of the application, we have determined that the Santreva™-ATK Catheter meets the eligibility criterion at § 419.66(b)(3) and (4).

In the CY 2027 OPPS/ASC proposed rule, regarding the device category eligibility criterion at § 419.66(c)(1), we noted that per the applicant, the existing pass-through code C1887 (Catheter, guiding (may include infusion/perfusion capability)) does not appropriately describe the Santreva™-ATK Catheter, because C1887 does not reflect the full scope of the device's function or the significant clinical improvement associated with the Santreva™-ATK Catheter, which facilitates the placement of guidewires beyond stenotic lesions by laterally cutting and then compressing plaque, to form an intraluminal channel to restore blood flow.

We stated that, based on the description the applicant provided, the Santreva™-ATK Catheter is intended to facilitate the intraluminal placement of guidewires beyond stenotic lesions, including chronic total occlusions (CTOs), in the femoropopliteal (arterial) peripheral vasculature, and therefore, may be appropriately described by C1887 (Catheter, guiding (may include infusion/perfusion capability)). Specifically, we stated our belief that the pass-through payment category C1887 may describe the Santreva™-ATK Catheter because the pass-through payment category includes guiding catheters and the Santreva™-ATK Catheter's primary function of crossing peripheral stenotic lesions to establish a revascularization pathway appears to be the same function performed by devices described in C1887. We stated, in addition, per the applicant, the Santreva™-ATK Catheter is introduced and removed prior to final treatment, which is also consistent with the use of the guiding catheters described in C1887. We noted that we do not establish pass-through device categories for the purpose of describing specific devices; rather, device categories are intended to encompass all devices that can be appropriately described by a given category. In this context, we stated our belief that the Santreva™-ATK Catheter may be appropriately described by C1887. We also stated that, after reviewing the information provided by the applicant, we were unable to determine that the Santreva™-ATK Catheter meets the device category eligibility criteria, and therefore, we proposed to deny transitional pass-through payment status for CY 2027.

We invited public comment on whether the Santreva™-ATK Catheter meets the device category eligibility criterion at § 419.66(c)(1). We also invited public comments on our proposal to deny transitional pass-through payment status for the Santreva™-ATK Catheter for CY 2027.

Comment: A commenter expressed its support for the denial of device pass-through payment for the Santreva™-ATK Catheter because it does not meet the criteria for device pass-through payment.

Response: We appreciate the commenter's input.

Comment: Several commenters, including the applicant, urged CMS to approve device pass-through payment for the Santreva™-ATK Catheter, stating that the Santreva™-ATK provides an additional treatment option for patients with complex peripheral arterial disease, including CTOs, and that approval of transitional pass-through payment would support appropriate physician and hospital adoption as well as improve patient access to innovative care. The commenters further stated that device pass-through payment status would encourage continued use of the Santreva™-ATK Catheter to address important safety, efficacy, durability of outcomes, and economic needs in complex peripheral vascular disease.

In response to our concerns that the Santreva™-ATK Catheter may be appropriately described by C1887, the applicant and commenters stated that they believe there are no existing categories or categories previously in effect that appropriately describe the Santreva™-ATK Catheter. Specifically, the applicant and commenters stated that while the Santreva™-ATK Catheter does perform the function of a guiding catheter, C1887 does not describe the Santreva™-ATK Catheter's additional capabilities that specifically contribute to the substantial clinical improvement the device provides.

The applicant stated that, as described by CMS, C1887 is intended for the introduction of interventional/diagnostic devices into the coronary or peripheral vascular systems and can be used to inject contrast material, function as a conduit through which other devices pass, and/or provide a mechanism for measuring arterial pressure, and maintain a pathway created by the guidewire during the performance of a procedure. The applicant stated that the Santreva™-ATK Catheter functions as an endovascular interventional device for complex lesions (occlusions) after it is delivered through such conduits and, at the end of its intervention, acts as a convenient conduit for other devices. The applicant also noted that the Santreva™-ATK Catheter's conduit function is not the focus of the transitional pass-through payment application. According to the applicant, the Santreva™-ATK Catheter directly contributes to revascularization in a way that traditional guiding catheters do not and is not associated with the introduction of other devices. Specifically, the applicant and another commenter stated that 90 percent of the evaluable subjects in Banerjee et al. (2026) had predominantly intraplaque crossing of the CTO and that intravascular ultrasound analysis of the intraplaque track found a mean luminal

gain of roughly 59 percent without any other revascularization interventions.

Furthermore, the applicant stated that CMS has created additional device categories that include guidance capabilities along with other functions, such as C1725 which describes a catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability). The applicant also stated that CMS has created numerous device categories to describe catheters that address calcified plaque through different approaches, including C1885 (Catheter, transluminal angioplasty, laser), C1725 (Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)), C1714 (Catheter, transluminal atherectomy, directional), C1724 (Catheter, transluminal atherectomy, rotational), and C1761 (Catheter, transluminal intravascular lithotripsy, coronary).

The applicant and several commenters stated that the Santreva™-ATK Catheter addresses plaque with a new multi-modal mechanism of action, atheroplasty, which is a wire- and energy-free mechanism that combines axial plaque disruption with low-pressure lateral plaque compression to form an intraluminal channel without actively stretching the vessel wall, and thus, does not fall into any of the existing categories (C1885, C1725, C1714, C1724, or C1761). These commenters also stated that atheroplasty disrupts, modifies, and compresses plaque in place against native plaque to create a channel while preserving the native vessel architecture unlike atherectomy, which debulks or removes plaque (classified as intraluminal artery stripper in the Code of Federal Regulation), or angioplasty (classified as hydraulic pressurization of vessel walls), which dilates the vessel wall via balloon expansion. The applicant and these commenters stated that atheroplasty therefore removes the obstruction to blood flow without physically removing the plaque from the body and that any interaction with the vessel wall structure during the procedure is atraumatic, whether mechanically or hydraulically. In addition, the applicant stated that vessel wall safety, high efficacy in difficult occlusions, and absence of periprocedural adverse events that could reduce durability of long-term outcomes are key substantial clinical improvements associated with the Santreva™-ATK Catheter's atheroplasty mechanism. The applicant concluded that it believes a new device category is needed to describe this approach and requested that CMS establish a new category of catheter, transluminal atheroplasty, wireless.

Response: We appreciate the applicant's and commenters' input. After consideration of the public comments received and our review of the application, we continue to believe that C1887 appropriately describes the Santreva™-ATK Catheter because the nominated device's primary function of crossing peripheral stenotic lesions to establish a revascularization pathway appears to be the same function performed by the guiding catheters described by C1887. Additionally, the Santreva™-ATK Catheter's introduction and removal prior to final treatment are also consistent with the use of guiding catheters described by C1887. While the applicant and commenters stated that C1887 does not describe the device's additional capabilities during CTO crossing, including plaque disruption, compression, and intraluminal channel formation, we disagree that these additional capabilities demonstrate that C1887 does not appropriately describe the Santreva™-ATK Catheter, because the evidence submitted does not establish that these capabilities constitute a distinct therapeutic function independent of crossing the lesion to establish a revascularization pathway. Furthermore, we note that we do not establish pass-through device categories for the purpose of describing specific devices; rather, device categories are intended to encompass all devices that can be appropriately described by a given category while ensuring that no medical device is described by more than one category in accordance with section 1833(t)(6)(B)(ii)(II) of the Act. While CMS has established separate categories for catheters that treat or modify vascular lesions through different mechanisms, the presence of additional capabilities or potential to simplify a procedure does not necessarily establish that the device performs a distinct function requiring a separate category. Therefore, we have determined that the Santreva™-ATK Catheter does not meet the device category eligibility criterion at § 419.66(c)(1), because it is appropriately described by an existing category or a category previously in effect.

After consideration of the public comments we received and our review of the application, the Santreva™-ATK Catheter does not meet the device category eligibility criterion to be considered for device pass-through payment. Therefore, in this final rule with comment period, we will not address whether the technology meets the remaining criteria required for device pass-through payment. We are not approving the Santreva™-ATK Catheter for device pass-through payment status for CY 2027 because the technology does not meet the device category eligibility criterion at § 419.66(c)(1).

3. Other Comments

Comment: Several commenters recommended that CMS define a transition pathway from pass-through status to permanent payment with clearer criteria, timeline, data requirements and advance notice. The commenters requested that CMS should ensure the public can comment on the impact of expiration of pass-through status and should evaluate the effect of expiration of transitional device pass-through payment on the total resources associated with the procedure before packaging the cost of devices into an existing payment rate. A commenter stated that, for products used by small patient populations or in specialized centers, CMS should take the resulting limitations in claims data into account when determining whether an APC has sufficient information to absorb the cost of the technology without creating access problems.

Response: We appreciate the commenters' input and ongoing support of the device pass-through payment program. As specified in section 1833(t)(6)(B) of the Social Security Act, under the OPPS, categories of devices are eligible for transitional pass-through payments for at least two, but not more than three years. After expiration, the device category HCPCS code remains active; however, its payment is included in the primary service. The complete list of current and historical device category codes created since August 1, 2000, which is the implementation date of the hospital OPPS, is available in the quarterly updated OPPS transmittals [71] and the Medicare Claims Processing Manual (Pub.100–04), Chapter 4, Section 60.4.2. The expiration dates of pass-through payment status for each device category receiving pass-through payment are detailed in the annual OPPS proposed rule and final rule with comment period, subject to public comments. We note that because charges related to packaged services are used for outlier and future rate setting, hospitals are advised to report the device category HCPCS codes on the claim whenever furnished in the hospital outpatient department setting, consistent with all applicable coding and billing instructions. We

[71] *https://www.cms.gov/medicare/regulations-guidance/transmittals.*

acknowledge the commenters' concerns regarding the impact of expiration of pass-through status and the limitations in claims data when calculating packaged APC payment rates. We will continue to monitor the available data and consider any additional public comments related to these issues.

Comment: A commenter requested that CMS revisit the methodology of device pass-through cost significance criteria to compare the cost of a proposed device using only the cost of the device or devices the proposed device replaces, especially when the new device does not replace all devices included in the device-related portion (DRP) of the associated APC. The commenter further recommended that, when issuing a transitional pass-through category, CMS should specify which portion of the DRP it will subtract from the costs of the new category, rather than assuming the full DRP applies, and should only subtract costs associated with devices being replaced.

Response: We appreciate the commenter's recommendations related to the methodology for device pass-through cost significance criteria and the calculation for the device offset of a pass-through device category. We will continue to consider the issues and any additional public comments related to them.

Comment: Multiple commenters expressed their support for, or concerns regarding CMS's repeal of the alternative pathway for new technology add-on payment and OPPS device pass-through applications and requirement for all applicants for new technology add-on payments and OPPS device pass-through payments to demonstrate that they meet the same eligibility requirements to receive add-on payments and/or pass-through payments.

Response: We appreciate commenters' feedback. As noted in section IV.A.2.a. of this final rule with comment period, in the FY 2027 IPPS/LTCH PPS final rule (91 FR 49767 through 49789; 91 FR 50346 through 50347), we finalized our policy, with modification, that, unless specifically exempted, all applications received for device pass-through payment status on or after October 1, 2026, including all applications received through the remainder of the CY 2028 application cycle ending on March 1, 2027, and applications received for subsequent calendar years will have to demonstrate that the technology met the requirements currently reflected at § 419.66(c)(2)(i). We also finalized our policy that device pass-through payment applications submitted to CMS as of September 30, 2026, for devices that are part of the FDA's Breakthrough Devices Program that received FDA marketing authorization for the indication covered by the Breakthrough Device designation will be evaluated and could be approved under the alternative pathway, provided that all other criteria have been met. In addition, we finalized a limited exception for a new device that had received FDA Breakthrough Device designation as of September 30, 2026, and has received marketing authorization for the indication covered by the Breakthrough Device designation. Such devices will remain eligible to apply for device pass-through payment under the alternative pathway, which will continue to accept applications for CYs 2028 and 2029. As such, to be considered for the limited exception, CMS must receive a complete application for eligible devices under the limited exception no later than March 1, 2028. We finalized revisions, with modifications, to paragraph § 419.66(c)(2)(ii) to reflect the finalized policy, effective October 1, 2026. We refer the readers to the FY 2027 IPPS/LTCH PPS final rule (91 FR 49767 through 49789) for a full discussion of the finalized policy, including comments received and our responses.

Comment: We received several public comments regarding applications or category codes not under review, or requesting changes to the device pass-through payment policies, such as eligibility of section 351 implantable biological products.

Response: These comments were outside the scope of the proposals included in the CY 2027 OPPS/ASC proposed rule and we are therefore not addressing them in this final rule with comment period.

B. Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent (79 FR 66795). Beginning in CY 2017, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilized devices, and the device costs for the associated HCPCS codes exceeded the 40 percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive procedures and is discussed in detail in section IV.B.4. of the CY 2026 OPPS/ASC proposed rule. A related device policy was the requirement that certain procedures assigned to device-intensive APCs require the reporting of a device code on the claim (80 FR 70422) and is discussed in detail in section IV.B.3. of the CY 2026 OPPS/ASC 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 final rule with comment period are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive status under our established methodology, including our policies on device edits and no cost/full credit and partial credit devices discussed in sections IV.C.3. and IV.C.4. of this final rule with comment period.

b. Use of the Three Criteria To Designate Device-Intensive Procedures

We clarified our established policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52474), where we explained that device-intensive procedures require the implantation of a device and additionally are subject to the following criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed.
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and
- The device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

We changed our policy to apply these three criteria to determine whether procedures qualify as device-intensive in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), where we stated that we would apply the no cost/full credit and partial credit device policy—which includes the three criteria listed previously—to all device-intensive procedures beginning in CY 2015. We reiterated this position in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), where we explained that we were finalizing our proposal to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which the CY 2016 device intensive policy will apply. Under the policies we adopted in CYs 2015, 2016, and 2017, all procedures that require the implantation of a device and meet the previously described criteria are assigned device-intensive status, regardless of their APC placement.

2. Device-Intensive Procedure Policy

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 believed allowing these additional procedures to qualify for device-intensive status would help ensure these procedures receive more appropriate payment in the ASC setting, which would 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, or has received an FDA 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 83 FR 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.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94214 through 92419), we finalized a change to our methodology for applying default device offset percentages for new device-intensive procedures. Under our previous policy, if a new CPT/HCPCS code did not have available claims data, either from the new HCPCS code or any predecessor code or clinically-similar code that uses the same device, and the CPT/HCPCS code otherwise met our criteria for device-intensive status, we would apply a default device offset percentage of 31 percent. However, we were aware of certain situations where the default device offset amount might not adequately reflect the existing device portion of the procedure's costs when compared to the cost of similar devices. A potential large difference between the default device offset amount and the device portion of similar devices might impede our ability to accurately remove device offset amounts from new device-intensive procedures under the OPPS and to set payment rates for device-intensive procedures under the ASC payment system.

Therefore, for CY 2025 and subsequent CYs, we finalized our proposal to modify our default device offset percentage policy for new device-intensive procedures. Specifically, for new CPT/HCPCS codes that both describe a procedure that requires the surgical implantation or insertion of a single-use device that exceeds 30 percent of the procedure's cost and that meets our requirements of a device as described here and lack claims data (from either the new HCPCS code or any predecessor code or clinically-similar code that uses the same device), 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 stated that 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 finalized our modification to our default device offset percentage for new device-intensive procedures. This methodological change was finalized for both the OPPS and ASC Payment System for CY 2025 and subsequent CYs and applies to new procedures assigned to clinical APCs, but not to new procedures assigned to New Technology APCs.

Additionally, in the CY 2025 OPPS/ASC final rule with comment period (89 FR 92414 through 92419), we stated that we were persuaded by commenters that the lack of a device edit for device-intensive procedures, particularly new technologies, might lead to an underreporting of device costs and total procedure costs and potentially impede beneficiary access to such new technologies over time. Therefore, in addition to finalizing a modification to our device edits policy for CY 2025, we finalized a modification to our device offset percentage calculation. For procedures subject to our modified device edits policy for CY 2025 that cannot report modifier ''CG'' to bypass this claims processing edit, the device offset percentages calculated (for the CPT/HCPCS code or its predecessor code) are based on hospital claims that reported a device code. We stated that we believed that hospital outpatient claims that report a device code with such procedures provide, in general, a more accurate representation of the

procedures' total costs. We also finalized, for purposes of determining device offset percentages, that we will not use claims data from procedures that had a status indicator of ''E1'' during the calendar year we are using for ratesetting and determining device offset percentages. Lastly, we refined our process for applying device offset percentages to use available claims data from predecessor codes annually, rather than the first year of the successor code's activation date, until we have available claims data from the successor code. In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53673 through 53679), we finalized our proposal to continue these policies for CY 2026.

2. Proposed Device-Intensive Procedure Policy

We proposed to continue the CY 2026 device-intensive procedure policies for CY 2027. Specifically, we proposed to continue use of HCPCS code-level device-intensive determination and three criteria to designate device-intensive procedures, in accordance with existing policies. We also proposed to continue our device-intensive procedure policy, our proposed use of CY 2025 claims information for determining device offset percentages and assigning device-intensive status, and our proposed default device offset policy for determining device offset percentages in the absence of claims data for device-intensive procedures (91 FR 41848). As we indicated in the CY 2019 OPPS/ASC proposed rule and final rule with comment period, additional information for our consideration of an offset percentage higher than the default of 31 percent (or the APC-wide default 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, should be directed to the Division of Outpatient Care 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters requested that CMS designate CPT code 52282 (Cystourethroscopy, with insertion of permanent urethral stent) as device-intensive and establish its CY 2027 device offset using manufacturer invoice data. The commenters stated that the historical claims are not representative because no FDA-approved permanent prostatic urethral stent was commercially available in the United States for approximately a decade, making the proposed zero device offset unreliable.

Response: As discussed in section III. of this final rule with comment period, we agree with the commenters that no FDA-approved permanent prostatic urethral stent had been available on the U.S. market for approximately 9 years before FDA approved such a device through the premarket approval application process in late 2025. Therefore, we believe that the CY 2025 claims data for CPT code 52282 do not accurately reflect the device and service costs associated with inserting a permanent prostatic urethral stent and are not an appropriate data source for calculating the device offset percentage for CPT code 52282. In the absence of representative CY 2025 claims data, we are accepting the commenters' recommendation to assign device-intensive status to CPT code 52282 for CY 2027. We are not accepting the commenters' recommendation to use manufacturer invoice data to calculate the device offset percentage. Instead, we will apply our default device offset methodology to CPT code 52282 for CY 2027.

Comment: Several commenters opposed removing device-intensive status from CPT code 55882 (Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducer for delivery of thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed) for CY 2027 under the ASC payment system. The commenters stated that the TULSA procedure requires proprietary, single-use transurethral ultrasound and endorectal cooling devices that are integral to the service, contact human tissue, and are temporarily inserted into the patient. They stated that the proposed offset is distorted by incomplete device reporting, noting that the average invoice cost of $8,089 represents approximately 49 percent of the proposed $16,366 geometric mean cost. The commenters also reported that claims identifying C1889 produced offsets above the 30-percent threshold, whereas many hospitals reported little or no device cost. They requested a 49-percent device offset based on documented acquisition costs.

Response: CPT code 55882 became effective January 1, 2025. In reviewing these comments, we discovered that we had correctly assigned device-intensive status to this procedure under the ASC payment system but had inadvertently not assigned device-intensive status to this procedure under the OPPS. In general, a new CPT code that meets our criteria for device-intensive status and is separately payable in both the OPPS and ASC payment system should be designated as device-intensive under both the OPPS and the ASC payment system. (Once claims data is available, differences in the claims data available under the two systems' ratesetting methodologies may result in a procedure receiving device-intensive status under the ASC payment system but not under the OPPS.)

The incomplete reporting of devices associated with CPT code 55882 under the OPPS underscores the importance of our device edits policy for device-intensive procedures. In the absence of an applicable device edit, we do not believe it would be appropriate to selectively determine which claims to use to calculate the device offset percentage; instead, we believe it is appropriate to rely on a full year of claims data during which CPT code 55882 is subject to the device edits policy. Therefore, because usable CY 2025 claims data are unavailable for CPT code 55882, we are accepting the commenters' recommendation to maintain device-intensive status for the code for CY 2027 and will apply our device edits and device credits policies to the procedure beginning in CY 2027 by assigning the procedure device-intensive status for both the ASC and OPPS settings. We are not accepting the commenters' recommendation to calculate the device offset percentage using acquisition-cost data and will instead apply our default device offset methodology.

Comment: Several commenters requested that we designate CPT code 0786T (Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed) as device intensive for CY 2027. The commenters stated that the procedure requires implantation of a single-use integrated sacral neuromodulation system and that the manufacturer-reported device cost of $18,500 represents approximately 83.5 percent of the proposed APC payment. The commenters stated that the two claims apparently used to determine device-intensive status were invalid or

unrepresentative because the code had status indicator ''E1'' until the device received FDA approval in June 2025 and commercial use did not begin until after November 2025. They requested that we disregard those claims and apply the default offset for the APC, manufacturer invoice pricing, or another appropriate new technology methodology.

Response: We agree with the commenters that we should disregard CY 2025 claims for CPT code 0786T. As we stated previously, in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94218), for purposes of determining device offset percentages, we will not use claims data from procedures that had a status indicator of ''E1''. Since CPT code 0786T was assigned a status indicator of ''E1'' for all of CY 2025, under our current policy, we will continue to assign CPT code 0786T device-intensive status for CY 2027 and will apply a device offset percentage based on our default device offset methodology.

Comment: Several commenters requested that we designate CPT code 0730T (Trabeculotomy by laser, including optical coherence tomography (OCT) guidance) as device intensive and apply a 65-percent device offset. The commenters explained that the procedure requires two proprietary, single-use optical interfaces that contact the cornea and are integral to OCT-guided imaging and laser treatment under a CMS-approved Category B IDE study. The commenters stated that the combined $3,750 acquisition cost represents approximately 65 percent of the proposed geometric mean cost for APC 5493 and therefore exceeds the 30-percent device-cost threshold.

Response: CPT code 0730T describes a minimally invasive glaucoma surgical procedure that reduces intraocular pressure by improving aqueous outflow. Specifically, CPT code 0730T describes a laser trabeculotomy procedure that noninvasively creates a channel through the trabecular meshwork, unlike other laser trabeculoplasty procedures that apply laser energy to stimulate biological changes that improve aqueous outflow. We are not accepting the commenter's recommendation to treat the patient interface system as a device for purposes of determining device-intensive status. Our criteria for device-intensive status require that a device be surgically inserted or implanted into the patient. In the CY 2006 OPPS/ASC final rule with comment period (70 FR 68629 through 68630), we explained that the surgical insertion or implantation criterion encompasses devices inserted or implanted through a natural or surgically created orifice, as well as devices inserted or implanted through a surgically created incision. We do not consider placement beneath the eyelid and against the ocular surface to constitute insertion through a natural or surgically created orifice or incision. Therefore, we do not consider the patient interface system associated with CPT code 0730T to be an insertable medical device for purposes of device-intensive status.

Comment: Several commenters requested that we expand device-intensive policy to permit CPT codes 0686T (Histotripsy (*i.e.,* non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance) and 0888T (Histotripsy (*i.e.,* non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including imaging guidance), which describe histotripsy of liver and kidney tumors, respectively, to qualify based on the cost of a nonimplantable ''single patient use device'' applied to the patient's skin. The commenters stated that the device will cost $7,500 in CY 2027 and stated that both procedures satisfy the 30-percent device-cost threshold, notwithstanding that the device is neither surgically inserted nor implanted. The commenters stated that revising the policy and increasing payment would facilitate beneficiary access to noninvasive histotripsy in the lower-cost ASC setting.

Response: While we understand the commenters' concerns regarding payment adequacy for capital-intensive procedures furnished in the ASC setting and may consider these concerns in future rulemaking, we did not propose revising the eligibility criteria for device-intensive procedures. We believe that expanding the definition of device-intensive procedures to include high-cost items that contact a patient's skin, but are not surgically implanted/inserted, could have significant unintended consequences for both the OPPS and the ASC payment system. Therefore, we are not accepting the commenters' recommendations.

Comment: A commenter opposed the proposed device offset percentage for CPT code 0885T (Colonoscopy, flexible, with initial transendoscopic mechanical dilation (*e.g.,* nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed) and requested that we continue to assign device-intensive status. The commenter stated that the three claims used to calculate the proposed offsets were erroneous because the ProTractX3 drug-coated balloon was available only through company-funded IDE trials and the facilities submitting the claims were not trial participants. The commenter requested that in the absence of sufficient claims data, the procedure should be assigned the APC-level device offset percentage under the OPPS.

Response: We rely on hospitals to accurately report device costs associated with procedures. However, based on this comment and other public comments raising concern with determining device intensive status for services with very few claims, we believe that in instances where a procedure has very few claims upon which to determine device intensive status it would be appropriate to apply a low volume methodology for device intensive status which we are finalizing for this CY 2027 OPPS/ASC final rule with comment period and which is discussed further later in this section of the preamble.

Under this low volume policy for device-intensive procedures, for procedures assigned device-intensive status in the current year with fewer than 10 claims in the ratesetting year, we will use the greater of: (1) the device offset percentage calculated from the available claims; or (2) the device offset percentage calculated under our default methodology, which is the greater of 31 percent or the device offset percentage of the APC to which the procedure is assigned.

Given the limited number of claims—three claims for this final rule with comment period—the device offset percentage of CPT code 0885T would fall under this low volume policy for device-intensive procedures and would be assigned a default device offset of 34.95 percent based on the APC-wide device offset of APC 5331 (Complex GI Procedures).

Comment: Commenters supported our proposal to designate CPT code 27486 (Revision of total knee arthroplasty, with or without allograft; 1 component) as device intensive and to continue the device-intensive designation for CPT code 31295 (Nasal/sinus endoscopy, surgical, with dilation (*e.g.,* balloon dilation); maxillary sinus ostium, transnasal or via canine fossa), noting that the associated device costs exceed the 30-percent threshold. The commenters requested that we also designate CPT codes 31296 (Nasal/sinus endoscopy, surgical, with dilation (*e.g.,* balloon dilation); frontal sinus ostium), 31297 (Nasal/sinus endoscopy, surgical, with dilation (*e.g.,* balloon dilation); sphenoid sinus ostium), and 31298 (Nasal/sinus endoscopy, surgical, with dilation (*e.g.,* balloon dilation); frontal and sphenoid sinus ostia) as device

intensive because these clinically related sinus procedures use similar balloon dilation devices; they noted that the calculated offset for CPT code 31296 exceeds 30 percent and recommended a stabilization policy for procedures such as CPT codes 31297 and 31298 that fluctuate near the threshold.

Response: We appreciate the commenters' recommendation to establish a stabilization policy for procedures with device offset percentages that fluctuate around the 30-percent device-intensive threshold. We addressed a related concern under the OPPS in prior rulemaking. Specifically, in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94219 through 94222), we modified our device edits policy to minimize disruptions resulting from procedures moving above and below the 30-percent threshold. Under that policy, once a procedure is designated as device-intensive for a calendar year, we continue to apply the device edits to the procedure in subsequent years, even if it no longer qualifies as device-intensive. Since the device offset percentage for each procedure is below our device-intensive threshold of 30 percent and there are 10 or greater singles for each procedure based on claims data available for this final rule with comment period, we are not assigning device-intensive status under the OPPS to CPT codes 31296, 31297, and 31298 for CY 2027.

Comment: A commenter supported our proposal to assign device-intensive status to CPT code 52284 (Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed) and recommended finalizing the associated device offsets. The commenter explained that the procedure requires the Optilume Stricture drug-coated balloon catheter and the proposed OPPS device offset appropriately reflects the device-intensive nature of the procedure.

Response: We appreciate the commenter's support and are assigning a device offset percentage to CPT code 52284 based on the CY 2025 claims data available for this final rule with comment period.

Comment: A commenter supported our proposal to assign device-intensive status to CPT code 64728 (Decompression; median nerve at the carpal tunnel, percutaneous, with intracarpal tunnel balloon dilation, including ultrasound guidance) but requested an increase from the proposed default device offset of 31 percent. The commenter recommended a device offset of 61.69 percent under the OPPS.

Response: We appreciate the commenter's support of our assignment of device-intensive status to CPT code 64728. In the absence of available claims data, we are relying on our default offset methodology which applies the greater of the default 31-percent device offset or the APC-wide device offset. We are finalizing our proposal to assign CPT code 64728 to APC 5431 (Level 1 Nerve Procedures) for CY 2027. The device offset percentage for APC 5431 is 1.4 percent; therefore, we are not accepting the commenter's recommendation and are assigning a default 31-percent device offset to CPT code 64728 for CY 2027.

Comment: A commenter requested that we designate CPT code 52649 (Laser enucleation of the prostate with morcellation, 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)) as device intensive, noting that the procedure requires single-use, insertable devices, including a morcellator reported with HCPCS code C1782 and a laser fiber reported with C1889. The commenter stated that the proposed device offset under the OPPS understate the costs of these required devices. Based on its claims analysis, the commenter reported that only approximately 21 percent of claims identified the morcellator and approximately 37 percent reported any relevant device code or revenue code, indicating inconsistent device reporting. The commenter recommended that we establish a targeted supplemental evidentiary pathway allowing validated acquisition-cost information, invoices, or other objective evidence to inform the device offset and device-intensive determination when claims do not reliably capture required device costs.

Response: For this final rule with comment period, the CY 2025 claims data included more than 10,000 single claims for CPT code 52649. We rely on hospitals to accurately report device costs associated with procedures and the device offset percentage calculated from this volume of claims indicates that the device costs associated with the procedure are below the 30-percent device-intensive threshold. Therefore, we are not accepting the commenter's recommendation and are calculating the device offset percentage for CPT code 52649 using the CY 2025 claims data available for this final rule with comment period.

Comment: Several commenters requested that CMS designate CPT code 53854 (Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy) as device intensive and calculate its device offset using only claims that identify the required single-use delivery device through HCPCS code C1889 or revenue center code 0278. The commenters stated that the device is integral to the procedure, used for one patient, contacts human tissue, and is surgically inserted, thereby satisfying CMS' device criteria. They reported that only 30.84 percent of claims identified the required device, producing an all-claims offset of 17.39 percent, whereas claims identifying the device produced an offset of 45.07 percent, above the 30-percent threshold.

Response: For this final rule with comment period, the CY 2025 claims data included more than 1,000 single claims for CPT code 53854. We rely on hospitals to accurately report device costs associated with procedures and the device offset percentage calculated from this volume of claims indicates that the device costs associated with the procedure are below the 30-percent device-intensive threshold. Therefore, we are not accepting the commenter's recommendation and are calculating the device offset percentage for CPT code 53854 using the CY 2025 claims data available for this final rule with comment period.

Comment: A commenter requested that CMS grant temporary device-intensive status to CPT code 66174 (Transluminal dilation of aqueous outflow canal (*e.g.,* canaloplasty); without retention of device or stent), which requires an advanced microcatheter that is surgically inserted into the eye. The commenter stated that the procedure previously qualified as device intensive in the CY 2025 proposed rule but lost that status following changes in reported costs and cost-to-charge ratios, despite subsequent efforts to improve hospital device-cost reporting. The commenter requested that CMS calculate the device offset using only claims reporting HCPCS code C1889 or include revenue code 0272 in offset calculations.

Response: For this final rule with comment period, the CY 2025 claims data included more than 2,000 single claims for CPT code 66174. We rely on hospitals to accurately report device costs associated with procedures and the device offset percentage calculated from this volume of claims indicates that the device costs associated with the procedure are below the 30-percent device-intensive threshold.

Additionally, revenue code 0272 is designated for sterile supplies associated with the operating room and would not be an applicable source of device costs under our device-intensive criteria. Therefore, we are not accepting the commenter's recommendation and are calculating the device offset percentage for CPT code 66174 using the CY 2025 claims data available for this final rule with comment period.

Comment: A commenter also requested that we increase the device offset for HCPCS code C9781 (Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (*e.g.,* balloon), includes debridement (*e.g.,* limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed) based on submitted invoice data demonstrating that the proposed offset understates the acquisition cost of the subacromial spacer.

Response: For this final rule with comment period, the CY 2025 claims data included more than 400 single claims for CPT code C9781. We rely on hospitals to accurately report device costs associated with procedures and the device offset percentage calculated from this volume of claims indicates that the device costs associated with the procedure are approximately 61 percent. Therefore, we are not accepting the commenter's recommendation and are calculating the device offset percentage for CPT code C9781 using the CY 2025 claims data available for this final rule with comment period.

Comment: A commenter opposed CMS's proposal to increase the device offset percentage for APC 5231 (Level 1 ICD and Similar Procedures) from 58 percent to 79 percent. The commenter stated that implantation of the WiSE CRT System, described by CPT code 0515T (Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; complete system (includes electrode and generator [transmitter and battery])), requires substantially greater non-device hospital resources than the conventional implantable cardioverter-defibrillator procedures assigned to the APC, including specialized personnel, laboratory time, anesthesia, imaging, device programming, and post-procedure monitoring. The commenter stated the higher offset would understate the non-device costs and reduce the transitional pass-through payment for the device.

Response: Based on the CY 2025 claims data available for this final rule with comment period, we calculated an APC-level device offset percentage of approximately 67 percent for APC 5231. The APC-level device offset reflects the weighted-average device costs associated with all procedures assigned to the APC. We do not believe it would be appropriate to reduce the device offset percentage below the amount supported by the claims data solely to increase the transitional pass-through payment for devices that currently have pass-through payment status under the OPPS. Therefore, we are not accepting the commenter's recommendation.

Comment: Several commenters recommended that CMS establish a specific process for determining device-intensive status for procedures removed from the inpatient-only list. The commenters stated that the limited outpatient claims generated while a procedure remained on the inpatient-only list may not reliably reflect typical outpatient resource or device costs. They recommended that CMS use inpatient claims and device revenue-code information to identify procedures involving high-cost implantable devices and estimate their device costs.

Response: We generally rely on outpatient claims data to determine device-intensive status and calculate device offset amounts. However, under the OPPS, we have adopted alternative methodologies when the available claims volume is insufficient to support reliable ratesetting. For example, under our universal low-volume APC policy, we use up to 4 years of claims data to determine the APC cost when an APC has fewer than 100 claims annually. We also generally exempt services assigned to New Technology APCs from reassignment under a policy when fewer than 10 claims are available during the 4-year lookback period.

We agree with the commenters that the limited outpatient claims generated for procedures while they remained on the inpatient-only list may not reliably reflect the device costs that hospitals will incur when furnishing those procedures in the outpatient setting. Therefore, we are accepting the commenters' recommendation and revising our device-intensive procedure methodology to address circumstances in which a low volume of claims may not accurately represent the underlying device costs associated with a procedure.

Specifically, for CY 2027 and subsequent years, when fewer than 10 claims are available in the ratesetting year, we will use the greater of: (1) the device offset percentage calculated from the available claims; or (2) the device offset percentage calculated under our default methodology, which is the greater of 31 percent or the device offset percentage of the APC to which the procedure is assigned. As discussed in section XIII.C.4. of this final rule with comment period, we are adopting this policy for the ASC payment system as well.

We believe this revision will reduce the likelihood that a small number of potentially unrepresentative claims will result in an inappropriately low device offset, while continuing to recognize the available claims data when those data indicate that the device portion of the procedure is significant. We also agree with the commenters that device revenue-code information from inpatient claims may provide relevant evidence when determining whether procedures removed from the inpatient-only list are device-intensive. Accordingly, we will consider such information, as appropriate, when making device-intensive designations for these procedures.

After consideration of public comments, we are finalizing our device-intensive procedures proposal with a modification for device-intensive procedures with fewer than ten claims in the ratesetting year, for which we will apply the greater of: (1) the device offset percentage calculated from the available claims; or (2) the device offset percentage calculated under our default methodology, which is the greater of 31 percent or the device offset percentage of the APC to which the procedure is assigned. We are also finalizing our proposed continued use of HCPCS code-level device-intensive determination and the three criteria to designate device-intensive procedures in accordance with existing policies as discussed in section IV.B.1.a. of the CY 2027 OPPS/ASC proposed rule (91 FR 41846). We are also finalizing our proposed continuation of our device-intensive procedure policy, proposed use of CY 2025 claims information for determining device offset percentages and assigning device-intensive status, and our proposed default device offset policy for determining device offset percentages in the absence of claims data for device-intensive procedures, in accordance with existing policies as discussed in section IV.B.1.b. of the CY 2027 OPPS/ASC proposed rule (91 FR 41846).

Comments and our responses related to device-intensive procedure policy and the procedures we proposed for device-intensive status under the ASC payment system for CY 2027 can be found in section XIII.C.4. of this final rule with comment period. Our responses and final determinations related to device-intensive status for

certain procedures under the ASC payment system are also applied to our final determinations of device-intensive status under the OPPS.

The full listing of the CY 2027 device-intensive procedures can be found in Addendum P to this final rule with comment period (which is available via the internet on the CMS website). Further, our claims accounting narrative contains a description of our device offset percentage calculation. Our claims accounting narrative for this final rule with comment period can be found under supporting documentation for the CY 2027 OPPS/ASC final rule with comment period on our website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

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 and 0616T, 0617T, and 0618T. (We note that CPT codes 0617T and 0618T were deleted effective January 1, 2025 and CPT code 0616T was deleted effective January 1, 2025 and replaced with new CPT code 66683.) We have noted that interested parties have previously recommended in past rulemaking that we reestablish all our previous procedure-to-device edits, but we do 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. In the CY 2025 OPPS/ASC final rule with comment period, we finalized to continue this policy for APC 5496 (Level 6 Intraocular Procedures) for CY 2025 and subsequent years.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 92419 through 92422), we finalized a modification to our device edits policy. While historically our device edits policy has only applied to procedures that are device-intensive based on the most recent claims data available, commenters had raised concerns about hospitals underreporting device costs in years when certain device-intensive procedures had lost device-intensive status because the device portion of a procedure can fluctuate above and below our device-intensive threshold of 30 percent. Commenters indicated to us that the presence of the device edit requirement can have a significant impact on the device portion and geometric mean cost of a procedure, particularly for newer technologies. Therefore, for CY 2025 and subsequent CYs, we finalized a policy to apply our device edits policy permanently once a procedure is designated as a device-intensive procedure in a given year. Additionally, we finalized a policy to reinstate our device edits policy for procedures that have been device-intensive since we began assigning device-intensive status at the HCPCS code level on January 1, 2017. We believed that by applying our device edit policy to procedures that were device-intensive on or after January 1, 2017, we might continue to receive device cost information for relatively new procedures with limited claims data, which may have been impacted by our policy to require that only existing device-intensive procedures be subject to our device edits policy.

We did not propose any changes to our device edit policy for CY 2027 (91 FR 41849). We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters recommended that CMS reinstate device-to-procedure edits for certain device-intensive services, noting that inconsistent or omitted device-code reporting understates device costs and produces unreliable offsets and payment rates. The commenters recommended that CMS establish or assign appropriate C-codes for certain urethral stents, a bone-anchored implant, cervical fusion devices, or for device-intensive procedures that are removed from the inpatient-only list, and publish a crosswalk identifying each procedure, its device-intensive status, and the applicable device code. A commenter also requested specific reporting instructions for C1776 on total joint arthroplasty claims and recommended using only claims containing C1776 for rate-setting. The commenter further recommended that hospitals report C1889 when a procedure-level C-code encompasses both the procedure and device but does not separately identify the device cost.

Response: We believe hospitals are experienced in coding and billing for joint replacement procedures and other device-intensive procedures which are subject to our device edits policy and do not believe it is necessary to reinstate specific procedure-to-device edits for device-intensive procedures. Additionally, while we may create new device category C-codes for device categories approved under transitional pass-through status to be paid at charges

reduced to cost, we do not believe it is appropriate or necessary to create additional device category C-codes outside of the transitional pass-through approval process. We believe hospitals are experienced in coding and reporting significant device costs correctly on hospital claims using the existing device category HCPCS C-codes as well as revenue codes.

Comment: A commenter requested distinct outpatient coding for customized aprevo® cervical and lumbar interbody fusion devices, noting that expired HCPCS code C1831 does not adequately distinguish their different anatomy, indications, procedures, and resource costs. If a future pass-through category is available, the commenter requested separate cervical and lumbar customized-device C-codes with zero-dollar device offsets. The commenter stated that distinct coding would permit accurate cost collection and support temporary New Technology APC assignments until sufficient outpatient claims become available. Finally, the commenter requested that we evaluate a new technology APC application for aprevo® Cervical procedure and aprevo® Lumbar procedures using hospital inpatient invoice data and manufacturer validated cases.

Response: We are not accepting the commenter's recommendations. As we discussed in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53637 through 53643), the aprevo® Cervical ACDF system was not approved for transitional pass-through payment status as the device did not meet the device category eligibility criterion at 419.66(c)(1) because it is appropriately described by an existing category or a category previously in effect. We do not believe additional product-specific coding is necessary to permit accurate cost collection as hospitals are experienced in device-reporting on outpatient claims across a wide variety of device products. Additionally, we note that the new technology APC application process is a subregulatory process. As a general note, interested parties can submit applications and reconsideration requests through MEARIS throughout the year.

After consideration of public comments, we are finalizing our proposal, without modification, to continue our device edits policy for CY 2027.

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 did propose any changes to our policies regarding payment for no cost/full credit and partial credit devices for CY 2027 in the CY 2027 OPPS/ASC proposed rule, and we did not receive public comments (91 FR 41850). We are finalizing our proposal to maintain our current policy for CY 2027.

V. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals

A. OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act (42 U.S.C. 1395*l*(t)(6)) provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals. A biological'' as used in this final rule with comment period, and as codified at 42 CFR 414.802 and 414.902 includes a ''product licensed under section 351 of the PHS [Public Health Service] Act''. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: current orphan drugs for rare diseases and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. ''Current'' refers to those types of drugs or biologicals mentioned previously 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 a Hospital Outpatient Department (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. Drugs and biologicals pass-through applications are accepted and approved on a quarterly basis in which pass-through payments for approved applications could begin on the next available OPPS quarterly update. Furthermore, our current policy, which was finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79662), is to allow for 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 to allow, on a prospective basis, for the maximum pass-through payment period 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. Final CY 2027 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to this final rule with comment period (which are available on the CMS website).[72]

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 (42 U.S.C. 1395u(o)) for the drug or biological exceeds the portion of the otherwise applicable Medicare Outpatient Department (OPD) fee schedule that the Secretary determines is associated with the drug or biological. The regulations at 42 CFR 419.64(d) specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the Ambulatory Payment Classification (APC) payment that CMS determines is associated with the drug or biological.

Section 1847A of the Act (42 U.S.C. 1395w–3a) establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this final rule with comment period, the term ''ASP methodology'' and ''ASP-based'' are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on our website at *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price.*

The pass-through application [73] 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. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2026

There are 49 drugs and biologicals for which pass-through payment status expires by December 31, 2026, as listed in Table 57. These drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of April 1, 2023 through December 31, 2026. In accordance with the policy finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79662) and described earlier, pass-through payment status for drugs and biologicals approved in CY 2017 and subsequent years will expire on a quarterly basis, with a pass-through payment period as close to 3 years as possible.

With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used [74] 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

[72] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

[73] 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 July 31, 2027.

[74] In the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948), we finalized the diagnostic radiopharmaceuticals policy to separately pay those products when the per-day costs are greater than a threshold. Please refer to section II.A.3.c. of the CY 2025 OPPS/ASC final rule with comment period for more information regarding this policy.

expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per-day cost and compare it with the OPPS drug packaging threshold for that calendar year, which was proposed to be $140 for CY 2027 for all drugs, biologicals, and therapeutic radiopharmaceuticals (for high-cost diagnostic radiopharmaceuticals, we would provide separate payment when their per-day cost is greater than the threshold we proposed to adopt of $665). These policies are discussed further in section V.B.1. of this final rule with comment period. If the estimated per-day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per-day cost of the drug or biological is greater than the OPPS drug packaging threshold, we provide separate payment at the applicable ASP methodology-based payment amount (which is generally ASP plus 6 percent), as discussed further in section V.B.2. of this final rule with comment period.

We welcomed public comments on the status indicator for expiring pass-through drugs and biologicals, in accordance with our existing policies on packaged drugs, biologicals, and radiopharmaceuticals, including the threshold packaging policy.

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TABLE 57: DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS WILL END BY DECEMBER 31, 2026

CY 2026 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9145	Injection, aprepitant, (aponvie), 1 mg	G	9107	04/01/2023	03/31/2026
J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg	G	9109	04/01/2023	03/31/2026
J9347	Injection, tremelimumab-actl, 1 mg	G	9110	04/01/2023	03/31/2026
J9380	Injection, teclistamab-cqyv, 0.5 mg	G	9111	04/01/2023	03/31/2026
J9381	Injection, teplizumab-mzwv, 4 mcg	G	9112	04/01/2023	03/31/2026

J0218	Injection, olipudase alfa-rpcp, 1 mg	G	9113	04/01/2023	03/31/2026
J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose	G	9138	04/01/2023	03/31/2026
J1449	Injection, eflapegrastim-xnst, 0.1 mg	G	9114	04/01/2023	03/31/2026
J1747	Injection, spesolimab-sbzo, 1 mg	G	9115	04/01/2023	03/31/2026
J1954	Injection, leuprolide acetate for depot suspension (lutrate depot), 7.5 mg	G	9136	04/01/2023	03/31/2026
J2403	Chloroprocaine hcl ophthalmic, 3% gel, 1 mg	G	9116	04/01/2023	03/31/2026
Q5128	Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg	G	9117	04/01/2023	03/31/2026
Q5130	Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg	G	9118	04/01/2023	03/31/2026
J2329	Injection, ublituximab-xiiy, 1 mg	G	9149	07/01/2023	6/30/2026
J1440	Fecal microbiota, live - jslm, 1 ml	G	9142	07/01/2023	6/30/2026
Q5129	Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg	G	9159	07/01/2023	6/30/2026
J9056	Injection, bendamustine hydrochloride (vivimusta), 1 mg	G	9154	07/01/2023	6/30/2026
J0208	Injection, sodium thiosulfate,100 mg	G	9119	07/01/2023	6/30/2026
J2781	Injection, pegcetacoplan, 1 mg	G	9158	07/01/2023	6/30/2026
J1961	Injection, lenacapavir, 1 mg	G	9155	07/01/2023	6/30/2026
J9350	Injection, mosunetuzumab-axgb, 1 mg	G	9150	07/01/2023	6/30/2026
J0402	Injection, aripiprazole, (abilify asimtufii), 1 mg	G	9246	10/01/2023	9/30/2026
J7214	Injection, factor viii/von willebrand factor complex, recombinant (altuviiio), per factor viii i.u.	G	9277	10/01/2023	9/30/2026
J0184	Injection, amisulpride, 1 mg	G	9247	10/01/2023	9/30/2026

J0577	Injection, buprenorphine extended-release (brixadi), less than or equal to 7 days of therapy	G	0732	10/01/2023	9/30/2026
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	Injection, epcoritamab-bysp, 0.1 mg	G	9250	10/01/2023	9/30/2026
A9608	Flotufolastat F 18, diagnostic, 1 millicurie	G	9254	10/01/2023	9/30/2026
J1304	Injection, tofersen, 1 mg	G	9262	10/01/2023	9/30/2026
J2799	Injection, risperidone, (uzedy), 1 mg	G	9266	10/01/2023	9/30/2026
J7353	Anacaulase-bcdb, 8.8% gel, 1 gram	G	0742	01/01/2024	12/31/2026
J3401	Beremagene geperpavec-svdt for topical administration, containing nominal 5 x 10^9 pfu/mL vector genomes, per 0.1 mL	G	0716	01/01/2024	12/31/2026
J7354	Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg)	G	0707	01/01/2024	12/31/2026
A9601	Flortaucipir f 18 injection, diagnostic, 1 millicurie	G	0709	01/01/2024	12/31/2026
J0177	Injection, aflibercept hd, 1 mg	G	0704	01/01/2024	12/31/2026
J2782	Injection, avacincaptad pegol, 0.1 mg	G	0705	01/01/2024	12/31/2026
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit	G	0703	01/01/2024	12/31/2026
J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose	G	0714	01/01/2024	12/31/2026
J1323	Injection, elranatamab-bcmm, 1 mg	G	0708	01/01/2024	12/31/2026
J9286	Injection, glofitamab-gxbm, 2.5 mg	G	0720	01/01/2024	12/31/2026
J0174	Injection, lecanemab-irmb, 1 mg	G	9157	01/01/2024	12/31/2026
J2508	Injection, pegunigalsidase alfa-iwxj, 1 mg	G	0715	01/01/2024	12/31/2026

J7165	Injection, prothrombin complex concentrate, human-lans, per i.u. of factor ix activity	G	0702	01/01/2024	12/31/2026
J0349	Injection, rezafungin, 1 mg	G	9267	01/01/2024	12/31/2026
J9333	Injection, rozanolixizumab-noli, 1 mg	G	0721	01/01/2024	12/31/2026
J3055	Injection, talquetamab-tgvs, 0.25 mg	G	0706	01/01/2024	12/31/2026
J1412	Injection, valoctocogene roxaparvovec-rvox, per mL, containing nominal 2 × 10^13 vector genomes	G	0713	01/01/2024	12/31/2026
J0217	Injection, velmanase alfa-tycv, 1 mg	G	0710	01/01/2024	12/31/2026
J9029	Intravesical instillation, nadofaragene firadenovec-vncg, per therapeutic dose	G	0717	01/01/2024	12/31/2026

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We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

3. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Expiring in or Continuing Through CY–2027

We proposed to end pass-through payment status in CY–2027 for 28 drugs and biologicals. These products, listed in Table 58, were initially approved for pass-through payment status between April 1, 2024 and January 1, 2025. We also proposed to continue pass-through payment status through CY 2027 for 45 drugs and biologicals, listed in Table 59, which were initially approved for pass-through payment status between April 1, 2025 and April 1, 2026. The APCs and Healthcare Common Procedure Coding System (HCPCS) codes for pass-through drugs and biologicals are assigned status indicator ''G'' (Pass-Through Drugs and Biologicals) in Addenda A and B to this final rule with comment period (which are available on the CMS website).[75] 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 2027, 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 2027. 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 will continue to be paid for pass-through drugs and biologicals under the CY 2027 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 radiopharmaceuticals[76] below the applicable cost threshold 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 2027, minus a payment offset for the portion of the otherwise applicable OPPS payment 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 OPPS payment amounts for them.

We note that in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963), we modified the regulation text at 42 CFR 419.2(b)(15) to specify that only those diagnostic radiopharmaceuticals with per-day costs at or below the per-day

[75] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

[76] In the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948), we finalized the diagnostic radiopharmaceuticals policy to separately pay those products when the per-day costs are greater than a threshold. Please refer to section II.A.3.c. of the CY 2025 OPPS/ASC final rule with comment period for more information regarding this policy.

diagnostic radiopharmaceutical packaging threshold for the applicable year are policy-packaged. Meaning, for those diagnostic radiopharmaceuticals that are below the diagnostic radiopharmaceutical packaging threshold, for purposes of pass-through co-insurance calculations, they are treated like policy-packaged drugs. For those diagnostic radiopharmaceuticals above the diagnostic radiopharmaceutical packaging threshold, they are not packaged, and are not considered policy-packaged; therefore, for purposes of pass-through co-insurance calculations, they are treated like separately payable drugs assigned to an APC. Accordingly, a $0 pass-through payment amount is assigned consistent with our policy described previously in this section for separately payable drugs assigned to an APC.

We will continue our policy to update pass-through payment rates on a quarterly basis on the CMS website during CY2027 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 CY2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2027, consistent with our CY 2026 policy for diagnostic and therapeutic radiopharmaceuticals, we will 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 2027, 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 is generally ASP plus 6 percent. If ASP data are not available for a radiopharmaceutical, we will continue to provide pass-through payment at WAC plus 3 or 6 percent, the equivalent payment provided for pass-through drugs and biologicals without ASP information. Additional detail on the WAC plus 3 or 6 percent payment policy can be found in section V.B.2.a. of this final rule with comment period. If WAC information also is not available, we will continue to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

We refer readers to Table 58 for the list of drugs and biologicals with pass-through payment status expiring during CY 2027 and Table 59 for the list of drugs and biologicals with pass-through payment status continuing through CY 2027. We note that there are 15 additional drugs and biologicals in Table 59 in this final rule with comment period to include the drugs and biologicals approved for pass-through status since the proposed rule with effective dates between July 1, 2026 and October 1, 2026.

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TABLE 58: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING IN CY 2027

CY 2026 HCPCS Code	CY 2027 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J7171	J7171	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
J2267	J2267	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
J3247	J3247	Injection, secukinumab, intravenous, 1 mg	G	0725	04/01/2024	03/31/2027
J3394	J3394	Injection, lovotibeglogene autotemcel, per treatment	G	0748	07/01/2024	06/30/2027
J3393	J3393	Injection, betibeglogene autotemcel, per treatment	G	0746	07/01/2024	06/30/2027
J3263	J3263	Injection, toripalimab-tpzi, 1 mg	G	0745	07/01/2024	06/30/2027
J0911	J0911	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis)	G	0744	07/01/2024	06/30/2027
J7355	J7355	Injection, travoprost, intracameral implant, 1 microgram	G	0749	07/01/2024	06/30/2027
A9506	A9506	Graphite crucible for preparation of technetium Tc 99m-labeled carbon aerosol, each	G	0760	07/01/2024	06/30/2027
J9028	J9028	Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram	G	0767	10/01/2024	09/30/2027
J9345	J9345	Injection, retifanlimab-dlwr, 1 mg	G	9280	10/01/2024	09/30/2027
Q5133	Q5133	Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg	G	0786	10/01/2024	09/30/2027
Q5135	Q5135	Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg	G	0784	10/01/2024	09/30/2027
J9026	J9026	Injection, tarlatamab-dlle, 1 mg	G	0768	10/01/2024	09/30/2027
J9172	J9172	Injection, docetaxel (docivyx), 1 mg	G	0757	10/01/2024	09/30/2027
J9324	J9324	Injection, pemetrexed (pemrydi rtu), 10 mg	G	0782	10/01/2024	09/30/2027
J1434	J1434	Injection, fosaprepitant (focinvez), 1 mg	G	0761	10/01/2024	09/30/2027
J1203	J1203	Injection, cipaglucosidase alfa-atga, 5 mg	G	0737	10/01/2024	09/30/2027
A9615	A9615	Injection, pegulicianine, 1 mg	G	0772	10/01/2024	09/30/2027

J2601	J2601	Injection, vasopressin (baxter), 1 unit	G	0778	01/01/2025	12/31/2027
A9697	A9697	Injection, carboxydextran-coated superparamagnetic iron oxide, per study dose	G	0814	01/01/2025	12/31/2027
J0175	J0175	Injection, donanemab-azbt, 2 mg	G	0765	01/01/2025	12/31/2027
Q5148	Q5148	Injection, filgrastim-txid (nypozi), biosimilar, 1 microgram	G	0811	01/01/2025	12/31/2027
J2468	J2468	Injection, palonosetron hydrochloride (posfrea), 25 micrograms	G	0815	01/01/2025	12/31/2027
J0870	J0870	Injection, imetelstat, 1 mg	G	0813	01/01/2025	12/31/2027
J9329	J9329	Injection, tislelizumab-jsgr, 1mg	G	0816	01/01/2025	12/31/2027

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TABLE 59: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS CONTINUING THROUGH CY 2027

CY 2026 HCPCS Code	CY 2027 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0138	J0138	Injection, acetaminophen 10 mg and ibuprofen 3 mg	G	2075	04/01/2025	03/31/2028
J3300	J3300	Injection, triamcinolone acetonide, preservative-free, 1 mg	G	1253	04/01/2025	03/31/2028
A9611	A9611	Flurpiridaz f 18, diagnostic, 1 millicurie	G	2065	04/01/2025	03/31/2028
Q5147	Q5147	Injection, aflibercept-ayyh (pavblu), biosimilar, 1 mg	G	2068	04/01/2025	03/31/2028
J9072	J9072	Injection, cyclophosphamide (avyxa), 5 mg	G	0719	04/01/2025	03/31/2028
J9292	J9292	Injection, pemetrexed (avyxa), not therapeutically equivalent to j9305, 10 mg	G	2076	04/01/2025	03/31/2028
J9054	J9054	Injection, bortezomib (boruzu), 0.1 mg	G	2066	04/01/2025	03/31/2028
Q2058	Q2058	Obecabtagene autoleucel, up to 400 million cd19 car-positive viable t cells, including leukapheresis	G	2061	04/01/2025	03/31/2028

		and dose preparation procedures, per therapeutic dose				
Q2057	Q2057	Afamitresgene autoleucel up to 10 billion mage-a4 tcr positive t-cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	2067	04/01/2025	03/31/2028
J9276	J9276	Injection, zanidatamab-hrii, 2 mg	G	2062	04/01/2025	03/31/2028
J1326	J1326	Injection, zolbetuximab-clzb, 1 mg	G	2063	04/01/2025	03/31/2028
J7172	J7172	Injection, marstacimab-hncq, subcutaneous, 0.5 mg	G	2064	04/01/2025	03/31/2028
J9174	J9174	Injection, docetaxel (beizray), 1 mg	G	0841	07/01/2025	06/30/2028
J9382	J9382	Injection, zenocutuzumab-zbco, 1 mg	G	0853	07/01/2025	06/30/2028
Q5152	Q5152	Injection, eculizumab-aeeb (bkemv), biosimilar, 2 mg	G	0846	07/01/2025	06/30/2028
J9011	J9011	Injection, datopotamab deruxtecan-dlnk, 1 mg	G	0835	07/01/2025	06/30/2028
J0614	J0614	Injection, treosulfan, 50 mg	G	0837	07/01/2025	06/30/2028
J9249	J9249	Injection, melphalan (apotex), 1 mg	G	0842	07/01/2025	06/30/2028
J9038	J9038	Injection, axatilimab-csfr, 0.1 mg	G	0839	07/01/2025	06/30/2028
J9289	J9289	Injection, nivolumab, 2 mg and hyaluronidase-nvhy	G	0848	07/01/2025	06/30/2028
Q5100	Q5100	Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg	G	0857	07/01/2025	06/30/2028
J9220	J9220	Injection, indigotindisulfonate sodium, 1 mg	G	0821	07/01/2025	06/30/2028
J0458	J0458	Injection, aztreonam/avibactam, 7.5 mg/2.5 mg (10 mg)	G	0878	10/01/2025	09/30/2028
J9256	J9256	Injection, nipocalimab-aahu, 3 mg	G	0893	10/01/2025	09/30/2028

J9326	J9326	Injection, telisotuzumab vedotin-tllv, 1 mg	G	0894	10/01/2025	09/30/2028
J3403	J3403	Revakinagene taroretcel-lwey, per implant	G	0897	10/01/2025	09/30/2028
Q5151	Q5151	Injection, eculizumab-aagh (epysqli), biosimilar, 2 mg	G	0852	10/01/2025	09/30/2028
A9616	A9616	Gallium ga-68 gozetotide (gozellix), diagnostic, 1 millicurie	G	0876	10/01/2025	09/30/2028
J7174	J7174	Injection, fitusiran, 0.04 mg	G	0889	10/01/2025	09/30/2028
Q9998	Q9998	Injection, ustekinumab-aekn (selarsdi), biosimilar, 1 mg	G	0859	10/01/2025	09/30/2028
Q9999	Q9999	Injection, ustekinumab-aauz (otulfi), biosimilar, 1 mg	G	0895	10/01/2025	09/30/2028
J0681	J0681	Injection, ceftobiprole medocaril sodium, 3 mg	G	0879	10/01/2025	09/30/2028
C9307	J9601	Injection, linvoseltamab-gcpt, 1 mg	G	0916	01/01/2026	12/31/2028
C9308	J9278	Injection, carboplatin (avyxa), 1 mg	G	0917	01/01/2026	12/31/2028
J1737	J1737	Injection, meloxicam (azurity), 1 mg	G	0898	01/01/2026	12/31/2028
J9184	J9184	Injection, gemcitabine hydrochloride (avyxa), 200 mg	G	0909	01/01/2026	12/31/2028
J9275	J9275	Injection, cosibelimab-ipdl, 2 mg	G	0915	01/01/2026	12/31/2028
J9282	J9282	Mitomycin, intravesical instillation, 1 mg	G	0913	01/01/2026	12/31/2028
Q5158	Q5158	Injection, denosumab-bnht (bomyntra/conexxence), biosimilar, 1 mg	G	0892	01/01/2026	12/31/2028
Q5160	Q5160	Injection, bevacizumab-nwgd (jobevne), biosimilar, 10 mg	G	0918	01/01/2026	12/31/2028
C9309	J3405	Injection, onasemnogene abeparvovec-brve, per treatment	G	0922	04/01/2026	03/31/2029
J3404	J3404	Injection, zopapogene imadenovec-drba suspension, per therapeutic dose	G	0924	04/01/2026	03/31/2029

J9183	J9183	Gemcitabine intravesical system, 225 mg	G	0926	04/01/2026	03/31/2029
J9277	J9277	Injection, pembrolizumab, 1 mg and berahyaluronidase alfa-pmph	G	0930	04/01/2026	03/31/2029
Q5162	Q5162	Injection, denosumab-nxxp (bildyos/bilprevda), biosimilar, 1 mg	G	0934	04/01/2026	03/31/2029
Q5161	Q5161	Injection, denosumab-kyqq (aukelso/bosaya), biosimilar, 1 mg	G	0951	07/01/2026	06/30/2029
J2789	J2789	Riboflavin 5'-phosphate, ophthalmic solution (epioxahd/epioxa), up to 2 mL	G	0941	07/01/2026	06/30/2029
J2361	J2361	Injection, depemokimab-ulaa, 1 mg	G	0940	07/01/2026	06/30/2029
A9574	A9574	Injection, ferumoxytol, 1 mg	G	0935	07/01/2026	06/30/2029
Q5146	Q5146	Injection, trastuzumab-strf (hercessi), biosimilar, 10 mg	G	0865	07/01/2026	06/30/2029
Q5098	Q5098	Injection, ustekinumab-srlf (imuldosa), biosimilar, 1 mg	G	0952	07/01/2026	06/30/2029
J9062	J9062	Injection, amivantamab 5 mg and hyaluronidase-lpuj	G	0942	07/01/2026	06/30/2029
C9310	J0644	Injection, leucovorin calcium (avyxa), 1 mg	G	0936	07/01/2026	06/30/2029
J1289	J1289	Injection, narsoplimab-wuug, 1 mg	G	0938	07/01/2026	06/30/2029
C9311	C9311	Injection, eplontersen, 1 mg (code may be used for medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	G	0958	10/01/2026	09/30/2029
C9312	C9312	Injection, trabectedin (apotex), not therapeutically equivalent to J9362, 0.01 mg	G	0959	10/01/2026	09/30/2029

J9186	J9186	Injection, etoposide (avyxa), 1 mg	G	0970	10/01/2026	09/30/2029
C9313	C9313	Injection, pivekimab sunirine-pvzy, 0.01 mg	G	0960	10/01/2026	09/30/2029
J9191	J9191	Injection, fluorouracil (avyxa), 10 mg	G	0971	10/01/2026	09/30/2029
A9613	A9613	Piflufolastat F-18 (pylarify truvu), diagnostic, 1 millicurie	G	0962	10/01/2026	09/30/2029

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We welcomed public comments on the status indicator for expiring pass-through drugs and biologicals, in accordance with our existing policies on packaged drugs, biologicals, and radiopharmaceuticals, including the threshold packaging policy.

We received a public comment on these proposals.

Comment: One commenter supported maintaining pass-through status for HCPCS code J7355 through June 30, 2027. In addition, the commenter believed that J7355 should be assigned a K status indicator upon pass-through status expiration effective July 1, 2027 since, per the commenter, the drug does not function as a supply in a surgical procedure and the per-day cost of the drug is significantly above the proposed OPPS drug packaging threshold of $140. The commenter further stated that the drug is provided to the patient through an administration procedure that puts the drug into the body and the current cost is $196.746 per microgram and beneficiaries typically receive a 75-microgram dose.

Response: We thank the commenter for their comment. We appreciate the support regarding proposed continuation of pass-through status for J7355 through June 30, 2027 and will consider the comment when assessing the appropriate status indicator for J7355 after pass-through status expires.

After consideration of public comments, we are finalizing as proposed with the modification of the additional 15 drugs and biologicals in Table 59 approved for pass-through status since the proposed rule.

B. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four-quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment 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 $140 for CY 2026 (90 FR 53698).

Following the CY 2007 methodology, for the CY 2027 OPPS/ASC proposed rule, we proposed to 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 2027 and round the resulting dollar amount ($142.40) to the nearest $5 increment, which yields a figure of $140. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IHS Global, Inc. (IGI). IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast various price indexes including the PPI Pharmaceuticals for Human Use (Prescription). Based on these calculations, we proposed a packaging threshold for CY 2027 of $140 for drugs, biologicals, and therapeutic radiopharmaceuticals. We also proposed that if more recent data subsequently becomes available after the publication of the CY 2027 OPPS/ASC proposed rule, we would use such updated data, if appropriate, to determine the final CY 2027 OPPS drug packaging threshold amount in the CY 2027 OPPS/ASC final rule with comment period.

We finalized in section II.A.3.c. of the CY 2025 OPPS/ASC final rule with comment period (89 FR 94238 through 94241) to pay separately for diagnostic radiopharmaceuticals with a per-day cost above the packaging threshold for CY 2025 of $630. We also finalized 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 IGI. For the diagnostic radiopharmaceutical packaging threshold, we finalized using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 and 68086)) to calculate the update to the OPPS drug packaging threshold. Specifically, we finalized that, starting with the CY 2026 rulemaking cycle, we would use the most recently available four-quarter moving average PPI levels to trend the CY 2025 threshold amount forward from the third quarter of the data year (CY 2024) to the third quarter of the payment year (CY 2025) and

round the resulting dollar amount to the nearest $5 increment. In the CY 2026 OPPS/ASC final rule, we finalized a technical refinement to this policy to use the most recently available four-quarter moving average PPI levels to trend the CY 2025 threshold amount of $630 forward from the third quarter of CY 2025 to the third quarter of the payment year (CY 2026) and round the resulting dollar amount to the nearest $5 increment. We believed using the most recently available forecast of the four-quarter moving average PPI levels more appropriately updates the packaging threshold amount from CY 2025 to the current payment year moving forward. For this final rule with comment period, we proposed to use the most recently available four-quarter moving average PPI levels to trend the final CY 2025 $630 diagnostic radiopharmaceutical packaging threshold forward from the third quarter of CY 2025 to the third quarter of CY 2027 and round the resulting dollar amount ($667.44) to the nearest $5 increment, which yielded a proposed radiopharmaceutical packaging threshold amount of $665 for CY 2027. We also proposed that if more recent data subsequently become available after the publication of the CY 2027 OPPS/ASC proposed rule, we would use such updated data, if appropriate, to determine the final CY 2027 diagnostic radiopharmaceutical packaging threshold amount in the CY 2027 OPPS/ASC final rule with comment period.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported continued use of the PPI methodology for updating the drug and diagnostic radiopharmaceutical packaging threshold. They also noted that the threshold for diagnostic radiopharmaceuticals has moved in a trajectory that appropriately reflects inflation in medical costs and should be maintained. Other commenters supported holding the drug packaging threshold at $140, a level that preserves separate payment for therapeutic radiopharmaceuticals and other high-cost products.

Response: We thank the commenters for their support. We believe using the four-quarter moving average PPI levels for Pharmaceuticals for Human Use, Prescription to adjust the OPPS drug and diagnostic radiopharmaceutical packaging threshold through notice-and-comment rulemaking is a transparent and predictable methodology that has been in use under the OPPS for many years.

Comment: Some commenters did not support continued increases to the drug packaging threshold and recommended maintaining the threshold at $140. These commenters expressed concerns that increases in the threshold may result in additional high-cost drugs being packaged, creating financial concerns. Commenters also recommended that CMS continue to evaluate whether packaging appropriately accounts for high-cost, low-utilization drugs and radiopharmaceuticals. Some commenters recommended establishing separate payment for certain high-cost, low-utilization cancer drugs, similar to the separate payment policy for certain diagnostic radiopharmaceuticals.

Response: We appreciate these perspectives; however, we believe that the PPI update factor provides aggregate changes in the selling prices of pharmaceuticals, which makes it an appropriate factor with which to update the OPPS drug packaging threshold to ensure that as costs change over time, the threshold continues to identify products appropriate for payment packaging, a fundamental principle of a prospective payment system. We also continue to believe that using the four-quarter moving average PPI levels for Pharmaceuticals for Human Use, Prescription to adjust the OPPS drug packaging threshold through notice and comment rulemaking is a transparent and predictable methodology that has been in use under the OPPS for many years. We acknowledge the concern that the threshold may result in additional high-cost drugs being packaged, which could create financial implications for providers. However, for CY 2027, the update to the inflation factor results in a lower final OPPS drug packaging threshold compared to CY 2026. We also appreciate commenters' recommendation to establish separate payment for certain high-cost, low-utilization cancer drugs similar to the policy for certain diagnostic radiopharmaceuticals. We do not believe it is appropriate to extend that policy to other drugs at this time, as the diagnostic radiopharmaceutical policy addresses circumstances specific to those products. We will continue to monitor and evaluate whether current packaging policies appropriately account for high-cost, low-utilization drugs and radiopharmaceuticals. We will take these commenters into consideration for future policy development.

After consideration of public comments, we are finalizing our proposal to 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 2027 and round the resulting dollar amount to the nearest $5 increment for the OPPS drug packaging threshold. We proposed that if more recent data subsequently become available after the publication of the CY 2027 OPPS/ASC proposed rule, we would use such updated data, if appropriate, to determine the final CY 2027 OPPS drug packaging threshold amount in the CY 2027 OPPS/ASC final rule with comment period. Using 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, we trended the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2027 and round the resulting dollar amount ($135.43) to the nearest $5 increment, which yields a figure of $135.

We refer readers to section II.A.3.c.(2). of this final rule with comment period for additional details regarding the diagnostic radiopharmaceutical packaging threshold comment and response discussion. We are finalizing our proposal to update the CY 2026 $655 threshold amount by the four-quarter moving average PPI levels for Pharmaceuticals for Human Use, Prescription to trend the $655 threshold forward. Specifically, we are using the most recently available forecast of the four-quarter moving average PPI levels for Pharmaceutical for Human Use, Prescription from the third quarter of 2025 to the third quarter of 2027, and to round the resulting dollar amount to the nearest $5 increment. We also proposed, and are subsequently finalizing, that if more recent data are subsequently available (for example, a more recent estimate of the PPI for Pharmaceuticals for Human Use, Prescription), we would use such data, if appropriate, to determine the CY 2027 diagnostic radiopharmaceutical packaging threshold in the final rule. Based on this methodology, using the most recent data available for this final rule, we trended the $630 threshold forward and rounded the resulting dollar amount ($634.80) to the nearest $5 increment, which yields a final diagnostic radiopharmaceutical packaging threshold figure of $635 per day for CY 2027.

b. Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Certain Radiopharmaceuticals Under the Cost Thresholds

To determine the proposed CY 2027 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 2025 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2025 claims processed through December 31, 2025, for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d. of this final rule with comment period, or for the following policy-packaged items that we proposed to continue to package in CY 2027: 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. of this final rule with comment period, 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.

To calculate the per-day costs for drugs, biologicals, diagnostic radiopharmaceuticals, and therapeutic radiopharmaceuticals to determine their proposed packaging status for CY 2027, 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 estimated payment rates for CY 2027 using the ASP methodology (ASP plus 6 percent, which is the payment rate we proposed for separately payable drugs and biologicals), as discussed in more detail in section V.A.1. and V.B.2. of the proposed rule and this final rule with comment period to calculate the proposed CY 2027 per-day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2025 (data that were used for payment purposes in the physician's office setting, effective April 1, 2026) to determine the proposed CY 2027 OPPS/ASC per-day costs.

As is our standard methodology, for CY 2027, we proposed to use payment rates based on the ASP data from the fourth quarter of CY 2025 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to the proposed rule (which are available via the internet on the CMS website) because these were the most recent data available for use at the time of development of the CY 2027 OPPS/ASC proposed rule. These data also are the basis for drug payments in the physician's office setting, effective April 1, 2026. Exceptions to our standard methodology include:

- For therapeutic radiopharmaceuticals that do not have pass-through status as of April 1, 2026, 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 final rule with comment period. Instead, we used their arithmetic mean unit cost derived from the CY 2025 hospital claims data to determine their per-day cost.
- For diagnostic radiopharmaceuticals that do not have pass-through status as of April 1, 2026, we used their arithmetic mean unit cost derived from the CY 2025 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 arithmetic mean unit cost reported for the product, consistent with our proposed policy described in section V.B.3. of this final rule with comment period.
- 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 the arithmetic mean unit cost of the items derived from the CY 2025 hospital claims data to determine their per-day cost.

We proposed 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 proposed to package those items with a per-day cost less than or equal to $665 and identify items with a per-day cost greater than $665 as separately payable. Consistent with our past practice (72 FR 667580), we cross-walked historical OPPS claims data from the CY 2025 HCPCS codes that were reported to the CY 2025 HCPCS codes that we displayed in Addendum B to this proposed rule (which is available on the CMS website)[77] for proposed payment in CY 2027.

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 (71 FR 68086; 78 FR75022; 89 FR 94238). 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 (71 FR 68086). 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 the proposed rule, we proposed to use ASP data from the fourth quarter of CY 2025, 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, 2026, along with updated hospital claims data from CY 2025. We note that we also propose to use these data for budget neutrality estimates and impact analyses for the proposed rule.

We proposed that payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B of the CY 2027 OPPS/ASC final rule with comment period would be based on ASP data from the second quarter of CY 2026. These data are the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2026. These payment rates would then be updated in the January 2027 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2027. 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 will calculate their arithmetic mean unit cost from all

[77] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

of the CY 2025 claims data and updated cost report information available for the CY 2027 final rule with comment period to determine their final per-day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and radiopharmaceuticals in the proposed rule may be different from the same drugs' HCPCS codes' packaging status determined based on the data used for the CY 2027 OPPS/ASC final rule with comment period. Under such circumstances, we proposed to continue to follow the established policies initially adopted for the CY 2005 OPPS final rule with comment period (69 FR 65780) in order to more equitably pay for those drugs whose costs fluctuate relative to the proposed CY 2027 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2027. 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 2027 and subsequent years, consistent with our historical practice, we proposed to apply the following policies to those HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were paid separately in CY 2026 and that are proposed for separate payment in CY 2027, and that then have per-day costs equal to or less than the CY 2027 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2027 final rule, would continue to receive separate payment in CY 2027.
- HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were packaged in CY 2026 and that are proposed for separate payment in CY 2027, and that then have per-day costs equal to or less than the CY 2027 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2027 final rule with comment period, would remain packaged in CY 2027.
- HCPCS codes for drugs, biologicals, and radiopharmaceuticals for which we proposed packaged payment in CY 2027 but that then have per-day costs greater than the CY 2027 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2027 final rule, would receive separate payment in CY 2027.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

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 currently 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 with per-day costs at or below the per-day diagnostic radiopharmaceutical packaging threshold for the applicable year, 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, products, excluding skin substitutes, that aid wound healing (§ 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 finalized diagnostic radiopharmaceutical packaging threshold that we discuss in section II.A.3. of this final rule with comment period, contrast agents, stress agents, and some other products. The category described by § 419.2(b)(16) currently includes skin substitutes and some other products. We believe it is important to reiterate that cost consideration is not a factor when determining whether an item is a surgical supply (79 FR 66875).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter suggested CMS should develop a payment policy for drugs that are administered at the time of ophthalmic surgery, that are direct substitutes for postoperative medications, or that have an FDA-approved indication to treat/prevent post-operative issues, such as pain, inflammation, or infection, separately under Medicare Part B.

Response: We thank the commenter for their suggestion. However, we do not believe it is appropriate to establish separate payment for these drugs. Under 42 CFR 419.2, in which 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) are appropriately packaged into the payment for the procedure in which they are used, and thus receive packaged payment. We believe drugs administered at the time of ophthalmic surgery that function as supplies to, and are supportive of, the procedure are consistent with this existing packaging framework, which reflects the fundamental OPPS principle of encouraging efficiency in the furnishing of covered services.

After consideration of public comments, we are finalizing this policy without modification in CY 2027.

d. Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows

hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we proposed to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2027.

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 2025 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 the proposed rule; and, as is our current policy for determining the packaging status of other drugs, we used the arithmetic mean unit cost available from the CY 2025 claims data to make the proposed packaging determinations for them: HCPCS 3471 (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 2027 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 2027 drug packaging threshold of $140 (in which case all HCPCS codes for the same drug or biological would be separately payable). The proposed and final packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2027 is displayed in Table 60.

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TABLE 60: HCPCS CODES TO WHICH THE CY 2027 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2027 HCPCS Code	CY 2027 Long Descriptor	Proposed CY 2027 Status Indicator (SI)	Final CY 2027 Status Indicator (SI)
C9257	Injection, bevacizumab, 0.25 mg	K	K
J9035	Injection, bevacizumab, 10 mg	K	K
J1460	Injection, gamma globulin, intramuscular, 1 cc	K	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N	N
J1644	Injection, heparin sodium, per 1000 units	N	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	E2	E2
J7030	Infusion, normal saline solution, 1000 cc	N	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N	N
J7050	Infusion, normal saline solution, 250 cc	N	N
J7100	Infusion, dextran 40, 500 ml	N	N
J7110	Infusion, dextran 75, 500 ml	E2	E2
J7515	Cyclosporine, oral, 25 mg	N	N
J7502	Cyclosporine, oral, 100 mg	N	N

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We proposed 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 2027 would also apply to diagnostic radiopharmaceuticals. This is because, as with drugs and biologicals, we believe that adopting standard HCPCS code-specific packaging determinations for radiopharmaceutical codes could lead to inappropriate payment incentives for hospitals to report certain

HCPCS codes instead of others. 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 2025 claims data across all the HCPCS codes that describe each distinct diagnostic radiopharmaceutical 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, and now final, CY 2027 diagnostic radiopharmaceutical packaging threshold of $665 (in which case all HCPCS codes for the same diagnostic radiopharmaceutical would be packaged) or greater than the proposed, and now final, CY 2027 diagnostic radiopharmaceutical packaging threshold of $665 (in which case all HCPCS codes for the same diagnostic radiopharmaceutical would be separately payable). We did not receive any public comments on our proposal, and we are finalizing our proposal without modification, and confirm that the final CY 2027 drug packaging threshold will be $135 per day as described in section V.B.1.a. of this final rule with comment period. All parts of the proposal are finalized without modification.

2. Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a ''specified covered outpatient drug'' (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and 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) of the Act. 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.[78]

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 2025.

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

[78] 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.*

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, biologicals, and certain radiopharmaceuticals. 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, biological, or radiopharmaceutical under section 1847A(c)(4) of the Act. When WAC-based pricing is used for a drug, biological, or radiopharmaceutical, but not under section 1847A(c)(4) of the Act, the payment of WAC plus 6 percent would apply. 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, biologicals, and radiopharmaceuticals 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 were listed in Addenda A and B to the proposed rule (available on the CMS website).[79] These addenda provide the proposed CY 2027 payment rates based on the ASP methodology for separately payable nonpass-through drugs, biologicals, and radiopharmaceuticals, with exceptions for certain radiopharmaceuticals previously discussed, and the ASP methodology for pass-through drugs, biologicals, and radiopharmaceuticals. Except for proposed payment rates for certain radiopharmaceuticals, these rates were 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, 2026, or WAC, AWP, or the arithmetic mean unit cost from CY 2025 claims data and updated cost report information available for the proposed rule. For nonpass-through therapeutic radiopharmaceuticals, payment rates were based on ASP data or the arithmetic mean unit cost. We proposed to pay separately at the arithmetic mean unit cost for diagnostic radiopharmaceuticals with per-day costs above the proposed threshold; the payment rates proposed for qualifying diagnostic radiopharmaceuticals are entirely the arithmetic mean unit cost if available (see section II.A.3.c.(3) of this final rule with comment period, regarding payment policy of qualifying diagnostic radiopharmaceuticals). In general, these published proposed payment rates will not be the same as the actual January 2027 payment rates. This is because payment rates for drugs, biologicals, and therapeutic radiopharmaceuticals with ASP information for January 2027 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2026 (July 1, 2026, through September 30, 2026) will be used to set the payment rates that are released for the quarter beginning in January 2027 in December 2026. In addition, in Addenda A and B to the proposed rule, payment rates for drugs, biologicals, and therapeutic radiopharmaceuticals for which there was no ASP, WAC, or AWP information available for April 2026, as well as all separately payable diagnostic radiopharmaceuticals, were based on the arithmetic mean unit cost in the available CY 2025 claims data.

As stated in the proposed rule, if new pricing information becomes available for payment for the quarter beginning in January 2026, 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 had ASP, WAC, or AWP information available for the proposed rule (reflecting April 2026 ASP data) that do not have ASP, WAC, or AWP information available for the quarter beginning in January 2027. These drugs, biologicals and therapeutic radiopharmaceuticals would then be paid based on the arithmetic mean unit cost data derived from CY 2025 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to the final rule were not for January 2027 payment purposes and were only illustrative of the CY 2027 OPPS payment methodology using the most recently available information at the time of issuance of the CY 2027 OPPS/ASC 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 ASP plus a statutorily mandated 6 percent add-on.

In CY 2025, we clarified that only ASP data or, if ASP data are not available, the arithmetic mean unit cost data, would be used to set payment rates for separately payable nonpass-through therapeutic radiopharmaceuticals under the OPPS. For CY 2027, we did not propose any changes to our policies for payment for separately payable therapeutic or diagnostic radiopharmaceuticals.

For CY 2027, we did not propose any additional changes to our policies for payment for separately payable drugs, biologicals, and radiopharmaceuticals. We proposed 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). However, please see additional details in section V.C. of this final rule with comment period.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposals related to the separate payment for separately payable nonpass-through drugs and biologicals under the OPPS. Commenters supported our proposal to continue using mean unit cost (MUC) derived from hospital claims data to determine payment for diagnostic radiopharmaceuticals with per-day costs above the CY 2027 packaging threshold. Commenters supported continuing to use MUC while CMS develops the infrastructure for ASP-based payment. One commenter recommended continuing to use MUC for certain multi-dose and generator-based products for which the commenter stated that an accurate per-dose ASP may be difficult to determine. Another commenter recommended retaining MUC as a supplemental payment reference if CMS transitions to ASP-based payment in the future.

Response: We thank the commenters for their support. We will consider commenters' recommendations regarding the continued use of MUC for certain products as we further develop our ASP reporting framework.

[79] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

Comment: Several commenters opposed continuing to use MUC and recommended that CMS use ASP to determine payment for separately payable diagnostic radiopharmaceuticals when sufficient ASP data are available. Commenters expressed concerns that MUC relies on historical hospital claims data and may not reflect current acquisition costs. Several commenters recommended a product-specific approach under which CMS would use ASP when sufficient data are available and MUC when ASP data are unavailable or insufficient. Commenters also recommended payment at ASP plus 6 percent, consistent with the payment methodology for certain other Part B drugs and biologicals and therapeutic radiopharmaceuticals.

Some commenters opposed packaging payment for high-cost, low-utilization cancer drugs once their pass-through status expires stating that it would reimburse hospitals at less than such drugs' actual cost, pushing patients toward older, less effective treatment options.

Response: We thank the commenters for their feedback. We will consider commenters' recommendations regarding the continued use of MUC for certain products as we further develop our ASP reporting framework. We will take these comments into consideration for future rulemaking, future issuance of sub-regulatory guidance, and future internal process improvements.

After consideration of public comments, we are finalizing, without modification, our proposals to continue our payment policy for separately payable drugs and biologicals subject to the policy finalized in section V.C. of this final rule with comment period.

b. Biosimilar Biological Products

In the CY 2024 OPPS/ASC final rule with comment period, 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 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported continuing the biosimilar packaging exception when the reference product is separately payable, stating that the policy supports biosimilar competition and avoids incentives to use higher-cost products. A commenter recommended expanding the exemption to cover any biosimilar so long as either its reference product or any other biosimilar in the class remains separately paid, stating a narrower exemption could still leave an incentive to shift utilization toward higher-priced products.

Response: We thank the commenters for their support of continuing the biosimilar packaging exception. We continue to believe this policy supports the use of biosimilars as lower-cost alternatives while preserving the incentives for efficiency inherent in the OPPS packaging policy. We continue to believe packaging is an essential component of a prospective payment system and do not support categorically excepting all biosimilars from the threshold packaging policy.

After consideration of public comments, we are finalizing our proposal without modification to continue the exception of biosimilars from the OPPS threshold packaging policy when their reference products are separately paid. For CY 2027, we will pay separately for these biosimilars even if their per-day cost is below the threshold packaging policy when their reference products are separately paid. We also refer readers to our policy finalized in section V.C. of this final rule with comment period for additional information regarding the payment of biosimilars.

c. Invoice Drug Pricing for CY 2027

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94243 to 94244), we finalized 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 arithmetic 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, the 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 expect invoice pricing to be temporary, lasting two to three quarters, for qualified drugs required to report ASP under section 1847A of the Act. For drug products that are not required to report ASP under section 1847A of the Act (for example, radiopharmaceuticals), invoice pricing may be used on a longer-term basis until an arithmetic mean unit cost (MUC) can be calculated. We finalized the invoice pricing policy for drugs to be effective January 1, 2026, with the intent to make technical updates to outpatient hospital claims and to allow providers time to prepare for any operational changes. We noted that the National Uniform Billing Committee (NUBC) created a value code that would allow for the reporting of invoice prices of drugs, biologicals, and radiopharmaceuticals, effective January 2026 for the purpose of this policy. The NUBC value code created is 92 (Drug/Biologic Invoice Cost), with the definition of: ''Invoice Cost of drug/biologic. For use with Revenue Category 0636 when required by federal regulation.'' In the CY 2026 OPPS/ASC final rule with comment period, we finalized a technical clarification to this policy and clarified that CMS will determine whether the drug is not policy packaged; however, the MAC will continue to determine whether the

per-day cost of the drug, biological, therapeutic radiopharmaceutical or diagnostic radiopharmaceutical is above the threshold packaging amount, as applicable (90 FR 53704). We reiterate that the drug or biological invoice cost would be the net acquisition cost minus any rebates, chargebacks, or post-sale concessions. We acknowledge any rebates, chargebacks, or post-sale concessions may not be immediately available after administration of the drug but hospital providers have 12 months from date of service to submit claims for payment and allowing providers to adjust submitted claims when the price concession becomes available.

For CY 2027, we did not propose any additional changes to our invoice pricing policy for payment for separately payable drugs, biologicals, and radiopharmaceuticals. We proposed to continue our payment policy if CMS does not have pricing information (specifically, that ASP, WAC, AWP, and arithmetic mean unit cost information is not available to determine a payment rate), MACs would calculate the payment based on provider invoices.

We received a public comment on these proposals. The following is a summary of the comment we received and our response.

Comment: A commenter supported the use of invoice pricing when ASP, WAC, or AWP data are unavailable, stating that invoice pricing is preferable to assigning nonpayable status to new drugs. The commenter recommended allowing MACs greater flexibility to determine payment using WAC, AWP, or invoice pricing, similar to the physician office setting. The commenter also recommended more frequent updates to Addendum B and requested that CMS make payable status retroactive to a product's launch date once pricing information becomes available.

Response: We thank the commenter for its support of using invoice pricing when ASP, WAC, or AWP data are unavailable. The invoice pricing policy aims to enhance transparency and accuracy in the determination of payment rates for drugs and biologicals when CMS lacks pricing information. Invoice pricing is a sequential fallback, used when ASP, WAC, AWP, and MUC information are unavailable. This is intended to ensure a consistent, predictable basis for invoice-based payment. Furthermore, invoice pricing eliminates the need for retroactive payable-status changes because the product can be payable from the outset, consistent with the policy's purpose of providing a payment rate while CMS awaits sufficient pricing data. We will continue to evaluate our payment processes for new drugs and biologicals as additional pricing information becomes available. Additionally, we appreciate the commenter's recommendations regarding the frequency of payment updates, and this will be taken into consideration as we continue to work to improve our payment operations.

After consideration of the public comments, we are implementing this policy without modification in CY 2027. We refer readers to the previous discussion when we finalized the policy in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94243 to 94244).

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 2027.

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 final rule with comment period will continue to apply for CY 2027. 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 arithmetic 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 2027. 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.

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 2025 arithmetic 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 CY 2027 payment rates for separately payable nonpass-through therapeutic radiopharmaceuticals are included in Addenda A and B of this final rule with comment period (which are available on the CMS website).[80]

Though we made no proposal regarding payment for therapeutic radiopharmaceuticals, we received public comments that were generally in support of these policies. We thank the commenters for their support. We are continuing our policies unchanged for CY 2027 subject to the policy finalized in section V.C. of this final rule with comment period.

b. Payment Policy for Diagnostic Radiopharmaceuticals Without Claims Data

For CY 2025, we finalized, as described in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963), to pay separately at arithmetic mean unit cost for diagnostic radiopharmaceuticals with a per-day cost above our diagnostic radiopharmaceutical packaging threshold (proposed at $665 for CY 2027). We also finalized our policy to pay for pass-through diagnostic radiopharmaceuticals based on ASP, WAC, and AWP.

We continue to believe that paying for nonpass-through diagnostic radiopharmaceuticals using the arithmetic mean unit cost would appropriately pay for the average price of a nonpass-through separately payable diagnostic radiopharmaceutical, as discussed in section II.A.3.c. of this final rule with comment period. In our view, the arithmetic MUC is an

[80] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

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, in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963), we finalized a proposal 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. To further clarify, these products will be paid based on ASP plus 6 percent, and at WAC plus 3 or 6 percent according to the policy in section V.B.2.a. of this final rule with comment period if ASP data are not available.

If the WAC also is unavailable, we proposed 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, WAC, or AWP until an arithmetic MUC is established for new diagnostic radiopharmaceuticals with HCPCS codes that do not have pass-through status or claims data.

Please refer to section II.A.3.c. of this final rule with comment period for information regarding our broader payment policies for diagnostic radiopharmaceuticals, including our policy to pay for separately payable diagnostic radiopharmaceuticals with claims data based on the arithmetic mean unit cost data derived from hospital claims, and a list of the qualifying diagnostic radiopharmaceuticals for CY 2027 in Tables 6 and 7 of this final rule with comment period. The proposed CY 2027 payment rates for separately payable nonpass-through diagnostic radiopharmaceuticals are included in Addenda A and B of the proposed rule. The CY 2027 final rule payment rates are included in Addenda A and B of this final rule with comment period (which are available on the CMS website).[81]

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported our proposed payment methodology for separately payable diagnostic radiopharmaceuticals without sufficient claims data. Commenters stated that the proposed methodology provides a market-based payment approach when hospital claims data are not available.

Response: We thank the commenters for their support.

Based on the comments received, we are continuing our policies unchanged for CY 2027 subject to the policy finalized in section V.C. of this final rule with comment period.

4. Payment for Blood Clotting Factors

For CY 2027, we proposed 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, authorized under section 1842(o)(5) of the Act. 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 CPI for medical care for the 12-month period ending with June of the previous year. The updated CY 2027 furnishing fee calculation based on that figure through the applicable program instructions will be posted on the CMS website at *https://www.cms.gov/medicare/payment/part-b-drugs/asp-billing-resources.*

We received a public comment on these proposals. The following is a summary of the comment we received and our response.

Comment: The commenter supported our proposal to continue to provide payment for the 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.

Response: We thank the commenter for their support of our policy.

After consideration of public comments, we are finalizing our proposal without modification to pay for clotting factors using the same methodology as other separately payable drugs and biologicals under the OPPS, subject to the policy finalized in section V.C. of this final rule with comment period, and to provide a clotting factor furnishing fee. For CY 2027, the blood clotting factor furnishing fee is $0.270. The actual percentage change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions are posted on the CMS website.[82]

5. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes but Without OPPS Hospital Claims Data

In the CY 2023 OPPS/ASC final rule with comment period, we adopted as final our proposal to continue our longstanding payment policy for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data for CY 2023 and subsequent years. Therefore, for CY 2027, 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, drugs, biologicals, therapeutic radiopharmaceuticals, and diagnostic radiopharmaceuticals, 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 payment rate for the product, typically the ASP methodology, to determine whether their payment will be packaged as well as their payment status indicators.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

[81] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

[82] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price.*

6. CY 2027 Prospective Adjustment to Payments for Non-Drug Items and Services To Offset the Increased Payments for Non-Drug Items and Services Made in CY 2018 Through CY 2022 as a Result of the 340B Payment Policy

a. Overview

Under the OPPS, we generally set payment rates for separately payable drugs and biologicals (hereinafter referred to collectively as ''drugs'' in this section) under section 1833(t)(14)(A) of the Act. Section 1833(t)(14)(A)(iii)(II) of the Act provides that, if hospital acquisition cost data are not available, the payment amount is the average price for the drug in a year established under sections 1842(o), 1847A, or 1847B of the Act, as the case may be. Payment rates for drugs have usually been established under section 1847A of the Act, which generally sets a default rate of the average sales price (ASP) plus 6 percent. Section 1833(t)(14)(A)(iii)(II) of the Act also provides that the average price for the drug in the year as established under section 1847A of the Act, is calculated and adjusted by the Secretary as necessary for purposes of paragraph (14).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371), CMS reexamined the appropriateness of paying the ASP plus 6 percent for drugs acquired through the 340B Drug Pricing Program (hereinafter referred to as the ''340B Program''), a Health Resources and Services Administration (HRSA)-administered program that allows covered entities to purchase certain covered outpatient drugs at discounted prices from drug manufacturers. Based on findings of the Government Accountability Office (GAO),[83] the HHS Office of the Inspector General (OIG),[84] and the Medicare Payment Advisory Commission (MedPAC) [85] that 340B hospitals were acquiring drugs at a significant discount under the 340B Program, CMS adopted a policy beginning in 2018 generally to pay an adjusted amount of ASP minus 22.5 percent for certain separately payable drugs or biologicals acquired through the 340B Program. This adjustment amount was based on our concurrence at the time with an analysis by MedPAC that concluded that the estimated average minimum discount of 22.5 percent of ASP adequately represented the average minimum discount that a 340B participating hospital received for separately payable drugs under the OPPS (82 FR 59354 through 59371). Our intent in implementing this payment adjustment was to reflect more accurately the actual costs incurred by participating hospitals in acquiring 340B drugs. We stated our belief that such changes would allow Medicare beneficiaries and the Medicare program to pay a more appropriate amount when hospitals participating in the 340B Program furnished drugs to Medicare beneficiaries that were purchased under the 340B Program (82 FR 59353 through 59371).

b. Payment for 340B Drugs and Biologicals in CYs 2018 Through 2022

From January 1, 2018 through September 27, 2022, under the OPPS we generally paid for certain separately payable drugs acquired through the 340B Program at ASP minus 22.5 percent. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), we finalized our proposal to adjust the payment rate for separately payable drugs (other than drugs with pass-through payment status and vaccines) acquired under the 340B Program from ASP plus 6 percent to ASP minus 22.5 percent. For ease of reference, the OPPS 340B drug payment adjustment policy is hereinafter referred to as the ''340B Payment Policy'' and refers both to the adjustments made to payment rates for 340B-acquired drugs described here and the corresponding rate adjustment for non-drug services and items described later in section V.B.6.c. of this final rule with comment period. We note that rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals were exempted from the adjustments made to payment rates for 340B-acquired drugs primarily due to these hospitals receiving special payment adjustments under the OPPS. In addition, as stated in the CY 2018 OPPS/ASC final rule with comment period, this policy change did not apply to drugs with pass-through payment status, which are required to be paid based on the ASP methodology, or vaccines, which were excluded from the 340B Program. We also noted that critical access hospitals are not paid under the OPPS and therefore were not subject to the 340B Payment Policy. Finally, in CY 2018, we did not initially apply the 340B Payment Policy to 340B-acquired drugs furnished in non-excepted off-campus provider-based departments (PBDs).

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58981), we continued the Medicare 340B payment policies that were implemented in CY 2018 and made a series of refinements to the 340B Payment Policy, including a policy to pay for nonpass-through 340B-acquired biosimilars at ASP minus 22.5 percent of the biosimilar's ASP, rather than minus 22.5 percent of the reference biological product's ASP. Additionally, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022), we finalized a policy to pay ASP minus 22.5 percent for 340B-acquired drugs furnished in non-excepted off-campus PBDs paid under the PFS. We adopted this payment policy for CY 2019 and subsequent years.

During the CY 2019 OPPS/ASC rulemaking cycle, we also clarified that the 340B payment adjustment applied to drugs priced using either wholesale acquisition cost (WAC) or average wholesale price (AWP), and since the policy was first adopted, we applied the 340B payment adjustment to 340B-acquired drugs priced using these pricing methodologies. We made this clarification because inquiries from interested parties following the finalization of the 340B Payment Policy in 2018 demonstrated that there was confusion as to whether drugs receiving WAC or AWP pricing were subject to the 340B payment adjustment (83 FR 33632). WAC is the drug manufacturer's list price for wholesalers or direct purchasers in the U.S., not including prompt payment or other discounts, rebates, or reductions in price, for the most recent month for which information is available, as reported in wholesale price guides or other publications of drug pricing data. AWP is set using industry-recognized AWP reference sources.[86] The 340B payment adjustment for WAC-priced drugs was WAC minus 22.5 percent. 340B-acquired drugs that were priced using AWP were paid an adjusted amount of 69.46 percent of AWP (83 FR 37125).[87]

[83] Government Accountability Office. ''Medicare Part B Drugs: ''Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals.'' June 2015. Available at *https://www.gao.gov/assets/gao-15-442.pdf.*

[84] Office of Inspector General. ''Part B Payment for 340B Purchased Drugs. OEI–12–14–00030''. November 2015. Available at *https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf.*

[85] Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at *https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program-pdf/.*

[86] *www.cms.gov/files/document/part-b-drug-payment-limits-overview.pdf.*

[87] The 69.46 percent of AWP was calculated by first dividing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup. Then we applied the 22.5 percent reduction to ASP/WAC-

As discussed further in section V.B.6.f. of this final rule with comment period, the results of this policy meant that hospitals received an estimated $10.6 billion less in 340B drug payments (including money that would have been paid by Medicare and money that would have come from beneficiaries as copayments) than they would have for drugs provided in CY 2018 through September 27th of 2022 had the 340B Payment Policy not been implemented (88 FR 77162). These reduced payments are detailed in Table 61 and are derived from Addendum AAA [88] published with the Final Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022 final rule with comment period (hereinafter referred to as the ''Final Remedy rule'') (88 FR 77150).

TABLE 61: APPROXIMATE IMPACT IN REDUCED OPPS PAYMENT FOR 340B-ACQUIRED DRUGS 2018 THROUGH 2022

	2018	2019	2020	2021	2022
Approximate Reduced OPPS Drug Payment (including beneficiary cost sharing) (billions)	$1.9	$2.2	$2.3	$2.4	$1.8*
*Amount January 1 to September 27, 2022. Reduced payments under the 340B Payment Policy were not in effect after September 27, 2022.					

For more detailed descriptions of our OPPS payment policy for drugs acquired under the 340B Program during this timeframe, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371); the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022); the CY 2020 OPPS/ASC final rule with comment period (84 FR 61321 through 61327); the CY 2021 OPPS/ASC final rule with comment period (85 FR 86042 through 86055); the CY 2022 OPPS/ASC final rule with comment period (86 FR 63640 through 63649); the CY 2023 OPPS/ASC final rule with comment period (87 FR 71972 through 71973); the CY 2024 OPPS/ASC final rule with comment period (88 FR 81789 through 81792); and the CY 2026 OPPS/ASC final rule with comment period (90 FR 53707 through 53722).

c. Payment for Non-Drug Items and Services in CY 2018 Through CY 2022

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59216, 59258), to comply with the statutory budget neutrality requirements under sections 1833(t)(9)(B) and (t)(14)(H) of the Act, we finalized our proposal to redistribute our original, estimated reduction in payments for separately payable drugs as a result of the 340B Payment Policy by increasing the conversion factor used to determine the payment amounts for non-drug items and services. As further described in the CY 2018 OPPS/ASC final rule with comment period, we used updated CY 2016 claims data and a list of 340B-eligible providers to calculate an estimated impact of $1.6 billion based on the final CY 2018 policy to pay for OPPS 340B-acquired drugs at a payment rate of generally ASP minus 22.5 percent. To effectuate the budget neutrality provisions of the OPPS for CY 2018, we redistributed an estimated $1.6 billion in reduced drug payments from adoption of the final 340B payment methodology to all hospitals paid under the OPPS by increasing the payment rates by 3.19 percent for nondrug items and services furnished by all hospitals paid under the OPPS for CY 2018. We carried through this conversion factor adjustment from CYs 2019 through 2022, increasing payments for non-drug items and services in these CYs. This resulted in approximately $7.769 billion, which for ease of reference in this final rule with comment period we hereafter refer to as $7.8 billion, in additional spending on non-drug items and services from CYs 2018 through 2022.

d. Litigation History of the 340B Payment Policy

The 340B Payment Policy was the subject of significant litigation. See the Proposed Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022 (hereinafter referred to as the ''proposed remedy rule'') for a more comprehensive summary of the litigation history (88 FR 44079 through 44080).

On June 15, 2022, the Supreme Court held that because HHS had not previously conducted a survey of hospitals' acquisition costs, we could not vary the payment rates for outpatient prescription drugs by hospital group. *See Am. Hosp. Ass'n* v. *Becerra,* 596 U.S. 724, 739 (2022). The Supreme Court declined to opine on the appropriate remedy, *see id.,* and on September 28, 2022, the district court vacated the prospective portion of the CY 2022 reimbursement rate for 340B-acquired drugs, *see Am. Hosp. Ass'n* v. *Becerra,* No. 1:18–cv–2084–RC, 2022 WL 4534617, at *5 (D.D.C.).[89] On January 10, 2023, the district court remanded without vacatur to give the agency the opportunity to determine the proper remedy for the reduced payment amounts to 340B hospitals under the payment rates in the final OPPS rules for CY 2018 through CY 2022. *See Am. Hosp. Ass'n* v. *Becerra,* No. 1:18-cv-2084-RC, 2023 WL 143337, at *6 (D.D.C.).[90]

e. Payment for 340B-Acquired Drug Claims for September 28, 2022 Through CY 2026

The agency complied with the district court's September 28, 2022 decision by uploading revised OPPS drug files to pay the default rate (generally ASP plus

similar AWP value to obtain the 69.46 percent of AWP, which was similar to either ASP minus 22.5 percent or WAC minus 22.5 percent.

[88] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1793-f.*

[89] *https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-79.*

[90] *https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-86.*

6 percent) for all CY 2022 claims for 340B-acquired drugs paid from September 28, 2022, through the end of CY 2022.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71970), we finalized a policy reversing the 340B Payment Policy so that going forward we would pay for 340B-acquired drugs no differently than we pay for drugs that are not acquired through the 340B Program. To do so, we first provided that drugs acquired through the 340B Program would be paid at the statutory default rate (generally ASP plus 6 percent) for CY 2023. Second, to ensure budget neutrality for CY 2023 OPPS payment rates as required by statute, we finalized a reduction of 3.09 percent to the 2023 OPPS conversion factor. This one-time adjustment to the conversion factor removed the effect of this aspect of the 340B Payment Policy, as originally adopted in CY 2018, for CY 2023 and subsequent years. This adjustment reduced the conversion factor to the conversion factor that would have been in place in CY 2023 if the 340B Payment Policy had never been implemented. For more detail on the payment rate for drugs acquired under the 340B Program for CY 2023 and the corresponding adjustment to the conversion factor to maintain budget neutrality as a result of reversing the 340B adjustment and paying for all separately payable drugs at ASP plus 6 percent (or WAC plus 3 or 6 percent or 95 percent of AWP), we refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71973 through 71976).

For CYs 2024 through 2026, consistent with our policy finalized for CY 2023, we continued to pay the statutory default rate for 340B-acquired drugs (88 FR 81789 through 81791).

f. Remedy Payment Adjustment for 340B-Acquired Drugs From CY 2018 Through September 27, 2022

The agency complied with the district court's January 10, 2023, remand order by issuing the Final Remedy rule on November 8, 2023 (88 FR 81540). The purpose of this rule was to address the reduced payment amounts to 340B hospitals under the reimbursement rates in effect for CY 2018 through September 27, 2022 and to comply with the statutory requirement to maintain budget neutrality under the OPPS.

To address the reduced payment amounts to 340B hospitals under the reimbursement rates in effect for CY 2018 through September 27, 2022, CMS made one-time lump sum payments to affected 340B covered entity hospitals, calculated as the difference between what an affected 340B covered entity hospital received for 340B-acquired drugs from CY 2018 through September 27, 2022 and what they would have received for those drugs if the 340B adjustment had not been in place. These one-time lump sum payments were issued in early 2024. For more information on the calculation and distribution of the one-time lump sum payments, see the Final Remedy rule (88 FR 77156 through 77170).

g. Prospective Adjustment to Payments for Non-Drug Items and Services To Offset the Increased Payments for Non-Drug Items and Services Made in CY 2018 Through CY 2022

As we described under section I.A.3. of the Final Remedy rule (88 FR 77151), to comply with statutory budget neutrality requirements, the decreased payments made to 340B hospitals for drugs in CY 2018 through September 27, 2022, were budget neutralized by corresponding increased payments to all hospitals for non-drug items and services starting in CY 2018 through CY 2022. When the past payments for these drugs were subsequently increased through the one-time lump sum payments in 2024, the same budget neutrality requirements obligated us to decrease the non-drug item and services payments made from CY 2018 through CY 2022.

To reduce the burden on providers of immediately offsetting the estimated $7.8 billion of increased non-drug item and services payments made from CY 2018 through CY 2022, we finalized a policy to implement the offset prospectively over the course of several years. As we explained in the Final Remedy rule (88 FR 77172), this approach was similar to the original budget neutrality adjustment in the 340B Payment Policy that increased the payment for every non-drug item and service for CY 2018 through CY 2022 to offset the downward adjustment in the payment rate for drugs acquired under the 340B Program. We finalized in the Final Remedy rule that, beginning in CY 2026, we would reduce the conversion factor for non-drug items and services to all OPPS providers—except any hospital that enrolled in Medicare after January 1, 2018 (as described further in this section of the preamble)—by 0.5 percent each year until the total offset was reached (which we estimated would take approximately 16 years (88 FR 77181)).

As we stated in the Final Remedy rule, we believed an annual reduction in the conversion factor was appropriate because it balanced the need to address the past payments for non-drug items and services to ensure budget neutrality while also ensuring that the offset was not immediately financially burdensome on impacted entities, which we believed would be the case if we were to apply an adjustment for the full offset amount in a single year (88 FR 77170).

Accordingly, the Final Remedy rule finalized changes to the calculation of the OPPS conversion factor applicable to non-drug items and services beginning in CY 2026. Specifically, we codified a 0.5 percent reduction in the OPPS conversion factor applicable to non-drug items and services in the regulations as codified at § 419.32(b)(1)(iv)(B)(*12*). As currently implemented, this 0.5 percent reduction remains in effect until the estimated payment reduction reaches $7.8 billion, which we estimated will occur in CY 2041. For a full discussion of the CY 2026 adjustment to the conversion factor for non-drug items and services, see the Final Remedy rule (88 FR 77156 through 77170).

In finalizing our policy to apply a prospective adjustment, we recognized that any hospital that enrolled in Medicare after January 1, 2018 (hereinafter referred to as a ''new provider'') received less than the full amount of the increased non-drug item and service payments made during that time than they otherwise would have received if enrolled prior to that date (88 FR 44080). We therefore exempted these providers from the prospective rate reduction, which was predominantly designed to account for non-drug item and service payments made during CY 2018 through CY 2022. As we explained, that means we calculate payment rates for new providers using the conversion factor before applying the 0.5 percent annual reduction to the conversion factor for non-drug items and services that apply to hospitals that are not ''new providers'' for purposes of this policy. For the purpose of designating a new provider, we define the date of enrollment in Medicare as the provider's CMS certification number (CCN) effective date. We codified the exclusion of these new providers from the prospective payment adjustment to the conversion factor for the duration of its application in the regulations by adding new paragraph (b)(1)(iv)(B)(*12*) to § 419.32.

The providers that were determined to be subject to the payment reduction based on our review of provider enrollment and OPPS billing records were listed in Addendum R—340B Remedy Offset Providers to the CY 2026 OPPS/ASC final rule with comment period. We indicated in the CY 2026

OPPS/ASC final rule with comment period that providers not included on this list (providers that began billing Medicare under the OPPS after January 1, 2018) would not be subject to the payment reduction. For a complete discussion of our exclusion of new providers from the prospective payment adjustment, we refer readers to the Final Remedy rule (88 FR 77182 through 77185) and the CY 2026 final OPPS/ASC rule with comment period (90 FR 53709 through 53710).

h. CY 2026 Prospective Payment Adjustment

In the CY 2026 OPPS/ASC proposed rule, we proposed to revise the annual reduction to the OPPS conversion factor under § 419.32(b)(1)(iv)(B)(*12*) used to determine the payment amounts for non-drug items and services from 0.5 to 2 percent effective January 1, 2026 (90 33634). Under this revised rate, we expected it would take approximately 6 years to reach the total offset of $7.8 billion. As we explained in the CY 2026 OPPS/ASC proposed rule, while we continued to believe that a reduction to the OPPS conversion factor was the best way to effectuate budget neutrality, we questioned whether a 0.5 percentage point annual reduction for approximately 16 years best achieved the goal of the Final Remedy rule, which was to restore hospitals to as close to the financial position they would have been in had the 340B Payment Policy never been implemented as is reasonably feasible. Specifically, we noted that the further away from CY 2018 through CY 2022 the conversion factor adjustments extend, the less likely it is that hospitals' relative utilization patterns of non-drug items and services would align with the relative utilization patterns of non-drug items and services from CY 2018 through CY 2022.

Because applying an annual reduction to the conversion factor for all non-drug items and services does not directly identify and recoup the specific amount owed by each hospital, but rather seeks to recoup the aggregate increased payments made to all hospitals for non-drug items and services starting in CY 2018 through CY 2022, it is important to apply the annual reduction to the OPPS conversion factor to the payment for non-drug items and services furnished during calendar years in which hospitals' utilization patterns for such non-drug items and services most closely resemble their utilization patterns during CYs 2018 through 2022. Doing so helps to ensure that each hospital repays an amount that best approximates the excess payments it received under the 340B Payment Policy.

We explained in the CY 2026 OPPS/ASC proposed rule (90 FR 53710) that a hospital's utilization of non-drug items and services would likely diverge more from CY 2018 utilization in CY 2041 than it would in CY 2031 or CY 2026. The longer the recovery timeframe, the more each hospital's utilization of non-drug items and services will likely diverge from what the hospital's utilization of non-drug items and services was during the 2018–2022 timeframe the 340B Payment Policy was in place. Consequently, under the current recovery timeframe, the cumulative reduction applied to each hospital is less likely to reflect the amount of payment the hospital received for increased non-drug services from 2018 through 2022. As a result, it is less likely that each hospital will be restored to the financial position it would have occupied had the 340B Payment Policy in effect from 2018 to 2022 not been implemented.

Another factor that caused us to question the appropriateness of a 16-year recovery timeframe was the fact that by beginning the decrease to non-drug item and service payments in CY 2026, there was already an 8-year delay between the first year of the OPPS 340B Payment Policy and the first year of the prospective offset. (90 FR 53710). Thus, we observed, the longer it takes for us to fully recover the $7.8 billion, the less suited the relative burden on hospitals from the adjustments would be to the relevant benefits those hospitals previously received. We also recognized the possibility that at least some hospitals that benefited from the increased payments from CY 2018 through CY 2022 would leave the market before 2041, increasing the risk that the remaining hospitals might ultimately account for a larger share of the payment reductions than they would have if the annual reduction to the OPPS conversion factor concluded sooner. We additionally noted that the $7.8 billion dollar figure calculated in the Final Remedy rule (88 FR 77150) does not, and will not, account for inflation and does not contain interest even though the prospective offset is occurring many years after both the start of the 340B Payment Policy in CY 2018 as well as the lump sum remedy payments made in CY 2024.

We acknowledged in the CY 2026 OPPS/ASC proposed rule (90 FR 33635) that revising the annual reduction from 0.5 percent to 2 percent would be a change to the approach we finalized in the Final Remedy rule and that, at the time of the Final Remedy rule, we considered but did not adopt a suggestion from a commenter requesting that we recover the amount over a shorter timeframe than 16 years (88 FR 77179). We indicated that our basis for not accepting the suggestion in the Final Remedy rule was that the 0.5 percent rate/16-year timeframe ''properly reverses the increased payments for non-drug items and services to comply with statutory budget neutrality requirements while at the same time accounting for any reliance interests and ensuring that the offset is not overly burdensome to impacted entities'' (90 FR 33635). We stated in the CY 2026 OPPS/ASC proposed rule that this balancing insufficiently accounted for the main premise of the Final Remedy rule, which is to implement the budget neutrality requirement in a manner that restores affected 340B covered entity hospitals to the financial position they would have been in had the 340B Payment Policy not been implemented in 2018. We explained that, for the reasons described previously, we believed that a 6-year time frame better achieved that main goal and better balanced that goal and our budget neutrality obligations against hospital burden and reliance interests. We noted that the 16-year timeframe was more than three times longer than the 5-year period the 340B Payment Policy was in place. The 6 years we expected that the revised policy would be in effect, by contrast, would be closer to the timeframe the 340B Payment Policy was in place, and that a 2 percent payment reduction was still well below the 3.19 percent payment increase hospitals received for that time period (82 FR 52624 through 52625). We also indicated that because we proposed this policy in advance of CY 2026 and before any rate reductions went into effect for OPPS and Medicare Fee for Service payments, any reliance interests hospitals had in a policy that had not been implemented yet for these payment systems would be minimal and outweighed by the other considerations discussed in the CY 2026 OPPS/ASC proposed rule (90 FR 33635).

We did not finalize our proposal to revise the annual reduction to the OPPS conversion factor under § 419.32(b)(1)(iv)(B)(*12*) in the CY 2026 OPPS/ASC final rule and the 0.5 percent reduction in the OPPS conversion factor applicable to non-drug items and services finalized in the Final Remedy rule went into effect on January 1, 2026. The decision not to finalize an increased reduction for CY 2026 was made in response to concerns brought forth by some commenters. Specifically, we said

''[w]hile we disagree with many of the arguments these commenters raise, we are persuaded by the commenters to the extent that we will not finalize in CY 2026 our proposal to increase to 2 percent the 0.5 percent adjustment in 42 CFR 419.32(b)(1)(iv)(B)(*12*). We currently anticipate delaying a change for just 1 year. Thus, while we will retain the original 0.5 percent adjustment in the conversion factor in CY 2026, hospitals should anticipate that we will implement a larger adjustment (such as 2 percent or other adjustment greater than 0.5 percent) beginning in CY 2027. . . . [¶] We do so based on the unique circumstances here.'' (90 FR 53714).

i. CY 2027 Proposed Prospective Payment Adjustment

Effective January 1, 2027, we proposed to increase the annual reduction to the OPPS conversion factor under § 419.32(b)(1)(iv)(B)(*12*) used to determine the payment amounts for non-drug items and services from 0.5 percent to 3 percent. Specifically, we proposed to revise § 419.32(b)(1)(iv)(B)(*12*) to limit the 0.5 percent reduction to CY 2026 and add a new paragraph (*13*) implementing an annual 3.0 percent reduction (excluding new providers with a CCN effective date of January 2, 2018, or later) starting in CY 2027 and continuing until the estimated payment reductions made in accordance with paragraphs (*12*) and (*13*) for all applicable hospital outpatient items and service reaches $7.769 billion. Under this revised rate, we stated that we expected that we would reach this total by the end of CY 2029 (see Table 62). We acknowledged that this proposed annual reduction was greater than the 2 percent annual reduction we originally proposed for CY 2026. We stated that we considered the following in establishing this proposal:

First, we explained that a 3 percent reduction was necessary to achieve the outcome for which we originally proposed the 2 percent annual reduction in CY 2026. That is, to implement the budget neutrality requirement in a manner that restores affected 340B covered entity hospitals to the financial position they would have been in had the 340B Payment Policy not been implemented in 2018. By recovering the funds during a timeframe that aligns with the period in which the funds were originally paid out and applying the reduction in calendar years for which a hospital's utilization of non-drug items and services is more likely to align with its utilization during the period when the 340B Payment Policy was in effect, CMS will better ensure that the reduction in payments to each hospital approximates the amount by which that hospital was overpaid. We stated that a total recoupment timeframe of roughly 6 years after the 340B remedy payments were made in CY 2024 would more closely align with the 5-year timeframe the 340B Payment Policy was in place, as compared to the 8 years from CY 2024 that we estimated a 2 percent recoupment would require (see Table 62). Based on our analysis, we explained that we believed that, as additional time elapses following the period during which the 340B Payment Policy was in effect, hospitals' utilization of non-drug items and services would be increasingly likely to diverge from their utilization patterns during that period. We further explained that since CMS is recouping the increased payments made for nondrug items and services while the 340B Payment Policy was effective by applying a reduced conversion factor to non-drug items and services furnished during the calendar years following the 340B Payment Policy's end date, the farther out these reductions apply, the less likely it would be that the total recoupment for each hospital would align with the amount each hospital was overpaid. For example, if a hospital's utilization rate of non-drug items and services is three times greater in 2030 than it was in 2020, then a reduced conversion factor applied to the non-drug items and services furnished in 2030 could result in CMS recouping more than what the hospital was initially paid in 2020. Consequently, it is less likely that the hospital would be restored to the financial position they would have been in had the 340B Payment Policy never been in effect. A total recoupment timeframe of 6 years would recover the funds in a manner that limits this divergence in utilization while avoiding the burden on providers that would result from a shorter recovery timeframe.

Second, we explained that a 3 percent payment reduction was the most logical and appropriate percentage to apply as it closely approximates the 3.19 percent payment increase hospitals received for non-drug items and services from CYs 2018 through 2022 to budget neutralize the reduced drug payments resulting from the 340B Payment Policy. We noted that this approach was also consistent with the approach we adopted in CY 2023 (87 FR 71975) to maintain budget neutrality when we returned to our policy of paying ASP plus 6 percent for 340B-acquired drugs.

With respect to implementing a 3 percent reduction in CY 2027 versus delaying implementation until a later CY to provide hospitals with additional time to prepare, we indicated that we had determined that implementing this payment reduction starting CY 2027 would be appropriate. We noted that we had repeatedly emphasized that shorter recoupment windows would be considered and/or proposed in CY 2027. We indicated that in the CY 2026/ASC final rule with comment period, we expressly stated ''hospitals should anticipate that we will implement a larger adjustment (such as 2 percent or other adjustment greater than 0.5 percent) beginning in CY 2027'' (90 FR 53714) and that elsewhere in that rule we stated that ''we anticipate implementing a larger adjustment (such as 2 percent or other adjustment greater than 0.5 percent) in next year's rulemaking'' (90 FR 53718). We also noted that we communicated this same message in the Medicare Fact Sheets and Press Releases for the CY 2026 OPPS/ASC final rule with comment period to ensure that hospitals were aware of the likely increase in the offset percentage in CY 2027.[91] Because hospitals had been aware that we would likely propose an increased payment reduction in CY 2027 rulemaking, we stated that we did not believe hospitals needed additional time to prepare for the proposed repayment schedule.

We sought comment on our proposal to increase the annual percent reduction to 3 percent. We also sought comment on the advisability of increasing the annual percent reduction to 2 percent.

[91] *https://www.cms.gov/newsroom/fact-sheets/calendar-year-2026-hospital-outpatient-prospective-payment-system-opps-ambulatory-surgical-center.*

TABLE 62: ILLUSTRATION OF THE PROPOSED 3 PERCENT AND ALTERNATIVE 2 PERCENT CONVERSION FACTOR ANNUAL REDUCTION TO THE OPPS NON-DRUG ITEMS AND SERVICES BEGINNING CY 2027 TO MAINTAIN BUDGET NEUTRALITY IN THE CY 2027 OPPS/ASC PROPOSED RULE

	CY 2024	CY 2025	CY 2026	CY 2027	CY 2028	CY 2029	CY 2030	CY 2031
Total Applicable OPPS Non-Drug Item and Service Spending (billions)	Remedy Payments Made in Q1 of CY 2024	No Remedy Offset Applied	67.5	77.0	83.6	90.6	97.7	105.1
			Alternative 2 Percent Payment Reduction					
Amount (millions)			300	1,500	1,700	1,800	2,000	500*
Estimated Total Cumulative Offset (millions)			300	1,800	3,500	5,300	7,300	7,769
			Proposed 3 Percent Payment Reduction					
Amount (millions)			300	2,300	2,500	2,700*		
Estimated Total Cumulative Offset (millions)			300	2,600	5,100	7,769		

* Note, the final year's offset is estimated to be less than 2 or 3 percent in order to meet the total estimated offset of $7.769 billion. The amounts illustrated in Table 62 reflect the total amount of reduced spending, which includes both Medicare and Beneficiary cost-sharing. Note, the figures in the table are rounded, which may create some display discrepancies, but all figures are calculated with the final recoupment amount being $7.769 billion.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal to revise the annual reduction to the OPPS conversion factor under § 419.32(b)(1)(iv)(B)(*12*) used to determine the payment amounts for non-drug items and services from 0.5 percent to 3 percent. A commenter stated that faster repayment would better align repayment with the hospitals that benefited from the earlier increase in non-drug OPPS payments. Another stated that the accelerated schedule would improve both the accuracy and the fiscal value of the remedy.

Response: We thank commenters for their support of our proposal.

Comment: Most commenters opposed our proposal to increase the annual percent reduction to 3 percent. Many of these commenters referenced previous comments they or others made to the Final Remedy rule alleging that CMS lacks the statutory authority to budget neutralize the remedy and that CMS' approach to budget neutrality is inconsistent with its past practices. Based on these reasons, these commenters requested that we abandon the proposal and rescind the regulation codified in that rule, 42 CFR 419.32(b)(1)(iv)(B)(*12*), to implement the offset.

Response: To briefly summarize our responses to these comments in the Final Remedy rule, we did not agree with commenters that sections 1833(t)(14) and (t)(2)(E) of the Act do not apply to the remedy payments we made and that, therefore, the budget neutrality requirements of those statutes also do not apply to the remedy payments. We also did not agree with commenters who stated that sections 1833(t)(14)(H), (t)(9)(B) and (t)(2)(E) of the Act did not provide us with the authority to unwind the non-drug item and service payments from the 340B Payment Policy. We were similarly not persuaded by commenters that our retroactive rulemaking authority in section 1871(e)(1)(A) of the Act does not authorize budget neutrality. We also disagreed with commenters who questioned our contention that, even if budget neutrality was not statutorily required, we could still exercise our authority under section 1833(t)(2)(E) of the Act and its longstanding inherent and common-law recoupment authority to offset the extra payments. We direct readers to our full responses to these comments in the Final Remedy rule at 88 FR 77150 through 77194.

Comment: One commenter repeated their argument from the CY 2026 OPPS/ASC proposed rule that CMS does not have the legal authority to apply an additional 3 percentage point reduction to OPPS rates because, under section 1833(t)(3)(C)(iv) of the Act, CMS is required to update OPPS rates by the same update that applied under the IPPS. Since CMS has already finalized an update of 2.3 percent for the FY 2027 IPPS, the commenter stated that CMS must apply the same update to the OPPS for CY 2027 without further changes.

Response: As we stated in the CY 2026 OPPS/ASC final rule (90 FR 53713), we disagree with the commenter, who conflates two distinct statutory obligations. Under section 1833(t)(3)(C) of the Act, the Secretary updates the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. The commenter is correct that we have implemented that fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act by applying the hospital inpatient market basket percentage increase applicable to hospital discharges under section

1886(b)(3)(B)(iii) of the Act, subject to sections 1833(t)(17) and (t)(3)(F) of the Act. As we explain in section XXVI. of this final rule with comment period, we continue to do so by increasing the OPD fee schedule for CY 2027 by a factor of 2.3 percent—the same as applicable to hospital discharges for fiscal year 2027 under section 1886(b)(3)(B)(iii) of the Act.

The commenter is incorrect, however, that the statute makes the fee schedule increase factor the only update the Secretary can make to the OPPS conversion factor each year. Section 1833(t)(3)(C)(iii) of the Act, for example, authorizes the Secretary further to modify the conversion factor in certain circumstances based on adjustments to service mix. And many parts of the OPPS statute require the Secretary to budget neutralize particular payments, including sections 1833(t)(2)(E), (t)(9)(B), and (t)(14)(H) of the Act. Since the very first payment rule implementing the OPPS, we have implemented OPPS's budget neutrality requirements by adjusting the conversion factor (65 FR 18476 (implementing budget-neutrality requirement)). We have long rejected the commenter's suggestion that section 1833(t)(3)(C)(iv) of the Act means that the conversion factor cannot account for these budget neutrality requirements, explaining that the ''[s]tatute requires us to ensure that a conversion factor for covered OPD services in subsequent years is an amount equal to the conversion factor applicable to the previous year before any increases due to the market-basket increase.'' (67 FR 66788.) We accordingly applied that same policy when we first decreased payments for 340B-acquired drugs in the CY 2018 OPPS/ASC final rule with comment period, which we budget neutralized through an upward adjustment of 1.0319 to the OPPS conversion factor on top of the annual OPD fee schedule increase factor under 1833(t)(3)(C)(iv) of the Act. (82 FR 59353 through 59371).

Comment: Several commenters reiterated arguments made to the CY OPPS/ASC 2026 proposed rule that the statute governing budget neutrality does not authorize CMS to impose an accelerated timeline and disagreed with CMS' stated justification for it, which these commenters characterized as ''that a shorter offset period is preferable because it more closely aligns with the duration of the unlawful 340B payment policy from 2018–2022 and will better account for changes in drug utilization patterns.'' These commenters contended that the statute does not authorize CMS to ''calibrate budget neutrality offsets based on temporal symmetry or administrative convenience'' and that such an approach ignores the disproportionate impact that a 3 percent annual reduction will have on hospitals.

Response: We continue to disagree that the statute prohibits the proposed budget neutrality adjustment schedule or amount, or that our rationale for that proposed schedule is flawed based on hospitals' reduced payments for drugs acquired under the 340B program from CY 2018 through 2022. As we explained in the CY 2027 OPPS/ASC proposed rule (91 FR 41872), the main reason we proposed to shorten the timeframe for the adjustment was to recognize that OPPS utilization changes over time. The purpose of any rate reduction is to unwind the 3.19 percent increase budget neutrality hospitals received from CY 2018 through 2022. For example, in the Final Remedy rule we explained that we finalized a minus 3.09 percent adjustment to the conversion factor in the CY 2023 OPPS/ASC final rule ''as this adjustment removes the effect of the 340B policy as originally adopted in CY 2018 . . . . The CY 2023 adjustment to the conversion factor ensures it is equivalent to the conversion factor that would be in place if the 340B Payment Policy had never been implemented.'' (88 FR 77170). Current OPPS utilization for a hospital is a reasonable proxy for past OPPS utilization for a hospital, but it becomes a less accurate proxy the longer the recoupment timeframe. The commenter is wrong to suggest that our proposed policy would pursue symmetry for symmetry's sake. By pointing out that adjusting rates by 3 percent for 3 years is similar to the initial policy of adjusting rates by 3.19 percent for 5 years, we meant to illustrate both that the proposed larger decrease would still be the type of ''adjustment'' to payment rates authorized by sections 1833(t)(2)(E), (9)(B), and (14)(H) of the Act (88 FR 77158 through 77159) and that the reduction would still fall within the type of year-to-year rate fluctuations in OPPS rates that hospitals should reasonably expect in annual ratemaking. Nor was it inherently unreasonable for us to consider how long it will take fully to implement the adjustment; no statute requires us to implement our budget neutrality obligations or exercise our discretion so that a policy in place only from CY 2018 through 2022 still drives payment rates in 2040.

Comment: Many commenters reiterated the reliance-interest arguments that they made on last year's CY 2026 OPPS/ASC proposed rule. They emphasized that we finalized the 0.5 percent reduction in the Final Remedy rule and that they have relied on that amount in good faith in the nearly 3 years since to engage in financial planning and long-term investment decisions. These commenters stated that our proposal fails to account for the long-term, multi-year nature of hospital budgeting and they described the many expenditures (opening new facilities, buying new medical equipment, hiring staff and expanding services lines, *etc.*) they have allegedly made based on the 0.5 percent reduction. One commenter opined that raising the offset from 0.5 percent to 3.0 percent barely a year after the 0.5 percent figure took effect ''upends the expectations the agency itself created.'' Another commenter alleged that ''the 2026 OPPS final rule specifically suggested CMS may in the future consider a recoupment larger than 0.5 percent, 'such as 2 percent.' At no point did CMS suggest an accelerated recoupment adjustment might exceed 2 percent, such as the currently proposed 3 percent adjustment.''

A third commenter contended that it was unreasonable to assume that hospitals were on notice of the change because of our statement in the CY 2026 OPPS/ASC final rule that ''hospitals should anticipate that we will implement a larger adjustment (such as 2 percent or other adjustment greater than 0.5 percent) beginning in CY 2027'' (90 FR 537114) and our statement in the CY 2027 OPPS/ASC proposed rule that ''[b]ecause hospitals have been aware that we would likely propose an increased payment reduction in CY 2027 rulemaking, we do not believe hospitals need additional time to prepare for this repayment schedule.'' (91 FR 41873). The commenter stated that ''[a] proposed rule is not a final rule. It is completely unreasonable to expect hospitals to assume that policies being considered will in fact be implemented. To do so would be not only irresponsible but practically impossible.'' Echoing their comment from the previous year, the commenter additionally stated that ''the only appropriate reliance interest for 340B hospitals is upon continued, stable and predictable payments in the OPPS'' and that ''CMS took this interest into account by deciding not to impose the 0.5 percent reduction until 2026 'allowing adequate time for impacted parties to assess and prepare for the new payment rates that will be calculated using a reduced conversion factor.' '' The commenter further contended, again repeating their comment from the previous year, that the CY 2027 OPPS/

ASC proposed rule ''not only entirely fails to address hospitals' reliance interest as envisioned in the Final Remedy rule but also undermines the separate reliance interests that CMS allowed to be built from the date of the Final Remedy rule's publication to the CY 2026 OPPS/ASC rule's publication.'' The commenter explained that ''many hospitals' budget process for CY 2027 may be substantially complete and a 2-month planning period (assuming a November OPPS/ASC final rule with comment period release) is wholly unreasonable.'' The commenter concluded by stating that ''[e]ven if hospitals were 'on notice' of a potential increase in the conversion factor reduction, hospitals were not similarly aware of the potential impact of CMS's proposed payment reductions in this Proposed Rule. Further, 340B hospitals have to balance and account for other unexpected changes impacting our finances, including the growing uninsured population, Medicaid cuts, the 340B rebate pilot program, and MDPNP, and the growing impact of manufacturer restrictions on 340B discounts. . . . CMS has not considered these impacts in developing its specific proposals, which belies a reasoned decision as required under the APA and risks recission on the grounds that it is arbitrary and capricious.''

Response: We disagree that we have failed to provide hospitals with sufficient notice of our proposed increase or that we have failed to adequately consider the impact of our policies. As noted by commenters, in the CY 2026 OPPS/ASC final rule, we repeatedly emphasized that while we were not finalizing our proposal to increase the rate in CY 2026 that we anticipated doing so for CY 2027:

- ''We currently anticipate delaying a change for just 1 year. Thus, while we will retain the original 0.5 percent adjustment in the conversion factor in CY 2026, hospitals should anticipate that we will implement a larger adjustment (such as 2 percent or other adjustment greater than 0.5 percent) beginning in CY 2027.'' (90 FR 53714).
- ''As we noted previously, however, we anticipate implementing a larger adjustment (such as 2 percent or other adjustment greater than 0.5 percent) in next year's rulemaking, and we can consider additional alternatives at that time.'' (90 FR 53718).
- ''As we note, while we are not finalizing that proposal at this time, we anticipate proposing a larger offset beginning in CY 2027.'' (90 FR 53720).
- ''However, also for the reasons discussed previously and in the 2026 OPPS/ASC proposed rule, we anticipate implementing a larger percent reduction (such as 2 percent or other reduction greater than 0.5 percent) beginning in CY 2027.'' (90 FR 53720).

As these repeated statements demonstrate, the commenter alleging that we at no point suggested an accelerated recoupment adjustment might exceed 2 percent is incorrect.

Additionally, in the 2023 Final Remedy rule we finalized outside the standard annual rulemaking cycle a 0.5 percent reduction to payment rates that would not begin for 2 years and explained that we were giving hospitals that second year before implementing the payment reduction in part ''to provide entities additional time to prepare for the new payment rate'' (88 FR 77180).

We also note that we changed hospital payments by over 3 percent through the annual ratemaking process for CY 2018 as part of our budget neutralization obligations, and so a 2.5 percentage point change through those same rulemaking procedures falls within the type of annual rate fluctuations hospitals can reasonably expect. Neither the APA nor the Medicare statute imposes a one-way ratchet in which we may increase payments through annual rulemaking but not decrease them through annual rulemaking.

Finally, while we recognize that the cumulative economic effect of the policies we are proposing for CY 2027, along with the alleged financial circumstances hospitals have faced over the past few years, may be significant for some hospitals, we believe these effects must be balanced against the windfalls hospitals received previously that we are statutorily obligated and/or have discretion to recover, our obligations under section 1833(t)(14) of the Act to periodically conduct surveys of hospitals' drug acquisition costs and take that data into account in setting payment rates, and our responsibility to adopt methods to control unnecessary increases in the volume of covered OPD services.

Further, even if an increased recoupment rate was not necessary to comply with our statutory budget neutrality obligations, we would nonetheless exercise our discretion under section 1833(t)(2)(E) of the Act and our longstanding inherent and common-law recoupment authority to make such an increase, as doing so is necessary to fulfill the purpose of the final remedy rule which was to restore affected 340B covered entity hospitals to the financial position they would have been in had the 340B Payment Policy not been implemented in 2018. As we have explained, a recovery timeframe that would last 16 years, concluding 19 years after the year in which the 340B Payment Policy ended, would not achieve this outcome because the further away from CY 2018 through CY 2022 the adjustments extend (1) the less likely that relative hospital utilization of non-drug items and services would correlate to the relative hospital utilization of non-drug items and services from 2018 through 2022 and (2) the less likely that the hospitals that received the increased payments would be the same hospitals that bear the corresponding reductions due to hospitals leaving the market over time. A recovery time frame of either 4 years under a 3 percent recoupment rate or 6 years under a 2 percent recoupment rate would far better fulfill the objective of the Final Remedy rule to restore affected 340B covered entity hospitals to the financial position they would have been in had the 340B Payment Policy not been implemented in 2018 while continuing to avoid burdening hospitals with the single year recovery which we considered but did not finalize in that rule.

While we believe we have provided hospitals with more than adequate notice of the proposed increase, in recognition of hospitals' concerns about burden, we are finalizing a 2 percent reduction for CY 2027 rather than the proposed 3 percent reduction. Although a 2 percent reduction, for the reasons described previously, is less ideal than 3 percent reduction in implementing the budget neutrality requirement in a manner that restores affected 340B covered entity hospitals to the financial position they would have been in had the 340B Payment Policy not been implemented in 2018, we think that a 6-year recovery would nonetheless satisfy that objective while also allowing us to account for the burden concerns brought forth by commenters.

Comment: Many commenters observed, as they did to the CY 2026 OPPS/ASC proposed rule, that in the Final Remedy rule we rejected annual percent reductions greater than 0.5 based on our conclusion that a 0.5 percent reduction ''properly reverses the increased payments for non-drug items and services to comply with statutory budget neutrality requirements while at the same time accounting for any reliance interests and ensuring that the offset is not overly burdensome to impacted entities'' (88 FR 77179). These commenters stated that CMS has failed to identify any material change that warrants changing the remedy in light of having specifically rejected shorter recovery periods when the remedy policy was finalized.

Response: We believe we have adequately explained our reasoning for revisiting and revising the recoupment timeframe. As we have explained in the CY 2026 OPPS/ASC proposed and final rules, the CY 2027 OPPS/ASC proposed rule, and this final rule, our motive for proposing to reduce the recoupment timeframe is to better fulfill the rationale underlying the Final Remedy rule: to implement the budget neutrality requirement in a manner that restores affected 340B covered entity hospitals to the financial position they would have been in had the 340B Payment Policy not been implemented in 2018. We proposed to increase the adjustment to 2 percent in CY 2026 and 3 percent in CY 2027 in furtherance of that goal: so that the hospital utilization that will ultimately determine each hospital's payment reduction would better map onto payment increases from CY 2018 through 2022 and to decrease the risk of hospitals subject to recovery leaving the marketplace before the recovery timeframe has concluded.

Comment: Several commenters contended that CMS abandoned the burden component of its rationale and has not provided a reasoned basis for its new approach. A commenter stated that CMS has ''conspicuously changed'' its criteria for judging the appropriate recoupment timeline criteria over time. Where previously the criteria was to ''comply with statutory budget neutrality requirements while at the same time accounting for any reliance interests and ensuring that the offset is not overly burdensome to the impacted entities,'' it has now changed to ''implement the budget neutrality requirement in a manner that restores affected 340B covered entity hospitals to the financial position they would have been in had the 340B Payment Policy not been implemented in 2018.'' The commenter contends that the burden consideration has been removed from the criteria and CMS has not adequately explained the change as required by the ''change-in-position'' doctrine.'' The commenter concludes that even if CMS had attempted to explain the decision, no justification could rationally support it due to the immense burden placed upon hospitals.

Response: We disagree that we have failed to consider the burden on providers in proposing to increase the recoupment timeframe or that we have not adequately explained the reasoning behind our proposal. As we stated in the Final Remedy rule, in determining the specific annual percent reduction by which to recover the funds from hospitals, our goal was to appropriately balance our statutory budget neutrality obligations against hospitals' burden and reliance interests. The adjustment we proposed in the CY 2027 OPPS/ASC proposed rule to the percent reduction we finalized in the Final Remedy rule is our attempt to more precisely balance these elements. We would also remind the commenter that the consideration of burden that the commenter claims we have abandoned is reflected in the multi-year nature of the remedy itself. Despite having received payment for the 340B drug underpayments that occurred from CY 2018 through 2022 in a single lump sum in early 2024, hospitals were not required to correspondingly repay the non-drug item and service overpayments they received during that timeframe as a lump sum. In fact, hospitals were not required to pay anything back until January of this year, and that repayment will continue for years to come. We also disagree that we have failed to adequately explain the decision. As the U.S. Supreme Court recently explained, when changing positions, ''the agency does not need to show that the reasons for the new policy are *better* than the reasons for the old one'' or ''provide a more detailed justification than what would suffice for a new policy created on a blank slate'' so long as it remains ''cognizant'' that ''longstanding'' policies might have engendered reliance interests. *Food & Drug Admin.* v. *Wages & White Lion Invs., L.L.C.,* 604 U.S. 542, 570 (2025) (internal quotation marks omitted and emphasis in original). We identified in the CY 2027 OPPS/ASC proposed rule that we were proposing to change our policy, and we gave an explanation for why we believed our proposed new policy reasonably balanced the relevant interests. We specifically considered reliance interests in the CY 2027 OPPS/ASC proposed rule and in this final rule with comment period. As we have explained in responses to previous comments above, we have determined that other interests and policy concerns outweigh any reliance interests in this context. Nothing more is required. *See, e.g., Dep't of Homeland Sec.* v. *Regents of Univ. of Cal.,* 591 U.S. 1, 32 (2020) (''[E]ven if [an agency] ultimately concludes that the reliance interests rank as serious, they are but one factor to consider. [The agency] may determine, in the particular context before it, that other interests and policy concerns outweigh any reliance interests.'').

Comment: Many commenters stated, as they did in comments to the CY 2026 OPPS/ASC proposed rule, that our proposal fails to appreciate the financial strain the proposed increased reduction would impose on hospitals that are already operating on tight margins and facing ''severe financial headwinds.'' In these commenters' view, CMS' proposal does not account for adverse financial trends that have occurred since 2023, such as increased costs of labor, supplies and pharmaceuticals, aging hospital infrastructure, inflation, changing practice patterns, inadequate government reimbursements that lag behind inflation, eroding margins, supply chain disruptions, an aging population with more complex, chronic conditions, the lingering effects of the COVID–19 PHE, Medicare sequestration, the OBBBA's reduction to Medicaid and Health Insurance Marketplace payments, and impending economic strains such as the Working Families Tax Cut Act, IRA drug reductions, and HRSA's 340B Rebate Model. These commenters stated that the financial burden imposed by the proposal would threaten the services that they provide.

Response: As we emphasized in our response to similar concerns expressed by commenters last year, while we recognize that hospitals may have experienced financial strain in recent years, there are other statutory provisions that address many of the issues hospitals raise like inflation or the medical complexity of the Medicare population, and we do not believe that relaxing OPPS's budget neutrality provisions, which are required by law, is the proper policy response. With respect to interest specifically, we note that the first of the increased payment amounts occurred in 2018, whereas the last of the recoupment amounts may not be until after 2031—in effect a more than 10-year loan without any attached interest. Ultimately, though, we cannot ignore the financial windfall that hospitals received from 2018 to 2022 and our statutory obligation and/or discretion to recover that windfall.

Comment: Many commenters expressed concern about the combined economic effect of the remedy proposal, the 340B drug payment proposal and the site neutral proposal. These commenters urged CMS not to view these proposals in isolation but to evaluate their cumulative effect. Several commenters suggested that CMS conduct a comprehensive assessment of the cumulative effect of these proposals on 340B hospitals, particularly hospitals providing complex outpatient services and serving significant Medicare and Medicaid populations. One commenter suggested that if CMS proceeds with shortening the recoupment timeframe, it should sequence any acceleration with drug payment reductions so that hospitals do not absorb multiple cuts

simultaneously. Another commenter requested that CMS publish year-by-year effects for hospitals in the highest quartile of 340B intensity and exclude hospitals simultaneously subject to the ASP minus 33.4 percent reduction.

Response: We recognize that the cumulative economic effect of the policies we are proposing for CY 2027, along with the financial circumstances hospitals have faced over the past few years, may be significant for some hospitals. However, we believe these effects must be balanced against the windfalls hospitals received previously that we are statutorily obligated and/or have discretion to recover, our obligations under section 1833(t)(14) of the Act to periodically conduct surveys of hospitals' drug acquisition costs and take that data into account in setting payment rates, and our responsibility to adopt methods to control unnecessary increases in the volume of covered OPD services. We note that our finalization of a 2 percent increase rather than a 3 percent increase, for the reasons previously described, will help mitigate the combined impact of these policies.

Comment: Many commenters characterized the offset, whether increased or not, as a penalty, arguing that it is unfair for hospitals to be penalized for mistakes or past unlawful actions by CMS.

Response: As we indicated last year in response to this characterization, the offset is not a penalty on hospitals. Rather, it is a rate adjustment under section 1833(t) of the Act that accomplishes an incremental and interest-free recovery of windfall payments to hospitals. It is calibrated to the amount of extra money hospitals received and thus achieves payment precision, not punishment. It returns hospitals to the position they would have been absent the unlawful 340B Payment Policy and ensures that the only money ultimately spent is the money authorized to be spent by the statute.

Comment: Multiple commenters expressed concern about the disproportionate financial effect the increased rate of recoupment would have on safety-net providers, rural providers, 340B hospitals and teaching hospitals and stated that the recoupment would reduce resources available to provide services to their patients, particularly to low-income, rural, underserved and vulnerable populations.

Response: As we said in response to similar concerns expressed by commenters in the Final Remedy rule, we recognize that our proposal to decrease future payments will have a financial impact across all hospitals paid under the OPPS, except for new providers, and we are particularly mindful of the impact on vulnerable patients and communities. But, as we also stated in the Final Remedy rule, future decreases are, on aggregate, the mirror image of prior payment increases that would otherwise be a windfall to providers and such windfalls are not cost-free; the costs are ultimately borne by beneficiaries and taxpayers—including the vulnerable patients and communities served by the hospitals to which commenters themselves refer. In fact, this remedy will reduce any beneficiary cost sharing obligations, and incrementally reduce beneficiary Part B premiums, for all Medicare beneficiaries, including the vulnerable patients to which the commenters refer. (88 FR 77180 through 77181).

Comment: Many commenters expressed concern that, if implemented, the 3 percent reduction would effectively wipe out the CY 2027 OPPS rate increase.

Response: Commenters are referencing distinct statutory obligations or potential future statutory obligations. 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. Sections 1833(t)(9)(B), (t)(14)(H) and (t)(2)(E) of the Act require that the OPPS be a budget neutral system, and we decline the commenters' suggestion to implement those budget neutrality provisions in a way that defeats the purpose of other statutory policies. We note, however, that our finalization of a 2 percent reduction rather than a 3 percent reduction, for the reasons previously described, will lessen the effect of the increased offset percentage on the CY 2027 OPPS rate increase.

Comment: Many commenters recognized our statutory obligation to implement a budget neutral recoupment but, based on concern about the financial impact of a 3 percent reduction, requested the reduction to remain at 0.5 percent. Some commenters requested that the reduction be no larger than 1 percent. One commenter requested that the reduction be no larger than 1.5 percent. A few commenters supported a 2 percent reduction.

Response: We appreciate commenters' acknowledgement of our statutory obligation to budget neutralize the recoupment and their suggestions for alternative annual percent reductions to do so. With respect to a 1 or 1.5 percent reduction, we do not believe that an approximately 8 to 12 year recoupment timeframe would appropriately implement the budget neutrality requirement in a manner that restores affected 340B covered entity hospitals to the financial position they would have been in had the 340B Payment Policy not been implemented in 2018. This would exceed the timeframe that the 340B Payment Policy was in place and exacerbate the concern that was driving our proposal to increase the reduction—that the longer it takes to complete the recoupment, the more likely hospital utilization or other payment factors will change from CY 2018 through 2022, and so the less each hospital's total payment reduction will correspond with that hospital's payment increase from CY 2018 through 2022. With respect to the 2 percent reduction, we are finalizing this reduction amount for CY 2027 for the reasons previously discussed.

Comment: Some commenters requested that if we proceeded with an increase that it should be phased-in. Others requested that the effective date of any increase be delayed until CMS has had the opportunity to conduct additional analysis.

Response: We appreciate commenters' suggestions and note that we are finalizing a 2 percent reduction rather than the 3 percent reduction we proposed, which may address some of the commenters' concerns. However, we think delaying or phasing-in the implementation of the increase would be inconsistent with the goal of restoring affected 340B covered entity hospitals to the financial position they would have been in had the 340B Payment Policy not been implemented in 2018.

Comment: Several commenters suggested that if we could not maintain the 0.5 percent reduction then we should exempt various hospitals from the increase, such as all non-340B hospitals, physician-owned hospitals, rural hospitals, sole community hospitals, Medicare-dependent hospitals, low-volume hospitals, teaching hospitals and legacy providers' newly established or expanded outpatient facilities.

Response: We acknowledge the commenters' concerns; however, we are statutorily required and/or have the discretion to recover the overpayments hospitals received for non-drug items and services as a result of the 340B payment policy, including hospitals of the type suggested for exemption by the commenters. Since these hospitals, including those hospitals that might have recently established additional outpatient facilities, received the increased payments for non-drug items

and services, it would be inconsistent with our budget neutrality obligations, and an unwarranted windfall for the hospitals, for us not to recoup the funds.

Comment: Several commenters suggested that if we proceed with an increased reduction that we should conduct robust monitoring for any unintended consequences and consideration of flexibilities or targeted supports for safety-net and teaching hospitals that may be disproportionately affected. Other commenters suggested that CMS report annually on the cumulative recoupment of the $7.8 billion.

Response: We agree that it is important to monitor the effects of the increase for any unintended consequences and will take the commenter's suggestion under consideration for future rulemaking. We also appreciate the commenter's suggestion with respect to future consideration of flexibilities or targeted supports for hospitals based on that monitoring. We will also consider this for future rulemaking.

Comment: One commenter identified an error in the first row in Table 62,''total applicable OPPS non-drug item and service spending (millions).'' The commenter pointed out that the row lists $77.0 million of spending in CY 2027 but it should be $77.0 billion.

Response: We thank the commenter for identifying this error and it has been corrected.

Comment: A commenter expressed skepticism about our claim that the risk that hospitals that benefitted from the increased payments from CY 2018 through CY 2022 would leave the market before 2041 and other hospital providers would have to account for a larger share of the payment reductions justified increasing the recoupment rate. The commenter stated that increasing the payment offset would accelerate the closure of any hospital that was operating at a breakeven margin and make it more likely the facility will close.

Response: We appreciate the commenter's concern; however, there are many reasons that might cause a hospital to leave the market over time, such as declining patient volume, aging infrastructure or other factors, and the longer the recoupment period, the smaller the pool of hospitals that will be subject to recoupment regardless of the recoupment rate. Given that reality, we think that a recoupment timeframe of 6 years at 2 percent will result in a more equitable recovery distribution amongst hospitals then a timeframe of 16 years at 0.5 percent.

Comment: Several commenters expressed concern about the indirect implications of the proposed reduction in OPPS non-drug payments for providers that contract with Medicare Advantage (MA) organizations. Several commenters stated that the accelerated recoupment rate would create a discrepancy between rates CMS pays to MA organizations and rates MA organizations pay to providers. Specifically, commenters stated that MA capitated prospective payment rates for CY 2026 and CY 2027 include a 0.5 percent prospective recoupment, while MA organizations frequently negotiate provider payments based on Original Medicare (OM) rates, and are required to base out-of-network payments for covered services on OM rates. Commenters expressed concern that this discrepancy would create a windfall for MA organizations and would harm providers, while providing no benefit to Medicare beneficiaries or the Part B trust fund.

Further, commenters stated that CMS has provided remedy payments under OM following *AHA* v. *Becerra* in accordance with the Final Remedy rule. Commenters further stated that MA organizations that adopted a similar reimbursement rate for 340B-acquired drugs during CYs 2018–2022 have not made the corresponding remedy payments to providers. Commenters emphasized that this could leave hospitals disadvantaged as they may not have received the benefit of a remedy payment from MA organizations, and they may be subject to the prospective reductions to provider reimbursement for non-drug payments. Several commenters stated that this dynamic unfairly shifts resources to MA organizations and compounds the financial strain on hospitals, particularly given high and growing MA enrollment.

Commenters requested CMS provide additional guidance to MA organizations to mitigate the impact of this proposed adjustment and to ensure the same standard of compliance and accountability as OM. Commenters specifically recommended CMS clarify that MA organizations are expected to make hospitals whole for 340B-acquired drugs administered between 2018–2022 and to prevent the prospective reductions from being passed through to providers absent repayment by MA organizations.

Response: We appreciate commenters' feedback on this issue. Under the MA program, CMS provides monthly, risk-adjusted capitated prospective payments to MA organizations, and in return, MA organizations must furnish, arrange for, or pay providers for the enrollee's Medicare Part A and Part B benefits. CMS calculated and paid CY 2018–2022 MA capitated prospective payment rates under the Advance Notice and Rate Announcement, and those MA prospective payment rates reflected the OM policies as of the time they were finalized. The statutory and regulatory provisions of the MA program constitute a broader bidding and payment structure that is distinct from the OM program. MA plan bids are an estimate of projected costs that plans expect to incur, in part based on policies under the OM program that are generally established each year before MA prospective payment rates are finalized and bids are submitted.

We acknowledge commenters' concerns regarding the potential implications of the Final Remedy rule for MA organizations' payments to providers. We understand from commenters that many MA organizations base their privately contracted reimbursement rates with providers on OM rates set by CMS and that existing MA contracts may not account for the remedy provisions established in the Final Remedy rule. However, CMS establishes payment policies and payment rates for services payable under OM through a separate, distinct process that is not directly related to the terms of private contracting arrangements between MA organizations and providers. Further, section 1854(a)(6)(B)(iii) of the Act prohibits CMS from requiring an MA organization to contract with a particular hospital, physician, or other entity to furnish items and services, including 340B-acquired drugs, or requiring a particular price structure for payment under such a contract. Providers and MA organizations may engage in dispute resolution under existing contracts and any contract negotiations or re-negotiations independently of CMS.

Section 1852(a)(2) of the Act mandates that MA organizations reimburse non-contract providers at least the amount they would have received under OM. We expect that MA organizations will comply with this statutory requirement. We note that the Final Remedy rule excluded providers that enrolled in Medicare after January 1, 2018, from the prospective rate reduction.

After consideration of public comments received, for the reasons discussed previously, we are finalizing an increase to the annual reduction to the OPPS conversion factor under 42 CFR 419.32(b)(1)(iv)(B)(*12*) used to determine the payment amounts for

non-drug items and services for hospitals for whom this adjustment applies from 0.5 percent to 2 percent. Specifically, we are finalizing (1) a revision to § 419.32(b)(1)(iv)(B)(*12*) to limit the 0.5 percent reduction to CY 2026 and (2) the addition of a new paragraph (*13*) implementing an annual 2.0 percent reduction (excluding new providers with a CCN effective date of January 2, 2018, or later) starting in CY 2027 and continuing until the estimated payment reductions made in accordance with paragraphs (*12*) and (*13*) for all applicable hospital outpatient items and service reaches $7.769 billion, which we estimate will occur in CY 2031. Please see Table 63, for an estimate of the impacts of the offset for CY 2027.

TABLE 63: ILLUSTRATION OF THE FINALIZED 2 PERCENT CONVERSION FACTOR ANNUAL REDUCTION TO THE OPPS NON-DRUG ITEMS AND SERVICES BEGINNING CY 2027 TO MAINTAIN BUDGET NEUTRALITY

	CY 2024	CY 2025	CY 2026	CY 2027	CY 2028	CY 2029	CY 2030	CY 2031
Total Applicable OPPS Non-Drug Item and Service Spending (billions)	Remedy Payments Made in Q1 of CY 2024	No Remedy Offset Applied	67.5	79.0	85.4	92.6	99.8	107.4
			Finalized 2 Percent Payment Reduction					
Amount (millions)			300	1,600	1,700	1,900	2,000	300*
Estimated Total Cumulative Offset (millions)			300	1,900	3,600	5,500	7,500	7,769
Amount (millions)								
Estimated Total Cumulative Offset (millions)								

* Note, the final year's offset is estimated to be less than 2 percent in order to meet the total estimated offset of $7.769 billion. The amounts illustrated in Table 63 reflect the total amount of reduced spending, which includes both Medicare and Beneficiary cost-sharing. Note, the figures in the table are rounded, which may create some display discrepancies, but all figures are calculated with the final recoupment amount being $7.769 billion.

7. All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

a. 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 the CY 2000 OPPS 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.[92] Due to the higher cost of living in Alaska, separate rates are calculated for Alaska and the lower 48 States. For CY 2026, the Medicare Outpatient per visit rate is $733 for the lower 48 States (hereinafter referred to as ''the lower 48 AIR'') and $1,233 for Alaska.[93]

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94280 through 94286), we finalized a policy to separately pay IHS and tribal hospitals for high-cost drugs, biologicals, and radiopharmaceuticals (hereinafter referred to as ''drugs'' for the purpose of this section) furnished in hospital outpatient departments through an add-on payment in addition to the AIR using the authority under which the AIR is calculated.[94] We finalized a continuation of this policy, without modification, in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53722 through 53723). We note that the AIR and the add-on payment are paid out of the Part B trust fund and are not subject to OPPS budget neutrality.

We defined high cost drugs (that is, drugs qualifying for the add-on payment) for the purpose of the policy as all drugs covered under Medicare

[92] *https://www.ihs.gov/BusinessOffice/reimbursement-rates/.*

[93] 91 FR 2787 (January 22, 2026); *https://www.federalregister.gov/documents/2026/01/22/2026-01178/reimbursement-rates-for-calendar-year-2026.*

[94] Sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248(a) 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.*).

Part B and for which payment would otherwise be made under the OPPS whose per-day cost exceeds two times the lower 48 AIR amount in effect at the time of the release of each year's OPPS/ASC final rule with comment period. In the CY 2026 OPPS/ASC final rule with comment period, this amount was identified as $1,436 (2 times the CY 2025 lower 48 AIR of $718).

To determine the calculated per-day cost for each drug HCPCS code, we employed a methodology similar to our longstanding methodology used to calculate the per-day cost of drugs for OPPS payment purposes. Specifically, to calculate the per-day cost for CY 2026, we used an estimated payment rate based on the ASP methodology payment rate, which for purposes of the policy was generally ASP plus 0 percent (which is the payment rate for separately payable IHS drugs under the policy). We then used the manufacturer-submitted ASP data from the fourth quarter of CY 2024 to determine the per-day cost. For drugs that did not have either an ASP-based payment rate or a payment rate based on WAC, we used arithmetic MUC of the items derived from the CY 2024 hospital claims data to determine their per-day cost. For HCPCS codes for drugs that were proposed for separate payment in the CY 2026 OPPS/ASC proposed rule with comment period but then had per-day costs equal to or less than $1,436 (2 times $718) in the CY 2026 OPPS/ASC final rule with comment period, based on the updated ASPs and hospital claims data used for the CY 2026 OPPS/ASC final rule with comment period, those drugs received separate payment in CY 2026.

We finalized that the amount of the add-on payment for a high-cost drug would be the ASP for the drug with no additional payment (that is, ASP plus 0 percent). We note that this add-on payment was implemented on a per-dose basis. In the event ASP pricing information was not available for a particular drug, we paid the WAC plus 0 percent and if WAC pricing information was not available, we paid 89.6 percent of AWP. If AWP was not available, we paid the arithmetic MUC. We also adopted a drug packaging threshold exception for biosimilars in which the add-on payment is made for biosimilars whose per-day costs do not exceed the threshold of two times the lower 48 AIR but whose reference products do exceed the threshold.

To implement this policy, we finalized in the CY 2025 OPPS/ASC final rule with comment period a recurring annual process in which the lower 48 AIR in effect at the time of the release of each year's OPPS/ASC final rule with comment period would be used to create a list of drugs qualifying for the add-on payment for the following calendar year. Once the drugs qualifying for the add-on payment were determined, the payment rate for a unit of the drug would be determined in accordance with the previously described pricing hierarchy. The results of that process for CY 2025 were displayed in Addendum Q to the CY 2025 OPPS/ASC final rule with comment period. We additionally finalized that during the calendar year, the list of drugs would be modified on a quarterly basis (January, April, July, October) to add new-to-market drugs with per-day costs that exceeded two times the lower 48 AIR and to update qualifying drugs' ASPs.

We finalized a continuation of this annual process, without modification, in the CY 2026 OPPS/ASC final rule and the results of that process for CY 2026 were displayed in Addendum Q to the CY 2026 OPPS/ASC final rule. For a full discussion of the AIR add-on payment policy for high cost drugs provided by IHS and tribal hospitals, we refer readers to the CY 2025 OPPS/ASC final rule with comment period (89 FR 94280 through 94286) and the CY 2026 OPPS/ASC final rule with comment period (90 FR 53722 through 53723).

b. AIR Add-On Payment for High-Cost Drugs Provided by IHS and Tribal Facilities Policy for CY 2027

For CY 2027, we proposed to continue the policy as described in the CY 2025 and CY 2026 OPPS/ASC final rules.

Consequently, for CY 2027, we proposed to continue 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 using the authorities under which the AIR is calculated.

We proposed to continue to define high cost drugs (that is, drugs qualifying for the add-on payment) for the purpose of the policy as any drugs covered under Medicare Part B and for which payment would otherwise be made under the OPPS which have per-day costs exceeding two times the lower 48 AIR amount in effect at the time of the release of the CY 2027 OPPS/ASC final rule with comment period. For CY 2027, we proposed that if the CY 2026 lower 48 AIR amount is in effect at the time of the release of the CY 2027 OPPS/ASC final rule with comment period, this amount would be $1,466 (2 times the CY 2026 lower 48 AIR of $733).

To determine the calculated per-day cost for each drug HCPCS code, we proposed to continue using an estimated payment rate based on the ASP methodology payment rate (generally ASP plus 0 percent) and then using the manufacturer-submitted ASP data from the fourth quarter of CY 2025 to determine the per-day cost. For drugs that do not have either an ASP-based payment rate or a payment rate based on WAC, we proposed to continue to use the arithmetic MUC of the items derived from the CY 2025 hospital claims data to determine their per-day cost.

We proposed that the amount of the add-on payment for each dose of a high-cost drug would continue to be the ASP for the drug with no additional payment (that is, ASP plus 0 percent). In the event ASP pricing information is not available for a particular drug, we proposed to continue to pay the WAC plus 0 percent. If WAC pricing information is not available, we proposed to continue to pay 89.6 percent of AWP. If AWP pricing information is not available, we proposed to continue to pay the arithmetic MUC. Finally, we proposed to continue the drug packaging threshold exception for biosimilars in which the add-on payment is made for biosimilars whose per-day costs do not exceed the threshold of two times the lower 48 AIR but whose reference products do exceed the threshold.

c. List of Drugs Qualifying for the Add-On Payment for CY 2027

Using two times the lower 48 AIR amount of $733 that is in effect for CY 2026 and applying the previously described per-day cost methodology and pricing hierarchy, we included as Addendum Q to the CY 2027 OPPS/ASC proposed rule a preliminary list of the drugs that would qualify for the proposed add-on payment and their proposed add on payment rates for CY 2027.

We proposed to create a final Addendum Q in the CY 2027 OPPS/ASC final rule with comment period using the claims data (units used per day) and ASPs, or pricing hierarchy, available at that time. We also proposed that for HCPCS codes for drugs that are proposed for separate payment in CY 2027, but then have per-day costs equal to or less than $1,466 (2 times $733) in the CY 2027 OPPS/ASC final rule with comment period, based on the updated ASPs and hospital claims data used for the CY 2027 OPPS/ASC final rule with comment period, those drugs would still receive separate payment in CY 2027.

Finally, as we did in CY 2025 and CY 2026, we proposed to modify the list on a quarterly basis (January, April, July, October) to add new-to-market drugs

with per-day costs that exceed two times the lower 48 AIR and to update qualifying drugs' ASPs.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: All commenters supported our proposal to continue 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 using the authorities under which the AIR is calculated.

Response: We thank commenters for their support.

Comment: A commenter, referring to the CY 2027 OPPS/ASC final rule with comment period generally, suggested that CMS should specifically evaluate how the proposed payment and policy changes would affect rural hospitals, Rural Emergency Hospitals, Indian Health Service facilities, Tribal health programs, and other safety-net providers. The commenter recommended that CMS include rural and Tribal impact assessments into future OPPS and ASC rulemaking and consult directly with nurses, Tribal leaders, rural hospital administrators, patients, and community representatives.

Response: We thank the commenter for their input and will keep it in mind for future rulemaking.

After consideration of the public comments we received, we are finalizing our proposed policy without modification to continue 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 using the authorities under which the AIR is calculated.

8. Medicare OPPS Drugs Acquisition Cost Survey

a. Background

(1) Publication of Notice of Intent To Conduct Medicare OPPS Drugs Acquisition Cost Survey

Section 1833(t)(14)(A)(iii) of the Act requires the Secretary to set payment rates for specified covered outpatient drugs (SCODs) [95] beginning in 2006 at the amount the Secretary determines to be the average acquisition cost for the drug for that year, at least when certain hospital acquisition cost survey data is available. To collect the cost survey data for the Secretary to use for 2006 payment rates, section 1833(t)(14)(D)(i)(I) of the Act required the Comptroller General of the U.S. to conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each SCOD. To inform payment rates in later years, section 1833(t)(14)(D)(ii) of the Act requires the Secretary periodically to conduct surveys of hospital acquisition costs for each SCOD. In developing that survey, section 1833(t)(14)(D)(i)(II) of the Act requires the Secretary to take into account certain recommendations from the Comptroller General regarding frequency and methodology of subsequent surveys.

The GAO conducted the required surveys in 2004 and 2005, and, in reporting the results in 2006, recommended that the Secretary thereafter validate, ''on an occasional basis—possibly every 5 or 10 years—ASP data that manufacturers report to CMS for developing SCOD payment rates.'' [96] As noted in the CY 2026 OPPS/ASC proposed rule (90 FR 33653), in the years following the GAO's recommendation, CMS had not yet conducted a survey of the acquisition costs for each SCOD for all hospitals paid under the OPPS. Additionally, on April 18, 2025, President Trump signed Executive Order (E.O.) 14273, ''Lowering Drug Prices by Once Again Putting Americans First.'' [97] Section 5 of the E.O., ''Appropriately Accounting for Acquisition Costs of Drugs in Medicare,'' directs the Secretary to publish in the **Federal Register** a plan to conduct a survey under section 1833(t)(14)(D)(ii) of the Act so he can determine the acquisition costs for SCODs at hospital outpatient departments.

Accordingly, in the CY 2026 OPPS/ASC proposed rule (90 FR 33653), we announced that under section 1833(t)(14)(D)(ii) of the Act we would be conducting a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS, including SCODs, and drugs and biologicals CMS historically treats as SCODs. We indicated that we intended for the survey to open starting at the end of CY 2025 to early CY 2026. We also stated that we had reviewed and taken into account the Comptroller General's recommendations regarding the frequency and methodology of these surveys in developing our proposed survey, and that we intended for the survey to be completed in time for the survey results to be used to inform policy making beginning with the CY 2027 OPPS/ASC proposed rule. We indicated that we intended to propose and seek comment on any payment rates for SCODs based on the survey results in CY 2027 rulemaking.

In the CY 2026 OPPS/ASC final rule (90 FR 53754 through 53766 and 54049 through 54052), after responding to public comments, including those received through the proposed survey Paperwork Reduction Act (PRA) submission process, we finalized our proposal outlining our intent to conduct a required outpatient drug acquisition cost survey to all hospitals paid under the OPPS, pending final approval from the Office of Management & Budget (OMB). OMB approval was granted on December 29, 2025 (OMB control number 0938–1487, expires December 31, 2028).[98]

(2) OPPS Drug Acquisition Cost Survey Design and Implementation

(a) Study Population

We identified approximately 4,500 entities for inclusion in the survey study population due to their submission of at least one qualifying Fee-For-Service claim under the OPPS during the survey study period (July 1, 2024 through June 30, 2025). Qualifying claims met all defined criteria: (1) claim date of service (July 1, 2024 and June 30, 2025), (2) claim type (Part B outpatient), (3) facility type code (12 [hospital inpatient/home heath], 13 [hospital outpatient], 14 [hospital other], and 76 [community mental health center]), (4) payment amount (greater than zero), and (5) status indicator denoting separately payable drugs or other relevant Part B outpatient services with status indicators (G, H, J1, J2, K, Q1, Q2, Q3, Q4, R, S, T, U, OR V). We removed all claims billed by hospital types that are not paid under the OPPS.[99] Finally, we ensured that each entity had valid Medicare enrollment during the survey study period using the Provider Enrollment, Chain, and Ownership System (PECOS). There was no sampling as all OPPS hospitals were invited to participate in the survey and provide the required data.

As described in the information collection approved by OMB under the

[95] For the definition of a SCOD, see section 1833(t)(14)(B) of the Act at *https://www.ssa.gov/OP_Home/ssact/title18/1833.htm.*

[96] *https://www.gao.gov/assets/gao-06-372.pdf.*

[97] *https://www.govinfo.gov/content/pkg/FR-2025-04-18/pdf/2025-06837.pdf.*

[98] *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202511-0938-014* and *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202512-0938-024.*

[99] As stated in 42 CFR 419.20(b), the following hospital types are not paid under the OPPS: critical access hospitals; Maryland waiver hospitals; hospitals located outside the 50 states, the District of Columbia, and Puerto Rico; Indian Health Service hospitals; and rural emergency hospitals. *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-419/subpart-B/section-419.20.*

PRA, we expect to survey these hospitals every four (4) years. We believe that this frequency will appropriately balance the burden imposed on hospitals of completing the survey with ensuring that we capture the required data to inform payment rates as required under section 1833(t)(14)(D)(ii) of the Act. However, this frequency is an intention and could be revised.

(b) Survey Scope and Design

The guiding principle in the design of the survey was to collect the data necessary to inform payment policy as required by statute in a manner that imposed the least amount of burden to the extent practicable on the hospitals providing the data. The survey collected acquisition cost data for separately payable outpatient drugs at the 11-digit National Drug Code (NDC) level for 1,843 NDCs, which correspond to 519 drug HCPCS.[100] We note that more than one NDC may be associated with a given HCPCS code and vice versa. These NDCs were identified by analyzing the drugs and biologicals that were separately payable under the OPPS during the survey period of July 1, 2024 through June 30, 2025 and for which there was a payment made under the OPPS during that period. We excluded NDCs with either an expiration date or a marketing end date prior to July 1, 2024, using FDA national drug code and structured product labeling data elements (NSDE) data [101] because these drugs would no longer be available for purchase during the study survey period.[102]

(c) Acquisition Date Reporting and Data Elements

The survey captured acquisition data for drugs purchased between July 1, 2024 and June 30, 2025. This 12-month time period aligns with GAO's 12-month survey period for their original study of July 1, 2003 through June 30, 2004. This time period also provided a 6-month window between the end of the survey period and the start of the survey submission window to ensure adequate time for all rebates, discounts, and price concessions to be finalized, so they could be included into the NDC acquisition cost submitted by hospitals.

The survey instructed hospitals to report 4 pieces of data for each NDC purchased during the 1-year survey period:

- Total Units Purchased—Non-340B
- Total Net Acquisition Cost—Non-340B
- Total Units Purchased—340B
- Total Net Acquisition Cost—340B

Net acquisition cost was defined as the total amount paid by the hospital inclusive of all discounts, rebates, and price concessions applicable at the NDC level.

This design reflected our recognition that certain discounts may apply depending on which provider furnished the drug and whether an eligible patient received the drug (for example, for drugs acquired through the 340B Program). Consequently, the survey requested hospitals to separately list their acquisition costs for drug NDCs acquired through the 340B Program and drug NDCs acquired outside of the 340B Program to ensure that all discounts were accurately captured and represented the hospital's acquisition costs.

(d) Treatment of Discounts and Price Concessions

The survey requested hospitals to include all rebates and discounts in their acquisition cost for each NDC. This included both discounts able to be directly applied to each individual NDC and those discounts that were not necessarily linked to a single NDC (*e.g.,* invoice-level discounts, wholesaler rebates, prompt pay discounts, and other financial concessions, or other discounts). Respondents were also requested to separately provide information about any non-NDC-specific discounts or rebates received as a result of membership in a Group Purchasing Organization (GPO) or other buying group.

(e) Data Collection Process

Data were collected through the CMS Fee-for-Service Data Collection System (FFSDCS) via the Medicare OPPS Drug Acquisition Cost Survey (hereinafter referred to as ''ODACS'') module. Hospitals first designated a Hospital Point of Contact (POC) and a Submitter responsible for data submission. Submitters then submitted data through (1) uploading of a standardized Excel (.xlsx) file; or (2) manual data entry through the FFSDCS via the ODACS module. Once the Submitter uploaded or entered the required data, they then officially submitted that data to CMS and attested to the validity, integrity, and completeness of the data being submitted.

(f) Data Validation and Quality Assurance

The FFSDCS ODACS module included automated validation checks to promote completeness, formatting accuracy, and logical consistency. For uploaded data, errors and missing information were flagged on the module upload page, accompanied by error explanations. For manually entered data, the module provided hover-over tips for data entry fields and was programmed to accept data only in specific formats. The system alerted users if data was formatted incorrectly. Submitters were able to correct and reupload data during the collection window prior to final attestation.

(g) Survey Window

The ODACS module opened on January 1, 2026 and closed on April 7, 2026. The original survey window was January 1, 2026 through March 31, 2026; however, after the survey window opened we extended the window for an additional week, through April 7, 2026, based on hospitals' request for additional time to respond. We believe that approximately 14 weeks was sufficient for hospitals to respond to the survey, particularly given the outreach and education that CMS engaged in prior to and during the survey window.

(h) Outreach and Education

We engaged in extensive outreach and education to hospitals in advance of the survey start date to ensure that respondents were aware of the survey and how to complete it. CMS began reaching out to hospitals using provider enrollment and other publicly available contact information in September 2025. Specifically, CMS identified a hospital POC from each hospital paid under the OPPS and reached out to them to make them aware of the survey and provide them with instructions on selecting a hospital representative (Submitter) to register with the CMS Identity Management System (IDM) to access the survey module and report the survey data. To walk respondents through this process, a step-by-step registration guide was issued by CMS in November 2025 and a data submission guide was provided on January 1, 2026.[103] These guides were posted to a new ODACS-specific web page [104] that was created by

[100] ODACS Acquisition Data Template: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/outpatient-prospective-payment-system-opps-drug-acquisition-cost-survey.*

[101] *https://www.fda.gov/industry/structured-product-labeling-resources/nsde.*

[102] The expiration date is the expiration date of the last lot distributed. The marketing end date signifies that the drug is no longer actively manufactured or promoted, or the company has officially decided to stop commercializing it.

[103] *www.cms.gov/files/document/submitter-user-guide.pdf.*

[104] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-*

CMS to serve as a central hub for information and resources for hospitals. CMS also conducted two educational webinars [105] with hospitals in December 2025, which were recorded and posted to the ODACS web page. To ensure that respondents had the support they needed during the survey, CMS established a dedicated email address and helpline to provide technical assistance. To address frequently asked questions, CMS posted a FAQ document [106] to the ODACS web page and updated it during the survey to reflect additional questions requested by respondents via email and the helpline as the survey progressed. Finally, prior to and throughout the survey period, CMS sent periodic communications to POCs to remind them of upcoming deadlines and resources available for assistance.

b. Data Analysis and Methodology

(1) Selection of a Methodology To Calculate Acquisition Cost Margins

In accordance with section 1833(t)(14)(D)(ii) of the Act, we took into account GAO's recommendations and analyzed the survey data to validate whether the manufacturers' reported drug ASP data appropriately and accurately reflects hospitals' drug acquisition costs. To do so, we compared hospitals' survey-reported acquisition costs for all survey-eligible drugs to the equivalent ASP-based Medicare payment amount for those drugs under the OPPS, less any drug-specific payment rate add-ons. This comparison was constructed as a percent difference between these two values, termed the acquisition cost margin.

We calculated this acquisition cost margin by first finding the difference between (1) the total acquisition costs reported for all NDCs in the survey and (2) the volume-weighted sum of their corresponding ASP payment rates, the latter of which was calculated by multiplying the survey reported units purchased for each NDC by its applicable ASP plus 0 rate.[107] We then divided that difference by the total ASP-based payment to find the percent margin between acquisition costs and ASP. Negative values indicate that hospitals reported acquisition costs below ASP and positive values indicate that hospitals reported acquisition costs above ASP.

We used the volume-weighted sum of all survey-eligible NDCs' ASP payment rates in order to produce a representative estimate of aggregate Medicare payments that would be comparable to hospitals' aggregate acquisition costs reported for those NDCs. This approach is consistent with longstanding OPPS principles of basing payment policy on observed utilization and resource use. We believe it is appropriate to compare hospitals' total acquisition costs to this weighted sum of ASPs rather than compare average acquisition costs to ASP because total acquisition costs encompass both the reported per-unit cost and the reported purchase volume for each NDC. In the absence of weighting by reported per-unit cost, drugs that encompass a very low percentage of hospitals' total acquisition costs could exert a disproportionate influence on the aggregate margin between acquisition costs and ASPs. And in the absence of weighting by reported purchase volume, the ASPs for drugs with relatively low reported volume but atypical acquisition costs could exert a disproportionate influence on the aggregate margin. By contrast, the volume-weighted approach ensures that the ASPs for the drugs representing a larger share of total purchasing activity contribute more significantly to the estimated margin. We will illustrate using the following fictitious example:

- Ten units of NDC 1 were purchased for $8 (average acquisition cost of $0.80 per unit) and NDC 1 has an adjusted ASP [108] of $1. The volume-weighted ASP is $10. NDC 1 was reported as purchased with a margin of minus 20 percent, or 20 percent below ASP.
- One unit of NDC 2 was purchased for $14 (average acquisition cost of $14 per unit) and NDC 2 has an adjusted ASP of $10. The volume-weighted ASP is $10. NDC 2 was reported as purchased at a margin of plus 40 percent, or 40 percent above ASP.

Aggregating the two above NDCs, the total acquisition cost is $22 ($8 + $14) and the volume-weighted sum of ASPs is $20 ($10 + $10). Calculating the percent difference yields a plus 10 percent margin, calculated as 100 * (($22 − $20)/$20). However, if no volume weighting methodology was applied, the sum of ASPs would be $11, and calculating the percent difference would yield a plus 100 percent margin, calculated as 100 * (($22 − $11)/$11).

We also considered weighting ASP payment rates for survey-eligible drugs by outpatient claims volume for survey-relevant HCPCS codes. We recognize the value of using OPPS claims data as it directly reflects real-world utilization. However, we did not adopt this approach because we believe it is appropriate to rely on a consistent survey-based framework for both acquisition costs and volume measures. We believe that weighting by survey-reported purchase volume avoids potential inconsistencies between external claims data and survey responses, ensures that the resulting margins are fully grounded in the reported acquisition cost data, better reflects the distribution of hospital drug purchasing activity as captured via the survey instrument, and is consistent with the statutory objective of approximating average acquisition cost in a manner that is both representative and methodologically sound. However, we sought comment on this approach to volume weight the average acquisition cost based on survey utilization data rather than OPPS claims data utilization.

We performed this acquisition cost margin calculation separately for non-340B and 340B drug purchases to analyze the data in the same manner in which it was collected. We then calculated acquisition cost margins using different ASP benchmarks, at different levels of data aggregation, and across a variety of scenarios to detect specific trends and variations in the submitted data. First, given that a drug's ASP can vary by quarter, we calculated each margin using both the mean ASP and median ASP across the four quarters of the specified time period (Q3 of 2024 to Q2 of 2025). Determining acquisition costs relative to both the median and mean ASP ensured that we properly accounted for any fluctuations in payment rate over time while mitigating the influence of any quarters with abnormal payment rates and allowed us to assess any differences in the margins that resulted from the two ASP benchmarks. Second, we calculated margins at the NDC level as well as aggregated to the HCPCS level; in the latter, acquisition costs were adjusted to the HCPCS level using the billing units per NDC package. Third, we calculated margins stratified by drug therapeutic class and hospital characteristics (340B participation status, ODACS drug purchase volume, outpatient drug claims billing volume, hospital size, rurality, geographic location, GPO

pps/outpatient-prospective-payment-system-opps-drug-acquisition-cost-survey.

[105] *https://www.cms.gov/files/document/odacs-training-webinar.pdf.*

[106] *https://www.cms.gov/files/document/odacs-faq.pdf.*

[107] ASP plus 0 is the ASP without any drug-specific payment rate add-ons (ASP plus 6 percent for most drugs and biologicals, ASP plus 8 percent for qualifying biosimilar products, or AMP plus 3 percent for select other drugs and biologicals).

[108] Since ASPs are reported by HCPCS billing unit, ASPs were adjusted to the NDC package units where necessary using an NDC–HCPCS adjustment factor.

membership, GPO discount amount, and teaching status). These various analytic scenarios were all undertaken to determine the differential between reported acquisition costs and ASP along relevant stratifications and characteristics as well as validate the robustness of the findings used in our proposal.

(2) Selection of a Methodology To Identify and Trim Outliers

In analyzing the survey data, it is appropriate to mitigate the influence of extreme and potentially anomalous observations that may reflect atypical purchasing arrangements, data anomalies, or reporting inconsistencies and could distort estimates of hospital drug acquisition costs. Consistent with standard statistical practice and our general approach under the OPPS to ensure that payment methodologies are based on representative data, we considered two different methods for identifying and excluding anomalous survey responses from the dataset. In both methods, the outlier identification and trimming process was performed separately for 340B and non-340B drug acquisitions, producing tailored outlier thresholds based on the unique data distribution for each drug through each purchasing channel.

First, we considered a trimming approach that excludes all observations with a per-unit acquisition cost more than three standard deviations from the geometric mean per-unit cost for each NDC. This approach is consistent with our standard methodology for processing extreme outliers to develop policy under the OPPS.[109] Application of the geometric mean trimming methodology necessitated removal of NDCs for which fewer than 10 survey respondents reported their purchase because outlier values cannot be detected with nine or fewer observations using this method.

We also considered the Tukey interquartile range (IQR) method [110] as an alternate outlier trimming approach and tested the impact of excluding outliers using the geometric mean approach compared to the IQR-based approach. Using the geometric mean approach to trim outliers removed 2,051 survey records (defined as the unique combination of hospital, NDC, and 340B or non-340B purchase from each survey response), or 1.3 percent of the total 160,430 original records while using the IQR approach to trim outliers removed 15,563 records, or 9.7 percent of the total 160,430 records. Upon manual review of the survey responses that were trimmed using each outlier approach and the data distribution for each NDC, we believed that the IQR approach erroneously identified some records as outliers despite their per-unit acquisition cost being generally in-line with the overall data distribution for that NDC. This is likely due to the distributional characteristics of the survey data, including evidence of skew in the distribution of reported acquisition costs for some NDCs. It has been established that the effectiveness of Tukey's IQR lessens when data are skewed and may lead to overidentification of observations as outliers.[111] [112] [113] In addition, we were concerned about the large number of survey records removed by the IQR trimming methodology, as one of our goals in conducting this survey was to analyze survey-reported drug acquisition costs using the largest amount of reasonable data received from hospitals as possible. Consequently, we did not propose to adopt the IQR-based outlier trimming methodology.

Rather, we proposed to use the geometric mean approach to exclude identified outlier observations from the analyses used to estimate acquisition cost relationships. Specifically, we proposed to trim records with per-unit acquisition costs more than three standard deviations from either the 340B or non-340B geometric mean per-unit acquisition cost for that NDC. We proposed this approach to maintain consistency with the standard OPPS outlier trimming methodology. It also ensured that we retain the maximum number of responses with nonextreme values to estimate acquisition cost relationships from the survey data. By ensuring that the resulting estimates are based on data that are representative of typical hospital acquisition costs and are not unduly influenced by a small number of extreme observations, this approach was consistent with our longstanding objective of analyzing reliable and representative data to determine payment policy changes. We sought comment on our proposal to trim records with per-unit acquisition costs more than three standard deviations from either the 340B or non-340B geometric mean per-unit acquisition cost for that NDC.

(3) Application of Data Refinements To Remove Anomalous Data

Consistent with our general approach to ensuring that payment methodologies are based on reliable and internally consistent data, we reviewed the survey responses for values that were not plausible given statutory requirements that covered entities cannot be required to pay more than the 340B ceiling price for drugs acquired under the 340B Program or that exhibited clear inconsistencies in reporting. We identified five scenarios in which reported data displayed anomalous values, which appeared to be the result of data entry error, miscalculation, or other respondent confusion. Below we detail each identified scenario and the number of survey records that fall into each. We proposed to exclude these survey responses from the analyses used to assess acquisition cost relationships to ensure that these calculations were not unduly influenced by implausible values.

First, we identified instances in which respondents that were not participating in the 340B Program during the relevant study time period (as verified using the 340B Office of Pharmacy Affairs Information System (340B OPAIS)) reported acquisition cost data in the 340B fields of the survey. These observations likely reflected reporting errors, given that these hospitals could not have accessed 340B discounts. Therefore, we proposed to exclude 340B acquisition cost data submitted by non-340B hospitals from analyses of 340B acquisition cost to maintain consistency with the survey design and statutory framework. This refinement removed 850 records out of the 160,430 records received through the survey.

Second, we identified instances in which respondents reported purchasing drugs through the 340B Program for 58

[109] *https://www.cms.gov/files/document/2026-nfrm-opps-claims-accounting.pdf.*

[110] Under this approach, for each NDC, we would calculate the first quartile (Q1) and third quartile (Q3) of per-unit acquisition cost based on the empirical distribution of hospitals' reported average acquisition cost values, and define the IQR as Q3 minus Q1. We would then establish outlier thresholds as follows: (1) an upper threshold equal to Q3 plus 1.5 times the IQR; and (2) a lower threshold equal to Q1 minus 1.5 times the IQR. Observations with per-unit acquisition costs that fall outside these thresholds are identified as outliers. Application of the IQR-based trimming methodology would necessitate removal of NDCs for which fewer than four survey respondents reported their purchase because outlier values cannot be detected with three or fewer observations using the Tukey IQR method.

[111] M. Hubert and E. Vandervieren, ''An adjusted boxplot for skewed distributions,'' *Computational Statistics & Data Analysis* 52, no. 12 (August 15, 2008): 5186–5201, *https://doi.org/10.1016/j.csda.2007.11.008.*

[112] Neil C. Schwertman, Margaret Ann Owens, and Robiah Adnan, ''A simple more general boxplot method for identifying outliers,'' *Computational Statistics & Data Analysis* 47, no. 1 (August 1, 2004): 165–174, *https://doi.org/10.1016/j.csda.2003.10.012.*

[113] Arefeh Mazarei et al., ''Online boxplot derived outlier detection,'' *International Journal of Data Science and Analytics* 19 (2025): 83–97, *https://doi.org/10.1007/s41060-024-00559-0.*

NDCs that did not have a 340B ceiling price during the survey time period. These observations may reflect reporting errors, such as reporting acquisition data for the incorrect NDC within a drug that was intended, given that no 340B agreement, or associated discount, was available for these NDCs. In some cases, where these NDCs had 340B ceiling prices during other quarters outside the survey time period, these observations may be the result of respondent confusion over the survey reporting period or the time period when these NDCs had a 340B ceiling price in place. Alternatively, hospitals may have acquired non-340B NDCs through the 340B Prime Vendor Platform (PVP) without receiving a 340B discount price;[114] while hospitals may have considered these purchases to be 340B acquisitions for the purposes of their survey reporting, evaluating these responses as part of 340B margin calculations would provide an inaccurate picture of the acquisition costs for NDCs with 340B discounts. We also did not elect to evaluate these responses as part of non-340B margin calculations as it was impossible to separate instances of reporting errors from non-340B purchases made through the 340B PVP. Therefore, we proposed to exclude 340B survey responses for these NDCs without 340B ceiling prices from analyses of both 340B and non-340B acquisition cost to maintain consistency with the survey design and statutory framework. This refinement removed 839 records out of the 160,430 records received through the survey.

Third, we identified a small number of responses from hospital subunits that submitted identical data to their parent unit. Hospital subunits were identified as entities where the third digit of its CMS Certification Number (CCN) is T (representing inpatient rehabilitation units) or S (representing psychiatric units). Parent units were identified as entities where all six digits of its CCN are numeric.[115] To identify a parent unit for each subunit, the T or S in the third digit was replaced with the numeric digit associated with the provider type of that subunit (either 0, 2, 3, or 4). If this replacement yielded more than one possible parent unit, the subunit was further matched with a parent unit based on CCN name and ZIP code. Identical parent–subunit data were identified as survey responses with the exact same number of total units and total net acquisition costs reported for the exact same NDCs. These observations likely reflect duplicative data reported by one submitter who was responsible for multiple entities. Accordingly, we proposed to exclude these duplicative responses from subunits in favor of only retaining the equivalent responses from the parent unit. We identified 27 subunits with duplicative data to their parent unit, and this refinement removed 4,799 records out of the 160,430 records received through the survey.

Fourth, we identified instances in which reported acquisition costs for drugs purchased under the 340B Program exceeded the maximum applicable 340B ceiling price during the survey time period. By statute, covered entities cannot be required to pay more than the 340B ceiling price for drugs acquired under the 340B Program. Such observations are not representative of actual acquisition costs and are likely attributable to reporting or data entry errors (for example, miscalculations or incorrect decimal placement). Accordingly, we proposed to exclude 340B drug purchases with average acquisition costs above the maximum ceiling price from our analysis. This refinement removed 4,667 records out of the 160,430 records received through the survey.

Fifth, we observed that certain respondents reported units for specific drugs, including clotting factors and certain respiratory therapies, in international units (IU) or milligrams (MG) rather than the required NDC-based units. IU is the HCPCS billing unit for the clotting factors and MG is the HCPCS billing unit for the respiratory therapies;[116] however, because the survey requires reporting at the NDC level, the use of IU- or MG-based units would result in substantial distortions in calculated per-unit acquisition costs, typically producing extremely high reported unit volumes and correspondingly low per-unit costs. These observations are not comparable to properly reported NDC-level data. To avoid possible selection bias that may result from specifically excluding responses with units reported in IU or MG, we therefore proposed to exclude all survey responses for affected NDCs with units reported in IU or MG from the analysis. This refinement removed 4,398 records out of the 160,430 records received through the survey. We note, if CMS included this data, the acquisition cost margins would have been significantly lower than Medicare payment rates.

The exclusion of these anomalous observations, in conjunction with the application of the outlier trimming methodology and other data standardization approaches described previously, improved the reliability and validity of the resulting estimates of acquisition costs. In particular, it ensured that the resulting estimates reflect plausible and internally consistent acquisition costs while minimizing the influence of erroneous or noncomparable data. Moreover, applying these five data refinement exclusions did not have a substantial impact on the overall number of survey records included in analyses of acquisition cost. Collectively, these five refinements removed 14,313 records out of the 160,430 records received through the survey. In other words, after applying these five exclusions, there remained 146,117 survey records in the dataset, 91.1 percent of the total 160,430 original records we received from respondents. We note that there are some overlaps in each individual exclusion of survey records, where the same survey record was excluded for meeting more than one exclusion criterion.

For each of the five scenarios discussed previously, we proposed to exclude survey responses for values that are not plausible given statutory requirements or that exhibit clear inconsistencies in reporting. Specifically, we proposed to exclude survey responses that were identified as meeting at least one of the five scenarios listed previously based on our manual review of the data, ASP pricing files, Health Resources and Services Administration (HRSA) 340B ceiling pricing files, and relevant policy and billing guidance. We believed that this approach represented the most appropriate and methodologically sound means of estimating the typical margin in the survey data between hospitals' survey-reported acquisition costs and ASP. We solicited comment on our approach to identifying and excluding anomalous data, as well as on the overall methodology used to

[114] The 340B PVP website states that ''The [PVP] . . . works with 155 manufacturers to obtain lower drug pricing for [340B covered entities] on non-340B items, such as vaccines. . . .''

[115] Hospital type for each parent unit was identified based on the final four digits of its CCN. Short-term (general and specialty) hospitals were identified as those in the range 0001–0899; long-term care hospitals were identified as those in the range 2000–2299; rehabilitation hospitals were identified as those in the range 3025–3099; children's hospitals were identified as those in the range 3300–3399; psychiatric hospitals were identified as those in the range 4000–4499; and IPPS-exempt freestanding cancer hospitals were identified as CCNs listed on the CMS website *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/pps-exempt-cancer-hospitals-pchs.*

[116] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Downloads/ASP-Report-in-units-other-than-NDC.pdf.*

evaluate the survey data for purposes of our proposal.

c. OPPS Drug Acquisition Cost Survey Results

(1) Survey Response Rate and Respondent Characteristics

We first determined the response rate and hospital characteristics of survey respondents to understand which entities had submitted a survey response, then compared them to the characteristics of nonrespondents and the survey-eligible population to assess their representativeness relative to the overall population. We also applied a methodology to refine the population of survey-eligible hospitals to more precisely reflect those entities with meaningful outpatient acquisition volume for drugs included in the survey.

Approximately 43.6 percent of the 4,494 entities eligible for OPPS payment (hereinafter referred to as ''survey-eligible hospitals'') submitted a survey response and approximately 29.8 percent of eligible hospitals reported that they had acquisition costs during the survey time period. We received a number of responses, many of which appeared to be coordinated form letters, from eligible hospitals indicating that they would not be providing their acquisition data and explaining their reasons for not doing so. Before refining the population, approximately 34.9 percent of non-340B hospitals and approximately 23.1 percent of 340B hospitals responded to the survey and reported that they had acquisition costs for survey-eligible drugs during the surveyed time period (Table 64).

TABLE 64: DESCRIPTIVE SURVEY RESPONDENT STATISTICS

Category	Non-340B Hospitals	340B Hospitals	Total Hospitals
Number of Survey-Eligible Hospitals	2,537	1,957	4,494
Number of Overall Respondents	1,421	537	1,958
Percent of Overall Respondents	56.0%	27.4%	43.6%
Number of Respondents Reported Data	885	453	1,338
Percent of Respondents Reported Data	34.9%	23.1%	29.8%

However, claims analysis of the eligible hospital population determined that a subset of entities that were included in the survey had zero outpatient claims for survey-relevant HCPCS codes during the survey study period. Many of these entities did not submit a survey response, likely because they did not acquire any survey-relevant drugs during the time period. Other entities were hospital subunits that did not submit a survey response or submitted a response reporting zero acquisition costs, but their parent unit submitted a survey response reporting acquisition data.

Consequently, we applied population refinements to consolidate subunits with their parent units and to remove entities from the survey that neither reported acquisition costs nor had outpatient billing volume for HCPCS codes corresponding to NDCs included in the survey during the specified time period. These refinements resulted in a slightly smaller population that may more appropriately reflect the universe of eligible hospitals with meaningful and relevant outpatient drug acquisition volume. This population was almost exclusively composed of short-term acute care hospitals: 2,977 out of 3,147 total CCNs (94.6 percent) in the refined population are short-term acute care hospitals as compared to 3,018 out of 4,494 total CCNs (67.2 percent) in the original population. This change occurred for two reasons. First, by consolidating subunits with their parent unit, all subunits (that is, psychiatric units and inpatient rehabilitation units), which had accounted for 742 (16.5 percent) in the original population no longer appear in the population as distinct hospitals. Second, this refinement also markedly reduced the number of psychiatric hospitals, long-term care hospitals, and rehabilitation hospitals in the refined population because the majority of these hospitals neither reported acquisition costs nor billed any relevant outpatient claims.

Of this refined study population, approximately 41.4 percent of hospitals responded to the survey and reported that they had acquisition costs during the surveyed study period. Additionally, approximately 53.3 percent of non-340B hospitals and approximately 28.6 percent of 340B hospitals in the refined population responded to the survey and reported that they had acquisition costs during the surveyed study period (Table 65). For discussion of analyses that we undertook to confirm that this response rate is sufficiently large to yield a statistically valid sample, we refer readers to the calculation of confidence intervals in section (3) Population Weight Adjustment and Statistical Validity.

TABLE 65: DESCRIPTIVE SURVEY RESPONDENT STATISTICS (REFINED POPULATION)

Category	Non-340B Hospitals	340B Hospitals	Total Hospitals
Refined Number of Survey-Eligible Hospitals Number	1,639	1,508	3,147
Refined Number of Respondents Reported Data	873	431	1,304
Refined Percent of Respondents Reported Data	53.3%	28.6%	41.4%

Using the refined population, we then compared observable hospital characteristics of survey respondents that reported acquisition costs to the characteristics of the survey-eligible population (Table 66). Compared to the overall survey-eligible population, hospitals that responded to the survey and reported acquisition cost data were slightly more likely to have lower claims billing volume, be smaller, be located in a rural area, and not be major teaching hospitals.

Given these slight differences in hospital characteristics between respondents and the overall population, we performed inverse probability weighting (IPW) to confirm that respondents' data yielded statistically representative estimates of hospital outpatient drug acquisition costs. We refer readers to the discussion of IPW-adjusted margins in section (3) Population Weight Adjustment and Statistical Validity.

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TABLE 66: COMPARISON OF HOSPITAL RESPONDENTS VS NONRESPONDENTS (REFINED POPULATION)

Hospital Characteristic	All Survey-Eligible Hospitals		Respondents Reporting Acquisition Cost Data		Nonrespondents	
	Number	Percentage	Number	Percentage	Number	Percentage
All Hospitals	***3,147***	***100.0%***	***1,304***	***100.0%***	***1,804***	***100.0%***
Outpatient Drug Claims Volume						
Bottom Quintile	591	18.8%	287	22.0%	287	15.9%
Second Quintile	622	19.8%	327	25.1%	284	15.7%
Third Quintile	626	19.9%	256	19.6%	364	20.2%
Fourth Quintile	627	19.9%	221	16.9%	403	22.3%
Top Quintile	628	20.0%	160	12.3%	466	25.8%
No Billing	53	1.7%	53	4.1%	0	0.0%
Hospital Size (Number of Beds)						
Bottom Quintile	502	16.0%	263	20.2%	230	12.7%
Second Quintile	542	17.2%	236	18.1%	293	16.2%
Third Quintile	647	20.6%	267	20.5%	373	20.7%
Fourth Quintile	715	22.7%	284	21.8%	424	23.5%
Top Quintile	741	23.5%	254	19.5%	484	26.8%
Geographic Rurality						
Metropolitan	2,320	73.7%	937	71.9%	1,356	75.2%
Micropolitan	544	17.3%	224	17.2%	315	17.5%
Rural	283	9.0%	143	11.0%	133	7.4%
Census Region						
New England	136	4.3%	33	2.5%	101	5.6%
Middle Atlantic	346	11.0%	129	9.9%	212	11.8%
South Atlantic	518	16.5%	219	16.8%	295	16.4%
East North Central	484	15.4%	166	12.7%	314	17.4%
East South Central	266	8.5%	129	9.9%	128	7.1%
West North Central	237	7.5%	87	6.7%	148	8.2%
West South Central	504	16.0%	295	22.6%	199	11.0%
Mountain	226	7.2%	100	7.7%	124	6.9%
Pacific	388	12.3%	125	9.6%	263	14.6%
Puerto Rico	42	1.3%	21	1.6%	20	1.1%
Teaching Status						
Major Teaching	400	12.7%	134	10.3%	265	14.7%
Not Major Teaching	2,657	84.4%	1,128	86.5%	1,495	82.9%
Unknown	90	2.9%	42	3.2%	44	2.4%

Note: The number of hospitals shown in the "Respondents Reporting Acquisition Cost Data" and "Nonrespondents" columns does not sum to the total number of hospitals in the "All Survey-Eligible Hospitals" column because 39 survey respondents that reported no drug acquisitions during the survey period are excluded from this table. Of these hospitals, 28 (71.8 percent) were non-340B hospitals and 11 (28.2 percent) were 340B hospitals. The 39 survey respondents that reported no drug acquisitions during the survey period are excluded from Table 66. These hospitals generally had low outpatient drug billing volume, tended to be smaller facilities, and were predominantly located in metropolitan areas. The hospitals were geographically distributed across Census regions, and only one hospital was classified as a major teaching hospital.

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We received public comments on our survey response rate and respondent characteristics. The following is a summary of the comments we received and our responses.

Comment: Two commenters raised concerns about the creation of the refined hospital population, especially in relation to analysis of the survey response rate. A commenter pointed out that the refinements resulted in a larger increase in the response rate for non-340B hospitals (from 34.9 percent to 53.3 percent) than for 340B hospitals (from 23.1 percent to 28.6 percent).

Response: The population of 4,494 CCNs that CMS initially identified for ODACS eligibility was intended to be maximally inclusive in order to identify all entities paid under the OPPS that could have purchased survey-relevant outpatient drugs during the ODACS study period. However, further claims analysis revealed that a subset of the 4,494 eligible CCNs did not submit any OPPS claims for survey-relevant HCPCS codes during the study period. Many of these entities, which were predominantly subunits or non-acute care hospitals, also did not submit an ODACS response or submitted a response reporting zero drug acquisitions. These observations are not unexpected given that many subunits likely acquire their outpatient drugs in conjunction with their parent unit and some non-acute care entities do not acquire or administer the specific outpatient drugs included in the survey at all.

To create a population with evidence of survey-relevant OPPS drug utilization—either via their ODACS response or claims data—CMS applied two refinements. CMS refers readers to Section 3.1.2 of the ODACS Technical Report for details on these refinements and their impact on the hospital population. Consequently, the refined population of 3,147 CCNs more precisely reflects the universe of hospitals with meaningful and relevant outpatient acquisition volume for drugs included in the survey and, in turn, better focuses on the universe of hospitals that would be impacted by the proposed policy change.

The survey response rate changes as a result of these refinements because the denominator of response rate changes. The response rate is calculated as the number of CCNs that submitted an ODACS response divided by all survey-eligible CCNs. In the initial population, the denominator of 4,494 CCNs yields a response rate of 29.8 percent ; in the refined population, the denominator of 3,147 CCNs yields a response rate of 41.4 percent. CMS believes that the refined population response rate of 41.4 percent better represents the share of hospitals that reported acquiring surveyed NDCs out of all hospitals that could have reasonably been expected to report OPPS acquisitions of the surveyed NDCs. These refinements had a larger impact on the non-340B response rate only because the vast majority of subunits and non-acute care entities in the initial population are non-340B entities.

Comment: Many commenters contended that the response rate, especially from 340B hospitals, does not meet section 1833(t)(14)(D)(iii) of the Act's statutory threshold of a ''large sample of hospitals'' and is therefore too low to justify the proposed policy change. One commenter cited the 2005 acquisition cost survey conducted by GAO, which aimed to receive responses from 1,000 hospitals after sampling 1,400 hospitals out of an initially eligible 3,450 hospitals, to justify a 29.8 percent response rate as meeting the requirement for a large sample. Some commenters also linked the response rate to concerns over data representativeness, arguing that because the response rate among 340B hospitals was lower than among non-340B hospitals, it calls into question the representativeness and comparability of the 340B and non-340B respondent populations.

Response: We note that CMS sampled more hospitals than the GAO. Rather than limit the survey to a subset of hospitals, CMS ensured through its methodology that the maximum number of hospitals could participate and fulfill their statutory obligation to respond to the survey. For a discussion of this statutory requirement, see the CY 2026 OPPS/ASC final rule (90 FR 53764–53765). Nowhere in statutory language is ''a large sample of hospitals'' defined nor is a particular threshold set for achieving ''a large sample of hospitals.'' Moreover, determining adequate sample size in any survey-based quantitative analysis is a complex challenge that involves evaluating factors unique to that analysis, including the sampling design, population size, and population variability. For instance, the 2005 GAO survey design employed a stratified random sampling methodology that explicitly sampled from the initial hospital population; therefore, applying a threshold of 29.8 percent is not comparable to CMS's ODACS survey design, which did not employ a sampling methodology. Rather, CMS invited all 4,494 hospitals identified as paid under the OPPS to respond to the survey and contribute any acquisition data for surveyed NDCs. A response-rate floor defined for a stratified sample does not have an established meaning for a census survey.

Consistent with generally accepted statistical practice, sample size sufficiency was evaluated through the calculation of confidence intervals (CIs) and IPW adjustment rather than seeking to meet an arbitrary threshold. CMS notes that a smaller sample size does not necessarily make a sample less representative; rather, representativeness is governed by response mechanism instead of sample size. Large samples can be more skewed in certain characteristics, yielding potentially larger biases. This possibility is why CMS performed IPW adjustment and statistical diagnostic tests to understand and account for potential sample size and data representativeness issues. The IPW adjustment and calculation of CIs indicated that the response rate yielded sufficiently precise estimates of hospitals' acquisition costs. As we explained in Section 3.5.2 of the ODACS Technical Report, to evaluate whether the number of survey responses received was sufficient to produce statistically valid estimates of hospitals' acquisition costs, we calculated CIs for both unadjusted and IPW adjusted acquisition cost margins. The CIs provide measures of whether the response rate adequately captures true population results. When response rate is insufficiently low, CIs are wide due to the high degree of uncertainty regarding where the true result lies. Conversely, when response rate is sufficient, CIs narrow as uncertainty lessens. CMS calculated the CIs using a bootstrap methodology. First, the full dataset of survey records (after applying data refinements and excluding geometric mean outliers) was repeatedly sampled with replacement using hospitals as the sample unit; acquisition cost margins were recalculated for each repeated sample. This process was repeated 10,000 times to generate distributions of unadjusted and IPW-adjusted acquisition cost margin estimates. Finally, the 95% CIs were identified for each margin estimate using the 2.5th percentile as the lower bound and the 97.5th percentile as the upper bound.

We reported the impact of IPW adjustment and CI calculation on acquisition cost margins in Section 4.4.2 of the ODACS Technical Report which described that applying IPW adjustment had minimal impact on acquisition cost margins for either non-340B or 340B acquired drugs. For drugs acquired outside the 340B Program, hospitals' survey-reported acquisition costs were 2.7 percent above the mean ASP before

IPW adjustment and 2.8 percent above the mean ASP after IPW adjustment. For drugs acquired through the 340B Program, hospitals' survey-reported acquisition costs were 33.4 percent below the mean ASP before IPW adjustment and 33.1% below the mean ASP after IPW adjustment (Table 67). The consistency between unadjusted and IPW-adjusted results supports the robustness and representativeness of the acquisition cost margins derived from survey responses.

TABLE 67: COMPARISON OF UNADJUSTED TO IPW-ADJUSTED ACQUISITION COST MARGINS AND CONFIDENCE INTERVALS

Aggregate Margin Calculations: Methodology Specifications	Non-340B Drugs			340B Drugs		
	Mean ASP Margin	95% CI Lower Limit	95% CI Upper Limit	Mean ASP Margin	95% CI Lower Limit	95% CI Upper Limit
Unadjusted	+2.7%	–3.8%	+6.9%	–33.4%	–34.7%	–32.3%
IPW-Adjusted	+2.8%	–1.6%	+6.5%	–33.1%	–34.3%	–32.1%

The 95 percent CIs for both unadjusted and IPW-adjusted acquisition cost margins did not substantially differ from each other, indicating that the weighting adjustment had minimal impact on the resulting estimates. For non-340B drugs, the CIs spanned 3.8 percent below the mean ASP to 6.9 percent above the mean ASP for the unadjusted margin and between 1.6 percent below the mean ASP to 6.5 percent above the mean ASP for the IPW-adjusted margin. For 340B-acquired drugs, the CIs were much narrower and spanned 34.7 percent to 32.3 percent below the mean ASP for the unadjusted margin and from 34.3 percent to 32.1 percent below the mean ASP for the IPW-adjusted margin.

The narrow CIs for 340B-acquired drugs support the statistical validity of the survey results on 340B drugs and indicate that the received sample is sufficiently large to produce reliable estimates of hospital outpatient drug acquisition costs for 340B drugs. The CIs for the non-340B drugs span a wider range of potential acquisition cost margins, which is expected given the greater distributional spread in the survey data for non-340B drugs.

Comment: Many commenters noted slight differences in composition between the respondent population and overall population of survey-eligible hospitals along observable hospital characteristics. Some alleged that CMS had not demonstrated data representativeness for groups of their interest such as major teaching hospitals, rural hospitals, and high-volume purchasers. Other commenters also requested more information about representation along particular stratifications (*e.g.,* payer mix and patient populations) and for particular groups (*e.g.,* rural referral centers, Disproportionate Share Hospital [DSH] status), expressing concern that there could be differences in population composition along these factors that were not considered. Finally, some commenters raised concerns that the outlier trimming and data exclusions could disproportionately impact certain hospital characteristics, impairing representativeness.

Response: CMS previously published results that evaluated data representativeness along many of the hospital characteristics mentioned by commenters, including, hospital size, geographic rurality and location, 340B participation, academic teaching status, and OPPS drug claims volume. CMS refers readers to Table 6 of the ODACS Technical Report for these results. CMS acknowledges that the population composition differed slightly across some of these characteristics between the respondent population and the overall survey-eligible population. These differences are precisely why CMS applied IPW, a widely used statistical technique that reweights received data to account for under- or overrepresentation of particular hospital characteristics such that the weighted sample replicates the characteristics of the overall population. Applying IPW adjustment had minimal impact on acquisition cost margins for non-340B and 340B-acquired drugs, supporting the robustness and representativeness of the acquisition cost margins derived from survey responses. CMS refers readers to Section 4.4.2 of the ODACS Technical Report for a full discussion of the IPW adjustment methodology and results.

To address commenters' concerns that the respondent population is not representative along additional hospital characteristics not previously discussed, CMS conducted further analysis of the population by share of Medicare patients, DSH percentage, and hospital type. Unadjusted results show that the respondent population does not meaningfully differ from the overall population of survey-eligible hospitals by either Medicare share or DSH percentage, two indices of payer mix and patient population. When stratifying by hospital type, the respondent population is composed of slightly more IPPS hospitals and slightly fewer RRCs or RRC/SCHs, relative to all survey-eligible hospitals. CMS then integrated these three new variables as covariates in our IPW adjustment, and their inclusion had no impact on existing acquisition cost margins for either 340B-acquired or non-340B drugs.

Comment: Many commenters raised concerns that CMS's IPW adjustment methodology does not adequately address the risks of nonresponse bias and therefore does not ensure representativeness of the resulting acquisition cost margins. Commenters noted that IPW adjustment, which uses observable hospital characteristics to reweight population composition, can be insufficient if either or both of (i) the likelihood of survey response and (ii) drug acquisition costs are influenced by unobservable factors. Commenters offered various examples of potential unobservable factors that could hypothetically be exerting influence, including administrative complexity, drug purchasing arrangements, health system affiliation, and access to bulk purchasing discounts. As such,

commenters stated that CMS lacks evidence that the adjustors and covariates are able to close potential gaps in responses or acquisition costs. Additionally, some commenters stated that the narrow confidence intervals produced by the margin analyses indicate consistency among the respondent hospitals but do not demonstrate that the respondents accurately reflect the population as a whole. Finally, one commenter questioned why CMS did not report the distribution of respondents by OPPS drug volume quintile after IPW adjustment.

Response: As CMS describes below, we believe the acquisition cost data received are representative of acquisition costs among the eligible hospital population. We acknowledge that to sufficiently account for all determinants of hospital response and acquisition cost is a complex challenge given that acquisition costs for nonrespondents are, by definition, unobservable. CMS conducted an internal analysis to address concerns about nonresponse bias, with the specific goal of addressing whether nonresponse is correlated with acquisition costs. We used cost-to-charge ratios (CCR) from hospital cost reports and claim line charges from each providers' Fee-For-Service (FFS) drug claims data to create a proxy measure of acquisition cost that could be evaluated for the full population of survey-eligible hospitals. This analysis found that, for the 340B hospital population, respondents and nonrespondents had no statistically significant difference in costs, and the magnitude of the difference was close to zero, suggesting that a hospital's cost burden was not associated with their likelihood of response. CMS believes the consistency of proxy drug acquisition costs among respondents and nonrespondents supports the conclusion that the narrow confidence intervals obtained through the analysis do not simply reflect a homogenous respondent group, but rather are consistent with a sample that is representative of the eligible hospital population in terms of acquisition cost.

CMS conducted other tests to ensure the appropriateness of the IPW model and its covariates. First, we ran diagnostics on the distribution of estimated propensity scores and the resulting weights. In none of our IPW models did the estimated response probabilities fall below 10 percent; this is within the range where weight instability is not a concern and implies that weight trimming or truncation is not necessary. Second, CMS calculated Kish's effective sample size for each model, a diagnostic that summarizes how concentrated influence is across the weighted sample (a value close to the actual sample size indicates that weights are spread evenly across hospitals, while a value near 1 would indicate the estimate is driven by a single observation). In all cases, the effective sample size was close to the actual sample size, indicating that no small set of high-weight hospitals exerted disproportionate influence on the results.

As to why CMS did not report the distribution of respondents by OPPS drug volume quintile after IPW adjustment, OPPS drug volume quintile was highly correlated with the hospital size (bed count) quintile variable; given this, OPPS drug volume quintile was not included as a covariate in the IPW adjustment model to avoid collinearity issues. To address this comment, CMS also tested whether the final IPW weights balance the observed OPPS drug volume quintiles. We found that the reweighted sample effectively replicates the distribution of the OPPS drug volume quintiles in the population, even when this variable was not directly included. See Table 60.

(2) Margins Between Survey-Reported Hospital Acquisition Costs and Volume-Weighted ASP

Using the methodology, refinements, and processes discussed throughout Section (2)(b) Data Analysis and Methodology, we evaluated the received survey data to determine the difference between hospitals' survey-reported acquisition costs and ASP-based Medicare payment amounts. We first identified the percent margin between aggregate acquisition costs and volume-weighted ASP for both non-340B and 340B drug acquisitions, then performed an analogous calculation to identify the margin between 340B ceiling prices and ASP as additional context for the 340B acquisition cost margins. Next, we tested alternate methodological specifications to evaluate whether these margins varied depending on the methods used. Finally, we stratified margins by individual therapeutic classes to identify possible variation in acquisition costs relative to ASP along drug type.

The survey provides valuable information regarding hospitals' drug acquisition costs. Following the GAO recommendation to validate Medicare payment rates using hospital acquisition costs, we assessed the survey data for trends where acquisition cost did not align with Medicare payment. The most immediately evident difference was between Medicare payment rates and acquisition cost data for 340B-acquired drugs by 340B-participating hospitals. Based on the survey response data and applying the methodologies discussed previously, we found that for drugs acquired through the 340B Program, hospitals' reported acquisition costs during the specified time period were approximately 33.4 percent below both the mean and the median ASP. For drugs acquired outside of the 340B Program, hospitals' survey-reported acquisition costs during the specified time period were approximately 2.7 percent above the mean ASP and 2.8 percent above the median ASP.

To help validate these findings, we compared aggregate 340B ceiling prices for drugs included in the survey during the corresponding survey period to ASP amounts.[117] Based on this analysis, during the survey study period 340B ceiling prices were, in aggregate, 28.0 percent below the mean ASP and 29.2 percent below the median ASP, respectively. These findings help validate the survey response data for 340B-acquired drugs, as the ceiling price average discount is generally representative of the maximum acquisition cost and minimum discount, though hospitals can negotiate additional discounts resulting in a sub-ceiling acquisition cost. This is reflected in the survey results where the aggregate 340B acquisition cost margin is approximately 33.4 percent below the mean ASP—several percentage points lower than the aggregate ceiling price margin of 28.0 percent below the mean ASP.

We sought to ensure that the resulting margins precisely reflected the relationship between hospitals' acquisition costs and ASP, and did not manifest substantial changes under different methodological specifications. To do so, we tested the impact of weighting acquisition cost margins by OPPS claims volume and retaining 340B survey responses above the maximum ceiling price (Table 68). Although we did not propose to adopt these alternative methodologies at this time for the reasons outlined in section V.B.8.b of this final rule with comment period, calculating acquisition cost margins with these specifications emphasizes two key points about 340B-acquired drugs. First, regardless of how

[117] The 340B ceiling prices are the maximum statutory amounts drug manufacturers can charge covered entities for outpatient prescription drugs. They are calculated by subtracting the unit rebate amount (URA) which is the Medicaid rebate manufacturers must pay to the government from the average manufacture price (AMP) which is the average price paid to the manufacturer by wholesalers for a given drug.

one analyzes the data, there are considerable differences between hospitals' acquisition costs for 340B-acquired drugs and ASP-based payment amounts for 340B drugs. Second, these alternate methodologies had minimal impact on the acquisition cost margins for 340B-acquired drugs; regardless of calculation methodology, hospitals' survey-reported acquisition costs remained relatively consistent between approximately 29.9 percent and 33.4 percent below the average ASP and between 29.8 percent and 33.4 percent below the median ASP.

Application of different methodological specifications resulted in slightly more variation in the estimated margin between hospitals' survey-reported acquisition costs and mean or median ASP-based payments for drugs acquired outside the 340B Program. This greater variability could be attributed to wider distributional spread in the reported acquisition costs for non-340B drugs; this, in turn, could cause the non-340B margins to be more sensitive to application of different weighting methodologies.

TABLE 68: ODACS STATISTICAL DATA METHODOLOGIES AND RESULTS

Aggregate Margin Calculations: Methodology Specifications			Acquisition Cost to ASP Margin			
			Non-340B		340B	
			Mean ASP Margin	Median ASP Margin	Mean ASP Margin	Median ASP Margin
Geometric Mean Outliers Removed	Weighted by Survey Purchase Volume	Responses > Ceiling Price Included	2.7%	2.8%	–31.9%	–31.8%
		Responses > Ceiling Price Excluded			–33.4%	–33.4%
	Weighted by Outpatient Claims Volume	Responses > Ceiling Price Included	6.7%	6.7%	–29.9%	–29.8%
		Responses > Ceiling Price Excluded			–31.2%	–31.1%

To assess whether the magnitude of margins remained the same across different drug categories, we also examined acquisition cost margins by therapeutic class [118] for both 340B-acquired and non-340B-acquired drugs. Hospitals' survey-reported 340B acquisition costs were at least 28.9 percent below the mean ASP—and for most therapeutic classes lower than that—for drugs in all high-spending therapeutic classes (that is, those with more than $100 million in reported acquisition costs) (Table 69). Again, this reinforces the significant, and consistent, differences between hospitals' acquisition cost for 340B-acquired drugs and ASP for these drugs regardless of therapeutic class.

The margins for non-340B drugs displayed greater variation relative to the 340B drugs, which is likely attributable to greater heterogeneity in drug mix, provider type, and purchasing arrangements present outside the 340B Program. For instance, only certain drugs and biologicals can be acquired through the 340B Program and only certain types of hospitals can enroll as 340B participants. These restrictions necessarily limit which drugs and hospitals can be included in the 340B calculations, leading to a somewhat more homogenous population. These restrictions do not play a role in the non-340B calculations. Additionally, and perhaps most significantly, certain types of 340B-participating hospitals have historically been prohibited from purchasing covered outpatient drugs through GPO arrangements,[119] which limits the purchasing arrangements applicable to 340B drugs, while non-340B drugs can be purchased under a variety of GPO or other buying group arrangements.

[118] Therapeutic class assignments were based on the Medi-Span Generic Product Identifier (GPI) classification system.

[119] *https://www.hrsa.gov/sites/default/files/hrsa/opa/prohibition-gpo-participation-02-07-13.pdf.*

TABLE 69: ACQUISITION COST MARGINS BY THERAPEUTIC CLASS FOR 340B DRUGS

Therapeutic Class	340B	
	Mean ASP Margin	Median ASP Margin
Antineoplastics and Adjunctive Therapies	–28.9%	–28.8%
Hematopoietic Agents	–38.3%	–37.8%
Endocrine and Metabolic Agents	–52.6%	–52.8%
Passive Immunizing and Treatment Agents	–30.8%	–30.4%
Gastrointestinal Agents	–29.3%	–29.1%
Psychotherapeutic and Neurological Agents	–31.2%	–31.3%
Miscellaneous	–29.6%	–29.6%
Analgesics	–71.4%	–71.4%
Neuromuscular Agents	–31.8%	–31.9%

We received public comments on the margins between survey-reported hospital acquisition costs and volume-weighted ASP. The following is a summary of the comments we received and our responses.

Comment: Several commenters suggested that the published 340B acquisition cost margin of ASP minus 33.4 percent may be influenced by respondents with particular characteristics (*e.g.,* large hospitals that could access bulk purchasing discounts) and requested that CMS release additional details about these margins stratified by hospital characteristics.

Response: CMS recognized the possibility of acquisition costs varying by hospital characteristic and calculated margins along these traits in our initial analysis. Results show remarkably little variation based on all measured hospital characteristics; regardless of stratification, acquisition cost margins for 340B drugs range from 30.4 percent to 39.7 percent below the mean ASP and 30.3 percent to 39.6 percent below the median ASP.

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TABLE 70: Acquisition Cost Margin for 340B Drugs by Hospital Characteristic

Hospital Characteristic	340B Drugs	
	Mean ASP Margin	Median ASP Margin
ODACS Drug Acquisition Volume		
Bottom Quintile	–38.9%	–39.0%
Second Quintile	–37.6%	–37.5%
Third Quintile	–35.5%	–35.4%
Fourth Quintile	–32.5%	–32.4%
Top Quintile	–33.9%	–33.8%
OPPS Drug Billing Volume		
Bottom Quintile	–35.5%	–35.4%
Second Quintile	–34.4%	–34.3%
Third Quintile	–39.7%	–39.6%
Fourth Quintile	–35.2%	–35.0%
Top Quintile	–32.3%	–32.2%
No Billing	–33.0%	–32.8%
Hospital Size (Number of Beds)		
Bottom Quintile	–34.7%	–34.6%
Second Quintile	–33.6%	–33.6%
Third Quintile	–32.1%	–32.0%
Fourth Quintile	–33.0%	–33.0%
Top Quintile	–33.7%	–33.6%
Geographic Rurality		
Metropolitan	–33.5%	–33.4%
Micropolitan	–32.8%	–32.7%
Rural	–32.6%	–32.5%
Census Region		
New England	–38.3%	–38.2%
Middle Atlantic	–32.1%	–32.1%
South Atlantic	–31.9%	–31.9%
East North Central	–31.7%	–31.7%
East South Central	–32.3%	–32.2%
West North Central	–32.6%	–32.6%
West South Central	–35.8%	–35.7%
Mountain	–33.3%	–33.3%
Pacific	–35.4%	–35.3%
Teaching Status		
Major Teaching Hospital	–34.8%	–34.8%
Not Major Teaching Hospital	–32.7%	–32.6%
Unknown	–31.6%	–31.5%
Share of Medicare Patients		

Hospital Characteristic	340B Drugs	
	Mean ASP Margin	Median ASP Margin
Bottom Quintile	–34.9%	–34.8%
Second Quintile	–31.3%	–31.3%
Third Quintile	–35.4%	–35.3%
Fourth Quintile	–32.1%	–32.0%
Top Quintile	–33.4%	–33.3%
Unknown	–31.6%	–31.5%
Disproportionate Share Percent		
Bottom Quintile	–30.4%	–30.3%
Second Quintile	–34.2%	–34.1%
Third Quintile	–31.6%	–31.5%
Fourth Quintile	–33.4%	–33.4%
Top Quintile	–34.8%	–34.7%
Not Applicable	–31.6%	–31.5%
Hospital Type		
IPPS Hospital	–34.5%	–34.5%
Rural Referral Center (RRC)	–32.6%	–32.6%
Sole Community Hospital (SCH)	–32.5%	–32.4%
RRC/SCH	–33.9%	–33.9%
Other/Unknown	–31.6%	–31.5%

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Comment: Several commenters discussed concerns regarding variation in acquisition costs by individual drug and/or therapeutic class, pointing out that a single adjustment to ASP may lead to underpayment for certain drugs and overpayment for others. Commenters referenced Table 53 from the proposed rule, which presents margins by drug class, as illustrating that acquisition costs for 340B drugs vary substantially by drug type. Commenters consequently noted against the implementation of any payment adjustments that are not drug-specific.

Response: As we noted in the CY 2027 OPPS/ASC proposed rule, we considered calculating payment rates derived from individual acquisition cost amounts for 340B drugs; however, given the dynamic nature of drug pricing, we concluded that it would be more appropriate to apply a single discount factor to ASP. We also explained that we believed that this approach would be more appropriate as ASP is also dynamic in nature. ASP changes over time (quarter to quarter), so tying the payment amount to an average discount of ASP results in a more accurate payment amount, by quarter, than if hospitals had to wait until the next survey cycle. Each drug HCPCS code has its own specific payment rate calculated that is unique to the drug described by the applicable HCPCS code. We indicated that we would apply an average discount, calculated as described under V.B.9.b. and V.B.9.c.(2). of the proposed rule, to the drug-specific ASP amount. This would make our proposed payment rate specific to the average acquisition cost for the drug. We also stated that applying the payment rate in this manner would allow for this average discount to apply to newly calculated ASPs as they are updated on a quarterly basis. We further explained that it would not be practical to calculate a drug-specific payment rate for each NDC, and each HCPCS code, based on the survey data, as the survey-collected data is based on a snapshot in time and would not reflect future changes in average acquisition costs. Therefore, as drug prices change, we believe it is appropriate and reasonable to continue to update the calculated ASPs and then to reduce payments by an appropriate percentage of ASP to better align payment with the average cost of the drug.

With respect to commenters' observation that a single adjustment to ASP may lead to underpayment for certain drugs and overpayment for others, we emphasize that the purpose of our policy is to better align payment for 340B-acquired drugs with their acquisition costs in the aggregate, not to ensure that hospitals receive a payment amount greater than the cost of acquisition for every drug purchase. This approach is not unique to the policy for 340B-acquired drugs; because the OPPS is a prospective payment system, payment for an individual item or service may be more or less than a hospital's cost in any specific case. We would additionally note that the alternative payment rate that we are finalizing, ASP minus 28 percent, is greater than the ASP minus 33.4 percent amount demonstrated by the survey and would therefore partially mitigate commenters' concerns.

We also note that payment rates are already set on a drug-by-drug basis using the ASP methodology, and this policy will similarly reflect the differing acquisition costs of specific drugs. The percentage adjustment applied to ASP has never been tailored to individual HCPCS codes and this policy is consistent with that longstanding approach. Further, CMS chose to

volume-weight the proposed ASP percentage adjustment to reflect the relative utilization and differing margins of individual drugs.

CMS performed an additional variation of the IPW analysis in an effort to further address concerns about differences in drug utilization mix across providers. We first analyzed drug utilization by therapeutic class in the respondent and non-respondent populations. For those drug classes that displayed differences between the two groups, we included variables measuring each respondent's utilization of the drug classes of interest into the IPW adjustment. The introduction of these drug mix variables showed no impact on the existing aggregate margins, indicating that differing drug mix across providers does not appear to be exerting undue influence on the comparisons of acquisition costs to ASP.

(3) Application of Population Weight Adjustment and Calculation of Confidence Intervals To Assess Statistical Validity

In accordance with section 1833(t)(14)(D)(iii) of the Act, after completing initial analysis of survey respondents' acquisition costs, we evaluated whether survey respondents comprised a large sample that is sufficient to generate statistically significant and representative estimates of hospitals' acquisition costs. To do so, we conducted sensitivity analyses using inverse probability weighting (IPW) and confidence intervals, which we believe support the statutory objective of obtaining acquisition cost estimates from survey responses that are accurate and representative of the outpatient drug acquisition costs incurred by all hospitals paid under the OPPS.

(i) IPW Methodology

IPW is a widely used statistical technique in survey research [120] [121] [122] [123] [124] to ensure that sample data produce estimates that accurately represent the population of interest. We applied IPW to account for the potential underrepresentation or overrepresentation of hospitals with particular characteristics among survey respondents and to evaluate whether acquisition cost margins derived from survey responses sufficiently reflected outpatient drug acquisition costs for all OPPS hospitals.

For purposes of the IPW analysis, we constructed respondent and nonrespondent populations that align with the refined hospital population discussed previously in (1) Survey Response Rate and Respondent Characteristics. We defined the respondent population as hospitals that submitted a survey response reporting the purchase of at least one surveyed NDC during the survey study period. We defined the nonrespondent population as survey-eligible hospitals that did not submit a survey response but billed at least one Fee-For-Service outpatient claim associated with a survey-relevant HCPCS code during the same period. Because acquisition cost margins were calculated separately for drugs purchased through the 340B Program and drugs purchased outside the 340B Program, we further stratified hospitals based on evidence of 340B drug use. Hospitals were identified as 340B participants using HRSA's 340B OPAIS enrollment information and claims submitted with 340B modifiers. Hospitals that neither submitted an ODACS response nor billed relevant outpatient claims during the survey period were excluded from the IPW-adjusted population. Subunits were collapsed with their corresponding parent unit prior to constructing the respondent and nonrespondent populations.

After identifying the respondent and nonrespondent groups, we calculated response propensity scores using logistic regression models based on observed hospital characteristics, including number of beds, teaching hospital status, geographic rurality, and Census division. Propensity scores were estimated separately for hospitals purchasing drugs outside the 340B Program and hospitals purchasing drugs through the 340B Program. A higher propensity score means that the hospital was more likely to submit a survey response; a lower propensity score means that the hospital was less likely to submit a survey response.

We then calculated inverse probability weights equal to the inverse of each hospital's estimated probability of responding to the survey. Hospitals with a higher likelihood of responding received smaller weights, while hospitals with a lower likelihood of responding received larger weights. The weights were used to adjust for differential representation of hospital characteristics between the respondent sample and the broader population of survey-eligible hospitals. Down-weighting hospitals with a high probability of response (which are overrepresented in the received sample) while upweighting CCNs with a low probability of response (which are underrepresented in the received sample) accounted for the differential representation of hospital characteristics in the sample as compared to the full population.

Finally, we calculated the IPW-adjusted acquisition cost margins by first applying the calculated weights to hospitals' average acquisition costs and corresponding ASP-based payment amounts, then recalculating aggregate acquisition cost margins by finding the difference between the IPW-adjusted acquisition costs and IPW-adjusted ASP-based payment and then dividing that difference by the IPW-adjusted ASP-based payment. We also applied the same methodology when calculating IPW-adjusted margins between acquisition costs and 340B ceiling prices.

(ii) Confidence Intervals Methodology

To evaluate whether the number of survey responses was sufficient to produce statistically valid estimates of hospitals' acquisition costs, we calculated confidence intervals for both unadjusted and IPW-adjusted acquisition cost margins. The confidence intervals provide measures of whether the survey response rate adequately captures true population-level results. When response rate is insufficiently low, confidence intervals are very wide due to the high degree of uncertainty regarding where the true result lies. Conversely, when response rate is sufficient, confidence intervals become narrower as uncertainty lessens.

We calculated confidence intervals using a bootstrap methodology. Specifically, we repeatedly sampled with replacement from the original survey dataset and recalculated acquisition cost margins for each repeated sample. We repeated this process 10,000 times to generate distributions of unadjusted and IPW-adjusted acquisition cost margin estimates. We then identified the 95 percent confidence intervals for each acquisition cost margin estimate using the 2.5th percentile as the lower bound and the 97.5th percentile as the upper bound.

[120] ''Behavioral Risk Factor Surveillance System: Weighting the Data (2011 Weighting Formula),'' U.S. Centers for Disease Control and Prevention, last modified July 19, 2013, *https://www.cdc.gov/brfss/annual_data/2011/2011_weighting.htm.*

[121] ''National Health and Nutrition Examination Survey—Weighting,'' U.S. Centers for Disease Control and Prevention, n.d., *https://wwwn.cdc.gov/nchs/nhanes/tutorials/weighting.aspx.*

[122] ''Weighting,'' U.S. Census Bureau, last modified January 12, 2022, *https://www.census.gov/programs-surveys/cps/technical-documentation/methodology/weighting.html.*

[123] ''Weighting,'' U.S. Census Bureau, last modified August 19, 2022, *https://www.census.gov/programs-surveys/sipp/methodology/weighting.html.*

[124] ''Consumer Expenditures and Income: Calculation,'' U.S. Bureau of Labor Statistics, last modified September 12, 2022, *https://www.bls.gov/opub/hom/cex/calculation.htm.*

(iii) Results of Population Weight Adjustments and Confidence Intervals From ODACS Data

Application of inverse probability weighting improved the alignment between the distribution of respondent hospital characteristics and the broader population of survey-eligible hospitals. We found that IPW-adjusted respondent characteristics more closely resembled the full population across measures such as rural/urban, teaching status, Census division, and 340B participation (Table 71).

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TABLE 71: POPULATION WEIGHT ADJUSTMENT BY HOSPITAL CHARACTERISTIC

Hospital Characteristic	Non-340B Drugs			340B Drugs		
	ODACS-Eligible Population	Unadjusted ODACS Respondents	IPW-Adjusted ODACS Respondents	ODACS-Eligible Population	Unadjusted ODACS Respondents	IPW-Adjusted ODACS Respondents
340B Enrollment						
340B Hospital	48.1%	32.8%	50.0%	100.0%	100.0%	100.0%
Non-340B Hospital	51.9%	67.2%	50.0%	N/A	N/A	N/A
Number of Beds						
Bottom Quintile	15.8%	20.0%	16.2%	7.4%	9.6%	6.9%
Second Quintile	17.1%	18.3%	16.9%	13.8%	16.7%	13.7%
Third Quintile	20.6%	20.6%	20.8%	17.5%	17.0%	17.7%
Fourth Quintile	22.7%	21.6%	23.4%	26.4%	27.0%	26.6%
Top Quintile	23.8%	19.6%	22.7%	35.0%	29.7%	35.2%
Rurality						
Metropolitan	73.8%	71.8%	74.6%	71.8%	69.5%	71.9%
Micropolitan	17.3%	17.2%	16.7%	20.0%	19.2%	20.3%
Rural	8.9%	11.0%	8.7%	8.3%	11.3%	7.8%
Census Region						
New England	4.3%	2.6%	4.6%	4.8%	3.4%	4.5%
Middle Atlantic	10.9%	9.7%	10.7%	12.1%	9.8%	13.1%
South Atlantic	16.6%	16.8%	16.0%	14.1%	11.8%	15.0%
East North Central	15.5%	12.9%	16.3%	17.0%	18.4%	16.6%
East South Central	8.3%	9.9%	8.3%	8.6%	9.8%	8.6%
West North Central	7.5%	6.6%	7.0%	8.3%	8.1%	8.1%
West South Central	15.8%	22.7%	15.9%	12.9%	18.2%	12.6%
Mountain	7.2%	7.7%	6.4%	6.3%	3.9%	6.4%
Pacific	12.6%	9.7%	13.0%	15.4%	15.0%	14.6%
Puerto Rico	1.2%	1.4%	1.9%	0.5%	1.5%	0.5%
Teaching Status						
Major Teaching	12.8%	10.2%	11.8%	19.5%	16.7%	19.5%
Not Major Teaching	84.4%	86.6%	85.6%	77.3%	79.1%	77.4%
Unknown	2.8%	3.3%	2.6%	3.2%	4.2%	3.1%

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(iv) Weighted Adjusted Acquisition Cost Margins

We found that application of IPW had minimal impact on estimated acquisition cost margins for either non-340B drugs or 340B-acquired drugs. For drugs acquired outside the 340B Program, the analysis conducted estimated that acquisition costs were approximately 2.7 percent above the mean ASP prior to IPW adjustment and approximately 2.8 percent above the mean ASP after IPW adjustment. For drugs acquired through the 340B Program, the analysis estimated that acquisition costs were approximately 33.4 percent below the mean ASP prior to IPW adjustment and approximately 33.1 percent below the mean ASP after IPW adjustment. The consistency between unadjusted and IPW-adjusted results supports the robustness and representativeness of the acquisition cost margins derived from survey responses (Table 72).

TABLE 72: EFFECT OF INVERSE PROBABILITY WEIGHT ADJUSTMENT ON ACQUISITION COST MARGINS AND 95 PERCENT CONFIDENCE INTERVALS (CI)

Aggregate Margin Calculations: Methodology Specifications		Acquisition Cost to Mean ASP Margin					
		Non-340B Drugs			340B Drugs		
		Mean ASP Margin	95% CI Lower Limit	95% CI Upper Limit	Mean ASP Margin	95% CI Lower Limit	95% CI Upper Limit
Responses > Ceiling Price Included	Unadjusted	+2.7%	–3.8%	+6.9%	–31.9%	–33.9%	–29.4%
	IPW-Adjusted	+2.8%	–1.6%	+6.5%	–31.6%	–33.4%	–29.3%
Responses > Ceiling Price Excluded	Unadjusted				–33.4%	–34.7%	–32.3%
	IPW-Adjusted				–33.1%	–34.3%	–32.1%

The 95 percent confidence intervals for both unadjusted and IPW-adjusted acquisition cost margins were not substantially different from each other, indicating the weighting adjustment had minimal impact on the resulting estimates. For non-340B drugs, the confidence intervals ranged from approximately 3.8 percent below the mean ASP to 6.9 percent above the mean ASP for unadjusted margin and between 1.6 percent below the mean ASP to 6.5 percent above the mean ASP for the IPW-adjusted margin. For 340B-acquired drugs, the confidence intervals were much narrower and ranged from approximately 34.7 percent to 32.3 percent below the mean ASP for the unadjusted margin and from 34.3 percent to 32.1 percent below the mean ASP for the IPW-adjusted margin (Table 72).

We believe the relatively narrow confidence intervals for 340B-acquired drugs support the statistical validity of the survey results on 340B drugs and indicate that the received sample is sufficiently large to produce reliable estimates of hospital outpatient drug acquisition costs for 340B drugs. We note that the confidence intervals for the non-340B drugs span a wider range of potential acquisition cost margins. This is expected given the greater distributional spread in the survey data for non-340B drugs, as discussed in this section V.B.2.8. of this final rule with comment period.

For an additional summary of our analysis of the survey results we refer readers to the 2026 Outpatient Prospective Payment System Drug Acquisition Cost Survey Technical Report posted on the Medicare Outpatient Prospective Payment System (OPPS) Drug Acquisition Cost Survey website.[125] We solicited comment on our process for how we evaluated ODACS data to determine the magnitude of the margins between hospitals' survey-reported acquisition costs and ASP-based Medicare payment amounts.

We received public comments on the application of population weight adjustment and calculation of confidence intervals to assess statistical validity. The following is a summary of the comments we received and our responses.

Comment: One comment noted that the quarterly ASP payment rate fluctuates across quarters. While CMS accounted for this fluctuation by publishing results comparing acquisition costs to both the mean and median ASP payment rate across the four quarters of the ODACS study period, this commenter suggests that a volume-weighted mean ASP would be a better comparison for scenarios when purchase volume is not evenly distributed across quarters.

Response: CMS thanks the commenter for raising this consideration. CMS did not volume-weight the mean ASP payment rate for two key reasons. First, the ASP payment rates for most drugs did not vary substantially across the quarters in the study period, so volume-weighting was not needed to make the mean ASP an appropriate measure. Additionally, drugs may not be acquired in the same quarter as they are administered, leading to potential misalignment between hospitals' acquisition cost and the applicable ASP payment rate. Still, CMS did perform additional analyses comparing reported acquisitions costs to the minimum, or lowest, payment rate published for each HCPCS during the study period in order to construct lower bound estimates of the margin between ASP and hospitals' acquisition costs. These analyses revealed only a small impact on the aggregate margins.[126] Thus, CMS proceeded with comparisons to the

[125] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/outpatient-prospective-payment-system-opps-drug-acquisition-cost-survey.*

[126] Comparing against the minimum ASP rather than the mean ASP yields an overall 340B margin of 31.8 percent instead 33.4 percent.

mean ASP as more representative of average payment rate during the study period.

Comment: Some commenters took issue with CMS's selected methodology to weight each drug's ASP by the total number of NDC units reported by all respondents. A commenter stated that because NDCs reported in higher volume have a greater impact on aggregate acquisition cost margins, these margins would be biased if respondents do not reflect the overall survey-eligible population. Another commenter compared the selected methodology with an alternate approach that CMS considered to weight by OPPS claims volume, contending that the latter is more appropriate because it would better reflect the services that would be impacted by the proposed 340B-acquired drug payment change. Commenters noted that the two methodologies yielded slightly different aggregate acquisition cost margin results and contended that CMS had arbitrarily chosen to weight by survey-reported unit volume without sufficient justification.

Response: CMS is unpersuaded by arguments that volume-weighting by survey-reported unit volume is inappropriate. Rather, this approach ensured that the ASPs for NDCs that represented a larger share of total survey-reported purchasing activity were proportionally represented in the estimated acquisition cost margins. Of key importance is the fact that hospitals' acquisition cost survey data captures all outpatient drug purchases, making weighting by survey volume necessary for internal consistency, whereas volume-weighting by OPPS unit volume only reflects Medicare FFS drug utilization. Additionally, there can be time lags between when a hospital purchased a drug and when it is administered, which would lead to misalignments between survey-reported unit volume for drugs purchased during the surveyed time period and OPPS claims volume for drugs billed during the surveyed time period. Accordingly, CMS believes that the selected volume-weighting method should consider all reported utilization volume, not just that for Medicare FFS beneficiaries, and ensure alignment with the surveyed time period to enable fair comparisons between survey-reported acquisitions and equivalent Medicare payment amounts. CMS does not find it problematic that the acquisition cost margins differ slightly between weighting methodologies. Slight divergences are to be expected given that unit volume is not identical between survey responses and billed claims for the two reasons listed above, and CMS believes that the merits of selecting the survey-reported unit volume weighting approach have been sufficiently justified. Finally, CMS refers readers to the discussion of representativeness analyses in section V.B.8.c. of this final rule with comment period to address concerns regarding potential respondent bias related to drug utilization volume.

Comment: Some commenters requested additional information and rationale regarding the selected outlier trimming methodology, noting that this methodological decision has significant impacts on the resulting acquisition cost margins. A commenter requested that CMS publish acquisition cost margins calculated before outliers were removed to better understand the impacts of the outlier trimming approach. Another commenter contended that using the geometric mean outlier trimming approach was inappropriate for these data and would result in only high outliers being removed while retaining low outliers in cases where three standard deviations below the mean is less than $0, thereby driving down the calculated acquisition cost margins. This comment suggested that CMS should have considered winsorizing these outlier observations instead of trimming them.

Response: CMS selected the geometric mean trimming approach to be consistent with our standard methodology for processing extreme outliers to develop policy under the OPPS.[127] This outlier identification was performed separately for 340B and non-340B drug acquisitions of each NDC, producing tailored outlier thresholds based on the unique data distribution for each drug through each purchasing channel. While CMS also considered the Tukey interquartile range (IQR) method as an alternate approach to trim outliers, we chose not to adopt it for reasons outlined in Section 3.4.1 of the ODACS Technical Report. CMS also notes that the majority of outliers, approximately 82 percent, identified and removed through the selected outlier trimming methodology were non-340B purchases. Due to the clustering of reported 340B acquisition costs at or closely below ceiling price, far fewer 340B responses were identified and trimmed as outliers.

When including survey responses that were identified as geometric mean outliers (while still applying all five data exclusions enumerated in Section 3.3 of the ODACS Technical Report), the calculated acquisition cost margin for 340B-acquired drugs was ASP minus 35.9 percent when compared to both the mean and median ASP and for non-340B drugs was ASP minus 0.2 percent (mean ASP) or ASP minus 0.1 percent (median ASP). In other words, the aggregate acquisition cost margin for both 340B and non-340B drugs was slightly lower with outliers retained, contrary to commenter's hypothesis. This indicates that, in aggregate, the geometric mean trimming method did not systematically remove only high outliers; on the contrary, including these outliers would have suggested that hospitals' acquisition costs are even lower than Medicare payment rates. CMS thanks the commenter for their suggestion of winsorizing outliers and may consider this approach in any future survey analyses, as applicable.

[127] ''Medicare CY 2026 Outpatient Prospective Payment System (OPPS) Final Rule Claims Accounting,'' *CMS,* accessed June 16, 2026, *https://www.cms.gov/files/document/2026-nfrm-opps-claims-accounting.pdf.*

TABLE 73: Acquisition Cost Margins With and Without Geometric Mean Outliers Included

Aggregate Margin Calculations: Methodology Specifications	Non-340B Drugs		340B Drugs	
	Mean ASP Margin	Median ASP Margin	Mean ASP Margin	Median ASP Margin
Geometric Mean Outliers Included	–0.2%	–0.1%	–35.9%	–35.9%
Geometric Mean Outliers Removed	+2.7%	+2.8%	–33.4%	–33.4%

Comment: Multiple commenters indicated that there are scenarios in which covered entities' acquisition costs for 340B drugs may exceed the published ceiling price (*e.g.,* obtaining products during drug shortages or supply chain disruptions when 340B inventory is unavailable; drugs purchased at WAC price before 340B replenishment). Thus, these commenters contend that survey responses above the ceiling price should have been retained in the 340B margin calculations.

Response: CMS appreciates the additional context discussed in these comments. CMS notes that any such acquisitions that were ultimately acquired through non-340B channels should have been reported as non-340B purchases in the survey data. Additionally, drugs initially purchased at WAC price should have had their acquisition costs reported post-340B replenishment, with all adjustments to comply with ceiling pricing already factored in. That said, in the event that these purchases were still reported as 340B acquisitions with costs exceeding the ceiling price, CMS conducted sensitivity analyses to assess the impact of retaining these observations. These results showed only a small impact, less than 2 percent, on the observed margins. Still, given the likelihood that responses above the ceiling price were not reported in accordance with survey guidance, CMS proceeded with excluding these observations.

Comment: One commenter requested more information regarding CMS's exclusion of certain clotting factor and respiratory therapy NDCs because CMS identified a subset of survey records for these NDCs were reported in IU or MG rather than NDC package units. The commenter requested CMS to clarify how these records were identified, how many records were reported in IU or MG units out of all records received for those NDCs, and whether conversion of IU or MG figures into NDC package units was considered as an alternative to exclusion. Finally, the commenter contended that the exclusion of these drugs meant that CMS was unable to determine acquisition cost estimates for the affected NDCs.

Response: CMS identified survey records as reported in IU or MG units by comparing each record's average acquisition cost to the average ASP and maximum ceiling price (reported in IU or MG) and average adjusted ASP (adjusted for NDC package size using an NDC–HCPCS conversion factor) for the NDC. As stated in Section 3.3.5 of the ODACS Technical Report, survey records reported in IU or MG units also displayed extremely high unit counts relative to their acquisition costs, which is to be expected given that hundreds—or even thousands—of IU or MG units are contained in one NDC package.

Between one-quarter and one-third of total survey records for these NDCs were identified as reported in IU or MG units; in many cases, the same hospital reported in IU/MG for multiple affected NDCs. These percentages were high enough that IU- and MG-based records were unable to be comprehensively detected as outliers using either of the two tested outlier methodologies. As such, including these NDCs in acquisition cost calculations (while applying all other data exclusions enumerated in Section 3.3 of the ODACS Technical Report and trimming geometric mean outliers) yielded a substantially lower aggregate 340B acquisition cost of ASP minus 55.3 percent. This is due to the substantial distortions in per-unit costs for IU/MG-reported survey records.

CMS tested the impact of fixing the IU/MG records by converting their units to NDC package units. With this adjustment, the 340B margin remained ASP minus 33.4 percent and the non-340B margin slightly lowered to ASP plus 2.6 percent (instead of ASP plus 2.7 percent). Margins with affected NDCs adjusted were very similar to the margins with affected NDCs removed because converting the IU/MG units to NDC package units greatly reduced their reported unit volume, so their margins had much less impact on the volume-weighted aggregate calculation. As such, CMS was in fact able to produce acquisition cost estimates including these NDCs.

However, CMS ultimately chose to not pursue this approach given our overarching objective to not alter hospital-submitted data. CMS was also unable to conduct outreach to hospitals submitting affected data given limited time and resources, particularly because a large number of entities did not submit their response until the end of the data collection period.

Comment: Some commenters felt that the proposed rule's analyses showing ceiling prices to be 28.0 percent below ASP overall introduced uncertainty regarding the main analyses comparing hospital-reported acquisition costs and ASP, particularly when they compared this percentage with the proposed ASP adjustment of ASP minus 33.4 percent. They requested further explanation for the difference between these two percentages.

Response: CMS believes these comments reflect a misunderstanding of what the ceiling price represents, as it is logical and expected that the results comparing ceiling price to ASP differ from results comparing hospital-reported 340B acquisition cost to ASP. The ceiling price is the maximum amount that covered entities can be required to pay by manufacturers, but hospitals are able to acquire drugs for less than the ceiling amount, and often reported doing so in the survey data. This is why the 340B acquisition cost data shows a larger percentage discount relative to ASP than the ceiling price data.

Comment: Several commenters expressed concerns with what they characterized as differential interpretation and treatment of the 340B and non-340B data received from hospitals via the ODACS. They requested clarity on why CMS is choosing to take action on payment rates impacting 340B covered entities while stating that more data and analysis are necessary before proposing any policy changes to payment rates affecting non-340B hospitals. A

commenter noted that since CMS is proposing to vary payment rates based on hospital group, it must determine not only acquisition costs for the 340B hospital group but also how those compare to the relative acquisition costs for the non-340B hospital group.

Response: CMS analyzed the data received for 340B and non-340B drugs using identical methodological approaches. What differed, however, were the results obtained from these analyses.

TABLE 74: Comparison of Unadjusted to IPW-Adjusted Acquisition Cost Margins and CIs for 340B and Non-340B Drugs

Aggregate Margin Calculations: Methodology Specifications	Non-340B Drugs			340B Drugs		
	Mean ASP Margin	95% CI Lower Limit	95% CI Upper Limit	Mean ASP Margin	95% CI Lower Limit	95% CI Upper Limit
Unadjusted	+2.7%	–3.8%	+6.9%	–33.4%	–34.7%	–32.3%
IPW-Adjusted	+2.8%	–1.6%	+6.5%	–33.1%	–34.3%	–32.1%

The acquisition cost margin calculated for 340B drugs of ASP minus 33.4 percent displayed a clear and substantial difference from the existing payment rate of ASP plus 6 percent. This finding was strengthened after calculating IPW-adjusted margins and 95 percent CIs for both the unadjusted and IPW-adjusted point estimates. Across both methodologies, 340B margins ranged from ASP minus 34.7 percent to ASP minus 32.1 percent, a narrow range spanning only 2.6 percentage points. The narrow CIs for 340B-acquired drugs support the statistical validity of the survey results on 340B drugs and underscore the stark difference between hospital-reported acquisition costs and current Medicare payment policy.

On the contrary, the acquisition cost margin calculated for non-340B drugs of ASP plus 2.7 percent was only slightly below the existing ASP plus 6 percent payment rate. CMS notes that this is consistent with GAO's findings in 2004 and 2005, which found average purchase prices for drugs in their survey to equal roughly ASP plus 3 percent. The data are not conclusive enough for CMS to take policy action at this time regarding non-340B-acquired drugs. The data must be analyzed further by CMS, including the addition of GPO discounts, and CMS seeks more information to understand whether hospital acquisition costs for drugs purchased outside the 340B Program differ notably from the existing ASP plus 6 percent payment rate.

340B covered entities may, and often do, acquire drugs outside of the 340B Program, and these acquisitions would continue to be paid at the ASP plus 6 percent rate in recognition of the fact that 340B covered entities cannot access the 340B discount price for those purchases.

Comment: Some commenters noted that the proposed rule did not discuss the impact of ''penny pricing'' scenarios, in which manufacturers are required to sell 340B drugs to covered entities at a price of $0.01, on the aggregate survey results. Comments expressed concern that including these observations would exert a substantial downward influence on the observed margins.

Response: Very few survey responses (approximately 0.5 percent of received records) were submitted to ODACS that reported acquisitions of apparently penny-priced drugs. This is somewhat of a departure from the 340B drug acquisition cost survey conducted in 2020, which received more responses indicating penny-priced acquisition, therefore necessitating dedicated methodological specifications to analyze these observations. CMS did not explicitly exclude these responses from ODACS in the interest of retaining the largest amount of available data. However, sensitivity analyses that excluded penny-priced drugs showed minimal impact on the final 340B margin. Therefore, in the interest of retaining a maximally large dataset, CMS proceeded with results derived with these observations included.

Comment: A couple commenters raised concerns that respondents may have differentially interpreted how to report financial concessions that could not be reasonably attributed to a specific NDC, leading to some hospitals including a particular rebate or discount into their NDC-level acquisition costs and other hospitals reporting the same type of rebate entirely in the separate Price Concessions field of the ODACS module. Commenters contended that this would produce inconsistencies in acquisition costs across respondents such that they could not be comparable, and that these issues would have a larger impact on non-340B hospitals because most 340B hospitals subject to the proposed policy change have historically been prohibited from using GPOs. Finally, one commenter stated that GAO's previous survey analysis found that hospitals were unable to report accurately or comprehensively on such rebates.

Response: CMS acknowledges the complexity and room for interpretation associated with reporting aggregate (*i.e.,* non-NDC-specific) price concessions, including those obtained through participation in a GPO. After consulting subject matter experts on GPOs, additional consideration is needed to assess how best to apply the reported numbers; however, all approaches considered would have lowered the final estimated average acquisition cost given that the reported GPO data would have applied an additional discount to hospitals' reported acquisition costs. However, given that the ASP minus 33.4 percent policy change applies only to 340B-acquired drugs and most 340B hospitals subject to the proposed policy change have historically been subject to restrictions regarding GPO participation, concerns over the consistency and comparability of hospital-reported aggregate GPO discount amounts do not meaningfully impact CMS's policy decision on payment for 340B-acquired drugs. These important nuances raised by commenters are one reason why CMS has elected to not advance policy changes to non-340B-acquired drugs at this current time and will continue to assess how to appropriately analyze and include GPO discounts for non-340B drug purchases.

Comment: Commenters brought up a variety of factors, both related to the survey design and external influences, that they state may have impacted the

validity of the received data and its applicability to inform Part B drug policymaking. First, commenters mentioned that several drugs included in ODACS were in shortage and/or experienced supply chain challenges during the surveyed time period of July 1, 2024 to June 30, 2025; according to these commenters, these disruptions may have influenced acquisition costs, product mix, and purchasing behavior in ways that do not reflect normal market conditions. Second, commenters contended that the one-year survey time period may be insufficient to comprehensively capture hospitals' acquisition costs and does not account for year-to-year variation in acquisitions; in their view, analyzing data from additional years would provide a more robust basis for refining Part B drug payment policy. Third, commenters raised concerns that because the collected data reflect a historical period (*i.e.,* July 1, 2024 to June 30, 2025), their applicability to the current and future Federal drug-pricing landscape is limited given continued evolution in policymaking (*e.g.,* the forthcoming implementation of negotiated Maximum Fair Prices for selected Part B drugs and ongoing consideration of alternative mechanisms for effectuating 340B ceiling prices) and the impact of these developments on hospitals' financial environment.

Response: CMS notes that all survey analyses inherently represent a point-in-time estimate based on when data were collected. Lengthening the surveyed time period would have increased the administrative burden for hospitals to complete the survey, given increased time necessary to review their purchasing records and aggregate data. Additionally, drugs may experience shortage or supply chain interruptions in any year and the Federal drug policymaking landscape is in continuous evolution, making it impossible to designate a particular time period as ''normal'' or baseline market conditions against which to form comparisons. CMS notes that the surveyed time period of one year (July 1, 2024 to June 30, 2025) aligns with the GAO-selected time period of one year (July 1, 2003 to June 30, 2004).

Comment: Some commenters pointed to CMS's discussion of the five exclusions applied to remove anomalous or duplicative survey records as evidence that the received data were low quality. A commenter specifically cited that 8.9 percent of all received records were excluded due to these criteria, alleging that this represented a large share of total records.

Response: Records that were excluded due to meeting at least one of the five criteria listed in Section 3.3 of the ODACS Technical Report do not necessarily represent inaccurate or low-quality data. In many cases, these records reflect drug- and context-specific misunderstandings of or misalignments with the exact survey design rather than being indicative of larger data quality issues. CMS refers readers to Section 3.3 of the ODACS Technical Report for discussion of each situation and possible explanations underlying these observed anomalies. For the exclusion described in section 3.3.5 specifically, CMS notes that not all responses for affected clotting factor and respiratory therapy NDCs displayed the unit-misalignment issue, but were removed to avoid potential selection bias from specifically excluding those survey records with units reported in IU or MG; therefore, this exclusion removes more than just records featuring the anomaly. Nevertheless, CMS elected to remove records in these five exclusion criteria to promote data alignment with the stated survey design and ensure consistency in analyzing the data.

These five specific exclusions, associated with likely misunderstandings of the exact survey design, resulted in exclusions that only composed a small share of total records. After applying these data restrictions, 146,117 records remained, 91.1 percent of the original records received, with which CMS calculated acquisition cost margins. Moreover, these 146,117 records detail the acquisition cost of drugs that comprise approximately 97 percent of payment for survey-relevant outpatient drugs from July 1, 2024 to June 30, 2025. Compared to this preponderance of data retained, these five data restrictions excluded a small share of total records.

Comment: Many commenters requested additional detail on CMS's methodology (including outlier identification and weighting), sensitivity analyses, representativeness of the survey data, and IPW model specifications. Numerous commenters also requested the release of the survey instrument and data collected, with or without anonymization applied.

Response: Hospitals were assured that their acquisition cost data would remain confidential as part of the ODACS data collection and analysis process, and this protection will be honored. Publishing de-identified survey data with anonymized hospital characteristics appended still presents an immense confidentiality risk due to the small number of respondent hospitals identified in multiple specific categories (*e.g.,* rural hospitals in specific Census regions). For details on methodology and results, CMS refers commenters to the ODACS Technical Report. Further, CMS has provided additional detail on methods and analysis results in comment response throughout this final rule with comment period.

C. CY 2027 OPPS Payment Methodology for 340B Purchased Drugs Based on Survey Results

As described previously, section 1833(t)(14)(D)(ii) of the Act requires the Secretary to conduct periodic surveys to determine the hospital acquisition cost for each SCOD for use in setting the payment rates for SCODs under section 1833(t)(14)(A) of the Act. Section 1833(t)(14)(A)(iii)(I) of the Act provides that the payment amount for a SCOD for a year is equal to the average acquisition cost for the drug (which at the option of the Secretary, may vary by hospital group) as determined by the Secretary, taking into account the survey data collected under subparagraph (D) of section 1833(t)(14) of the Act. Based on our analysis of the survey data, the most immediately evident and significant difference found between Medicare payment and acquisition cost was for 340B drugs acquired by 340B-participating hospitals, where the selected methodology shows that aggregate acquisition costs were approximately ASP minus 33.4 percent. This indicates average acquisition costs that were 37.2 percent lower than the general OPPS payment rate (ASP plus six percent). These results clearly demonstrate that ASP plus 6 percent is not an appropriate payment proxy for hospitals that acquire drugs through the 340B Program. Consequently, we proposed to adjust the OPPS payment policy for 340B drugs to better align payment with the acquisition costs demonstrated by the survey. Specifically, for CY 2027, we proposed to pay for drugs acquired under the 340B Program at ASP minus 33.4 percent.

Conversely, for non-340B drugs, after taking into account the survey data, we proposed to maintain the current payment rate, which is generally ASP plus 6 percent, under the authority at section 1833(t)(14)(A)(iii)(I) of the Act. As displayed in Table 67, the heterogeneity in acquisition costs for non-340B drugs is slightly greater than for 340B drugs; this variation has led us to believe this area warrants additional analysis by CMS and input from interested parties. The results of the survey for non-340B drugs generally indicate lower acquisition costs than current OPPS payment; however, the

discrepancy is not as clear and significant as with 340B drugs. Therefore, we are continuing to analyze the data from this survey, aligning those reported costs with hospital claims billing patterns, to see if any additional significant trends exist that merit further adjustments to OPPS payment policy in future years. We are also assessing billing patterns among those hospitals that did not respond. Finally, we collected and analyzed information on non-NDC-specific GPO discounts that hospitals receive and are still considering how these discounts could be factored into future analysis and policymaking. We will consider these issues for future rulemaking.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to pay for 340B-acquired drugs at ASP minus 33.4 percent based on the survey results. These commenters stated that aligning the 340B payment rate more closely with hospitals' actual acquisition costs, as reflected by the survey data, would improve the accuracy of Medicare payment, reduce incentives to choose more expensive drugs or shift drug administration to higher-cost settings, promote transparency and accountability, direct statutorily-required budget-neutral savings toward non-drug OPPS services and help ensure beneficiaries share in the value of 340B discounts through lower cost sharing. A commenter stated that CMS's findings are consistent with analyses from the Medicare Payment Advisory Commission (MedPAC) and the U.S. Department of Health and Human Services Office of Inspector General (HHS OIG) showing that Medicare payments for 340B-acquired drugs have substantially exceeded 340B drug acquisition costs. A commenter endorsed the proposal on the basis that it is a reasonable and overdue correction to the way Medicare pays hospitals for administering drugs. Another commenter stated that this policy reflects that Federal payment rates should rest on evidence of what something actually costs. A commenter stated that the survey made evident that the acquisition cost for SCODs through the 340B Program is far lower than the statutory default rate of ASP plus six percent and that with this clear survey data, CMS is required to set payment based on the average acquisition cost for 340B-acquired drugs. Citing our example of a beneficiary's coinsurance alone exceeding the entire price the hospital paid for the drug, many commenters emphasized the positive effect the proposed policy would have in reducing beneficiary drug copayments due to those copayments being calculated based on the amount Medicare pays the hospital rather than the hospital's acquisition cost for the drug.

Response: We thank commenters for their support.

Comments: Many of these commenters additionally provided criticisms of the 340B Program generally and proposed various reforms for CMS to consider to address those criticisms.

Response: We note feedback related to 340B Program policies are outside the scope of the proposed rule and are not addressed in this final rule with comment period. However, we thank the commenters for their insights and concerns.

Comment: A few commenters commented on our observation in the proposed rule (91 FR 41880) that we received a number of letters in response to the survey, many of which appeared to be coordinated form letters, from eligible hospitals indicating that they would not be providing their acquisition data and explaining their reasons for not doing so. A commenter stated that they supported our proposed payment policy, despite what the commenter believes was a concerted effort to obstruct the survey. Another commenter challenged our observation that we received a number of responses, many of which appeared to be coordinated form letters, from eligible hospitals indicating that they would not be providing their acquisition data and explaining their reasons for not doing so. The commenter stated that there is no proof of coordinated non-response among 340B-participating hospitals.

Response: We disagree that there is no proof of a coordinated response. The hundreds of nearly identical letters and email templates themselves supply evidence of such coordination. We find it highly unlikely that hundreds of hospitals would independently submit letters informing us that they would not be providing their acquisition cost data and explaining their alleged reasons for not doing so using identical or nearly identical language. The record also reflects that several large law firms publicly promoted such a strategy.[128]

Additionally, shortly after the survey first launched, several major hospital associations purporting to represent more than 3,000 hospitals paid under OPPS jointly issued a widely publicized letter to CMS claiming that it was wrong of CMS to tell hospitals they ''are to'' respond to the survey.[129] CMS made this requirement clear by publishing in numerous places throughout the CY 2026 OPPS/ASC proposed and final rule, the OMB-approved PRA package, and educational materials that the survey was required of hospitals. These hospital associations made no known attempt to help their member hospitals complete the survey and fulfil their statutory obligation; rather, the record reflects that these hospital associations cast doubt on the requirement for survey participation and encouraged non-compliance among their member hospitals. These same hospital associations now criticize the response rate to the survey, incorrectly claiming that not enough hospitals responded for

[128] *See* K&L Gates LLP, *The 2026 OPPS Final Rule: Hospitals Now at a Decision Point Regarding Drug Acquisition Cost Survey* (Dec. 1, 2025) (advising that hospitals should consider ''[r]espond[ing] to the survey only to state that the hospitals' costs are not minimal, but that the hardships in responding preclude the full response CMS is seeking''), *https://www.klgates.com/thought-leadership/The-2026-OPPS-Final-Rule-Hospitals-Now-at-a-Decision-Point-Regarding-Drug-Acquisition-Cost-Survey-12-1-2025;* McDermott Will & Schulte LLP, *Strategic Defenses and the ''Silence Option'' in the CY 2026 OPPS Drug Cost Survey* (Dec. 16, 2025) (advising that ''[c]onsultation with legal counsel may be helpful in making the decision whether to report some or all drug acquisition cost data in response to the CMS survey''), *https://www.mcdermottlaw.com/insights/strategic-defenses-and-the-silence-option-in-the-cy-2026-opps-drug-cost-survey/;* K&L Gates LLP, *The 2026 OPPS Drug Acquisition Cost Survey: Additional Considerations as Deadline Nears* (Mar. 6, 2026) (advising that ''for any entity not responding [to the survey], it should consider filing a submission to CMS that states that the burden to obtain and present the requested data is far larger than CMS had estimated''), *https://www.klgates.com/thought-leadership/The-2026-OPPS-Drug-Acquisition-Cost-Survey-Additional-Considerations-as-Deadline-Nears-3-9-2026;* K&L Gates LLP, *The 2026 OPPS Drug Acquisition Cost Survey: Response Deadline Extended* (Mar. 25, 2026) (advising that ''if large numbers of hospitals do not respond to the survey request, then CMS, by statute, will not be able to use its results to cut reimbursement to 340B-covered entities''), *https://www.klgates.com/thought-leadership/The-2026-OPPS-Drug-Acquisition-Cost-Survey-Response-Deadline-Extended-3-25-2026; see also* Ganny Belloni, *Hospitals Rebuff HHS's Request to Survey Drug Acquisition Costs,* Bloomberg Law (Apr. 22, 2026) (quoting a K&L Gates LLP partner as stating that ''CMS truly got an anemic response [to the survey] . . . . If CMS does move forward and the response is as low as some of us think it is, then it's going to be a battle of statisticians in court''), *https://www.bloomberglaw.com/product/blaw/bloomberglawnews/bloomberg-law-news/XLG9V0G000000.*

[129] Press Release, Am. Hosp. Ass'n, et al., *AHA, other groups: It's wrong to tell hospitals they 'are to' complete drug acquisition cost survey* (Jan. 12, 2026), *https://www.aha.org/news/headline/2026-01-12-aha-other-groups-its-wrong-tell-hospitals-they-are-complete-drug-acquisition-cost-survey; see also* Belloni, *Hospitals Rebuff HHS's Request to Survey Drug Acquisition Costs* (discussing associations' joint letter to CMS).

CMS to make the necessary, statutory payment determinations.

Comment: Many commenters stated that the payment reductions would threaten their ability to continue providing services, particularly to low-income, uninsured, under-insured, geographically isolated, medically complex and other vulnerable patients. Many commenters stated that the effect of the payment reductions and corresponding budget neutrality increase would be to subsidize for-profit hospitals at the expense of 340B hospitals and the vulnerable populations they serve.

Response: We are not persuaded that more closely aligning our payment amounts for 340B-acquired drugs with their acquisition costs would threaten 340B hospitals' ability to continue to provide services to vulnerable patients or would constitute a subsidization of for-profit hospitals at the expense of 340B hospitals and those patients. Although 340B hospitals would receive reduced payment for 340B drugs, they would also receive the same percentage increase to payments for non-drug items and services as non-340B hospitals. Further, this policy ensures that the reduced drug costs, and associated reduced drug cost sharing obligations, are passed directly to the beneficiaries that these hospitals serve. We acknowledge that some hospitals will potentially experience greater reductions to drug payments than increases to non-drug items and services as a consequence of our policy. However, that does not change our statutory obligation under section 1833(t)(14) of the Act to conduct a survey of drug acquisition costs and adjust payment rates taking those costs into account.

Comment: Many commenters stated that the proposed reduction was contrary to the Congressional intent behind the 340B program, which was designed to enable covered entities to stretch scarce Federal resources as far as possible to provide services to low-income and uninsured patients. Many commenters also stated that CMS had failed to account for the effect of the proposal on 340B hospitals and that failure renders the proposed policy arbitrary and capricious.

Response: We disagree that we have failed to account for the effect of the proposal in formulating and proposing our policy, and we do not agree with commenters that our proposed policy is contrary to the Congressional intent behind the 340B program. We are fulfilling our statutory obligation under section 1833(t)(14) of the Act to periodically conduct a survey of hospital acquisition costs and use the resulting data to inform payment rates. The purpose of the proposed policy is to better align our payment amounts for 340B-acquired drugs with their actual acquisition costs as demonstrated by the survey.

Comment: Many commenters expressed concern about the combined economic effect of the 340B drug payment proposal, the remedy proposal and the expansion of the volume control method. Many of these commenters cited the millions of dollars they expected to lose as a result of these policies. These commenters urged CMS not to view these proposals in isolation but to evaluate their cumulative effect. Many of these commenters additionally referenced ''severe financial headwinds'' that they are experiencing due to a variety of past and impending economic factors.

Response: We recognize that the cumulative economic effect of the policies we are proposing for CY 2027, along with the financial circumstances hospitals have faced over the past few years, may be significant for some hospitals. However, we believe these effects must be balanced against the windfalls hospitals received previously that we are statutorily obligated and/or have the discretion to recover, our obligations under section 1833(t)(14) of the Act to periodically conduct surveys of hospitals' drug acquisition costs and take that data into account in setting payment rates, and our responsibility to adopt methods to control unnecessary increases in the volume of covered OPD services.

Comment: Many commenters urged us to delay or phase-in (or both) the implementation of the proposal. Commenters suggested that delaying implementation would provide additional time for CMS to conduct a more complete hospital-level impact analysis of the combined effect of the 340B drug payment proposal, the remedy proposal and the site neutral proposal and other OPPS payment changes. Another commenter suggested that CMS could use the delay to establish a limit on how much money hospitals could lose if they rely heavily on 340B drugs and develop a methodology that would ensure a more equitable distribution of the savings resulting from the proposed payment reduction. Commenters also noted that an implementation delay would provide interested parties with additional time to comment on the payment proposal and underlying survey. Commenters that recommended phasing-in the payment policy recommended that we do so over multiple years and stated that it would allow hospitals and CMS to evaluate the actual effects on access, service availability, beneficiary cost sharing, and hospital financial stability before the full reduction takes effect. Commenters also stated that it would give hospitals time to adapt to the financial impact of the policy and help avoid abrupt disruptions to patient services.

Response: We understand commenters' emphasis on taking a measured approach to implementing the proposal. However, we believe that the payment misalignment that our proposed policy will address has been in effect for many years and it is important to implement this policy now that we have conducted the required survey and have data clearly demonstrating that the existing payment rate for 340B-acquired drugs is not even close to a representative proxy for the cost of their acquisition. Given the extent of the payment misalignment identified by the survey results and the length of time the misalignment has likely been in place, we think that delaying or phasing-in the changes would be inconsistent with our obligations under section 1833(t)(14) of the Act and our goal of ensuring that Medicare and Medicare beneficiaries are paying for drugs commensurate with the cost of their acquisition.

Comment: Many commenters opposed the proposal on the grounds that it would establish a dangerous precedent that non-Medicare payers might follow. These commenters stressed that Medicare payment policies often influence other entities, such as Medicaid or commercial payers, to ''piggyback'' off CMS' payment decisions. These commenters expressed concern that this would fundamentally undermine the purpose and effectiveness of the 340B program to financially assist hospitals that serve a high volume of low-income patients.

Response: We do not have control over how our proposed policy might influence other non-CMS payers in the future. What those other payers may or may not do in the future would not be a valid reason for us to refrain from better aligning OPPS payment for 340B-acquired drugs with their acquisition costs as demonstrated by the survey, consistent with section 1833(t)(14)(iii)(I) of the Act.

Comment: Several commenters expressed concern about the indirect implications of the proposal to pay ASP minus 33.4 percent for 340B-acquired drugs for providers that contract with Medicare Advantage (MA) organizations. Commenters stated that MA organizations and private PBMs

will cite these OPPS rate reductions as justification to impose their own cuts for 340B drugs, further weakening the ability to utilize 340B savings. Commenters urged CMS to clarify that the proposed payment methodology of ASP minus 33.4 percent, including any downstream budget neutral impacts, is Original Medicare (OM) payment policy and does not itself establish, require or permit a corresponding payment reduction under MA contracts.

Response: We appreciate feedback on this issue. CMS establishes payment policies and payment rates for services payable under OM through a separate, distinct process that is not directly related to terms of private contracting arrangements between MA organizations and providers. Further, section 1854(a)(6)(B)(iii) of the Act prohibits CMS from requiring an MA organization to contract with a particular hospital, physician, or other entity to furnish items and services, including 340B-acquired drugs, or requiring a particular price structure for payment under such a contract. Providers and MA organizations may engage in dispute resolution under existing contracts and any contract negotiations or re-negotiations independently of CMS. MAOs must pay non-contract providers or facilities for services and items at least the amount they would have received under OM payment rules, in accordance with section 1852(a)(2) of the Act.

1. Statistically Significant Estimate

Under section 1833(t)(14)(D)(iii) of the Act, the periodic surveys conducted by the Secretary under section 1833(t)(14)(D)(ii) of the Act must ''have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug.'' Our survey results meet this standard, particularly because hospital acquisition cost is a price measure.[130] Reliable price measures require far less sampling than quantity or revenue measures because markets tend to compress this distribution of prices across transactions but do not compress the distribution of quantities or expenditures.[131] While hospital acquisition cost for a branded drug would not be exactly equal across hospitals in the 340B Program, it would not differ by a factor of 1000 and rarely even a factor of 2. Because the standard errors of the 340B-hospital sample mean and the non-340B-hospital sample mean are each proportional to the standard deviation of the underlying population, a compressed price distribution translates directly into small standard errors and high statistical significance.[132]

As discussed previously and shown in Table 74, the 95 percent confidence intervals for 340B drugs were relatively narrow, ranging from approximately 34.7 percent to 32.3 percent below ASP for the unadjusted margin and from approximately 34.3 percent to 32.1 percent below ASP for the IPW-adjusted margin. These results support the statistical validity of the estimated acquisition cost margins and indicate that the survey data provide reliable estimates of the acquisition cost discounts realized by 340B hospitals relative to ASP. These sampling requirements for price measurement are well known in national accounting. For example, the Department of Labor's Bureau of Labor Statistics measures prices for the Consumer Price Index (CPI) using about 100,000 commodity-and-service price observations per month, while the Producer Price Index (PPI) uses approximately 64,000 monthly price quotations from about 16,000 establishments.[133] These samples are tiny relative to the transactions they are designed to represent: the CPI commodity-and-service sample alone is less than 0.01 percent of such payments.[134]

In our efforts to obtain data from a statistically significant sample of hospitals paid under the OPPS, we initially included for survey participation 100 percent of OPPS hospitals. From this, we received replies from 53.3 percent of non-340B hospitals and 28.6 percent of 340B hospitals. These response rates are similar to past surveys of health care providers as determined by a separate meta-analysis[135] and have resulted in sample sizes that show significant differences in acquisition costs between the two hospital categories.[136] While we applied data cleaning to exclude specific survey records with anomalous or implausible data, very few hospitals were excluded from our population: only 27 subunits that reported identical and duplicative data to their parent unit. Additionally, while we applied refinements to narrow the population of hospitals to only those who either responded to the survey or had OPPS claims for survey-relevant HCPCS codes, these refinements did not remove any hospital with relevant data from analysis. These efforts were undertaken to maintain the largest possible pool of hospitals and data to evaluate. It is our view based on efforts to sensitivity test the responses and reweight the findings that the conclusion of statistical difference in the average acquisition costs for 340B and non-340B hospitals would likely not change.

Comment: Multiple commenters concurred with CMS that the survey generated a statistically significant estimate. One commenter stated that:

CMS opened the survey to all hospitals that received OPPS payments for outpatient drugs during the survey period. Because this survey was meant to determine hospital acquisition costs for outpatient drugs paid under OPPS, this is the correct universe. As explained in the survey, 3,147 entities were eligible to complete it. Of these, 1,343 (42.7%) submitted a response and 1,304 reported acquisitions of one of the surveyed drugs. While the statutory text ''a large sample'' has no objective meaning, nor does it have any statistical definition, expert judgment is called for to determine whether the CMS survey's sample would qualify. There are several

[130] Hospital acquisition cost is the price paid in a business-to-business market, particularly in transactions between hospitals and wholesalers or distributors. Unlike revenue, hospital acquisition cost is measured per unit quantity.

[131] With some exaggeration, this is known in economics as the ''law of one price.'' The Chicago Price Theory textbook explains with more nuance that ''[p]rice is sometimes easier to measure than quantity because price can be seen from a sample; just go to one of the sellers in the market—say, a grocery store—and look at their price for eggs. Quantity measurement can be more difficult—you have to ask every seller what they sold; you'd need some kind of census of sellers.'' (Sonia Jaffe, Robert Minton, Casey B. Mulligan and Kevin M. Murphy, *Chicago Price Theory,* 2019, p. 48).

[132] Weighting observations by volume shares, as the CMS sample does, further reduces standard errors and further increases statistical significance.

[133] Bureau of Labor Statistics, ''Handbook of Methods: Consumer Price Index—Data Sources'' (last modified Jan. 30, 2025), *https://www.bls.gov/opub/hom/cpi/data.htm* and Bureau of Labor Statistics, ''Producer Price Index (PPI): Overview'' (last modified Mar. 16, 2023), *https://www.bls.gov/ppi/overview.htm.*

[134] As a back-of-the-envelope denominator for 100,000 CPI observations, the Federal Reserve Bank of Atlanta's 2024 Survey and Diary of Consumer Payment Choice reports that U.S. consumers made 48 payments per consumer per month on average. Multiplying 267 million adults by 48 payments per month gives approximately 12.8 billion consumer payments per month. This is a conservative comparison for item-level CPI observations because a single consumer payment, such as a grocery receipt, may cover multiple items.

[135] Vincent Maurice Meyer et al., ''Global Overview of Response Rates in Patient and Health Care Professional Surveys in Surgery: A Systematic Review,'' Annuals of Surgery 275, no. 1 (January 2022): e75–e81, *https://pubmed.ncbi.nlm.nih.gov/32649458/.* The Meyer et al. meta-analysis found an average response rate of 53.3% (±24.5%) over 1,746 surveys of health care professionals.

[136] Vincent Maurice Meyer et al., ''Global Overview of Response Rates in Patient and Health Care Professional Surveys in Surgery: A Systematic Review,'' *Annuals of Surgery* 275, no. 1 (January 2022): e75–e81, *https://pubmed.ncbi.nlm.nih.gov/32649458/.*

reasons to believe it does. For one, this sample is larger than the original GAO survey conducted in 2005. In that survey, the original, official survey conducted as required by statute, only 1,157 hospitals responded. GAO determined that this sample was ''reliable for estimating [Specified Covered Outpatient Drugs] prices.'' It went on to say that estimates of prices were more precise for drugs purchased by many hospitals. Further, the responding hospitals included hospitals across the relevant categories defined by GAO and frequently used in health care policy, such as teaching and non-teaching, urban and rural. Because each category was represented in the final sample, there was data CMS was able to use to transform the results such that they would match the population of hospitals, similar to how political polls feature weights such that they can reflect an entire voting population.

Another commenter stated that:

CMS employed a census-based approach that sought information from all hospitals relevant to the proposed policy and ultimately obtained responses from a substantial number of hospitals, generating what [the commenter] understands to be the largest volume of acquisition cost data for hospital outpatient drugs ever collected in connection with the Medicare program. After applying appropriate data-cleaning and validation procedures, CMS used inverse probability weighting to account for differential response rates among hospital types and evaluated the resulting estimates using established statistical techniques. Importantly, the survey produced a narrow 95 percent confidence interval for the acquisition cost of 340B-acquired drugs, with estimates ranging only from ASP minus 32.3 percent to ASP minus 34.7 percent (a range of only 2.4 percentage points). CMS calculated these confidence intervals using 10,000 bootstrap replications, a sound and established statistical technique designed to assess the precision and reliability of survey estimates. The narrowness of this confidence interval confirms that the survey data are reliable and sufficiently precise for purposes of informing CMS's determination of the average acquisition cost of 340B-acquired drugs and implementing an acquisition-cost-based payment methodology. Moreover, CMS's approach to addressing nonrespondents likely results in a more conservative estimate of the discount associated with 340B-acquired drugs and therefore is favorable to 340B hospitals. CMS used inverse probability weighting to ensure that responding hospitals appropriately represented nonresponding hospitals in the overall population, a methodology that is widely accepted and that improved the representativeness of the final sample. To the extent that 340B hospitals with the lowest acquisition costs were less likely to respond, CMS's weighting methodology would tend to increase estimated acquisition costs for 340B-discounted drugs relative to the acquisition costs that might have been observed had all hospitals responded. Thus, if anything, the survey methodology is more likely to overstate average acquisition costs for 340B-acquired drugs than understate them. Taken together, the survey's large volume of data, rigorous weighting methodology, and narrow confidence intervals provide strong support for CMS's conclusion that the survey generated a statistically significant and reliable estimate of the average acquisition cost of 340B-acquired drugs.

Finally, a third commenter found the survey to be

[. . .]methodologically sound and has response rates that compare favorably to other drug cost surveys, such as the National Average Drug Acquisition Cost (NADAC) survey, which CMS has relied on for over a decade as the accepted benchmark for Medicaid fee-for-service pharmacy reimbursement. The ODACS identified 4,494 survey-eligible hospitals and all valid survey responses were used in the analysis. Of the initial population, 43.6 percent of hospitals submitted a response. This design and response profile appears robust when compared to NADAC. NADAC similarly collects voluntary, invoice-level net acquisition cost data from a random monthly sample of independent and chain retail community pharmacies but only 18–24 percent of surveyed pharmacies respond to the monthly survey request, a response rate below the 41.4 to 43.6 percent range achieved by the ODACS. The ODACS's methodology and point estimates provide compelling evidence for reducing 340B drug payment rates under OPPS.

Response: We thank commenters for their support. We concur with their assessment that our survey meets and exceeds the statutory standard.

Comment: Many commenters contended that CMS did not meet statutorily specified requirements to ''conduct a survey . . . to determine the hospital acquisition cost for each specified covered outpatient drug'' and raised concerns that the survey did not ''have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug.'' Commenters pointed to the fact that drugs for which fewer than 10 survey responses were received were dropped from the final margin calculations as evidence that CMS did not demonstrate that the survey sample was large enough to support statistically significant estimates of the average acquisition cost for each, individual outpatient drug.

Response: We disagree with the statement that the survey lacked adequate breadth and achieved an insufficient response rate to analyze the universe of specified covered outpatient drugs in a statistically significant manner. To the contrary, CMS fulfilled its statutory duties to request, collect, and analyze data for each specified covered outpatient drug. CMS gave nearly 4,500 hospitals the opportunity to submit their acquisition cost data for consideration. The survey included 1,843 NDCs for outpatient drugs and biological products, corresponding to 519 HCPCS codes. All but 10 drugs with nonzero outpatient claims utilization received at least one survey response. The drugs that received at least one survey response represent virtually all Medicare use and spending, comprising 99.9 percent of payment for survey-relevant outpatient drugs from July 1, 2024 to June 30, 2025. The fact that some low-volume drugs received fewer responses—consistent with their utilization patterns in practice—does not invalidate the data collected by the survey instrument or make it inapplicable for policymaking.

Commenters referenced the fact that outlier identification required the exclusion of drugs with fewer than 10 hospitals reporting acquisitions. While CMS excluded drugs that received fewer than 10 survey responses in the process of outlier identification, this enabled us to retain the vast majority of HCPCS codes during this stage of analysis, particularly in the context of overall use and spending. Even with this restriction applied, we retained observations for drugs representing 93.8 percent of Medicare payment for survey-relevant outpatient drugs from July 1, 2024 to June 30, 2025. CMS also reiterates that outlier identification and trimming is only one aspect of the survey analysis process, and extensive analyses were performed upon the full population of data received.

Section 1833(t)(14)(D)(iii) of the Act requires that the survey have a ''large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug'' but does not

specify how this is to be determined. While GAO deemed a response rate of 1,000 out of 3,450 eligible hospitals would meet the requirement for a large sample when designing the initial surveys in 2004 and 2005, their assessment—specific to their survey design and constraints at the time—does not constitute a specific, authoritative response rate that all subsequent surveys must precisely meet. We reiterate that our survey design invited 100 percent of the 4,494 eligible hospitals to participate, and approximately 41 percent of the refined population of 3,147 hospitals reported acquiring surveyed drugs. Additionally, the volume of data collected overall through ODACS is substantially larger than what was collected in GAO's initial surveys: GAO only considered 53 non-radiopharmaceutical outpatient drug HCPCS codes in their surveys of hospitals' reported acquisition costs, a tenth of the number of Part B drug HCPCS codes that were analyzed through ODACS. As such, our survey greatly exceeds the comprehensiveness of GAO's survey in terms of included hospitals and drugs. Furthermore, as detailed in section V.B.8.b of this final rule, the data received in the CMS survey produced statistically significant results—particularly for 340B-acquired drugs—that are representative of the overall survey-eligible population as shown through the IPW and confidence interval analyses among other factors cited in this final rule. Detailed discussion of the statistical significance of the data collected through ODACS can be found in the ODACS Technical Report and elsewhere in this final rule.

2. Grouping Hospitals by 340B Covered Entity Status

Section 1833(t)(14)(A)(iii)(I) of the Act authorizes the Secretary to set the amount of payment for SCODs at an amount equal ''to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D).''

In accordance with this authority, we proposed to vary the amount of payment for 340B-acquired drugs by the group of hospitals that are enrolled in the 340B Program as 340B covered entity hospitals because their drug acquisition costs vary significantly from those not enrolled in that program. The significant drug acquisition cost discounts that 340B covered entity hospitals receive for 340B-acquired drugs enable these hospitals to acquire drugs at much lower costs than non-340B hospitals incur for the same drugs. Accordingly, we proposed to use 340B covered entity status as a relevant characteristic to group hospitals for purposes of payment based on average acquisition cost under section 1833(t)(14)(A)(iii)(I) of the Act. Therefore, for 340B drugs acquired by 340B covered entity hospitals, we proposed changes to better align Medicare payment with average acquisition cost for the drug as specified in statute.

As discussed in more detail below, for drugs not acquired through the 340B Program, we proposed that 340B and non-340B hospitals would continue to receive payment at a payment rate that is generally ASP plus 6 percent.

We acknowledged (91 FR 41888) we could set a single payment rate for a drug for a hospital group (such as 340B hospitals) regardless of whether the drug was acquired through the 340B Program, but that does not align with our intent to more appropriately align payment with acquisition costs. As such, we are only applying the reduced payment rate to drugs acquired through the 340B Program by the hospital group defined as 340B hospitals, as this most appropriately aligns payment with acquisition cost of drugs of this hospital group. For non-340B drugs acquired by 340B hospitals, we proposed that payment will not be adjusted. We sought comment on these proposals. Specifically, we sought comment on our proposal to use 340B covered entity status as a relevant characteristic to group hospitals for purposes of payment based on average acquisition cost under section 1833(t)(14)(A)(iii)(I) of the Act and our proposal to vary the amount of payment for 340B-acquired drugs by the group of hospitals that are enrolled in the 340B Program to more appropriately align payment with the average acquisition cost for the drug.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to vary the amount of payment for 340B-acquired drugs by the group of hospitals that are enrolled in the 340B Program. These commenters stated that doing so would better align payment for these drugs with their acquisition cost, resulting in more accurate Medicare payment and reduced beneficiary copayment for these drugs.

Response: We thank the commenters for their support.

Comment: Many commenters stated that CMS lacks the authority under section 1833(t)(14)(A)(iii)(I) of the Act to vary payments by groups defined by 340B Program participation. These commenters characterized CMS' proposal to do so as arbitrary and capricious, contrary to the text of the Medicare statute, and not in accordance with 5 U.S.C. 706(2)(A). These commenters recognized the Secretary's authority under section 1833(t)(14)(A)(iii)(I) to vary payment ''by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)'' but stated that 340B status is not a relevant characteristic. They stated that 340B status is not a relevant characteristic because 340B Program participation designations are not CMS hospital groups, but rather determinations made by a separate agency unrelated to Medicare program considerations. They stated that the intent of Congress was never to include participation in the 340B Program, a Federal program codified in another statute, the Public Health Service Act, as a characteristic that should be used to vary payment. One of these commenters stated that:

If Congress intended 340B participation to be used as a factor to differentiate Medicare drug payment, it would have included it as one of the relevant characteristics in establishing the SCOD payment rate methodology, given that in passing the [Medicare Modernization Act] in 2003, the 340B program had already been in existence for over a decade. That is, Congress well knew that 340B hospitals had lower acquisition costs. Congress chose not to reference 340B in its SCOD reimbursement methodology but also took additional steps to ensure 340B prices do not affect Medicare reimbursement. It would be counterintuitive for Congress to enact a program that is intended to enable hospitals to purchase certain drugs at lower acquisition costs and realize savings through these discounts, only to completely eliminate the benefit of these discounts on Medicare drugs—a sizable portion of 340B hospitals' utilization—by allowing CMS to set their payment rate at 340B acquisition cost. In passing the 340B statute, Congress intended that the 340B program would function by allowing covered entities to purchase these drugs at lower costs and to retain the difference between reimbursement and the drug purchase price as a way to allow them to 'stretch scarce Federal resources as far as possible, reaching

more eligible patients and providing more comprehensive services.'

In support of their argument, the commenter pointed to the absence of 340B status on CMS enrollment forms, GAO reports from 2004 and 2005 in which the GAO did not include 340B participation as a relevant characteristic when examining differences in hospital acquisition costs, and Congress's exclusion of 340B prices from the calculation of ASP under section 1847A(c)(2)(A) of the Act.

Response: We do not agree that we lack the authority under section 1833(t)(14)(A)(iii)(I) of the Act to vary payments by groups defined by 340B Program participation. Section 1833(t)(14)(A)(iii)(I) of the Act authorizes the Secretary to establish appropriate Medicare OPPS payment rates for covered outpatient drugs equal to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D). As demonstrated by its plain language, the best reading of the statute is that it delegates significant discretionary authority to the Secretary. We do not see anything in the statute that would limit the Secretary's discretion in the manner described by commenters. The Secretary is generally empowered to define hospital groups ''based on volume of covered OPD services or other relevant characteristics'' and there is nothing in section 1833(t)(14) of the Act or elsewhere to indicate the Secretary is foreclosed from defining a hospital group based on a hospital's voluntary participation in a program (the 340B Program) that has a direct and significant effect on the hospital's ability to acquire drugs at a substantial discount.

As described earlier in this section, we assessed a variety of hospital characteristics, such as hospital size, 340B participation status, ODACS drug purchase volume, outpatient drug claims billing volume, rurality, geographic location, GPO membership, GPO discount amount, and teaching status. Our detailed analysis found that 340B drug acquisition resulted in a nearly 40 percent differential from current Medicare payment, by far the most significant discrepancy between current Medicare payment and hospital acquisition cost, clearly making 340B status a relevant characteristic[ ] for purposes of varying OPPS payment.

After consideration of public comments we are finalizing our proposal to vary the amount of payment for 340B-acquired drugs by the group of hospitals that are enrolled in the 340B Program as 340B covered entity hospitals.

3. Applying a Single Reduction Percentage to ASP for 340B-Acquired Drugs

Section 1833(t)(14)(A)(iii)(I) of the Act provides that the payment amount for a SCOD for a year is equal to the average acquisition cost for the drug ''as determined by the Secretary taking into account'' the survey data collected under subparagraph (D). In accordance with this authority, we proposed to apply a single discount factor to ASP for drugs acquired by 340B hospitals in lieu of calculating individual acquisition cost amounts for 340B-acquired drugs. Applying a single discount factor to ASP creates a standardized payment reduction. Conversely, calculating individual acquisition costs links reimbursement directly to the exact, variable purchase prices hospitals pay for specific 340B drugs.

We considered calculating payment rates derived from individual acquisition cost amounts for 340B drugs; however, given the dynamic nature of drug pricing we concluded that it would be more appropriate to apply a single discount factor to ASP. We believe this is more appropriate as ASP is also dynamic in nature. ASP changes over time (quarter to quarter), so tying the payment amount to an average discount of ASP results in a more accurate payment amount, by quarter, than if hospitals had to wait until the next survey cycle.

Each drug HCPCS code has its own specific payment rate calculated that is unique to the drug described by the applicable HCPCS code. We would apply an average discount, calculated as described previously under V.B.9.b. and V.B.9.c.(2). of this final rule with comment period, to the drug-specific ASP amount. This makes our proposed payment rate specific to the average acquisition cost for the drug. Applying the payment rate in this manner also allows for this average discount to apply to newly calculated ASPs as they are updated on a quarterly basis. It would not be practical to calculate a drug-specific payment rate for each NDC, and each HCPCS code, based on the survey data, as the survey-collected data is based on a snapshot in time and would not reflect future changes in average acquisition costs. Therefore, as drug prices change, we believe it is appropriate and reasonable to continue to update the calculated ASPs and then to reduce payments by an appropriate percentage of ASP to better align payment with the average cost of the drug.

As an alternative to establishing one aggregate discount amount based on survey data, we considered establishing one aggregate discount amount based on 340B ceiling prices from HRSA.[137] Under this alternative, we would use HRSA's 340B ceiling price data, rather than survey data, to calculate an average discount. As described previously, when assessing the 340B ceiling price, we calculated an analogous acquisition cost margin of ASP minus 28 percent for 340B drugs, which was calculated as the difference between the 340B ceiling price for each NDC in the survey and ASPs that were volume-weighted by 340B OPPS claims data utilization during the duration of the survey. We believed this could be a reasonable alternative to our proposal, as it is based on objective data, can be updated regularly (such as quarterly or annually) with the release of new ceiling prices and new claims utilization data, and significantly diminishes the discrepancy between Medicare payment and hospital acquisition costs for these drugs. We sought comment on this alternative to set OPPS payment for 340B acquired drugs at ASP minus 28.0 percent, per the methodology described to calculate this OPPS claims volume weighted mean margin of the 340B ceiling price from ASP. We note this figure is volume-weighted using OPPS claims data for the duration of the survey, but we also solicited comment on volume-weighting this average based on the claims data available for the applicable calendar year in which the policy would be effective. For example, for the CY 2027 rule, this would be volume-weighted based on claims data available for that year's rule, which would be claims data from CY 2025. At the end of this section in the proposed rule, we also provide estimated impacts of this alternative policy proposal of ASP minus 28 percent based on the 340B ceiling price data, so interested parties were aware of these impacts if CMS

[137] HRSA calculates the ceiling price for each covered outpatient drug. The 340B ceiling price is the drug's average manufacturer price (AMP) minus the unit rebate amount (URA), which is a statutory formula that varies depending on whether the drug is an innovator single source drug (no generic available), an innovator multiple source drug (a brand drug with available generic(s)), or a non-innovator multiple source (generic) drug. The 340B ceiling price represents the maximum price a participating drug manufacturer can charge a covered entity for the drug.

ultimately adopted this policy for CY 2027.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Multiple commenters supported our proposal to apply a uniform ASP adjustment rather than a drug-specific adjustment. A commenter stated that ''to the extent CMS's proposed reimbursement rate accurately reflects surveyed acquisition costs, [the commenter] supports the proposed rate, whether CMS ultimately finalizes ASP minus 33.4 percent or another rate supported by the data, such as ASP minus 28 percent as discussed in the proposed rule. The proposal will reduce Medicare and beneficiary spending that exceeds hospitals' acquisition costs, advancing both program integrity and beneficiary affordability.'' Another commenter agreed with CMS that the proposed payment rate for 340B-acquired drugs ''more accurately reflects the hospital acquisition cost, and we respectfully urge CMS to finalize this proposed payment change.''

Response: We thank commenters for their support.

Comment: Many commenters opposed CMS's proposal to apply a uniform ASP adjustment rather than a drug-specific adjustment and stated that CMS lacks the statutory authority to uniformly reduce reimbursement for all 340B-eligible drugs paid under the OPPS. These commenters maintain that section 1833(t)(14) of the Act requires CMS to calculate and set payment rates for each specified covered outpatient drug. In other words, on a drug-by-drug basis.

Response: We disagree that section 1833(t)(14) of the Act requires CMS to calculate and set payment rates for each specified covered outpatient drug. While the statute indicates that data should be collected for specific drugs, it is not prescriptive regarding how that data should ultimately be used to set payment rates. Payment rates are already set on a drug-by-drug basis using the ASP methodology, and this will continue to be the manner in which payment rates for individual drugs are set. The percentage adjustment applied to the ASP (ASP plus six percent) has never been tailored to individual HCPCS codes; this policy mirrors that approach. Further, the proposed ASP percentage adjustment was volume-weighted to reflect the relative utilization and differing margins of individual drugs.

As stated in the proposed rule, it would not be practical to calculate a drug-specific payment rate for each NDC, and each HCPCS code, based on the survey data, as the survey-collected data is based on a snapshot in time and would not reflect future changes in average acquisition costs. Therefore, as drug prices change, we believe it is appropriate and reasonable to continue to update the calculated ASPs and then to reduce payments by an appropriate percentage of ASP to better align payment with the average cost of the drug.

Comment: Some commenters supported our alternative proposal to set OPPS payment for 340B-acquired drugs at ASP minus 28.0 percent based on 340B ceiling price data. Most of these commenters indicated that they supported neither alternative but that if CMS nonetheless proceeded with a payment adjustment that they preferred ASP minus 28 percent because an approach grounded in objective, regularly updated ceiling price data would be less disruptive than the survey-based methodology. Another commenter stated that this approach would be better because it relies on a more complete, independently maintained data source. Several commenters suggested that if we proceeded with the ASP minus 28 percent approach that we should weight it using Medicare claims volume for the applicable calendar year. A commenter urged CMS to more fully evaluate this alternative, which they contended avoided many of the response-rate and representativeness concerns expressed by commenters.

Response: We agree with commenters that our alternative approach would have several advantages compared to our proposed survey-data-based approach. A payment rate based on ceiling price data would be objective and could be updated annually with far less burden to hospitals and CMS than an annual survey. We also think that this approach is appropriate based on the survey results, which, as we noted previously, found that hospitals' survey-reported 340B acquisition costs were at least 28.9 percent below the mean ASP for drugs in all high-spending therapeutic classes (that is, those with more than $100 million in reported acquisition costs).

We thank the commenters for their comments regarding updating the ceiling price payment rate weighted by claims volume for the applicable calendar year, in this case 2025 claims for CY 2027 rulemaking, rather than claims data from the duration of the survey. CMS will consider this for future rulemaking, but for CY 2027 will calculate the 340B ceiling price data using claims data mirroring the survey timeframe.

Comment: A few commenters recommending the ASP minus 28 percent alternative suggested that we phase it in gradually over several years, which would provide us with the opportunity to provide additional drug-level information, evaluate actual claims experience, establish an appropriate payment for pharmacy and clinical infrastructure, and create hospital groupings that recognize safety-net, teaching, trauma, pediatric, and rural responsibilities. One of these commenters stated that such an approach would recognize CMS' legitimate interest in better aligning payment with acquisition cost without immediately adopting the largest reduction supported by an aggregate survey whose 340B hospital response rate and drug-level representativeness remain contested.

Response: We appreciate the commenters' suggestions to phase-in in our policy; however. as we stated previously, we believe that the payment misalignment that our proposed policy would address has been in effect for many years and it is important to implement this policy without delay now that we have conducted the required survey and have data clearly demonstrating that the existing payment rate for 340B-acquired drugs is so far out of line as a representative proxy for the cost of their acquisition.

Comment: Several commenters opposed our alternative proposal to set OPPS payment for 340B-acquired drugs at ASP minus 28.0 percent based on 340B ceiling price data. One of these commenters expressed confusion as to what feedback CMS might be requesting since, in their view, the Supreme Court's decision in *AHA* v. *Becerra* forecloses HHS from setting payment for 340B drugs based on ''subjective measures.'' In this commenter's view, under the statute, CMS can only vary payment by hospital group when it is using the survey data to set payment rates: ''In *AHA* v. *Becerra,* the Supreme Court held that if HHS collects hospital acquisition cost survey data from hospitals, then HHS may use the data to set reimbursement rates equal to the average acquisition cost for the drug. . . . Importantly, in that circumstance, HHS may vary reimbursement rates by hospital group. While CMS conducted a survey for 2027, it is not proposing to use that survey data to set acquisition costs by hospital group; instead, it is using the survey as attempted cover to rely on what would otherwise be an improper source of data on which to base payment adjustments by hospital group.'' (Internal quotation marks omitted.) Additionally, several

commenters stated that ASP minus 28 percent was not an acceptable substitute because a ceiling price is a statutory maximum, the highest price a manufacturer may charge a covered entity, not a measure of what hospitals actually pay or what it costs them to dispense a drug. One of these commenters opined that setting payment by reference to ceiling prices would convert a price cap into a presumed actual acquisition cost, which is not the ''average acquisition cost for the drug'' the statute directs CMS to determine. One commenter urged CMS not to adopt the alternative rate of ASP minus 28 percent because the proposed 33.4 percent reduction is derived from valid, newly collected hospital acquisition data and represents the most accurate market reality.

Response: We disagree that the statute or the Supreme Court's decision in *AHA* v. *Becerra* requires us to set payment rates using the hospital acquisition cost survey data as a precondition to vary payment by hospital group. Section 1833(t)(14)(A)(iii)(I) of the Act requires the Secretary to ''take into account'' the hospital acquisition cost survey data. It does not require the Secretary to apply the actual data from the survey to set payment rates. We have taken into account the hospital acquisition cost survey data; indeed, it is our thorough analysis of that data that demonstrates (1) the clear and substantial discrepancy between current payment for 340B-acquired drugs and acquisition cost for 340B drugs that requires a prompt and reasonable solution, and (2) that a payment rate of ASP minus 28 percent would reflect a reasonable and conservative estimate of the average acquisition costs for 340B drugs for 340B hospitals given the survey results shows an average acquisition cost of ASP minus 33.4 percent. This is consistent with the approach we adopted in response to the GAO's survey in 2006. When the GAO conducted their survey and released their report, CMS did not use the survey data to directly set drug payment rates prospectively. Rather, CMS used that information to validate the appropriateness of ASP plus 6 percent as the Medicare payment rate. In its report, the GAO stated that ''[t]o ensure that Medicare payments for SCOD products are based on sufficiently accurate data, we recommend that the Secretary . . . validate, on an occasional basis, manufacturers' reported drug ASPs as a measure of hospitals' acquisition costs using a survey of hospitals or other method that CMS determines to be similarly accurate and efficient.''[138] CMS conducted the survey and the survey demonstrated that (1) current Medicare payment for 340B-acquired drugs is not based on sufficiently accurate data, as evidenced by the nearly 40-percent discrepancy between average acquisition cost and Medicare payment; and (2) that ASP minus 28 percent would reflect a reasonable and conservative estimate of the discounts 340B hospitals receive on 340B drugs.

We acknowledge that 340B ceiling prices are the maximum prices that pharmaceutical manufacturers can charge hospitals participating in the 340B Program. However, we do not agree that renders them unsuitable to inform Medicare payment rates.

Comment: A few commenters stated that the existence of the two alternatives suggests that neither should be adopted. According to these commenters, the two alternatives constitute ''materially different estimates'' from Federal data sources, which underscore both the uncertainty surrounding the underlying analysis and the limitations of using a single national average discount assumption to establish payment rates for a highly diverse set of drugs and providers.

Response: We do not agree with commenters' assessment of the two alternatives. We acknowledge their differing natures; however, we do not believe that they signify uncertainty in our analysis or limitations in using a single national average discount to establish payment rates for 340B-acquired drugs. In fact, we believe that the relative uniformity of these two estimates of ASP minus 28.0 percent and ASP minus 33.4 percent augers for the validity and accuracy of these two estimates, with the ASP minus 28.0 percent estimate naturally and predictably reflecting a slightly more conservative estimate of the discounts 340B hospitals receive on 340B-acquired drugs.

Comment: A commenter preferred the proposed ASP minus 33.4 percent methodology over the alternative ASP minus 28 percent approach because it is grounded directly in observed hospital acquisition costs. The commenter observed that while an ASP minus 28 percent methodology might slightly lessen the fiscal impact of the revised policy, the acquisition-cost survey provides a more direct empirical foundation than an alternative derived from estimates of statutory ceiling prices.

Response: We agree with the commenter that the proposed ASP minus 33.4 percent methodology has several advantages in comparison to the ASP minus 28 percent alternative in that it is based on real world acquisition cost data and would more fully capture the discount hospitals are receiving. However, as previously discussed, we believe ceiling price payment methodology volume-weighted by OPPS claims data is a reasonable alternative, as it is based on objective data, can be updated regularly (at least annually, and perhaps quarterly in the future as we gain more experience with this process) with the release of new ceiling prices and new claims utilization data, and significantly diminishes the discrepancy between Medicare payment and hospital acquisition costs for these drugs. It is a reasonable, empirically based payment methodology and the accuracy of our estimate is reinforced by the survey finding similar, but slightly larger, average discounts for 340B drugs acquired by 340B hospitals.

After consideration of public comments received and after taking into account the hospital acquisition cost survey data, we are finalizing our alternative proposal to set OPPS payment for 340B-acquired drugs at ASP minus 28 percent based on 340B ceiling price data and we are revising 42 CFR 419.41(d) and adding a new paragraph (k) to implement this payment change. While we believe both alternatives to be excellent proxies for hospitals' acquisition costs for 340B-acquired drugs, we think that the virtues of setting the payment rate for 340B drugs acquired by 340B hospitals at ASP minus 28 percent based on the 340B ceiling data as validated by the ODACS outweigh the advantages of using the ASP minus 33.4 percent payment rate based on the survey data alone. ASP minus 28 percent is based on objective data, is a reasonable and conservative estimate of hospital 340B drug acquisition costs as validated by the ODACS, and is responsive to commenters' concerns that a payment rate of ASP minus 33.4 percent would result in too significant of a payment reduction and would inhibit beneficiary access to these drugs. ASP minus 28 percent is also in line with the minimum discount by major therapeutic class CMS found from the ODACS, where the acquisition costs varied from a high of ASP minus 28.8 percent to a low of ASP minus 71.4 percent. Additionally, our 95 percent confidence interval analyses of the survey data determined that acquisition costs fell between ASP minus 34.7 percent and ASP minus 32.3 percent. When including the IPW analysis, this 95

[138] *https://www.gao.gov/assets/gao-06-372.pdf.*

percent confidence interval became ASP minus 34.3 to minus 32.1 percent. It additionally is in line with the average acquisition costs stratified by various hospital characteristics as shown in Table 70. Specifically, and as previously discussed, we assessed the survey data by drug acquisition volume, OPPS drug billing volume, hospital size (number of beds), geographic rurality, census region, teaching status, share of Medicare patients, disproportionate share percent, and hospital type. Through all of these different hospital characteristics, assessing both the mean and median results, the margin drops as low as ASP minus 39.7 percent, and as high as ASP minus 30.3 percent. Through these 96 permutations of the data, these tight ranges not only support the integrity of the survey results but also make the ceiling price alternative that we are adopting reasonable and should help alleviate any commenter concerns that the payment rate based on the survey data is inappropriate.

We note that in the event that our authority under section 1833(t)(14) of the Act was determined to not provide sufficient flexibility to utilize the 340B ceiling price data as validated by the ODACS to set a payment rate of ASP minus 28 percent for 340B-acquired drugs for CY 2027, we believe the payment rate of ASP minus 33.4 percent—as determined by the average 340B drug acquisition cost in the ODACS—to be a better, more accurate determination of such hospital acquisitions costs than our prior policy of ASP plus 6 percent.

4. Add-On Payment for 340B Drugs

Under the OPPS, Medicare pays separately payable drugs at rates that approximate their acquisition costs, such as at ASP or WAC. These drugs may also receive an add-on payment. Under the OPPS, section 1833(t)(14)(E) of the Act authorizes, but does not require, the Secretary to make an adjustment to payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Because we took a prudent approach in estimating the average acquisition costs for 340B-acquired drugs, we did not believe that it was necessary to establish an add-on for overhead and handling as we believed that a conservative estimate may already account for the costs of overhead. We also believed that hospitals would likely negotiate additional discounts that will render an additional add-on payment unnecessary. This approach also aligned with the requirement under section 1833(t)(14)(A)(iii) of the Act to pay at the average acquisition cost. Therefore, for CY 2027 and subsequent years, we proposed to pay for 340B drugs acquired under the 340B Program by 340B hospitals at ASP minus 33.4 percent with no add-on payment. We sought comment on our proposal to not include an add-on payment.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter supported our proposal not to provide an add-on. This commenter cautioned CMS about layering additional payments onto the survey-derived amount without clear evidence that they represent costs not already captured in the methodology. The commenter found our proposal reasonable ''insofar as the underlying acquisition-cost estimate already provides an appropriate approximation of hospitals' costs associated with obtaining these drugs. A separate adjustment should require evidence of a distinct and material expense rather than become another mechanism through which the gap between Medicare reimbursement and acquisition cost gradually reemerges.''

Response: We thank the commenter for their support.

Comment: Many commenters objected to our proposal not to include an add-on payment for overhead and handling and faulted our proposed payment methodology for failing to capture all of the costs associated with furnishing a drug and complying with the 340B Program. Commenters listed many of these expenses, including acquiring, storing, preparing, administering, and monitoring medications, implementing software, hiring additional staff, inventory management, infusion center infrastructure and clinical staffing, medication safety and quality programs, information technology and electronic health record infrastructure, regulatory and compliance requirements, sterile compounding facilities, USP compliance, hazardous drug protections, medication-use technology, waste handling and disposal, shortage mitigation efforts, diversion prevention programs, audit readiness activities, 24/7 clinical support, cybersecurity protections, accreditation standards, emergency preparedness capabilities, dedicated 340B pharmacy staff, split-billing software, annual licensing fees, daily reconciliation of 340B and non-340B inventory to prevent diversion, preparation for HRSA audits and responses to manufacturer audits, with associated legal and compliance costs, as well as ongoing regulatory monitoring, cold-chain management, nuclear medicine technologists, nurses, and multidisciplinary care coordination, hot lab, infusion, dedicated bathroom infrastructure, dose calibration, decay correction, and radiation safety oversight. A commenter emphasized the importance of the add-on payment for hospitals dispensing high-cost cellular and gene therapy products, including CAR–T therapies, that require specialized apheresis and cell-processing capacity; chain-of-custody and chain-of-identity protocols; and compliance with many additional requirements.

Many commenters disagreed with our rationale for not establishing an add-on. In the proposed rule we stated that an add-on was unnecessary because (1) we took a prudent approach in estimating the average acquisition costs for 340B-acquired drugs and we believe that that prudent estimate of acquisition cost may already account for overhead and (2) we believe that hospitals will likely negotiate additional discounts. A commenter characterized the decision as arbitrary and capricious, stating that CMS provides no justification for the exclusion and ''merely states that its cost estimate may already account for the costs of overhead, a weak statement that undermines confidence in the adequacy of the resulting payment rate.'' Several commenters shared their view that CMS' assumption that hospitals will likely negotiate additional discounts was inconsistent with market realities. A commenter indicated that in their experience, voluntary discounts for high-cost drugs were rare, particularly those for which a limited number of manufacturers dominate the market. A few commenters alleged that CMS's assumption is internally inconsistent with the underlying premise of the proposed payment methodology. These commenters stated that we propose to establish a payment rate based on survey data that we describe as representative and sufficiently reliable to estimate average acquisition cost. These commenters then ask, if the survey is statistically valid and accurately measures acquisition costs, how can CMS simultaneously justify the absence of an overhead add-on by speculating that hospitals may receive undocumented and unmeasured discounts beyond those reflected in the survey? ''Either the Survey accurately captures acquisition costs or it does not,'' a commenter stated. A few commenters alleged that, in setting the payment rate, CMS failed to account for how cost structures vary dramatically across different types of hospitals.

Many commenters emphasized that acquisition costs and overhead costs are two separate measures and that in setting the payment rate CMS conflated the reported acquisition costs with overhead costs. A commenter pointed out that the current payment rate of ASP plus 6 percent contains the average sales price (a proxy for acquisition cost) plus a 6 percent add-on for overhead costs and that in the survey, CMS collected only a hospital's total net acquisition cost for a drug defined as ''the total amount paid by the hospital inclusive of all discounts, rebates, and price concessions applicable at the NDC level.'' The commenter stated that hospitals were not instructed to report any additional costs that they incurred to administer the drugs, such as overhead, pharmacy services, and handling costs.

Many commenters alleged that not including a 6 percent add-on for 340B drugs would arbitrarily create a payment differential for overhead costs compared to non-340B drugs that is not supported by the survey or other analysis. Another commenter stated that the proposal is flawed because the agency is proposing to continue providing an add-on payment to hospitals exempt from its proposed payment policy, but not for hospitals subject to its proposed policy. In doing so, the commenter states, the agency recognizes that overhead costs are real and legitimate components of Medicare payment policy for some hospitals, but not for others. ''CMS provides no rationale for why the same overhead, pharmacy operations, drug handling, storage, inventory management, compliance, billing, and patient care costs disappear when the same drug is acquired by a 340B hospital subject to its proposed payment policy. Excluding any add-on payment from the proposed 340B payment rate therefore creates an arbitrary and internally inconsistent payment policy that recognizes overhead costs for some hospitals and some drugs, while ignoring those same costs for others.'' Another commenter alleged that the proposed policy creates a logical disconnect between reimbursement for drugs at 340B and non-340B sites. ''Payment policy for the former would reject the need for an add-on that covers overhead costs, and the latter would recognize the need to reimburse these costs. At no point does CMS make a case for this distinction.'' Another commenter requested CMS to explain why comparable operational costs are recognized for non-340B drugs but not for 340B-acquired drugs and radiopharmaceuticals.

Response: We acknowledge the many costs that are associated with the delivery of a drug; however, as we have explained, we believe that, due to our prudent approach in determining an average acquisition cost, our proposed payment amount for 340B-acquired drugs does not support CMS exercising its discretion to include an add-on or adjustment in payment for overhead costs. Many of the costs mentioned by commenters are standard operating costs of hospitals and healthcare facilities and are not necessarily related to the cost of the drug. Additionally, as we are finalizing the alternative ASP minus 28 percent payment rate, a significantly conservative average acquisition cost, it is not necessary to provide an add-on. Finally, an add-on percentage, such as a 6 percent add-on to ASP, can create incentives for some providers to choose higher-priced products over lower-priced products even when the two products are clinically equivalent.

After consideration of public comments, we are finalizing our proposal to not include an add-on payment for 340B-acquired drugs.

5. 340B Payment Policy for Drugs for Which ASP Is Unavailable

Section 1847A of the Act establishes the average sales price (ASP) methodology, which provides the amount payable for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. Based on this, our historic policy has been to pay for most drugs at ASP plus 6 percent. There are some situations, however, where it is not possible to pay ASP because, for example, a drug is sufficiently new so there is no sales data available upon which to derive an average. In these situations, our historic policy has been to pay for the drug according to the following hierarchy: In general, if ASP information is not available, payment is based on the WAC with WAC plus 6 percent. If WAC information also is not available, then payment is based on AWP with 95 percent of AWP being paid. If AWP is not available, then payment is based on Mean Unit Cost (MUC). And if MUC is not available, then payment is based on the invoice price.

Consistent with this policy, starting in CY 2027, we proposed that payment for 340B drugs when ASP is unavailable mirrors CMS's historic payment policies for drugs paid under OPPS. If ASP information is not available, payment is based on the WAC, with WAC minus 33.4 percent. If WAC information also is not available, we proposed a payment rate of 59.69 [139] percent of AWP. This percent was calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to WAC with no percentage markup. Then we applied the 33.4 percent reduction WAC-similar AWP value to obtain the 59.69 percent of AWP, which is similar to either ASP minus 33.4 percent or WAC minus 33.4 percent. For 340B drugs paid based on MUC, we proposed to continue to pay them at 100 percent of MUC. These MUC-based payments are calculated based on hospital claims data, which already account for hospital acquisition costs and do not need to be discounted further. Similarly, we proposed to continue to pay for invoice priced 340B drugs at the invoice amount as the invoice price amount should already reflect the 340B discount. We sought comment on this proposal.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter requested clarification as to whether we are proposing to pay MUC only for 340B drugs for which ASP is unavailable or are we also proposing to pay for 340B drugs for which ASP is available but is paid under the MUC under non-340B settings. Another commenter noted that while ASP minus 33.4 percent appears to be higher than most proposed MUC-based rates for CY 2027, applying different reimbursement methodologies to 340B-acquired drugs, biologics, and diagnostic radiopharmaceuticals without pass-through status that are subject to MUC-based payment may create additional confusion for hospitals. The commenter requested that CMS provide additional clarification, as needed, in the CY 2027 OPPS Final Rule.

Response: If ASP information is not available, payment is based on the WAC. If WAC information also is not available, payment is based on AWP. If AWP is not available, then payment is based on arithmetic MUC. If MUC is not available, then payment is based on invoice pricing. However, certain products, such as nonpass-through diagnostic radiopharmaceuticals with claims data, will continue to be paid based on arithmetic MUC as discussed in this final rule with comment period. MUC-based payments are calculated based on hospital claims data, including 340B and non-340B drugs, which

[139] Except for new drugs and biologicals that have not been assigned a HCPCS code. Under section 1833(t)(15) of the Act, these drugs and biologicals are required to be paid at 95 percent of AWP.

already account for hospital acquisition costs and do not need to be discounted further. If we were to discount this payment rate, then we would be accounting for 340B discounts twice.

After consideration of these public comments, we are finalizing our payment hierarchy for when ASP is not available as proposed: If ASP information is not available, payment will be based on the WAC; if WAC information is not available, payment will be based on AWP; if AWP is not available, payment will be based on MUC; and if MUC is not available, payment will be based on the invoice price. However, given our adoption of the proposed alternative of ASP minus 28 percent, we are not finalizing the reduction amounts that we proposed for WAC and AWP. Consistent with the reduction amount we are adopting, we are finalizing WAC minus 28 percent and 64.53 percent of AWP. We are finalizing our proposal to pay 100 percent of MUC for 340B drugs paid based on MUC and the invoice amount for invoiced priced 340B drugs as proposed.

6. Applicability

We proposed to apply our proposed policy to pay for drugs acquired under the 340B Program at ASP minus 33.4 percent to all separately payable drugs, biologicals, biosimilars and radiopharmaceuticals acquired under the 340B Program. This approach would establish a uniform payment policy consistent with our historic OPPS payment policy of paying the same payment rate for SCODs and non-SCODs. We noted our proposal to apply this policy to separately payable drugs and biologicals that are not SCODs was a policy proposal rather than a statutory requirement. We note that the survey included both SCODs and drugs and biologicals that we have historically treated as SCODs for payment purposes. We have treated non-SCOD drugs as SCODs for payment purposes since CY 2006. We sought comment on this proposal.

The payment policy would not apply to vaccines, as they are excluded from the 340B Program; drugs with transitional pass-through payment status, which are paid under section 1833(t)(6)(D) of the Act; and non-opioid pain management drugs as defined under section 1833(t)(16)(G) of the Act, as we believe reducing payment for those drugs would be inconsistent with statutory instructions on payment amount for those qualifying products. As previously described in the information collection request approved by OMB under the PRA, CMS may continue to validate the results of this survey on a periodic basis; for example, perhaps as often as every 4 years. We sought comment on this proposal. Specifically, we sought comment on the proposal that the policy to pay for drugs acquired under the 340B Program at ASP minus 33.4 percent would apply to all separately payable drugs, biologicals, biosimilars and radiopharmaceuticals acquired under the 340B Program, and would not apply to vaccines, drugs with transitional pass-through payment status and non-opioid pain management drugs.

Additionally, as we proposed to apply a single discount factor to the ASP for 340B-acquired drugs in lieu of calculating individual acquisition cost amounts for 340B-acquired drugs, we believed it was appropriate to apply this payment adjustment using the single discount factor to existing and new drugs that are paid under the OPPS.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that CMS lacks the statutory authority to apply a 340B-differentiated rate to drugs that are not SCODs. These commenters point to section 1833(t)(14)(B) of the Act which defines a SCOD as ''a covered outpatient drug (as defined in section 1927(k)(2)) for which a separate ambulatory payment classification group (APC) has been established and that is (I) a radiopharmaceutical agent; or (II) a drug or biological for which payment was made [on a pass-through basis] on or before December 31, 2002'' and excludes drugs that first received pass-through payment on or after January 1, 2003. These commenters state that if CMS wants to apply the ASP minus 33.4 percent rate to separately payable drugs not meeting this definition (*i.e.,* drugs CMS has historically treated as SCODs), then CMS must identify, drug by drug or class by class, the statutory authority on which that differential rests. A commenter requested that CMS enumerate in the final rule which HCPCS codes CMS treats as SCODs and state the authority applied to each separately payable drug outside that definition.

Response: We disagree that we lack the statutory authority to apply our proposed payment policy to drugs that we have historically treated as SCODs. We note that in the event that our authority under section 1833(t) of the Act was determined not to be sufficient to adjust payment for 340B-acquired SCODs to ASP minus 28 percent, we would continue to apply an adjusted payment rate for 340B-acquirednon-SCODs. Similarly, we note that in the event that our authority under the Act was determined not to be sufficient to adjust payment for 340B-acquired non-SCODs, we would continue to apply an adjusted payment rate for 340B-acquired SCODs.

Comment: Most commenters who commented on our proposal not to apply the payment adjustment to vaccines, drugs with transitional pass-through payment status, and qualifying non-opioid pain management drugs under section 1833(t)(16)(G) of the Act supported it. One commenter thanked CMS for recognizing that failing to exempt NOPAIN Act-qualifying drugs would undercut—or severely limit—the underlying policy goal of increasing use of and access to non-addictive pain management approaches. Similarly, another commenter expressed strong support for our proposal not to apply the payment adjustment to qualifying non-opioid pain management drugs under section 1833(t)(16)(G) of the Act because applying an additional 340B payment adjustment to these products would be inconsistent with the statutory framework governing payment for eligible non-opioid treatments. The commenter stated that finalizing the exclusion would help preserve the integrity of the separate payment policy established by Congress, ensure that qualifying non-opioid products continue to be reimbursed in a manner consistent with the statutory methodology applicable to them and help ensure Medicare beneficiaries retain access to clinically appropriate alternatives to opioids.

Response: We thank commenters for their support.

Comment: A commenter requested that CMS confirm that the proposed policy does not apply to 340B-acquired diagnostic radiopharmaceuticals with pass-through status.

Response: Please see section V.A. of this final rule with comment period for discussion of pass-through payment for drugs, biologicals, biosimilars, and radiopharmaceuticals. As previously discussed, the payment policy would not apply to drugs with transitional pass-through payment status, which are paid under section 1833(t)(6)(D) of the Act, as we believe reducing payment for those drugs would be inconsistent with statutory instructions on payment amount for those qualifying products. However, we will continue to monitor the effects of this policy and will consider changes as appropriate.

Comment: A commenter requested clarification as to how drugs will be treated during the calendar year in

which their temporary pass-through status expires. Will the drug remain excluded for the remainder of that year or become subject to the reduced payment rate upon expiration? A few commenters expressed concern that drugs graduating from pass-through status would be underpaid due to such drugs accruing little or no inflation penalty and having a ceiling price of 23.1 percent upon expiration. A commenter recommended establishing a smaller reimbursement reduction for drugs leaving temporary pass-through status. Another suggested a minimum three-year delay of application of the reduction to drugs graduating from pass-through status.

Response: CMS operationalizes pass-through expiration on a quarterly basis as discussed in section V.A. of this final rule with comment period. Once pass-through expires, the applicable payment rate would be effective the following quarter.

Comment: One commenter expressed concern about the proposal to exclude drugs with transitional pass-through status from the proposed payment adjustment for 340B-acquired drugs. This commenter requested that CMS acknowledge that the exclusion could result in significant payment differentials among therapies treating the same condition where some drugs qualify for transitional pass-through status and others do not. The commenter referenced studies demonstrating that payment differentials among clinically competing products can significantly affect product utilization at 340B covered entities during periods of differential reimbursement. The commenter suggested that CMS consider available authorities, including its equitable adjustment authority under section 1833(t)(2)(E) of the Act, to mitigate these disparities and promote a more uniform payment policy by January 1, 2027. The commenter additionally requested that CMS acknowledge that covered entities maintain flexibility and may purchase outside of the 340B Program on a drug-by-drug basis at prices above the 340B ceiling price and code those claims accordingly, which would trigger reimbursement at the standard OPPS rate.

Response: We thank the commenter for bringing this matter to our attention and we acknowledge the potential for the payment disparities they have identified. We anticipate examining this issue in annual rulemaking in the near future and we welcome engagement from interested parties as to how we might do so. If hospitals follow all required guidance and regulations, they may purchase outside of the 340B program as necessary. Readers should follow the finalized billing modifier requirements as discussed later in this section and comply with all relevant requirements to ensure proper payment. We remind readers that dispensing or furnishing drugs solely to take advantage of differences in reimbursement structures, rather than based on the patient's medical needs, may raise concerns under applicable federal fraud and abuse laws. Such conduct may also implicate section 1156(a)(1) of the Act, which states that items and services provided by a hospital for which payment may be sought under Medicare ''will be provided economically and only when, and to the extent, medically necessary.''

Comment: Multiple commenters suggested additional drugs for CMS to consider excluding from the proposed payment policy. Several commenters suggested that biosimilars should be excluded. These commenters contended that biosimilars are fundamentally different from both single-source drugs and innovator biologics and should not be subject to a payment adjustment derived from a survey methodology that does not adequately account for their unique market characteristics. A commenter suggested that, if not exempted, the payment adjustment should be reduced for biosimilars because reimbursing biosimilars at the same reduced rate as their reference or originator products would eliminate an important financial incentive for covered entities to preferentially use lower-cost biosimilars over more expensive originator products. A few commenters expressed concern that applying the reduction to biosimilars would be inconsistent with requirements of the Inflation Reduction Act (IRA), which directs CMS to provide a payment rate of ASP plus 8 percent. A few commenters suggested that radiopharmaceuticals be excluded. A of these commenters recommended that CMS exempt therapeutic radiopharmaceuticals pending a targeted analysis of radiopharmaceutical therapy (RPT)-specific costs. One commenter recommended that CMS exclude plasma protein therapies from the payment adjustment given the unique facets of plasma protein therapies and the dependence of Medicare beneficiaries on them. The commenter alleges that both Congress and CMS have previously recognized the unique aspects of plasma protein therapies by excluding them from previous reimbursement initiatives. The commenter cited as examples CMS's implementation of the competitive acquisition program, in which it excluded certain plasma protein therapies (*e.g.,* blood clotting factors and immune globulin products), and the statutory exclusion from the Medicare drug pricing negotiation program for products derived from human whole blood or plasma. A commenter suggested oncology drugs. Another commenter suggested cell and gene therapies. This commenter stated that cell and gene therapies are materially different from the mature, higher-volume drugs that likely drive the aggregate 340B acquisition-cost estimate. These therapies are newly launched, patient-specific or otherwise operationally complex, used in very small populations, and frequently supported by too few survey observations to establish a reliable product-level acquisition cost. Other commenters did not recommend a specific class of drug be excluded but rather drugs in shortage or with documented supply vulnerabilities or drugs with limited manufacturer competition where reimbursement reductions could threaten market sustainability. Another commenter suggested exempting drugs whose Medicare spending per beneficiary exceeds $100,000 annually. In the commenter's view this exemption would protect beneficiary access to therapies that cost more than $100,000 annually, such as advanced oncology, immunotherapy, rare disease, and specialty biologic treatments. The commenter stated that applying the proposed payment adjustment to these high-cost drugs would make it very difficult for hospitals to acquire them, particularly given the continued price increases from pharmaceutical companies. Using an annual treatment-cost threshold would provide a transparent, objective, and administratively feasible approach that relies on data already available to CMS while protecting access to the therapies most critical to vulnerable Medicare beneficiaries.

Response: We thank commenters for their feedback and analysis of our proposed policy. While we understand drug payment and pricing is a dynamic issue, we believe the most ideal policy is one that is consistent and universal to the extent possible.

Comment: Two commenters suggested that Drugs Covered as Preventive Services (DCAPS), which include HIV PrEP medicines, be excluded because they are covered and reimbursed under a separate statutory framework from traditional Medicare Part B drugs.

Response: We thank the commenters for their suggestion. While the OPPS payment for DCAPS mirrors the amounts set forth in the fee schedule established under section 1833(a)(1)(W)(ii) of the Act, DCAPS furnished in HOPDs are paid under section 1833(t) of the Act, not section 1833(a)(1) of the Act. Section 1833(a)(1) of the Act sets forth payment amounts for services described in section 1832(a)(1) of the Act, which excludes medical and other health services (including additional preventive services) furnished by a provider of services (including a hospital). Rather, DCAPS furnished in HOPDs are described in section 1832(a)(2)(B) of the Act—medical and other health services furnished by providers of services. Section 1833(a)(2)(B)(iii) of the Act provides that services described in 1832(a)(2) of the Act (with exceptions not relevant here) are paid an amount determined under section 1833(t) of the Act—that is, the OPPS. In the CY 2025 OPPS/ASC final rule (89 FR 94295 to 94304), we finalized an OPPS payment amount for DCAPS, codified at § 419.41(j), that was consistent with the fee schedule established under section 1833(a)(1)(W)(ii) of the Act; we did not, however, establish a policy to pay for DCAPS under the section 1833(a)(1)(W)(ii) fee schedule itself. DCAPS furnished in a HOPD are thus paid under the OPPS, and not under section 1833(a)(1)(W)(ii) of the Act.

However, the OPPS DCAPS payment framework is separate and distinct from the payment methodologies set forth at section 1833(t)(14)(A)(iii)(I) and (II) of the Act. We did not propose to revise the OPPS payment methodology applicable to DCAPS. As such, DCAPS are not subject to our finalized 340B payment adjustment made pursuant to our authority at 1833(t)(14)(A)(iii)(I) of the Act at this time. We may consider revisions to the OPPS DCAPS payment methodology in future rulemaking.

Comment: We received a few comments relating to periodic revalidation of the survey. All commenters supported CMS periodically revalidating the survey. A commenter said CMS should periodically repeat or otherwise validate the survey so that the adjustment reflects changes in purchasing patterns, discounts, and the composition of the 340B market rather than allowing a one-time estimate to become a permanent payment convention. Most commenters requested that CMS conduct the survey more frequently than every 4 years, and most commenters requested that CMS conduct the survey on an annual basis. In the commenters' view, conducting an annual survey would be more appropriate because acquisition costs, drug mix and 340B enrollment are not static. One commenter stated that an annual series produces trend data that can inform purchasing patterns and impact on beneficiary access. Another commenter, noting CMS's reporting that it had received a number of responses, many of which appeared to be coordinated form letters declining to provide their acquisition data, stated that an annual survey would diminish the leverage of a single year's non-response. Another commenter pointed out that an annual survey cadence would create a more durable evidentiary record for future OPPS rulemaking and would help ensure that payment policy remains responsive to changes in drug pricing, utilization, and provider purchasing behavior. Finally, one commenter acknowledged the administrative burden of an annual survey on hospitals and CMS but noted that the survey infrastructure now exists, and the marginal burden of a repeat administration is materially lower than the burden of conducting the survey the first time. One commenter encouraged CMS to continue refining its data collection and analysis methods in future rulemaking cycles, including by addressing potential non-response when CMS next validates the acquisition cost survey.

Response: We appreciate the commenters' suggestions and will take them into account for future rulemaking. We acknowledge the administrative burden of an annual survey on hospitals but agree, as commenters noted, that the survey infrastructure now exists, and the marginal burden of a repeat administration is materially lower than the burden of conducting the survey the first time.

Comment: A few commenters stated that the survey window was too short.

Response: We disagree with commenters that the survey window was too short. It ran for fourteen weeks (January 1, 2026 through April 7, 2026), was supported by two pre-survey training webinars, a dedicated phone line and email address for technical support, a dedicated web page featuring multiple guidance documents (FAQs, user guides, fact sheets, etc.) and featured a survey instrument designed to minimize, to the extent reasonably possible, the amount of effort necessary for hospitals to collect and report the required information to CMS. Hospitals were put on notice as early as April 2025 with the President's Executive Order that a survey was coming, nearly a year prior to the survey close date, with the majority of the survey requirements being available with the CY 2026 OPPS/ASC proposed rule with comment period published in July 2025.

After consideration of public comments, we are finalizing our proposal to apply our payment proposal to all separately payable drugs, biologicals, biosimilars and radiopharmaceuticals acquired under the 340B Program as proposed, with exceptions as discussed. We are also finalizing our proposal to not apply the payment proposal to vaccines, drugs with transitional pass-through payment status and non-opioid pain management drugs as proposed.

7. Beneficiary Copayments

An important consequence of our final policy is that it will reduce Medicare beneficiaries' copayments for Medicare Part B drugs. Medicare beneficiaries are liable for a copayment that is typically equal to 20 percent of the OPPS payment rate, which is currently generally ASP plus 6 percent (regardless of the 340B purchase price for the drug). As the survey demonstrates, in some cases, beneficiary coinsurance alone exceeds the amount the hospital paid to acquire the drug under the 340B Program. For example, Lupron Depot (NDC 00074–3663–03) had a mean adjusted ASP of $4,690.08 compared to an average 340B acquisition cost of $667.94, excluding outliers and responses above the 340B ceiling price, yielding an absolute margin of −$4,022.14 and a percent margin of −85.8 percent. As the drug is paid at ASP plus 6 percent, the payment rate for one package of the NDC averaged $4,971.49, of which a beneficiary would pay 20 percent, or $994.30. Therefore, a beneficiary's copay would be over $300 above the average hospital's 340B acquisition cost. During the ODACS study period, 3,544 beneficiaries had an OPPS claim for Lupron Depot, meaning that a sizeable beneficiary population is affected by these high coinsurance amounts. This is also not a small sample size aberration: 137 hospitals reported purchasing this drug through the 340B Program (after excluding outliers and responses above the 340B ceiling price).

Additionally, sections 11101 and 11102 of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, enacted August 16, 2022) established requirements under which drug manufacturers must pay inflation rebates if they raise their prices for certain drugs payable under Part B and/or covered under Part D faster than the rate of inflation. Specifically, section 11101 of the IRA amended section

1847A (i) of the Act, which establishes a requirement for drug manufacturers to pay rebates into the Federal Supplementary Medical Insurance Trust Fund for Part B rebatable drugs for each calendar quarter beginning on or after January 1, 2023, if the specified amount, as determined under section 1847A(i)(3)(A)(ii) of the Act, exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. Pursuant to section 1847A(i)(5) of the Act, the IRA also provides for an adjustment to the beneficiary coinsurance amount in cases where the price of a Part B rebatable drug increases faster than the rate of inflation such that the beneficiary coinsurance is calculated based on the lower inflation-adjusted payment amount instead of the applicable payment amount.

Section 11101(b) of the IRA amended section 1833(t)(8) of the Act by adding a new subparagraph (F) to modify OPPS copayments for Part B rebatable drugs. In the CY 2024 OPPS/ASC final rule with comment period, we codified the OPPS program payment and cost sharing amounts for Part B rebatable drugs as required by section 1833(t)(8)(F) of the Act by adding a new paragraph (e) to § 419.41, which states in the case of a rebatable drug (as defined in section 1847A(i)(2)(A) of the Act), except if such drug does not have a copayment amount as a result of application of section 1833(t)(8)(E) of the Act, for which payment is not packaged into payment for a covered OPD service (or group of services) furnished on or after April 1, 2023, and the payment for such drug under the outpatient prospective payment system is the same as the amount for a calendar quarter under section 1847A(i)(3)(A)(ii)(I) of the Act, in lieu of the calculation of the copayment amount and the Medicare program payment amount otherwise applicable under § 419.41(d) (other than application of the limitation described in paragraph § 419.41(c)(4)(i)), the copayment and Medicare program payment amounts determined under §§ 410.152(m) and 489.30(b)(6) of this chapter shall apply. In the CY 2025 PFS final rule, we codified policies regarding the computation of the inflation-adjusted beneficiary coinsurance, including § 427.201, which specifies that the methodology set forth in § 427.201(b) will be used to calculate the inflation-adjusted beneficiary coinsurance and associated Medicare payment percentage for Part B rebatable drugs as set forth in §§ 410.152(m), 419.41(e), and 489.30(b)(6). The methodology at § 427.201(b) ensures that coinsurance adjustments are not applied in a manner that would increase beneficiary coinsurance. For additional details on this coinsurance policy, we refer readers to the full discussion at 89 FR 98237 and 98238.

Under section 1833(t)(8)(F) of the Act and current OPPS regulations at § 419.41(e), beneficiary coinsurance is adjusted for Part B rebatable drugs paid under the OPPS only where a Part B rebatable drug is paid the same as the amount for a calendar quarter under section 1847A(i)(3)(A)(ii)(I) of the Act—that is, for single source drugs and biologicals, paid 106 percent of the lesser of ASP or WAC, and for biosimilar biological products, paid the amount determined under section 1847A(b)(8) of the Act. Because, as proposed, separately payable, nonpass-through, 340B-acquired drugs would be paid an amount other than the amount under section 1847A(i)(3)(A)(ii)(I) of the Act, the coinsurance adjustment provisions of the Medicare Part B Inflation Rebate Program would not apply to separately payable, nonpass-through, 340B-acquired drugs under the proposed payment policy. We believed this was appropriate and consistent with the statutory intent of the Medicare Part B Inflation Rebate Program, as the coinsurance adjustment at section 1847A(i)(5) of the Act is intended to reduce the coinsurance amount to equal that of 20 percent of the inflation-adjusted payment amount described at section 1847A(i)(3)(C) of the Act, and we expected that the applicable coinsurance under the payment proposal for 340B-acquired drugs would likely be lower than 20 percent of such inflation-adjusted payment amount. We sought comment on the interaction between coinsurance adjustments under section 1847A(i)(5) of the Act and the proposed policy to pay for drugs acquired under the 340B Program at ASP minus 33.4 percent.

We anticipated that our proposed policy to pay for separately paid drugs acquired under the 340B Program at ASP minus 33.4 percent would collectively reduce beneficiary copayments by an estimated $1.15 billion for CY 2027.

We received public comments. The following is a summary of the comments we received and our responses.

Comment: Many commenters appreciated the effect of the proposed policy on reducing beneficiary copayments.

Response: We thank commenters for their support.

Comment: Many commenters challenged our statement that the proposed payment adjustment would reduce copayments for Medicare beneficiaries. In their view we failed to disclose that due to budget neutrality Medicare beneficiaries will pay higher copayments for all non-drug Part B items and services by roughly the same amount. Consequently, in these commenters' view, the out-of-pocket burden on patients is redistributed, not decreased, by the proposed policy. One of these commenters recommended that CMS calculate and report the net impact on beneficiary spending across the complete episode of care, rather than presenting the drug-specific reduction as though it were a direct reduction in total patient expense. A few commenters found fault with the example we cited of a drug, Lupron Depot, for which the beneficiary copayment exceeded the 340B price paid by the hospital. A commenter stated that this one illustration was insufficient data to draw any conclusions about the reliability of CMS' estimation of beneficiary savings. Another commenter stated that the observation that beneficiary cost-sharing sometimes exceeded a hospital's 340B purchase price describes the intended design of the 340B statute, in which the differential between acquisition cost and payer reimbursement is the mechanism by which Congress chose to fund safety-net care.

Response: We thank the commenters for expressing their concerns. As we acknowledged throughout the proposed rule and this final rule, including the regulatory impact section, this policy will largely be implemented in a budget neutral manner. From an individual beneficiary experience, their reduced payment for 340B drugs will be substantial and noticeable. We also emphasize that our proposal to apply this reduction to non-excepted, off-campus PBDs will not be budget neutralized and therefore will generate savings for beneficiaries.

Comment: Some commenters expressed concern that the proposed payment adjustment would arbitrarily create cost-sharing disparities between Medicare beneficiaries. These commenters pointed out that while a beneficiary who receives a Part B drug at a 340B hospital will see reduced coinsurance liability for that drug, a beneficiary receiving the identical drug at a non-340B hospital will face higher coinsurance despite having the same coverage via Medicare. Some of these commenters said that this disparity could result in a distortion of the beneficiary experience. Since beneficiary out-of-pocket liability would vary significantly by facility status,

patients would be steered toward specific health systems based on financial incentives rather than quality, provider access, or clinical outcomes. Similarly, these commenters contend, this payment structure would place a disproportionate burden on beneficiaries whose care needs are driven by procedures, diagnostic scans, or emergency visits rather than specialty Part B drugs.

Response: The intent of our proposed policy is to better align payment for 340B-acquired drugs with their acquisition costs as demonstrated by the ODACS. A consequence of that increased accuracy is that beneficiaries will pay more accurate copayments. We do not think that it would be appropriate to continue to pay what we now know to be less accurate rates for drugs, and make beneficiaries pay higher copays for those drugs, simply to maintain parity in beneficiaries' copayment experience between 340B and non-340B hospitals. With respect to the proposed reduction having a disproportionate effect on beneficiaries whose care needs are driven by non-drug items and services, we reiterate our response to the previous comment. We note that the 340B program in general is outside the scope of this final rule with comment period.

Comment: One commenter stated that because the large majority of Part B coinsurance is paid not by beneficiaries out of pocket but by supplemental coverage, including Medigap, employer wrap plans, and Medicaid, realized out-of-pocket savings to beneficiaries are a fraction of the amount cited by CMS. The commenter additionally noted that budget neutrality requires an increase of approximately 8.44 percent in the conversion factor for non-drug services, which raises beneficiary coinsurance on every non-drug outpatient service at every OPPS hospital and that the proposed rule nowhere nets this offsetting increase against the claimed drug savings.

Response: We note that, even though many beneficiaries have supplemental coverage, beneficiaries often pay a premium for such supplemental coverage and those plans make coinsurance payments for the beneficiary. Thus, to the extent Medicare would be lessening the coinsurance amount such supplemental plans would have to make, we would expect the price of such plans to decrease or otherwise reflect these lower costs in the future, thereby lowering the amount that beneficiaries pay for supplemental plan coverage. Further, for the millions of Medicare beneficiaries who do not have supplemental coverage at all or who have a supplemental plan that does not cover all of a beneficiary's cost-sharing obligation, the proposed policy would directly lower out-of-pocket spending for 340B-acquired drugs for those beneficiaries. We also note that the budget neutral nature of this policy is required by statute.

We thank commenters for their input. As we indicated above, we are revising 42 CFR 419.41(d) and adding a new paragraph (k) to implement our finalized policy to pay ASP minus 28 percent for all separately payable drugs, biologicals, biosimilars and radiopharmaceuticals acquired under the 340B Program . We anticipate that this policy will collectively reduce beneficiary copayments for drugs by an estimated $1.1 billion for CY 2027.

8. 340B Payment Policy Exemptions

We proposed to exempt children's hospitals and PPS-exempt cancer hospitals from our proposed policy to adjust OPPS payments for drugs acquired under the 340B Program. In accordance with section 1833(t)(7)(D)(ii) of the Act, we make transitional outpatient payments (TOPs) to both children's and PPS-exempt cancer hospitals. This means that these hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS. Accordingly, if we were to reduce drug payments to these hospitals on a per claim basis, it is very likely that the reduction in payment would be paid back to these hospitals at cost report settlement, given the TOPs structure. Consequently, we believe it is appropriate to exempt children's and PPS-exempt cancer hospitals from the alternative 340B drug payment methodology.

In addition to the children's and PPS-exempt cancer hospitals, Medicare has long recognized the particularly unique needs of rural communities and the financial challenges rural hospital providers face. Across the various Medicare payment systems, CMS has established a number of special payment provisions for rural providers to maintain access to care and to deliver high quality care to beneficiaries in rural areas. With respect to the OPPS, section 1833(t)(13) of the Act provided the Secretary with the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act. We have continued this 7.1 percent payment adjustment since 2006.

For CY 2027 and subsequent years, we proposed that rural sole community hospitals (as described under the regulations at 42 CFR 412.92 and designated as rural for Medicare purposes), children's hospitals, and PPS-exempt cancer hospitals would be exempted from the 340B payment adjustment and that these hospitals would continue to generally be paid ASP plus 6 percent for drugs. We stated that we may revisit our policy to exempt rural SCHs, as well as other hospital designations for exemption from the 340B drug payment adjustment, in future rulemaking.

We noted that hospitals listed under 42 CFR 419.20(b),[140] such as Critical Access Hospitals (CAHs) and Rural Emergency Hospitals (REHs), would not be subject to our proposed payment adjustment for 340B-acquired drugs.

We sought comment on our proposal to exempt children's hospitals, PPS-exempt cancer hospitals and rural SCHs from the 340B drug payment adjustment.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: All commenters that commented on our proposed exemption for rural SCHs supported the exemption. These commenters emphasized that rural SCHs already operate on thin margins and are frequently the only source of hospital-based and emergency care across large, sparsely populated service areas. They appreciated CMS' recognition of the unique role they play in ensuring access to care and supporting the health of rural populations and the unique financial challenges they face.

Response: We thank the commenters for their support.

Comment: Nearly all commenters that commented on our proposed exemption for PPS-exempt cancer hospitals supported the exemption. These

[140] *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-419/subpart-B/section-419.20.*

commenters appreciated CMS's acknowledgement that PPS-exempt cancer centers necessitate unique reimbursement structures and indicated that a cancer-specialty hospital's portfolio of 340B drugs is focused upon high-complexity, high-cost anti-cancer therapeutics, that cancer-specialty hospitals are already subject to a highly restrictive version of the 340B Program rules that include the GPO prohibition and orphan drug exclusion, and that the exception would ensure that they would be able to continue to provide high complexity care to socioeconomically vulnerable populations.

Response: We thank the commenters for their support.

Comment: A commenter opposed the proposed exemption for PPS-exempt cancer hospitals from the 340B payment adjustment. The commenter disagreed with our rationale for excluding them, that PPS-exempt cancer hospitals receive transitional outpatient payments under section 1833(t)(7)(D) of the Act and that a reduction in claim-level drug payment could therefore be offset, in whole or in part, through the hospital's subsequent hold-harmless payment at cost-report settlement. The commenter stated that that interaction, by itself, should not justify maintaining ASP plus six percent payment for 340B-acquired drugs at these hospitals. Instead, the commenter recommended that CMS determine whether the transitional outpatient payment methodology can be administered, consistent with the statute, so that it does not negate an otherwise applicable acquisition-cost-based payment adjustment for 340B-acquired drugs. The commenter also expressed concern that exempting PPS-exempt cancer hospitals would perpetuate different Medicare payment for the same 340B-acquired drug based solely on the institutional status of the hospital furnishing it. It would allow qualifying cancer hospitals to continue receiving ASP plus six percent even when the hospital's acquisition cost is substantially below ASP, while other 340B hospitals would receive payment based on the survey-derived acquisition-cost relationship. Such a distinction would undermine CMS's objectives of aligning payment with acquisition cost, reducing inappropriate payment differentials, and reducing beneficiary cost sharing. If CMS nonetheless proceeds with exempting PPS-exempt hospitals, the commenter requested that CMS explain the statutory constraint in detail, quantify the resulting payment and beneficiary cost-sharing effects, and consider any available mechanisms to prevent the hold-harmless methodology from restoring 340B drug payments that exceed acquisition costs.

Response: We appreciate the commenter's input; however, we do not think that the qualified exemption for PPS-exempt cancer hospitals suggested by the commenter would be administratively feasible. As previously described, by statute, these hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive hold-harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS. Accordingly, if we were to reduce drug payments to these hospitals on a per claim basis, it is very likely that the reduction in payment would be paid back to these hospitals at cost report settlement, given the TOPs structure.

Comment: All commenters that commented on our proposed exemption for children's hospitals supported the exemption. These commenters stressed that children's hospitals serve a uniquely vulnerable patient population and rely on 340B savings to help offset systemic underpayments and sustain access to specialized pediatric services.

Response: We thank the commenters for their support.

Comment: Several commenters requested that we make our exemptions for rural SCHs, PPS-exempt cancer hospitals and children's hospitals permanent.

Response: As noted in the proposed rule, we are proposing the exemptions for rural SCHs, PPS-exempt cancer hospitals and children's hospitals for CY 2027 *and subsequent years;* however, we may revisit these exemptions in future rulemaking.

Comment: A commenter cautioned that, to the extent CMS retains exemptions, they should be justified narrowly by identifiable statutory, payment system, or access considerations.

Response: We agree with the commenter that we should employ a careful and considered approach in determining whether to continue or discontinue an exemption.

Comment: One commenter requested that the final rule and implementation guidance confirm that the term ''rural sole community hospitals'' includes an SCH reclassified as rural under 42 CFR 412.103.

Response: Hospitals must (1) either be a sole community hospital, as set forth in the regulations at 42 CFR 412.92, or be an essential access community hospitals, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, that is (2) located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103. *Comment:* Many commenters requested CMS to provide exemptions for additional hospital types and services. Multiple commenters stated that the proposed exemptions do not capture the universe of disadvantaged rural safety-net providers and requested that other rural hospitals, including SCHs, MDHs, and LVHs be exempted. Some of these commenters requested that all rural hospitals be exempted. These commenters stated that these hospitals serve the same populations as rural SCHs and depend on 340B savings for the same reasons. Others maintained that rural SCHs were exempted from the 340B payment adjustment primarily because these hospitals are in a more vulnerable financial position and already receive a special payment adjustment under OPPS and, given that reasoning, CMS should extend the exemption to the additional rural hospital designations as well. Others suggested that all DSHs or DSH safety-net hospitals operating oncology programs serving high Medicaid, uninsured, and medically vulnerable populations be exempted. Others suggested rural referral centers and academic medical centers. Other commenters requested more general exemptions for ''hospitals serving high proportions of Medicaid, uninsured, and low-income patients and hospitals located in or primarily serving health professional shortage areas and medically underserved areas,'' and ''hospitals with substantial federal engagement and funding that serve very large rural regions.'' Other commenters invited CMS to use its equitable adjustment authority to exempt hospitals with significant safety-net responsibilities that would be disproportionately affected by the proposed payment adjustment. These commenters offered various criteria for CMS to use to define these hospitals along with names to identify them: ''essential health systems,'' ''qualifying disadvantaged hospitals,'' ''frontline hospitals,'' and ''hospitals with extraordinary safety-net responsibilities.'' One commenter stated that an exemption limited to IPPS-exempt children's hospitals would not fully protect the pediatric delivery system and requested that all children's hospitals, including freestanding children's hospitals, children's hospitals within larger systems, and pediatric service lines be exempted. Finally, a few commenters suggested more targeted exemptions such as qualifying sites that administer complex cell and gene

therapies or cancer and infusion services.

Response: We understand commenters' concerns; however, we emphasize that the exemptions we are proposing are justified by the very specific circumstances of the hospital types we propose to exempt. As explained in the proposed rule, we proposed to exempt rural SCHs based on our historical analysis of the costs between hospitals in rural areas and urban hospitals, which revealed a difference in costs for rural SCHs. We also proposed to exempt PPS-exempt cancer hospitals and children's hospitals due to their unique payment structure. We decline at this time to exempt hospitals not falling into either of these two categories; however, we may revisit our policy to exempt other hospital designations from the 340B drug payment adjustment in future rulemaking.

Comment: One commenter requested clarification as to whether the proposed payment adjustment would apply to hemophilia treatment centers.

Response: Hospitals paid under the OPPS, including excepted and non-excepted provider-based departments of the hospital, are subject to this policy. To the extent that entities are paid under OPPS and participate in the 340B Program, they are subject to the payment policy unless otherwise exempted.

After consideration of public comments, we are finalizing our proposal to exempt rural SCHs, children's hospitals and PPS-exempt cancer hospitals from our proposed policy to adjust OPPS payments for drugs acquired under the 340B Program as proposed for CY 2027 and subsequent years.

9. 340B Payment Policy for Drugs Furnished by Nonexcepted Off-Campus Departments of a Hospital

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699), we discussed implementation of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015, which amended section 1833(t) of the Act. Specifically, this provision amended section 1833(t) of the Act by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and will instead be paid ''under the applicable payment system'' under Medicare Part B if the requirements for such payment are otherwise met. We indicated that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65. Accordingly, we refer to an ''off-campus outpatient department of a provider,'' which is the term used in section 603 of the Bipartisan Budget Act of 2015, as an ''off-campus outpatient provider-based department'' or an ''off-campus PBD.'' For a detailed discussion of the legislative history and statutory authority related to payments under section 603 of the Bipartisan Budget Act of 2015, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and interim final rule with comment period (81 FR 79720 through 79729).

To implement the amendments made by section 603 of Public Law 114–74, we issued an interim final rule with comment period (81 FR 79720), which accompanied the CY 2017 OPPS/ASC final rule with comment period to establish the PFS as the ''applicable payment system'' that applies in most cases, and we established payment rates under the PFS for those nonexcepted items and services furnished by nonexcepted off-campus PBDs. Specifically, we established a PFS relativity adjuster that is applied to the OPPS rate for the billed nonexcepted items and services furnished in a nonexcepted off-campus PBD to calculate payment rates under the PFS. The PFS relativity adjuster reflects the estimated overall difference between the payment that would otherwise be made to a hospital under the OPPS for the nonexcepted items and services furnished in nonexcepted off-campus PBDs and the resource-based payment under the PFS for the technical aspect of those services with reference to the difference between the facility and nonfacility (office) rates and policies under the PFS. The current PFS relativity adjuster is set at 40 percent of the amount that would have been paid under the OPPS (90 FR 53770). These PFS rates include the same packaging rules that are unique to the hospital outpatient setting under the OPPS, including the packaging of drugs that are unconditionally packaged under the OPPS. This includes packaging certain drugs and biologicals that would ordinarily be separately payable under the PFS when furnished in the physician office setting. For a full discussion of our initial implementation of section 603, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and the interim final rule with comment period (79720 through 79729). For a detailed discussion of the current PFS relativity adjuster related to payments under section 603, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 52356 through 52637) and the CY 2019 PFS final rule with comment period (82 FR 59505 through 59513).

We note that, ordinarily, Medicare pays for drugs and biologicals furnished in the physician's office setting at ASP plus 6 percent. This is because section 1842(o)(1)(A) of the Act provides that if a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under Medicare Part B and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount for the drug or biological is equal to the following: The amount provided under section 1847, section 1847A, section 1847B, or section 1881(b)(13) of the Act, as the case may be for the drug or biological.

Generally, in the hospital outpatient department setting, low-cost drugs and biologicals are packaged into the payment for other services billed under the OPPS. Separately payable drugs (1) have pass-through payment status, (2) have a cost per day exceeding a threshold, or (3) are not policy-packaged or packaged in a C–APC. As described in sections V.A. and V.B. of this final rule with comment period, section 1847A of the Act establishes the 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 WAC, and the AWP (90 FR 53682). As noted in section V.B. of this final rule with comment period, since CY 2013, our policy has been to pay for separately payable drugs and biologicals at ASP plus 6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default) (90 FR 53702). Consequently, in the case of services furnished in a hospital outpatient department, Medicare has historically paid ASP plus 6 percent for separately payable Part B drugs and biologicals. For a detailed discussion of our current OPPS drug payment policies, we refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 53697 through 53766).

As a general matter, in the nonexcepted off-campus PBD setting, we pay hospitals under the PFS for all drugs and biologicals that are packaged under the OPPS based on a percentage of the OPPS payment rate, which is determined using the PFS relativity adjuster. Because OPPS packaging rules apply to the PFS payments to nonexcepted off-campus PBDs, the PFS payment for some nonexcepted items and services that are packaged includes payment for some drugs and biologicals that would be separately billable under the PFS if a similar service had been furnished in the office-based setting. As we noted in the CY 2017 final rule with comment period, in analyzing the term ''applicable payment system,'' we considered whether and how the requirements for payment could be met under alternative payment systems in order to pay for nonexcepted items and services, and considered several payment systems under which payment is made for similar items and services (81 FR 79712). Because the PFS relativity adjuster that is applied to calculate payment to hospitals for nonexcepted items and services furnished in nonexcepted off-campus PBDs is based on a percentage (40 percent) of the amount determined under the OPPS for a particular item or service, and the OPPS is a prospective payment system, we believed that items and services furnished by nonexcepted off-campus PBDs paid under the PFS were payable on a prospective payment basis. Therefore, we believed we had flexibility to pay for separately payable drugs and biologicals furnished in nonexcepted off-campus PBDs at an amount other than the amount dictated by sections 1842(o)(1)(C) and 1847A of the Act.

As discussed previously, our proposal to adjust the payment rate for separately payable drugs and biologicals (other than vaccines, drugs on pass-through payment status and non-opioid pain management drugs) acquired under the 340B Program from ASP plus 6 percent to ASP minus 33.4 percent would apply to separately payable drugs and biologicals paid under the OPPS. Under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, however, nonexcepted items and services furnished by nonexcepted off-campus PBDs are not covered outpatient department services and, therefore, are not payable under the OPPS. This means that, absent our inclusion of them in our proposed policy, nonexcepted off-campus PBDs would not be subject to the payment changes we proposed. Because hospitals can, in some cases, acquire drugs and biologicals under the 340B Program for use in nonexcepted off-campus PBDs, we believe that not adjusting payment for these departments would present a significant incongruity between the payment amounts for these drugs depending upon where (for example, excepted or nonexcepted PBD) they are furnished. This incongruity would distort the relative accuracy of the resource-based payment amounts under the site-specific PFS rates and could result in significant perverse incentives for hospitals to acquire drugs, biologicals, biosimilars, and radiopharmaceuticals under the 340B Program and avoid Medicare payment adjustments that account for the discount by providing these drugs to patients predominantly in nonexcepted off-campus PBDs. It would also undermine our goals of reducing beneficiary cost-sharing for these drugs and biologicals and moving towards site neutrality through the section 603 amendments to section 1833(t) of the Act. To avoid such perverse incentives and the resulting distortions, we proposed for CY 2027 and subsequent years, to pay an amount equal to ASP minus 33.4 percent, or equivalent, for drugs, biologicals, biosimilars, and radiopharmaceuticals acquired under the 340B Program that are furnished by nonexcepted off-campus PBDs.

Consistent with the approach to budget neutrality we adopted when we previously implemented a reduction for 340B-acquired drugs furnished by nonexcepted off-campus PBDs (83 FR 59021) and our approach to budget neutrality for items and services provided by nonexcepted off-campus PBDs generally (83 FR 58832), these adjusted payments would not be budget neutralized.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal to apply the proposed 340B payment adjustment to drugs furnished in nonexcepted off-campus PBDs. A commenter stated that consistent payment treatment for 340B-acquired drugs would help ensure that the site at which a drug is administered is not selected merely because of a payment differential. Another commenter stated that they ''particularly support[ed] applying the proposed 340B payment adjustment to drugs furnished in nonexcepted off-campus PBDs.'' The commenter explained that ''[t]hese departments remain hospital-owned and may have access to 340B acquisition discounts even though Medicare generally pays for their services under a methodology intended to approximate payment in the physician office setting. Leaving 340B-acquired drugs furnished in these departments at ASP plus six percent would preserve a substantial payment advantage based solely on hospital ownership, and undermine the purpose of moving toward site neutral payment.'' The commenter agreed with CMS that failing to apply the adjustment would create distorted incentives for hospitals to furnish 340B drugs through these departments and encouraged CMS to continue examining Medicare payment policies that create different financial incentives for the same service based primarily on site of care or ownership. ''Payment differentials can influence organizational decisions about where services are furnished and contribute to consolidation without improving the care patients receive.'' The commenter concluded by encouraging CMS to consider the proposed 340B payment adjustment ''as part of its broader efforts to reduce unnecessary site-of-service payment disparities while ensuring that savings attributable to these reforms benefit patients and the Medicare program.''

Response: We thank commenters for their support.

Comment: Several commenters referenced previous comments they or others made to the CY 2019 final rule alleging that CMS lacks the authority under 1833(t)(21)(C) of the Act to adjust drug payments to nonexcepted off-campus PBDs or to do so in a non-budget neutral manner.

Response: We direct readers to our responses to those comments in the CY 2019 final rule at 83 FR 59020 through 59022.

Comment: Several commenters alleged that CMS's proposal is arbitrary and capricious because it undermines Congress's intent under the 340B statute.

Response: We have explained earlier in this rule why we do not believe that our proposed policy undermines Congress's intent under the 340B statute. The purpose of this policy is to align Medicare payment with average acquisition costs as required by statute.

Comment: A commenter stated that we lack a sound rationale for applying the proposed reduction to nonexcepted off-campus PBDs. The commenter contends that we provide no empirical evidence for our conclusion that not applying the reduction to nonexcepted off-campus PBDs could result in significant perverse incentives for hospitals to acquire drugs under the 340B Program and avoid Medicare payment adjustments. The commenter

requests that CMS publish the data and methodological information necessary to independently verify the accuracy of the agency's estimates, including which 340B providers CMS used to estimate its payment impact, whether the agency applied any exclusion criteria, and how CMS accounted for hospitals that are not included in the OPPS impact file but would be subject to the agency's proposed 340B payment adjustment policy.

Response: We disagree that we lack a sound rationale for applying the proposed reduction to nonexcepted off-campus PBDs. We do not think that it is unreasonable to assume that if an entity can furnish a drug in one setting and receive significantly more (nearly 40 percent) payment for the drug then it would receive furnishing the same drug in a different setting, that there exists an incentive for the entity to provide the drug in the setting in which they would receive the higher payment.

After consideration of public comments, we are finalizing our proposal to apply our payment policy to 340B-acquired drugs furnished in nonexcepted off-campus PBDs as proposed.

We expect that for CY 2027 this will result in savings of approximately $640 million to the Medicare Part B Trust Fund and would collectively reduce beneficiary copayments by an estimated $160 million. These beneficiary savings are included in the $1.1 billion figure for reduced beneficiary copayments for drugs in section 7. Beneficiary Copayments.

10. Billing Modifiers

To effectuate the payment adjustment for 340B-acquired drugs, we proposed that, beginning January 1, 2027, providers who are not exempted from the 340B payment adjustment would report modifier ''JG'' (Drug or biological acquired with 340B Drug Pricing Program Discount) to identify if a drug was acquired under the 340B Program. The phrase ''acquired under the 340B Program'' would include all drugs acquired under the 340B Program or Prime Vendor Program, regardless of the level of discount applied to the drug. Drugs that were not acquired under the 340B Program would not be reported with the modifier ''JG.'' For separately payable drugs (status indicator ''K''), application of modifier ''JG'' would trigger a payment adjustment such that the 340B-acquired drug is paid at ASP minus 33.4 percent.

We additionally proposed that, beginning January 1, 2027, for drugs or providers that are exempted from the 340B drug payment policy for CY 2027, which include pass-through drugs (status indicator ''G''), non-opioid treatment for pain relief drugs authorized under section 4135 of the CAA, 2023 (status indicator ''K1''), rural SCHs, children's hospitals, and PPS-exempt cancer hospitals, should not report modifier ''JG.'' Instead, these exempted providers should report the informational modifier ''TB'' (Drug or Biological Acquired With 340B Drug Pricing Program Discount, Reported for Informational Purposes) to identify OPPS separately payable drugs purchased with a 340B discount. The informational modifier ''TB'' will facilitate the collection and tracking of 340B claims data for OPPS providers that are exempted from the payment adjustment in CY 2027. However, use of modifier ''TB'' will not trigger a payment adjustment, and these providers will generally receive ASP plus 6 percent for separately payable drugs furnished in CY 2027, even if such drugs were acquired under the 340B Program.

We also proposed that, beginning January 1, 2027, all providers report a distinct modifier to identify drugs and biologicals that were not acquired under the 340B Program. Specifically, we proposed to establish a new modifier, designated in the proposed rule with the placeholder modifier code ''XX'' (Drug or biological not acquired under the 340B Drug Pricing Program), which would be required to be reported for all separately payable drugs that were purchased outside of the 340B Program.

The requirement to use modifier ''XX'' would apply to all providers paid under the OPPS, including excepted and nonexcepted off-campus PBDs. Reporting the modifiers ''XX,'' ''JG,'' or ''TB'' for applicable drugs would ensure that all drug claims are consistently categorized as either 340B-acquired or non-340B-acquired. We believe that requiring the use of modifier ''XX'' for non-340B drugs will improve the completeness and consistency of claims data, facilitate program integrity and oversight, and enhance our ability to monitor acquisition patterns across providers. The use of modifier ''XX'' would not trigger a payment adjustment and such drugs would continue to be paid at the applicable OPPS rate (generally ASP plus 6 percent for separately payable drugs) consistent with existing policy. In summary, we proposed all separately paid drug claims reported under the OPPS would be reported with a modifier of either ''JG,'' ''TB,'' or ''XX'' (Table 75). We solicited comment on our proposal to require all separately paid drug claims to be reported with a modifier of either ''JG,'' ''TB,'' or ''XX.''

As stated in the CY 2027 OPPS/ASC proposed rule, we believe the addition of this new modifier is consistent with the decisions that hospitals are already making (is the drug a 340B-acquired drug or a non-340B-acquired drug) when billing for these drugs. As previously mentioned, we believe requiring the use of modifier ''XX'' for non-340B drugs will improve the completeness and consistency of claims data—this requirement could even decrease burden on hospitals as it may improve the accuracy of billing, thus decreasing the need for hospitals to reprocess claims that were billed incorrectly. We requested comment as to whether the addition of modifier ''XX'' would create unnecessary, undue burden for hospitals.

TABLE 75: PROPOSED DRUG CLAIM MODIFIERS FOR ENTITIES PAID UNDER THE OPPS

Hospital Type	Pass-through Drug (SI "G")	Separately Payable Drug (SI "K")	Non-Opioid Treatment for Pain Relief Drug (SI "K1")	Packaged Drug (SI "N")
340B Drugs				
340B Hospitals	TB	JG	TB	TB
Children's Hospitals	TB	TB	TB	TB
PPS-Exempt Cancer Hospitals	TB	TB	TB	TB
Rural Sole Community Hospitals	TB	TB	TB	TB
Non-340B Drugs				
All OPPS Hospitals	XX			XX Optional

Additionally, we acknowledged this billing modifier proposal would have implications for how we identify billing units of drugs acquired through the 340B Program under the Medicare Part B Drug Inflation Rebate Program. In the CY 2025 Physician Fee Schedule (PFS) final rule (89 FR 98583), we codified at § 427.303(b)(1)(iv) that we will exclude from Part B rebate calculations separately payable billing units in claim lines for institutional claims that are billed with the ''TB'' modifier for claims with dates of service on or after January 1, 2025. As we stated in the proposed rule, establishing a requirement to use the ''JG'' modifier, in addition to the requirement to use the ''TB'' modifier would necessitate changes to how we identify 340B units to exclude from Part B rebate calculations.

Consequently, we proposed a conforming change at § 427.303(b)(1)(iv) to reflect proposed changes to the requirements to use billing modifiers for 340B-acquired drugs as described in section V.B.10. of this final rule with comment period. Specifically, to account for these billing modifier proposals, at § 427.303(b)(1)(iv), we proposed to add ''or successor billing modifiers to identify 340B units.'' This means, for the purposes of Part B inflation rebate calculations, we would exclude billing units acquired under the 340B Program as identified through separately payable units in claim lines billed with the ''TB'' modifier, or successor billing modifiers to identify 340B units for 340B-acquired drugs, for claims with dates of service on or after January 1, 2025. Therefore, as a matter of operations, effective January 1, 2027, CMS would identify separately payable billing units in claim lines billed with the ''TB'' modifier and proposed ''JG'' modifier. We recognized that policy amendments for the Medicare Prescription Drug Inflation Rebate Program are typically proposed in the PFS; however, we believed it was appropriate to propose an amendment to § 427.303(b)(1)(iv) in the OPPS/ASC proposed rule due to timing differences in the publication of the CY 2027 PFS proposed rule relative to the OPPS/ASC proposed rule and to ensure we are able to appropriately exclude 340B units from Part B rebate calculations starting January 1, 2027.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters unreservedly supported our proposals relating to modifiers. One commenter stated that, ''taken together, these three modifiers would, for the first time, categorize every separately payable drug claim under the OPPS as either 340B-acquired or non-340B-acquired. That completeness will further make the data usable and meaningful.'' Another commenter praised the proposal as a step toward greater transparency in the 340B Program. A third commenter called the modifier ''long awaited'' and stated that it would help ensure Medicare has reliable claims-level data to distinguish drugs that should be subject to the 340B payment adjustment from those that should not, helping prevent inaccurate payments before they are made. Another commenter stated that ensuring every separately paid drug claim is consistently categorized as either 340B or non-340B will improve the completeness and consistency of claims data, facilitate program integrity oversight, and enhance CMS's ability to monitor acquisition patterns.

Response: We thank commenters for their support.

Comment: Several commenters provided suggestions for the use of the

modifiers beyond what we proposed. One commenter suggested that we use the claims modifiers to annually recalculate the budget-neutrality adjustment factor to ensure that the 340B payment policy is being implemented in a consistently budget-neutral manner. Another commenter urged CMS to expand the application of the XX claims modifier and require all Medicare claims, including under Part D and Medicare Advantage, to have the appropriate modifier within 10 days of dispense. A third commenter recommended that CMS consider the following implementation refinements to ensure consistent administration and compliance with the Inflation Reduction Act (IRA): (1) extend this requirement beyond drugs paid for under the OPPS to all Part B claims that report a drug; and (2) extend the XX modifier requirement to all non-340B drugs, not just those that are separately payable.

Response: We thank commenters for their suggestions and will potentially consider them for future rulemaking where appropriate.

Comment: A commenter supported the use of modifiers but requested that we limit their application to separately payable drugs furnished by 340B hospitals.

Response: We thank the commenter for their suggestion; however, for the reasons discussed in the proposed rule, it is necessary to apply the proposed modifier requirement to 340B and non-340B hospitals to effectively implement our 340B Payment Policy.

Comment: Many commenters opposed the proposal as being administratively burdensome. These commenters expressed concern with the costs associated with implementing the modifiers such as adapting their electronic health record and billing systems and training their staff. A commenter noted the immense technical complexity of adopting the new modifier, requiring extensive reconfigurations across electronic health records (EHRs), pharmacy management systems, charge description masters, and revenue cycle platforms systemwide. Another commenter stated that ''because 340B drugs are generally managed through a replenishment model, the purchasing information necessary to identify how a drug is ultimately replenished may not be available at the same point in time that the claim is submitted. This may require hospitals to develop additional processes to reconcile pharmacy purchasing information with claims data.'' The commenter encouraged CMS to ensure that any modifier requirements account for the operational realities of the 340B replenishment process and do not add administrative burden. Many commenters claimed that it would not be feasible to implement the proposed changes by January 1, 2027, and requested a delayed or phased-in implementation start date coupled with robust implementation guidance. These commenters stated that hospitals would need to modify their systems, interfaces, edits, training, quality controls, reconfigure charge description masters, pharmacy inventory systems, split billing software, claim scrubbers, and revenue cycle logic, and retrain pharmacy and billing staff between publication of a final rule around November 1 and an effective date of January 1. Commenters suggested various alternative timeframes for making the modifier changes effective as well as requesting that CMS issue sub-regulatory billing guidance by a date certain, provide claim edit testing, and refrain from denials or recoupments for good-faith modifier errors during a defined transition period.

Many commenters stated that the scope and complexity of implementing the new modifier would greatly increase the risk of errors. A commenter stated that it would be difficult to identify every non-340B claim accurately and that that would create a high volume of potential billing mistakes, which could lead to rejected claims or compliance audits. Another commenter cautioned that minor misconfigurations or data mapping errors could trigger widespread claim rejections and payment denials. A third commenter found the XX modifier to be especially concerning because non-340B status may depend on purchasing, replenishment, mixed-use inventory, patient eligibility, accumulator logic, wholesaler data, and retrospective claim information and a missing or incorrect modifier could result in denials, underpayment, reprocessing, audits, and compliance exposure.

Many commenters also allege that new modifier XX is unnecessary and duplicative. These commenters state that the new modifier is not needed because CMS would be able to identify 340B drugs with the TB and JG modifiers. A commenter stated that ''[a]ny drugs that do not have either of those modifiers appended would be a non-340B drug, so the 'XX' modifier is unnecessary.'' Another commenter alleges that ''[a]ny claim line without either modifier is, by definition, already identifiable as a non-340B drug. The XX-placeholder modifier is therefore redundant: requiring hospitals to affirmatively identify what is already the logical default would add a data field without providing new information.''

A commenter urged CMS to consider other, less-burdensome options, such as creating a neutral clearinghouse for 340B claims.

Response: We recognize that implementation of the new XX modifier may be the source of some amount of administrative burden for some hospitals. However, the XX modifier is a necessary component of our proposal, and we do not believe that its implementation would be unduly burdensome or warrant a delay or phased-in approach. This modifier does not require the provider to obtain any additional information to use as it only requires information that the provider already has: whether the drug was acquired under the 340B Program.

The addition of this new modifier is consistent with the decisions that hospitals are already making (is the drug a 340B-acquired drug or a non-340B-acquired drug) when billing for these drugs. As previously mentioned, we believe requiring the use of modifier ''XX'' for non-340B drugs will improve the completeness and consistency of claims data—this requirement could even decrease burden on hospitals as it may improve the accuracy of billing, thus decreasing the need for hospitals to reprocess claims that were billed incorrectly.

We question those commenters who stated they would be unable to identify the non-340B claims as the provenance of the drug is something that the entities should know.

With respect to comments about timing to operationalize the new modifier, we note that hospitals have been on notice since the proposed rule went on display at the Office of the Federal Register on July 7, 2026 that CMS was considering establishing a new modifier for non-340B drugs, if finalized. In addition, the new modifier will not be required until January 1, 2027, which after display of this final rule with comment period will give hospitals two additional months to operationalize the modifier. Under section 1835(a) of the Act, providers have 12 months after the date of service to timely file a claim for payment. Therefore, for those hospitals that may need more time to ensure that they are in compliance with the modifier requirements, they have 12 months from the date of service to do so.

Comment: A few commenters commented on our proposed conforming amendment to 42 CFR 427.303(b)(1)(iv) to account for successor billing modifiers used to

identify 340B units. All commenters supported our proposal. One commenter suggested additional textual revisions. Specifically, the commenter recommended that CMS conform the regulatory text to the preamble by using disjunctive rather than conjunctive phrasing: ''The preamble proposes to add 'or successor billing modifiers to identify 340B units, 'but the proposed regulatory text reads' billed with the 'TB' modifier and successor billing modifiers to identify 340B units.' Read literally, the codified text's conjunctive phrasing would require both modifiers on the same claim line. Because TB and JG are mutually exclusive in CMS's own design, that reading would exclude far fewer 340B units than CMS intends and would increase manufacturers' rebatable billing units correspondingly. CMS should revise the codified text to reflect the disjunctive phrasing in the preamble.''

Response: We appreciate the feedback from the commenter and, after reviewing the proposed regulation at § 427.303(b)(1)(iv), we agree that this appears to be an unintended technical error. We are therefore finalizing a modification to the text at § 427.303(b)(1)(iv) to replace ''and'' with ''or'' so that it reads: ''Separately payable billing units in claim lines billed with the 'TB' modifier or successor billing modifiers to identify 340B units, for claims with dates of service on or after January 1, 2025.''

After consideration of public comments, we are finalizing our proposal to require all separately paid drug claims to be reported with a modifier of either ''JG,'' ''TB,'' or ''XX'' as proposed. We note placeholder ''XX'' is being replaced with permanent modifier ''ND'' as reflected in the final table below. We are also finalizing with modification our proposal for a conforming amendment to 42 CFR 427.303(b)(1)(iv) to account for successor billing modifiers used to identify 340B units.

TABLE 76: FINAL DRUG CLAIM MODIFIERS

Hospital Type	Pass-through Drug (SI "G")	Separately Payable Drug (SI "K")	Non-Opioid Treatment for Pain Relief Drug (SI "K1")	Packaged Drug (SI "N")
340B Drugs				
340B Hospitals, non-excepted and excepted Off Campus PBDs	TB	JG	TB	TB
Children's Hospitals	TB	TB	TB	TB
PPS-Exempt Cancer Hospitals	TB	TB	TB	TB
Rural Sole Community Hospitals	TB	TB	TB	TB
Non-340B Drugs				
All OPPS Hospitals, non-excepted and excepted Off Campus PBDs	ND			ND Optional

D. CY 2027 OPPS Payment Methodology for Non-340B-Acquired Drugs Based on ODACS

CMS analyzed acquisition cost data collected through the ODACS for drugs acquired outside the 340B Program and evaluated several methodologies for estimating the relationship between hospitals' acquisition costs and ASP-based payment amounts as previously discussed in this section.

Using our preferred proposed methodology, which calculates acquisition cost margins using the geometric mean of survey-reported acquisition costs, we estimate that hospitals' acquisition costs for non-340B drugs were approximately 2.7 percent above ASP during the survey period. However, we recognize that acquisition costs reported through the survey may not fully reflect all manufacturer rebates, chargebacks, administrative fees, or other post-purchase price concessions received by hospitals, as we have not included GPO discounts into the ASP plus 2.7 percent figure. Therefore, even ASP plus 2.7 percent, the reported acquisition costs, may overstate hospitals' net acquisition costs. As a result, the estimated margin of ASP plus 2.7 percent may, in part, reflect differences in how manufacturer

rebates and other retrospective discounts were reported rather than solely the underlying acquisition costs of the drugs.

The survey results for non-340B drugs exhibit greater variation than the survey results for 340B-acquired drugs. As a result, the confidence intervals for the estimated non-340B acquisition cost margins span a slightly wider range of potential values. We believe this finding is expected given the diversity of purchasing arrangements, contracting structures, and acquisition channels available to hospitals when acquiring drugs outside the 340B Program. The broader distribution of survey-reported acquisition costs suggests greater uncertainty regarding the precise average acquisition cost margin for non-340B drugs relative to the margin observed for 340B-acquired drugs.

Although the survey data suggest that hospitals' acquisition costs for non-340B drugs may be lower on average from the current payment rate of ASP plus 6 percent, the survey results are subject to slightly greater variability and may be affected by differences in the reporting of manufacturer rebates and other price concessions. Consequently, we believe the survey data should be interpreted further as we assess the need for a payment rate change for non-340B drugs.

Given the need to further consider the non-340B survey results for the reasons mentioned, including the range of reasonable acquisition cost estimates supported by the data, we did not propose to establish a survey-based payment rate for non-340B drugs. Rather, for CY 2027, after taking into account the survey results, we proposed to continue paying separately payable non-340B drugs, biologicals, biosimilars, and radiopharmaceuticals as we do in CY 2026, which is generally at a rate of ASP plus 6 percent. We believe this approach appropriately considers the survey findings, including the uncertainty associated with manufacturer rebate reporting and the broader distribution of acquisition cost estimates, while maintaining stability in payment rates and allowing CMS to continue evaluating acquisition cost information obtained through its survey authority under section 1833(t)(14)(D)(ii) of the Act.

Under the same survey-based methodology proposed for determining payment for 340B-acquired drugs, such an approach for non-340B drugs would be based on the geometric mean acquisition cost estimate derived from the survey data, resulting in a payment rate of approximately ASP plus 2.7 percent. In the case of the 340B-acquired drugs, the discrepancy between acquisition cost and Medicare payment is substantial and obviously apparent; however, the discrepancy between acquisition cost and Medicare payment for non-340B acquired drugs is much less significant. Therefore, we proposed to continue paying for non-340B acquired drugs at a rate of ASP plus 6 percent. We also intended to continue evaluating the acquisition cost survey data for non-340B-acquired drugs and noted we may consider the results of this analysis in future rulemaking.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to maintain the current payment rate for CY 2027 for separately payable drugs and biologicals without pass-through payment status that are not acquired under the 340B Program. These commenters stated that this method of payment makes hospital reimbursement predictable, accurate, and maintains parity with the physician office setting. One of these commenters stated that applying a payment change to non-340B drugs on the strength of data that is more widely dispersed than the data for 340B drugs would introduce risk for products that are dispensed infrequently as compared to non-orphan drugs. Several of these commenters cautioned CMS against future reductions to non-340B drugs. A commenter opined that applying any reimbursement reductions for drug purchases would be particularly difficult to justify because non-340B hospitals generally acquire drugs without the substantial discounts available through the 340B Program. Multiple commenters observed that since survey reported acquisition costs were only 2.7 percent above the mean ASP and 2.8 percent above the median ASP, that this means that for any given non-340B drug, it is likely that ASP will be roughly the same as the non-340B purchase price.

Response: We thank commenters for their support. With respect to future payment adjustments to non-340B drugs, as we indicated in the proposed rule, we are continuing to evaluate the survey data.

Comment: Several commenters expressed concern with the asymmetry of applying survey findings to reduce OPPS payment for 340B drugs but not to adjust payment for non-340B drugs. One commenter alleged that this demonstrates that CMS is ''applying the survey aggressively when it produces savings but disregards it where application would reduce payment to non-340B hospitals.'' The commenter contends that this inconsistency undermines our rationale that payments should reflect actual acquisition cost. The commenter also pointed out that the failure to reduce OPPS payments for non-340B drugs will create a situation where non-340B hospitals will see their total OPPS reimbursements increase due to budget neutrality. The commenter finds this outcome to be unfair and discriminatory based on 340B status. The commenter contends that the proposed payment rate will result in an underpayment for some 340B drugs since the 340B discount can range from 23.1 percent to 100 percent depending on manufacturers' actions. CMS' proposal to apply a single ASP percentage reduction of 33.4 percent to all drugs supposedly will underpay hospitals for 340B drugs subject to any discount above 33.4 percent. The commenter says that based on this underpayment of some 340B drugs, they will choose to not dispense a 340B drug to patients where the 340B payment would result in an underpayment. Instead, the commenter will purchase those drugs at the list price (wholesale acquisition cost), submit the claim without a 340B modifier, and receive the ASP plus 6 percent payment. It is the commenter's belief that other hospitals and health systems will do the same thing, which will significantly impact CMS proposed budget savings of $5.7 billion from this proposed payment adjustment.

Response: We acknowledge that we are proposing to adjust payment for 340B-acquired drugs but not for non-340B-acquired drugs in CY 2027. However, this asymmetry is simply the result of our analysis of the survey data in conjunction with ceiling prices required under the 340B Program for which there is no corollary outside of that program. As we explained in the proposed rule, based on the respective confidence intervals for 340B and non-340B drugs, we believe it is appropriate to move forward with an adjustment for 340B-acquired drugs in CY 2027 but to continue to study the data with respect to non-340B-acquired drugs. We disagree with the commenter that we are discriminating against 340B hospitals in doing so. We are better aligning our payment for 340B-acquired drugs with the cost of their acquisition, as demonstrated by the survey and supported by ceiling-price data, in compliance with section 1833(t)(14) of the Act and we are budget neutralizing that payment adjustment in compliance with our statutory budget neutrality

obligations. The nearly 40 percent discrepancy for 340B-acquired drugs is so drastic and obvious it needs to be addressed immediately; however, the preliminary non-340B average acquisition cost is only a few percentage points away from the current payment rate and warrants additional consideration before proposing changes, especially considering there is no non-340B corollary to 340B ceiling prices.

Comment: One commenter suggested that, based on the confidence interval spread for 340B drugs, CMS should conclude that the current payment rate for non-340B drugs is in fact the current payment rate for non-340B drugs (ASP plus 6 percent). Alternatively, the commenter indicated that they also supported our determination in the proposed rule that hospital acquisition data is not currently available for non-340B drugs such that payment under section 1833(t)(14)(A)(iii)(II) (*i.e.,* ASP plus 6 percent) continues to be appropriate.

Response: We thank the commenter for their suggestion and for their support of our proposal to pay ASP plus 6 percent for non-340B-acquired drugs for CY 2027. As we indicated in the proposed rule, we continue to evaluate acquisition cost information obtained through CMS's survey authority under section 1833(t)(14)(D)(ii) of the Act.

After consideration of public comments, we are finalizing our proposal to continue paying for non-340B-acquired drugs at a rate of ASP plus 6 percent for CY 2027.

E. Summary

In summary, after consideration of public comments received, for the reasons discussed above, we are not finalizing our proposal for CY 2027 and subsequent years to pay for drugs acquired under the 340B Program at ASP minus 33.4 percent. Instead, we are finalizing our alternative proposal for CY 2027 and subsequent years to pay for drugs acquired under the 340B Program at ASP minus 28 percent and are revising 42 CFR 419.41(d) and adding a new paragraph (k) to implement this payment change. We are finalizing our proposal to pay for drugs acquired outside of the 340B Program at ASP plus 6 percent. We are also finalizing our proposal to exempt rural SCHs, PPS-exempt cancer hospitals and children's hospitals from the 340B Payment Policy for CY 2027 and subsequent years. We are also finalizing our proposal that hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS (such as CAHs or REHs) or exempted from the 340B drug payment policy for CY 2027, are required to report modifier ''JG'' on the same claim line as the drug HCPCS code to identify a 340B-acquired drug; the modifier ''TB'' for all pass-through drugs, non-opioid treatment for pain relief drugs, and 340B-acquired drugs reported by rural SCHs, children's hospitals and PPS-exempt cancer hospitals for informational purposes; and the modifier ''XX'' (finalized as ''ND'') for all drugs that were not acquired through the 340B Program. We note these payment policies apply to both excepted and non-excepted provider-based departments of a hospital. Finally, we are finalizing our proposal with modification to make a conforming change to § 427.303(b)(1)(iv) to ensure our process to identify 340B units for purposes of Part B inflation rebate calculations aligns with our proposed 340B modifier billing requirements. All of these finalized proposals are effective January 1, 2027.

F. Budget Neutrality

As we proposed the previously defined payment adjustments through our authority under section 1833(t)(14)(A)(iii)(I) of the Act, we also proposed making this adjustment in a budget neutral manner. To maintain budget neutrality within the OPPS, we estimated that OPPS payment for 340B-acquired drugs would be reduced by approximately $4.85 billion in CY 2027; however, these payments would be redistributed in an equal offsetting amount to all hospitals paid under the OPPS through increased payment rates for non-drug items and services furnished by all hospitals paid under the OPPS. Specifically, the redistributed dollars would increase the conversion factor for OPPS non-drug items and services by 8.44 percent for CY 2027.

We also estimated the alternative methodology previously described to pay 340B-acquired drugs at ASP minus 28 percent, which is the average acquisition cost calculated from the 340B ceiling prices and volume weighted by OPPS utilization data. Through this method, we estimated that OPPS payment for 340B-acquired drugs would be reduced by approximately $4.68 billion in CY 2027. Specifically, the redistributed dollars would increase the conversion factor for OPPS non-drug items and services by 8.14 percent for CY 2027.

For additional details on our proposed budget neutral implementation of this policy, please see section II.B. of this final rule with comment period.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters acknowledged our statutory obligation to budget neutralize our proposed payment adjustment. One commenter stated that ''this adjustment is both appropriate and required.''

Response: We thank commenters for recognizing our statutory obligation to budget neutralize our proposed payment adjustment.

Comment: Several commenters supported budget neutralizing our proposed payment adjustment due to the benefit the budget-neutral redistribution would provide to many hospitals, including those serving rural and underserved communities. One of these commenters expressed disappointment that physician practices would not receive the corresponding increase in OPPS payment for non-drug items and services. The commenter opined that payment under the Medicare PFS continues to lag OPPS payment for many comparable services and stated that this distributional effect underscores the need for CMS, through PFS rulemaking, to ensure that payment to independent physician practices reflects the realistic cost of furnishing high-quality care and supports continued beneficiary access.

Response: We thank commenters for their support. With respect to the commenter's suggestion that we address differences in payment between the PFS and the OPPS, as acknowledged by the commenter this issue is outside the scope of this rulemaking.

Comment: Several commenters, including MedPAC, supported reducing payment for 340B-acquired drugs generally but lamented our statutory obligation to budget neutralize those reductions. These commenters disliked its effect of increasing beneficiary copayments for non-drug items and services and contributing to greater differences in Medicare's payment rates for those services delivered in both the hospital and office settings. These commenters urged us to work with Congress to enable us to implement the payment adjustment in a non-budget neutral manner.

Response: We thank MedPAC and the other commenters for their feedback and will take their suggestion under consideration for future rulemaking, if applicable.

Comment: Many commenters requested that CMS recalculate the budget-neutrality adjustment on an annual basis, using OPPS claims data from the prior year to ensure the policy is implemented in a fully budget neutral manner. These commenters pointed to

the implementation of our previous 340B payment policy and stated that because we did not recalculate the budget neutrality adjustment to account for volume changes in drug claims and non-drug claims over the duration of that policy, the original adjustment did not reflect actual claims.

Response: We are fully implementing budget neutrality for CY 2027. We will consider recalculating the budget-neutrality adjustment on an annual basis for future rulemaking.

Comment: Many commenters claimed that budget neutrality does not require a uniform redistribution across hospitals and that CMS should prioritize ''essential hospitals,'' ''true safety-net hospitals,'' teaching hospitals, non-exempted children's hospitals, ''hospitals that demonstrably serve the greatest numbers of Medicare beneficiaries, Medicaid beneficiaries, dual-eligible individuals, and low-income patients,'' and ''hospitals whose operations and missions are consistent with the intent of the 340B Program, particularly nonprofit hospitals with a demonstrated commitment to providing charity care and serving underserved populations'' in the budget neutral redistribution.

Response: While we recognize the commenters' concerns regarding the effect of budget neutrality on the hospital types they list, we note that the purpose of the 340B Payment Policy is not to replace the 340B Program. We have attempted to address some of these concerns through the finalized exemptions for rural sole community hospitals, PPS-exempt cancer hospitals, and children's hospitals.

Comment: Many commenters observed that the 8.44 percent increase to payment for non-drug items and services would not make all hospitals whole. The commenters state that hospitals with substantial 340B drug volume would experience a drug payment reduction, while hospitals with comparatively little or no 340B exposure would receive the benefit of the increased payments for non-drug services. A commenter stated ''[t]here is no assurance that the hospital will recover what it loses.'' Another commenter observed that ''[a] hospital that experiences a substantial reduction in drug payments will not necessarily receive sufficient additional reimbursement through non-drug services to offset its actual losses. CMS should therefore evaluate budget neutrality at the hospital level and by hospital type rather than relying solely upon aggregate OPPS neutrality.''

Response: We acknowledge that some hospitals will potentially experience greater reductions to drug payments than increases to non-drug items and services as a consequence of our policy. However, that does not change our statutory obligation under section 1833(t)(14) of the Act to conduct a survey of drug acquisition costs and adjust payment rates taking those costs into account.

Comment: A commenter expressed concern about APC calibration. The commenter stated that ''[w]hile CMS anticipates that reductions in 340B drug reimbursement will be offset through corresponding increases in payment for non-drug OPPS services, hospitals must have confidence that the APC recalibration accurately and fully reflects the funds removed from 340B drug reimbursement. However, CMS has not demonstrated that the resulting redistribution appropriately reflects the hospitals, service lines, and patient populations most affected by the proposed drug payment reductions. Because reductions in drug reimbursement and increases in APC payments are not distributed uniformly across providers and service lines, the effects of the proposal are likely to vary considerably across hospitals and clinical programs. Therefore, CMS should provide greater transparency regarding both the calculation of the budget neutrality adjustment and the distributional impact of the proposal to ensure that hospitals can appropriately evaluate its effects.''

Response: We agree that it is important to provide transparency in calculating budget neutrality for this finalized payment adjustment. For this reason, we have provided discussion throughout the proposed and final rules regarding the calculations and impact involved. We further note that we provide a separate column describing the impacts of the budget neutral distribution for this adjustment for various categories of OPPS providers in section XXVII of this final rule.

Comment: Many commenters requested that we conduct additional analyses and release additional information relating to budget neutrality before finalizing our proposal. Multiple commenters requested CMS conduct and publish a detailed analysis of the proposal's impact on 340B hospitals, safety-net providers, access to care, and essential outpatient services before finalizing the policy. A commenter suggested that CMS publish hospital-specific net-impact estimates before finalizing the policy and establish protections for hospitals facing material losses. The commenter additionally requested that CMS evaluate whether the redistribution changes incentives to furnish complex outpatient therapies or affects access in communities already experiencing hospital financial stress. Another commenter requested that CMS publish a combined beneficiary cost-sharing analysis that nets the claimed drug coinsurance savings against the coinsurance increases produced by the budget-neutral conversion factor adjustment.

Another commenter alleged that CMS provided no explanation of its methodology for calculating the impact of the payment reductions and included no accompanying data files providing the data that went into its calculation of the aggregate impact. The commenter stated that ''[i]t is imperative that prior to implementing a policy of such magnitude, CMS be transparent in its methodology for modeling the cut and the corresponding budget neutrality adjustment, so that interested parties can replicate these models and verify CMS' calculations. CMS should publish its methodology for modeling the impact, which would include how CMS identified 340B hospitals and 340B drugs, including which data sources it used. CMS should also publish a hospital-level impact file with the results of the payment cut.''

Response: We thank commenters for their many suggestions for information for us to release and analyses for us to conduct prior to finalizing our proposal. As we have noted previously; however, we believe that the payment misalignment that our policy will address has been in effect for many years and it is important to implement this policy without delay now that we have conducted the required survey and have data clearly demonstrating that the existing payment rate for 340B-acquired drugs is not even close to a representative proxy for the cost of their acquisition. With respect to the commenter's suggestion to establish protections for hospitals facing material losses, as we discussed in our earlier response to a commenter, we have attempted to address some of these concerns through the finalized exemptions for rural sole community hospitals, PPS-exempt cancer hospitals, and children's hospitals. We also note that with respect to potential future impacts, our budget neutrality calculations are based on what exists in the claims data and the direct changes associated with policy. We do not predict behavioral changes or hospital decisions as a result of those policies. With respect to beneficiary cost savings, these savings are likely to stay flat or increase, saving beneficiaries more as a result. As is true of any update, there will be some redistribution of

copayments because the 20 percent beneficiary cost sharing for drugs gets ''transferred'' over as 20 percent into the broader OPPS through the conversion factor budget neutrality adjustment for the 340B policy. That budget neutrality adjustment will make many of the overall OPPS payment rates and their associated copayments higher. OPPS cost-sharing for a service is capped at the applicable Part A hospital inpatient deductible amount for that year for each service. That means that when OPPS payments and therefore their associated copayments, increase relative to that fixed amount, more services are likely to get capped at the inpatient deductible amount. Finally, we note that the impact file includes all proposed/final budget neutrality adjustments and updates, as well as the 340B remedy where applicable. The impact analysis looks at the existing claims, applies the proposed/finalized policies but not does not consider behavioral changes or provider decision making.

We thank commenters for their input. We estimate that OPPS payment for 340B-acquired drugs will be reduced by approximately $4.65 billion in CY 2027 as a result of our adoption of this policy. When factoring in our finalized policy for 340B drug payment in non-excepted PBDs, our total estimated reduction in 340B drug spending is $5.45 billion for CY 2027, which includes both Medicare and beneficiary payments.

G. Final Payment Rates for Skin Substitute APCs

In the CY 2026 OPPS/ASC final rule with comment period, we finalized a policy to separately pay for skin substitute products as incident-to supplies in the physician office, hospital outpatient, and ambulatory surgical center settings effective January 1, 2026 (90 FR 53729 through 53748). We excluded skin substitutes approved as biological products under section 351 of the PHS Act, which would continue to be paid consistent with section 1847A of the Act, from our policy to pay for skin substitute products as incident-to-supplies. As part of this final policy, we assigned sheet-form skin substitute products to one of three clinical APCs we created on ''FDA regulatory categories'': [141] APC 6000 (PMA Skin Substitute Products), APC 6001 (510(k) Skin Substitute Products), and APC 6002 (361 HCT/P Skin Substitute Products). For CY 2026, we set an initial payment rate of $127.14/cm^2 for APCs 6000 (PMA Skin Substitute Products), 6001 (510(k) Skin Substitute Products), and 6002 (361 HCT/P Skin Substitute Products). We stated we would update the payment rates for skin substitute categories annually through rulemaking using the most recently available calendar quarter of ASP data, when available, to set the rates. In the event ASP data was not available for a particular product, we stated we would use the outpatient hospital MUC data. If MUC was not available, we stated we would use the product's WAC or 89.6 percent of AWP if WAC was also unavailable. We finalized a policy to include all skin substitute products used across both settings as well as the combined product utilization patterns and, as soon as data was available that reflects the results of this policy, to determine a weighted average per-unit cost by group to set the payment rates for each of the three categories.

As stated in the proposed rule, at this time, we do not believe we have sufficient data upon which to propose a revised payment rate for all three skin substitute product APCs. We also believe that updating the payment rates for CY 2027, before the impacts of the payment policy are reflected in the CY 2026 claims that will be used for CY 2028 OPPS/ASC and PFS rulemakings, could result in payment disruptions or introduce unnecessary volatility. Because updated use patterns reflecting the CY 2026 policy changes are not yet available, we proposed for CY 2027 to continue the policy finalized for CY 2026 in its entirety, which includes maintaining the payment rate of $127.14/cm^2 for APCs 6000 (PMA Skin Substitute Products), 6001 (510(k) Skin Substitute Products), and 6002 (361 HCT/P Skin Substitute Products).

We note that, effective April 1, 2026, CMS created new HCPCS Level II codes to describe the application of non-sheet form skin substitute products HCPCS codes G0681 through G0684:

- G0681—*Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute for a wound surface area up to 100 sq cm; first 25 sq cm or less of wound surface area.*
- G0682—*Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute for a wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure).*
- G0683—*Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute graft for a wound surface greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1 percent of body area of infants and children.*
- G0684—*Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute graft for a wound surface greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area or part thereof, or each additional 1 percent of body area of infants and children, or part thereof (list separately in addition to code for primary procedure).*

As explained in the CY 2026 OPPS/ASC Final Rule, we did not finalize changes to the payment arrangement under the OPPS for products that are not in sheet form and explained that we would continue to explore the issue for future rulemaking (90 FR 53739). Accordingly, we assigned the new non-sheet form application codes a status indicator of ''N'' to indicate that payment for the application is packaged effective April 1, 2026.

For CY 2027, we proposed to maintain the payment arrangement for non-sheet form skin substitute products under the OPPS; we proposed to assign status indicator ''N'' to both the non-sheet form application codes (G0681 through G0684) and the non-sheet form skin substitute products, themselves. Therefore, for CY 2027, we proposed to continue to package both the non-sheet form products and the application codes used to apply them.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported finalizing a single blended payment rate for CY 2027. Commenters supported a period of stable payment to ensure beneficiary access to skin substitute products.

[141] The use of the term ''FDA regulatory categories'' in this final rule refers to those described in the CY 2026 PFS and OPPS/ASC PPS final rules and is not intended to reflect or imply that such products under CMS's payment policy are characterized as such or grouped together by FDA. Specifically, CMS clarified that ''use of short descriptors and associated FDA regulatory categories may reflect current FDA regulation but are not intended to imply that FDA has determined that a product meets any specific FDA statutory or regulatory requirements. FDA's statutory and regulatory framework, including, for example, FDA's findings that a product is 'safe and effective,' is not controlling of Medicare's determination under its own authorities of whether a product is 'reasonable and necessary' for a Medicare beneficiary and meets all preconditions for Medicare coverage and payment. FDA does not make Medicare coverage or payment determinations, nor do FDA statutes and regulations govern Medicare coverage or payment determinations.'' (90 FR 53448 at 53,725).

Response: We thank the commenters for their support.

Comment: Some commenters did not support continuing to pay for sheet-form skin substitute products at the $127.14/cm² payment rate for CY 2027 as proposed. Some commenters believed that the proposed payment rate is punitive and overcorrects for abuses seen in the skin substitute space. Commenters suggested that targeted program integrity tools directed at improper billing patterns rather than an across-the-board payment reduction that applies to both compliant and noncompliant providers would more precisely address CMS's concerns without impacting access to medically necessary care. Several commenters requested that CMS finalize a payment rate that is more reflective of the costs and utilization volume for skin substitute products. Some commenters recommended that we finalize a revised payment rate between $478/cm² and $715.45/cm². Several commenters did not recommend a new specific payment rate and instead proposed alternative methodologies for calculating a new payment rate for skin substitute products. For example, several commenters requested that we reconsider using OPPS utilization data to determine the payment rate for skin substitute products in the HOPD and physician office setting, with some explaining that the quantity of a skin substitute purchased or utilized is not a measure of its clinical value. A few commenters suggested that we revise the payment methodology finalized in the CY 2026 OPPS/ASC final rule to instead utilize providers' acquisition costs up to a CMS-established payment ceiling, at the lower of an invoice or a cap. These commenters believed a cap would minimize payment-driven selection of products, support clinically appropriate utilization, and ensure providers are compensated for the resources required to deliver high-quality patient care. Other commenters recommended that, if utilization data were to be used, CMS adopt a volume-weighted geometric mean instead of a volume-weighted arithmetic average to determine the payment rate.

Response: We thank the commenters for their input regarding the proposed CY 2027 payment rate of $127.14/cm² for sheet-form skin substitute products and for their suggestions on alternative payment methodologies to calculate a new payment rate. We note that several of the comments were extremely similar to those provided to CMS in response to the proposed payment methodology for skin substitute products in the CY 2026 OPPS/ASC proposed rule. As we explained in the CY 2026 OPPS/ASC final rule, we calculated a single rate for each FDA regulatory category by taking the volume-weighted average ASP for skin substitute products in each FDA regulatory category from Q4 2024, using hospital outpatient utilization to weight each category, and applied the highest of the three resulting rates uniformly across all three categories for CY 2026. We used the highest average for the three FDA regulatory categories to ensure we would not underestimate the resources involved with furnishing these services. We refer readers to the discussion in the CY 2026 OPPS/ASC final rule for a summary of the comments and detailed responses regarding the payment methodology that was finalized for CY 2026 (90 FR 53728 through 53748).

We continue to believe that it is premature to adjust the payment rate for skin substitute products because updated use patterns reflecting the CY 2026 policy changes are not yet available. Therefore, we are finalizing our proposal to maintain the $127.14/cm² payment rate for sheet-form skin substitute products paid under the OPPS.

Comment: Several commenters requested CMS evaluate utilization patterns following the implementation of the revised $127.14/cm² rate and to monitor beneficiary access and distinguish reductions in inappropriate utilization from reductions in clinically appropriate utilization. Commenters requested that we review the available 2026 claims data to assess changes in several measures, including utilization rates of skin substitute products by site of service; clinical outcomes for patients with chronic, non-healing wounds, and utilization rates of medical visits.

Response: We thank the commenters for their suggestions. CMS is generally interested in better understanding the effects of all of our payment policies, including potential impacts to beneficiary access and clinically appropriate utilization. We do not yet have a sufficient volume of claims data reflecting the revised payment rate to draw reliable conclusions regarding several of the measures requested by the commenter as the policy was only implemented in CY 2026. We intend to continue monitoring relevant claims data as it becomes available.

Comment: Several commenters requested that CMS update the payment rate for skin substitute products using a defined inflation index, such as the Consumer Price Index for All Urban Consumers (CPI–U) or the Medicare Economic Index, rather than recalculating them based on new ASP data. Commenters thought updating the payment rate annually for inflation would keep reimbursement aligned with rising costs and help ensure continued beneficiary access to advanced wound care technologies.

Response: We appreciate the commenters for their input. We believe that, over time, the ASP data we are collecting will more accurately reflect the market impacts of our policy to treat skin substitute products as incident-to supplies. By relying on ASP, payment updates will be responsive to changes in the actual cost of skin substitute products as a result of market pressures, whereas an index like the CPI–U is a general inflation measure that does not account for pricing dynamics. Therefore, we believe that updating the payment rates, based on ASP data will more likely result in payment rates that reflect the changing dynamics of the market rather than anchoring the cost to the initial payment rate for CY 2026, and finalized payment rate for CY 2027, based on data collected prior to the implementation of this policy. We do understand the merits of the commenters' suggestion and will keep it under consideration for future policy development as this policy evolves.

Comment: We received two comments regarding the payment methodology for skin substitute products licensed as biological products under section 351 of the PHS Act, meaning those that have gone through the FDA BLA process. A commenter supported continuing this approach because it recognizes their distinct regulatory status. Another commenter did not support continuing to pay for 351s under the ASP plus 6 percent methodology arguing that evidentiary standards for 351s are likely being lowered due to external pressure to reduce the barrier-to-entry for approval.

Response: We thank the commenters for their input and perspective on this issue. We note that the evidentiary standards for biological products under section 351 of the PHS Act are out of scope for CMS rulemaking. We are not finalizing changes to the ASP methodology for biological products licensed under section 351 of the PHS Act at this time.

Comment: We received comments regarding our proposal to continue to categorize skin substitute products by FDA regulatory pathway, as finalized in the CY 2026 OPPS/ASC final rule. While one commenter supported implementing a three-tiered approach with differing payment rates per FDA regulatory category, most commenters urged CMS not to pursue payment differentiation or categorize skin

substitute products by FDA regulatory category. A commenter noted that because FDA regulatory requirements and pathways evolve over time, using regulatory history as a permanent basis for payment differentiation would also create arbitrary disparities among products that serve the same clinical purpose today, based solely on when and how each product entered the market. The commenter recommended that CMS should base any future payment distinctions on demonstrated clinical performance and resource costs, not regulatory classification. Similarly, another commenter requested that CMS clarify that FDA regulatory pathway by itself will not establish clinical superiority or therapeutic hierarchy among skin substitute products. A commenter explained that products previously subject to more burdensome PMA requirements would today likely enter the market under a 510(k) pathway, so relying on FDA regulatory history as a proxy for payment differentiation risks entrenching outdated distinctions that no longer reflect current practice. One commenter further supported maintaining a single payment rate for all three categories because they believed the waste, fraud, and abuse observed in the skin substitute market is the result of certain 361 HCT/P manufacturers taking advantage of easy market entry to manipulate reimbursement, and that by differentiating payment by FDA approval, CMS risks enabling further price manipulation from some 361 HCT/Ps without the moderating impact of PMA and 510(k) product prices.

Response: We thank the commenters for their input. We continue to believe that categorizing skin substitute products by FDA regulatory pathway remains appropriate at this time. We note, however, that under the finalized policy, for CY 2027, all sheet-form skin substitute products would be paid at the same $127.14/cm^2 rate. We continue to believe that it is premature to adjust the payment rate for skin substitute products because updated use patterns reflecting the CY 2026 policy changes are not yet available. We will continue to analyze claims data as it becomes available and will propose any changes in payment through the rulemaking process.

Comment: We received several comments requesting that we align payment for non-sheet form skin substitutes with payment for sheet-form skin substitute products. Specifically, commenters requested that CMS change the status indicator of the non-sheet application codes (HCPCS codes G0681–G0684) from ''N'' to ''T'' to allow for payment, and assign the non-sheet application codes to the same APCs as the sheet-form application codes (CPT codes 15271–15278). Specifically, commenters requested that CMS assign HCPCS code G0681 to APC 5053 (Level 3 Skin Procedures) and HCPCS code G0683 to APC 5054 (Level 4 Skin Procedures). HCPCS codes G0682 and G0684, which describe add-on codes, should be treated the same as the sheet-form application add-on codes (CPT codes 15272, 15274, 15276, and 15278) and be assigned to status indicator ''N,'' per the commenters. In addition, commenters requested that CMS pay separately for non-sheet skin substitute products to align with payment for sheet-form skin substitute products. Commenters believed that non-sheet products service similar clinical purposes as sheet products, and, therefore, aligning for non-sheet forms and sheet-forms recognizes the clinical non-sheet forms offer, preserves physician flexibility to select the best product for each patient, supports innovation, ensures skin substitute products are evaluated on therapeutic value rather than disadvantaged by coding or reimbursement policy, and maintains site neutrality with products applied in the physician office setting.

Response: We thank the commenters for their input. Payment for application of non-sheet skin substitute products could benefit from parity with payment for the application of sheet form skin substitute products, and not doing so could fail to appropriately recognize the resource costs expended when applying non-sheet products. Accordingly, we are not finalizing our proposal to maintain the status indicator of ''N'' for HCPCS codes G0681 and G0683. For CY 2027, we are finalizing to change the status indicator for HCPCS codes G0681 and G0683 from ''N'' to ''T'' and assign G0681 to APC 5053 (Level 3 Skin Procedures) and G0683 to APC 5054 (Level 4 Skin Procedures), consistent with the APC assignments for the analogous sheet form application codes (CPT codes 15271 through 15278). We are finalizing assignment of status indicator ''N'' to add-on codes G0682 and G0684, consistent with the treatment of the sheet form application add-on codes (CPT codes 15272, 15274, 15276, and 15278), as proposed. The final CY 2027 payment rates can be found in Addendum B to this final rule with comment via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator definitions for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website. As previously discussed, we will continue to monitor the effects of this policy in general, including this newly finalized aspect.

We are not finalizing separate payment for non-sheet skin substitute products at this time. Non-sheet products are not manufactured, applied, or measured in the same standardized manner as sheet form products, which are billed in per cm^2 units. Because of these differences, we believe it is more appropriate to continue packaging payment for non-sheet form products under the OPPS. We recognize the interest commenters have expressed in separate payment for non-sheet form skin substitute products, and we will continue to consider the issue of separate payment for non-sheet products moving forward.

Comment: We received a comment requesting that CMS provide a clear, operational definition of a non-sheet skin substitute product.

Response: We thank the commenter for this suggestion and will take it into consideration. One difficulty with the commenter's request is that non-sheet products cover a wide range of physical forms and may not share a common structure the way sheet-form skin substitute products do. We note that we have described the form of some non-sheet skin substitute products in the CY 2026 OPPS/ASC Final Rule as gels, powders, liquids, injectables, 3D-printed constructs, etc. (90 FR 53739) that have units that are difficult to standardize for payment purposes. We will consider providing additional clarifications in future rulemaking.

Comment: We received a comment from a manufacturer requesting separate payment for Omeza Complete Matrix, a non-sheet skin substitute product described by HCPCS code A2014 (Omeza collagen matrix, per 100 mg). The commenter stated that separate payment is appropriate for this product because, in the commenter's view, a product's starting form as a non-sheet product should not determine its payment category so long as the product forms a sheet-like scaffolding once applied.

Response: We appreciate the commenter's request. We believe it is necessary to apply a consistent payment methodology across non-sheet form skin substitute products for CY 2027. Consistent with the approach finalized in this final rule, application of Omeza Complete Matrix, as described by HCPCS codes G0681 and G0683, will be paid separately, while the product itself will be packaged for CY 2027. We do not believe it is appropriate to except

this product from the non-sheet product payment methodology based on its post-application form, given that the product is supplied in mg and applied in non-sheet form. As stated earlier, we will continue to consider the issue of separate payment for non-sheet products more broadly.

Comment: We received requests for billing guidance pertaining to our skin substitute payment policies. Several commenters requested that CMS provide guidance clarifying that providers may bill for the total amount of skin substitute product clinically necessary to treat a wound, rather than only the two-dimensional surface area of the wound bed. Commenters explained that, especially for deep wounds, the amount of product needed to treat the wound often exceeds the cm^2 surface area. Commenters requested CMS provide billing instructions that would allow providers to calculate the relevant surface area for the application codes based on the interior surface area of the wound plus an appropriate margin for graft fixation. A commenter recommended a specific formula for providers to use to calculate the total therapeutic area. Commenters requested that CMS provide guidance that states that providers can bill for the total amount of skin substitute product needed to treat the entire wound area, for sheet form and non-sheet form products, to enable providers to bill accurately for the services they furnish and to give MACs a consistent framework for adjudication.

Response: We appreciate the input from the commenters. We do not believe it is necessary at this time to issue additional guidance on how providers should bill for the total amount of skin substitute product used to treat a wound. The application codes that would be used to bill for the application of the products, namely CPT codes 15271 through 15278 for sheet form products and HCPCS codes G0681 through G0684 for non-sheet products, already specify defined wound surface area amounts for purposes of reporting the applicable code. Providers are expected to select the appropriate application code and report the units of product that correspond to the total wound surface area treated. We note that this same coding structure, and the same expectation that providers report the total wound surface area treated using these application codes, were in place prior to the CY 2026 OPPS/ASC skin substitute policy was in effect, even when the products were packaged into the application payment at that time. We do not believe the manner in which the application codes describe and are used to report wound surface area has changed in a way that necessitates new guidance at this time. However, we will continue to consider whether such guidance is necessary going forward.

Comment: We received a comment from Kerecis, a skin substitute product manufacturer, explaining that two of their products have different code coding classifications. Specifically, the manufacturer stated that one product is described by a Q-code and another is described by an A-code. Per the manufacturer, the coding classification distinction creates administrative burden due to the confusion it causes for both physicians and MACs. The commenter requested that CMS address this issue to ensure there are no inappropriate burdens or barriers to accessing clinically appropriate skin substitute products.

Response: We appreciate the commenter for sharing their concern regarding the current bifurcated system. We will take comments about the coding differences between the products into consideration for future rulemaking.

In summary, for CY 2027, we are finalizing the \$127.14/cm^2 payment rate for all sheet form skin substitute products as proposed. We are also finalizing our proposals regarding payment for non-sheet skin substitute application codes and non-sheet products with modifications. Specifically, we are finalizing to assign HCPCS code G0681 to APC 5053 (Level 3 Skin Procedures) with status indicator ''T'' and G0683 to APC 5054 (Level 4 Skin Procedures APC) with status indicator ''T.'' We are finalizing to continue to assign HCPCS codes G0682 and G0684 to status indicator ''N,'' as proposed. Finally, we are not finalizing changes to the current payment arrangement under the OPPS for products that are not in sheet form at this time and, therefore, non-sheet skin substitute products will remain assigned to status indicator ''N.'' We refer readers to Addendum B for the final CY 2027 APC and status indicator assignments for skin substitute products. The final CY 2027 payment rates can be found in Addendum B to this final rule with comment via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator definitions for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

H. Add-On Payment for Technetium-99m (Tc-99m) Derived From Domestically Produced Molybdenum-99 (Mo-99)

As discussed in prior rulemaking, in collaboration with the Department of Energy, National Nuclear Security Administration (DOE/NNSA), CMS provided an additional payment of \$10 for the marginal cost for Tc-99m produced by non-Highly Enriched Uranium (HEU) sources in an effort to support access to Technetium-99m (Tc-99m), a critical radioisotope used in the majority of diagnostic imaging services, and produced through the radioactive decay of molybdenum-99 (Mo-99) from CY 2013 to CY 2025. We stated that we believe such an adjustment would ensure equitable payments in light of market influences, cost differentials, and cost variations and their potential to create significant payment inequities among hospitals (77 FR 68323). Accordingly, we established HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) to describe the Tc-99m radioisotope produced by non-HEU methods and used in a diagnostic procedure.

In January 2022, the Secretary of Energy issued a certification that stated that there is a sufficient global supply of non-HEU-sourced Mo-99 to meet the needs of patients in the United States (86 FR 73270). Additionally, in March 2023, the last major global producer of Mo-99 converted from HEU to low-enriched uranium (LEU) targets, and all Mo-99 used in the United States is now produced without HEU. As such, in the CY 2024 OPPS final rule with comment period (88 FR 81803), we adopted a policy to end the additional \$10 add-on payment described by HCPCS code Q9969 for non-HEU-sourced Tc-99m at the end of CY 2025. We explained that given that all Mo-99 used in the U.S. is now produced without HEU, we believe that starting in CY 2026 the Medicare claims data utilized to set payment rates 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 providers would use in CY 2026. That being the case, we believe there would no longer be a need for the additional \$10 add-on payment for non-HEU-sourced Tc-99m for CY 2026 or future years.

In the CY 2025 OPPS/ASC proposed rule with comment period (89 FR 59377 through 59378), we shared that 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 also cause payment inequity among outpatient hospital providers. We noted that foreign Mo-99 production has historically been subsidized by foreign governments, resulting in prices below the true cost of production. These artificially low, foreign government-subsidized prices have created a disincentive for domestic investments in Mo-99 production infrastructure and a barrier to entry for new producers, including U.S. companies, which in turn has resulted in unreliable production and periodic shortages. Subsequently, using our equitable adjustment authority under section 1833(t)(2)(E) of the Act, we proposed and finalized a policy to address the payment inequity resulting from the higher cost of Tc-99m derived from domestically produced Mo-99 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. Furthermore, we stated that the Department of Energy, National Nuclear Security Administration (DOE/NNSA) would establish the criteria to certify whether the Tc-99m radiopharmaceutical dose is derived from domestically produced Mo-99 and eligible for the add-on payment, which would be included in the CY 2026 OPPS/ASC proposed rule with comment period. We also stated that we would continue to develop the technical implementation of this additional payment after a definition for domestically produced Tc-99m radiopharmaceutical was established, including any requirements for providers to document that the Tc-99m radiopharmaceutical used in a procedure was domestically produced and could qualify to receive the add-on payment. Additionally, we stated that our intent was to have the regulatory framework for this policy in place prior to the domestic production of Mo-99 and Tc-99m, to increase provider awareness of the availability of additional payments for domestically sourced Tc-99m radiopharmaceuticals. Likewise, producers of domestic Mo-99 would have certainty that the Medicare OPPS payment policy takes into account the additional costs of Tc-99m derived from domestically produced Mo-99.

a. Criteria for Classifying a Tc-99m Radiopharmaceutical Dose as Domestically Produced

In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53751–53755), for purposes of the add-on payment for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99, we finalized our definition of a domestically produced dose of Tc-99m as a dose of Tc-99m generated from domestically produced Mo-99. We also finalized the following definitions:

- *Domestically produced dose of Tc-99m:* A dose of Tc-99m generated from domestically produced Mo-99;
- *Domestically produced Mo-99:* Mo-99 that was both irradiated and processed in the U.S.;
- *Irradiated:* The process of bombarding a uranium or molybdenum target with radiation in order to produce Mo-99, and to specify that irradiation is typically performed with a nuclear reactor or particle accelerator;
- *Processed:* In this context, processed refers to the purification of Mo-99 from irradiated material.

Additionally, we finalized a policy that a dose of Tc-99m generated from Mo-99 that was irradiated or processed outside the U.S. would not qualify for this add-on payment, even if the Mo-99 was loaded into a Tc-99m generator in the U.S. or if the Tc-99m was eluted at a radiopharmacy in the U.S. We also finalized the codification of the aforementioned definitions and references for domestically produced Mo-99 to § 419.49 to specify when a dose of Tc-99m generated from domestically produced Mo-99 could be eligible for the add-on payment.

b. Coding and Documentation for the Add-On Payment for Tc-99m Derived From Domestically Produced Mo-99

In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53751–53755), we also finalized the establishment of HCPCS C-code C9176 (Tc-99m from domestically produced non-HEU Mo-99, [minimum 50 percent], full cost recovery add-on, per study dose), effective January 1, 2026. Hospitals may report HCPCS code C9176 once per dose, along with any diagnostic scan or scans furnished using Tc-99m derived from domestically produced Mo-99, if they can certify that at least 50 percent of the Mo-99 in the Tc-99m generator used to produce the Tc-99m was domestically produced Mo-99. We also finalized the implementation plan, including the $10 per-dose add-on payment and the certification and tracking approach described in the CY 2026 rulemaking.

For CY 2027, we did not propose any changes to the add-on payment policy for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99. We received public comments regarding this policy, which we summarize and respond to below.

Comment: Although we did not propose any changes to the add-on payment for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99 for CY 2027, we received comments regarding the policy. One commenter supported continuation of the $10 per-dose add-on payment and HCPCS code C9176, stating that the policy helps account for the higher costs associated with domestic production and supports investment in a more secure and resilient domestic Mo-99 supply chain. The commenter also encouraged CMS to continue monitoring whether the $10 add-on payment remains sufficient over time in light of production, compliance, transportation, and supply-chain costs.

Another commenter opposed continuation of the add-on payment and urged CMS to discontinue the policy for CY 2027. The commenter stated that the add-on payment does not effectively incentivize domestic Mo-99 production because payments are made to hospitals rather than directly to domestic producers and expressed concern that hospitals may have difficulty identifying when a dose qualifies for the add-on payment. The commenter also stated that the policy could disrupt existing Tc-99m supply and distribution arrangements, including generator contracting, and potentially affect patient access, particularly in rural communities.

Response: We thank the commenters for their feedback. As discussed in the CY 2025 OPPS/ASC final rule with comment period, we established the $10 per-dose add-on payment using our equitable adjustment authority under section 1833(t)(2)(E) of the Act to address the payment inequity resulting from the higher cost of Tc-99m derived from domestically produced Mo-99. In the CY 2026 OPPS/ASC final rule with comment period, we finalized the implementation framework for this policy, including the criteria for a domestically produced dose of Tc-99m, the 50-percent threshold for domestically produced Mo-99, and HCPCS code C9176.

We continue to believe that the add-on payment appropriately accounts for the additional costs to hospital outpatient departments associated with utilizing Tc-99m derived from domestically produced Mo-99. As we explained in prior rulemaking, establishing the payment framework in advance of domestic production provides hospitals with information regarding the availability of additional payment for qualifying doses and provides domestic producers with greater certainty that Medicare OPPS

payment policy takes into account the additional costs associated with domestic production. After a consideration of the comments received, noting we did not propose changes to this policy for CY 2027, we are continuing the existing policy without modification.

We appreciate commenters' perspectives regarding the amount of the add-on payment, implementation of the policy, and potential effects on the Mo-99 and Tc-99m supply chain. We will continue to monitor relevant information regarding the implementation of the policy, including information regarding the costs associated with domestically produced Mo-99 and the availability of Tc-99m, and may consider whether future refinements are warranted.

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 2027 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 2027. 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 2026 or beginning in CY 2027. The sum of the proposed CY 2027 pass-through spending estimates for these two groups of device categories equals the proposed total CY 2027 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 2026 OPPS/ASC final rule with comment period (90 FR 53766 through 53769). We noted 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), we 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 (79 FR 66885 through 66888). In CY 2026, we finalized a policy to consider skin substitutes with an approved Biologics License Application (BLA) under transitional drug pass-through payment status, while skin substitutes with FDA Premarket Approval or FDA 510(k) clearance continue to be evaluated under transitional device pass-through payment status (90 FR 53636). Therefore, for CY 2027, we also proposed to include an estimate of any skin substitutes and similar products with FDA Premarket Approval or FDA 510(k) clearance in our estimate of pass-through spending for devices and skin substitutes with an approved BLA under transitional drug pass-through spending for drugs and biologicals.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Consistent with current policy, we proposed to apply a rate of ASP plus 6 percent to most drugs and biologicals for CY 2027, and therefore our estimate of drug and biological pass-through payment for CY 2027 for this group of items was $12.2 million.

Payment for certain drugs,[142] specifically 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 non-pass-through drugs and biologicals that function as supplies when used in a diagnostic test or procedure unless a high-cost diagnostic radiopharmaceutical with a per-day cost greater than the finalized per-day cost threshold referenced in section II.A.3.c. of this final rule with comment period is used for the diagnostic test or procedure. We policy-package all drugs and biologicals that function as supplies when used in a surgical procedure or for anesthesia, and other categories of drugs and biologicals, as discussed in section V.B.1.c. of this final rule with comment period. Consistent with current policy, for CY 2027, we proposed that policy-packaged drugs and biologicals with pass-through payment status will be paid at ASP plus 6 percent, like other pass-through drugs and biologicals less the policy-packaged drug APC offset amount described later in this section of the preamble. Our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2027 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

[142] In the CY 2025 OPPS/ASC final rule with comment period, we finalized the high-cost diagnostic radiopharmaceuticals policy to separately pay those products when the per-day costs are greater than a threshold. Please refer to section II.A.3.c. of this final rule with comment period for more information regarding this policy.

biologicals. In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81774 through 81776), we discussed 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 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 described in section V.A.5. of this final rule with comment period, if we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we proposed to reduce our estimate of pass-through payments for these drugs or biologicals by the APC offset amount.

Similar to pass-through spending estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2027. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in CY 2027. The sum of the CY 2027 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2027 pass-through spending estimate for drugs and biologicals with pass-through payment status.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

B. Final Estimate of Pass-Through Spending for CY 2027

For CY 2027, we proposed to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2027, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2026 (90 FR 53767). The pass-through payment percentage limit is calculated using pass-through spending estimates for devices and for drugs and biologicals.

The first group of devices consists of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2027. We stated in the CY 2027 OPPS/ASC proposed rule, there would be 15 active categories for CY 2027, described by HCPCS codes C1605, C1606, C8000, C1735, C1736, C1737, C1738, C1739, C9610, C1740, C1741, C1742, C1607, C1608, and C1743. Based on CY 2025 Medicare hospital outpatient claims data available by the time of the proposed rule and information from the device manufacturers provided in their respective pass-through applications regarding the device cost and the projected CY 2027 OPPS utilization, we estimated the CY 2027 pass-through expenditures for each of the 15 device categories and proposed an estimate for the first group of devices of $177.6 million in the CY 2027 OPPS/ASC proposed rule (91 FR 41897 through 41898).

We did not receive any public comments on our proposed estimate. Based on updated CY 2025 Medicare hospital outpatient claims data available by the time of this final rule with comment period and information from the device manufacturers provided in their respective pass-through applications regarding the device cost and the projected CY 2027 OPPS utilization, we estimated the CY 2027 pass-through expenditures for each of the 15 device categories in Table 77.[143] Therefore, we have finalized the CY 2027 spending estimate for the first group of devices of approximately $180.3 million.

[143] Estimated costs are updated to reflect the Medicare hospital outpatient claims data for each HCPCS code as such data becomes available. Prior to the availability of Medicare hospital outpatient claims data, estimated costs are based on the device cost and projected CY OPPS utilization provided by the device manufacturer in the device pass-through application. As such, in the CY 2027 OPPS/ASC final rule with comment period, the estimated pass-through costs for HCPCS codes C1605, C1606, C8000, C1735, C1736, C1737, C1738, C1739, and C9610 are based on CY 2025 Medicare hospital outpatient claims data available for the CY 2027 OPPS/ASC final rule with comment period. The estimated pass-through costs for HCPCS codes C1740, C1741, C1742, C1607, C1608, and C1743 are based on information provided by the device manufacturers in the respective device pass-through applications regarding the device cost and the projected CY 2027 OPPS utilization.

TABLE 77: ESTIMATED PASS-THROUGH EXPENDITURES FOR DEVICE CATEGORIES THAT ARE CURRENTLY ELIGIBLE AND WILL CONTINUE TO BE ELIGIBLE FOR PASS-THROUGH PAYMENT IN CY 2027

HCPCS Code	Effective Date	Pass-through Expiration Date	Estimated Pass-through Expenditures in CY 2027
C1605	07/01/2024	06/30/2027	$8.6 million
C1606	07/01/2024	06/30/2027	$0.3 thousand
C8000	10/01/2024	09/30/2027	$0.9 million
C1735	01/01/2025	12/31/2027	$7.5 million
C1736	01/01/2025	12/31/2027	$4.0 million
C1737	01/01/2025	12/31/2027	$1.4 million
C1738	01/01/2025	12/31/2027	$0.1 million
C1739	01/01/2025	12/31/2027	$0.9 million
C9610	01/01/2025	12/31/2027	$37.3 million
C1740	10/01/2025	09/30/2028	$31.7 million
C1741	10/01/2025	09/30/2028	$7.5 million
C1742	10/01/2025	09/30/2028	$0.7 million
C1607	01/01/2026	12/31/2028	$12.5 million
C1608	01/01/2026	12/31/2028	$22.4 million
C1743	04/01/2026	03/31/2029	$44.9 million

In estimating our proposed CY 2027 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 2027; (2) additional device categories that we estimated could be approved for pass-through status after the development of the CY 2027 OPPS/ASC proposed rule and before January 1, 2027; and (3) contingent projections for new device categories established in the second through fourth quarters of CY 2027. For CY 2027, we proposed to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. In the CY 2027 OPPS/ASC proposed rule, we proposed to continue device pass-through payment status for seven device pass-through applications that were granted conditional approval in CY 2027, and we proposed to deny six CY 2027 device pass-through applications. The proposed estimate of CY 2027 pass-through spending for this second group of device categories was $5.6 million (91 FR 41898).

We did not receive any public comments on this proposed estimate. As stated earlier in section IV.A.2. of this final rule with comment period, we are finalizing pass-through payment status for all seven device pass-through applications that were granted conditional approval in CY 2027, including the MY01 Continuous Compartmental Pressure Monitor, RemeOs™ Screw LAG Solid, WiSE® CRT System, SetPoint System, TOUCH® CMC 1 Prosthesis, Esprit™ BTK Everolimus Eluting Resorbable Scaffold System, and TOPS™ System.[144] We are also approving two additional device pass-through applications for Altius® Direct Electrical Nerve Stimulation System and TIDAL™ Fusion Cage System (Ossera™ AFX). For this final rule with comment period, based on information from the device manufactures provided in their respective pass-through applications regarding the projected CY 2027 OPPS utilization, we estimate the amount of spending for the second group of devices would be approximately $5.6 million for TOPS™ System; $58.1 million for Altius® Direct Electrical Nerve Stimulation System; and $4.0 million TIDAL™ Fusion Cage System (Ossera™ AFX). Therefore, we are finalizing an estimate of $67.7 million for this second group of devices for CY 2027.

To estimate proposed CY 2027 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 2027, we proposed to use the CY 2025 Medicare hospital outpatient claims data regarding their utilization, information provided in

[144] As discussed in section IV.A.2.b.(1) of this final rule with comment period: the pass-through applications for MY01 Continuous Compartmental Pressure Monitor, RemeOs™ Screw LAG Solid, and WiSE® (Wireless Stimulation of the Endocardium Technology) CRT System were approved for transitional pass-through payment under the alternative pathway effective October 1, 2025; the pass-through applications for SetPoint System and TOUCH® CMC 1 Prosthesis were approved for transitional pass-through payment under the alternative pathway effective January 1, 2026; the pass-through application for Esprit™ BTK Everolimus Eluting Resorbable Scaffold System was approved for transitional pass-through payment under the alternative pathway effective April 1, 2026; and the pass-through application for TOPS™ System was approved for transitional pass-through payment under the alternative pathway effective July 1, 2026. Due to the timing of the preliminary approvals, the CY 2027 spending estimate for MY01 Continuous Compartmental Pressure Monitor, RemeOs™ Screw LAG Solid, WiSE®, SetPoint System, TOUCH® CMC 1 Prosthesis, and Esprit™ BTK Everolimus Eluting Resorbable Scaffold System is included in the CY 2027 spending estimate for the first group of devices, and the CY 2027 spending estimate for the TOPS™ System is included in the CY 2027 spending estimate for the second group of devices.

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 2027 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged contrast agents, drugs, biologicals, radiopharmaceuticals with per-day costs at or below the packaging threshold 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 2027, we estimated the pass-through payment amount as the difference between the general payment rate of ASP plus 6 percent and the payment rate for non-pass-through drugs and biologicals that would be separately paid. Because we proposed to utilize a payment rate of ASP plus 6 percent for most separately payable drugs and biologicals in the proposed rule, the proposed payment rate difference between the pass-through payment amount and the non-pass-through payment amount was $0 for this group of drugs.

Because payment for policy-packaged drugs and biologicals is packaged if the product is not paid separately due to its pass-through payment status, we proposed to include in the CY 2027 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP plus 6 percent (or wholesale acquisition cost (WAC) plus 3 or 6 percent according to the policy in section V.B.2.a. of this final rule with comment period, or 95 percent of average wholesale price (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. Diagnostic radiopharmaceuticals that currently have pass-through status, but would likely be paid separately because of the policy initially established in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93953) to separately pay for high-cost diagnostic radiopharmaceuticals with per-day costs greater than the proposed per-day cost threshold and which we proposed to continue as discussed in section II.A.3.c. of this final rule with comment period, are not considered to be policy-packaged and therefore are not included in this group. For this first group of policy-packaged drugs and biologicals, we estimated pass-through spending for CY 2027 of $2.2 million.

We did not receive any public comments on our proposed estimate. Using our methodology for this final rule with comment period, we are finalizing the CY 2027 spending estimate for this first group of drugs and biologicals to be $2.4 million based on additional data available at the time of this final rule with comment period.

To estimate proposed CY 2027 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of the proposed rule were newly eligible or recently became eligible for pass-through payment in CY 2026, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2027, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2027), we proposed to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2027 pass-through payment estimate. We also proposed to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2027 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $10 million.

We did not receive any public comments on our proposed estimate. Using our methodology for this final rule with comment period, we are finalizing our estimate of pass-through spending for the second group of drugs and biologicals to be $10 million.

We estimated for the CY 2027 OPPS/ASC proposed rule (91 FR 41899) 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 2027 and the amount of pass-through spending for those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2027 would be approximately $195.3 million (approximately $183.1 million for device categories and approximately $12.2 million for drugs and biologicals), which would represent only 0.18 percent of total projected OPPS payments for CY 2027 (approximately $111 billion). Therefore, we estimated that pass-through spending in CY 2027 would not exceed the 2.0 percent of total projected OPPS CY 2027 program spending limit provided for in section 1833(t)(6)(E) of the Act.

We estimate for this final rule with comment period that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2027 and the amount of pass-through spending for those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2027 will be approximately $260.4 million (approximately $248.0 million for device categories and approximately $12.4 million for drugs and biologicals), which represents only 0.23 percent of total projected OPPS payments for CY 2027 (approximately $114 billion). Therefore, we estimate that pass-through spending in CY 2027 will not exceed the 2.0 percent of total projected OPPS CY 2027 program spending limit provided for in section 1833(t)(6)(E) of the Act.

VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2027, we proposed to continue our current clinic and emergency department (ED) hospital outpatient visit 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 through 70449). We also proposed to continue our payment policy for critical care services for CY 2027 (91 FR 41899). For a description of this policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449 through 70453), 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 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 subsequent years (86 FR 63664). As stated in the CY 2018 PFS final rule (82 FR 53020 through 53024), the PFS-equivalent rate for CY 2018 and

subsequent years is 40 percent of the proposed OPPS payment. Under this policy, these departments will be paid 40 percent of the OPPS rate for the clinic visit service in CY 2027 (91 FR 41899).

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051), we finalized a policy for CY 2023 and subsequent years that excepted off-campus 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).

We did not receive specific public comment on our existing clinic visit, critical care and ED hospital outpatient visits payment policies, except for comments submitted in the context of the proposed expansion of our volume control method to other services. Therefore, we are finalizing as proposed to continue these policies. For discussion of the existing clinic visit policy in the context of the proposed expansion of our volume control method to other services, see section X.A. of this final rule with comment period.

VIII. Payment for Partial Hospitalization and Intensive Outpatient Services

Since CY 2000, Medicare has paid for partial hospitalization program (PHP) 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 program (IOP) services furnished by hospital outpatient departments, community mental health centers (CMHCs), 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.

We note that some commenters made comments on PHP and IOP topics that were not discussed in the CY 2027 OPPS/ASC proposed rule. These topics are out of scope for purposes of this notice and comment rulemaking, but we will consider these comments as we consider these issues for future rulemaking.

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 for an individual determined (not less frequently than monthly) by a physician to have a need for such services for a minimum of 20 hours per week 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 program 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 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.

PHP policies and payment have been addressed under OPPS since CY 2000. In CY 2008, we began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes, by implementing two refinements to the methodology for computing the PHP median. For a detailed discussion on these policies, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In CY 2009, we implemented several regulatory, policy, and payment changes. For a detailed discussion on these policies, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68697). In CY 2010, we retained the two-tier payment approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP Ambulatory Payment Classification (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). We also instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates. For a detailed discussion, we refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994). In CY 2012, we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively on hospital data (76 FR 74348 through 74352). In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43621 through 43622) and CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75047 through 75050). In the CY 2016 OPPS/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 with comment period data with respect to hospital-based PHP providers, and renumbered the PHP APCs. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687

through 79691), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs and finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and for hospital-based PHPs. We also implemented an 8-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities. For a comprehensive description of PHP payment policy, including a detailed methodology for determining PHP per diem amounts, we refer readers to the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70453 through 70455 and 81 FR 79678 through 79680, respectively).

In the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59373 through 59381 and 83 FR 58983 through 58998, respectively), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs, designated a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, and proposed updates to the PHP allowable HCPCS codes. We finalized these proposals in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61352).

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61339 through 61350), we finalized a proposal to use the calculated CY 2020 CMHC geometric mean per diem cost and the calculated CY 2020 hospital-based PHP geometric mean per diem cost, but with a cost floor equal to the CY 2019 final geometric mean per diem costs as the basis for developing the CY 2020 PHP APC per diem rates. Also, we continued to designate a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS, excluding outlier payments.

In the April 30, 2020 interim final rule with comment (85 FR 27562 through 27566), effective as of March 1, 2020 and for the duration of the COVID–19 Public Health Emergency (PHE), hospital and CMHC staff were permitted to furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, 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 with comment period (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. In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63665 and 63666), as a result of the COVID–19 PHE, 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 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, 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 that 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 with comment period, 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 three or four 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.

In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53770 through 53780), we modified the payment rate methodology for calculation of CMHC costs for PHP. We applied the 40 percent MPFS Relativity Adjuster to the hospital-based PHP costs to determine the CMHC costs for PHP.

2. Intensive Outpatient Program Services

Section 4124(b) of the CAA, 2023, amended section 1861(ff) of the Act, establishing 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 section 1861(ff)(2) of the Act 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, by a CMHC, by a Federally qualified health center (FQHC), or by a rural health clinic (RHC) as 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).

Consistent with the statutory definition of intensive outpatient services under section 1861(ff)(4) 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 three or four IOP services in a day.

For IOP services provided by an RHC or FQHC, we established a three-service per day payment rate based on the same rate as APC 5861, which is the three-service hospital-based IOP rate (§ 405.2462(j)). In the CY 2025 PFS final rule, we established a four or more services per day payment rate for an IOP provided by an RHC or FQHC based on the same rate as APC 5862, which is the four or more services hospital-based IOP rate (89 FR 98017 and 98018). Information regarding payment policies for IOP services furnished by FQHCs and RHCs, including information regarding CY 2027 policies for those settings, can be found in the CY 2027 PFS final rule, which is published elsewhere in the **Federal Register**.

Furthermore, in the CY 2024 OPPS/ASC final rule with comment period, we established a payment adjustment for IOPs provided by an OTP based on three times the payment rate for APC 5861 beginning in CY 2024 (§ 410.67(d)(4)(i)(F)). We finalized regulations at § 410.67(d)(4)(ii) to add that the payment amount for OTP intensive outpatient services will be geographically adjusted using the Geographic Adjustment Factor (GAF) described in § 414.26. Lastly, we amended § 410.67(d)(4)(iii) to add that payment for OTP intensive outpatient services is updated annually using the Medicare Economic Index described in § 405.504(d). Payment rates for IOP provided in the OTP setting are updated as part of the OTP fee schedule and are not addressed in this final rule with comment period.

In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53770 through 53780), we modified the payment rate methodology for calculation of CMHC costs for IOP. We applied the 40 percent MPFS Relativity Adjuster to the hospital-based IOP costs to determine the CMHC costs for IOP.

B. Coding and Billing for PHP and IOP Services Under the OPPS

In the CY 2024 OPPS/ASC final rule with comment period, 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 OPPS/ASC final rule with comment period 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/ASC final rule with comment period 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 with comment period 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/ASC final rule with comment period for a detailed discussion of this policy (88 FR 81823 through 81825).

As finalized in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81821 and 81822), 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 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 cross walked 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.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94266 through 94268) and CY 2026 OPPS/ASC final rule with comment period (90 FR 53770 through 53780), we did not add any new services not described at § 410.43(a)(4) or § 410.44(a)(4) to the list of PHP and IOP services.

We did not propose to add any new services to the list of PHP and IOP services for CY 2027. The following is a summary of the comments we received regarding these policies and our responses.

Comment: A few commenters expressed support for the PHP and IOP list of services, the two-tiered structure based on the number of services per day, and the consolidated list of HCPCS codes for PHP and IOP services.

Response: We appreciate commenters' support.

Comment: A commenter expressed support for our coding policies for occupational therapy services furnished in PHPs and IOPs, noting that these policies reinforce the importance of occupational therapy services in PHPs and IOPs. This commenter stated that providers misinterpret program requirements regarding reporting, documentation, and integration of OT services in PHP and IOP and requested that CMS clarify billing compliance and reimbursement guidelines to improve beneficiary access to OT services. This commenter also advocated for including measures specific to occupational therapy in quality reporting programs. They further stated that caregiver training and PIN services should count toward the determination of whether a PHP or IOP day is paid at the 3-service or 4-service rate.

Response: We thank the commenter for their support of our coding policies for occupational therapy services furnished in PHPs and IOPs. We will take the commenter's suggestions into consideration to potentially inform future rulemaking about quality measures. As explained in the CY 2024 OPPS/ASC final rule with comment period, we believe it is appropriate to exclude caregiver-focused services from the determination of the number of services provided per day, but we do include such services in the calculation of cost per day for determining the PHP and IOP payment rates (88 FR 81822).

Comment: A commenter encouraged CMS to ensure that future payment analyses and policy development recognize the resources required to provide comprehensive medication management as part of high-quality behavioral health care and that such services be reimbursed appropriately.

Response: We appreciate the comment regarding the importance of medication management. We agree that medication is an integral part of partial hospitalization and intensive outpatient programs and note that under §§ 410.43(a)(4) and 410.44(a)(4), partial hospitalization and intensive outpatient services include drugs and biologicals furnished for therapeutic purposes (other than drugs that can be self-administered); the services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients (including patients with substance use disorder); and patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment. Therefore, payment under the PHP or IOP benefit could include daily monitoring of medication compliance, side effects, and patient education. We further note that existing codes in the list of HCPCS applicable for PHP and IOP, such as CPT code 90792 (Psych diag eval w/med srvcs), include medication management (88 FR 81827 through 81828). We will take the commenter's recommendations into consideration as we consider potential future payment analyses and policy development.

Comment: A commenter stated that providers have communicated to them that the Medicare National Coverage Determination list of group 1 diagnosis codes for PHP or IOP approved for G0129 omits several commonly seen diagnoses including post-traumatic stress disorder (PTSD), complex or prolonged grief diagnoses, borderline personality disorder (BPD), and generalized anxiety disorders (GAD). They requested that CMS include these diagnoses in the list of group 1 diagnosis codes for PHP or IOP approved for G0129.

Response: We thank the commenter for raising the concerns of providers on this topic. There is no National Coverage Determination for G0129. We are aware that there are Partial Hospitalization and Intensive Outpatient Services related Local Coverage Determinations (LCDs) and LCD Reference Articles that are developed by our Medicare Administrative Contractors (MACs). More information on the LCD development process can be found at publication 100–08, Program Integrity Manual (PIM), Chapter 13 at *https://www.cms.gov/medicare/regulations-guidance/manuals/internet-only-manuals-ioms.* Should the commenter believe that a change to the LCD is needed, we encourage the commenter to work with their local MAC (found at *https://www.cms.gov/Medicare/Coverage/InfoExchange*) to request an informal meeting prior to requesting an LCD reconsideration. The LCD reconsideration process is also outlined in chapter 13 of the PIM.

Comment: A commenter requested that CMS identify administrative barriers to the use of telemedicine in PHP and IOP programs and work with Congress to remove them.

Response: As we have previously discussed in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72000), section 1861(ff)(3)(A) of the Act, which defines partial hospitalization services, 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)(4) of the Act defines IOP by reference to section 1861(ff)(3) of the Act; that is, IOP services must be furnished in a location other than an individual's home or inpatient or residential setting. Accordingly, the limitation on furnishing PHP and IOP services in an individual's home is statutory. However, we will take this comment into consideration as we develop PHP and IOP policies for potential future rulemaking.

C. CY 2027 Payment Rates for PHP and IOP

For CY 2027, we proposed to maintain the current payment rate methodology that we use for calculating PHP and IOP payment rates for hospital-based providers. It has been our longstanding policy since CY 2011 to pay separate PHP APC per diem payment rates for CMHCs and hospital-based PHPs (75 FR 71992). As we explained in the CY 2026 OPPS/ASC final rule with comment period, beginning in CY 2024, we applied this payment structure to IOP because we expected (and subsequently have observed) differences in resource use between CMHCs and hospital OPDs for the provision of both PHP and IOP services (90 FR 53777).

Consistent with the payment methodology finalized in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53775 through 53776), we explained in the CY 2027 OPPS/ASC proposed rule (91 FR 41901) that we would apply the 40 percent MPFS Relativity Adjuster to calculate PHP and IOP payment rates for CMHCs. Specifically, we would multiply the CY 2027 rates for the hospital-based PHP and IOP APCs by 0.4 to calculate the payment rates for the CMHC PHP and IOP APCs.

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 OPPS data set, instead of using hospital-based PHP data only. We explained that using the broader OPPS 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 OPPS data for PHP days and non-PHP days that include three 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 OPPS/ASC final rule with comment period (88 FR 81829 and 81830), 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 OPPS/ASC final rule with comment period (72 FR 66672), it was never our intention that days with only three units of service should represent the number of services provided in a typical PHP day. Our intention was to cover days that consisted of three units of service only in certain limited circumstances. For example, as we noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41513), we believe 3-service days may be appropriate when a patient is transitioning towards discharge (or days when a patient 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.

In the same CY 2024 OPPS/ASC final rule with comment period, 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 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) for a more complete discussion of these trims, data exclusions, and CCR adjustments. In prior rules, we typically included a discussion of PHP-specific data trims, exclusions, and CCR adjustments; we did not include that discussion in the CY 2024 OPPS/ASC proposed rule or final rule with comment period. 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 three services per day and four services per day based on cost per day using the broader OPPS 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 OPPS.

We stated in the CY 2024 OPPS/ASC final rule with comment period (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 OPPS more generally. Additionally, we stated that prior to the CAA, 2023, CMS had begun gathering information from interested parties on IOP under Medicare. In the CY 2023 OPPS/ASC proposed rule (87 FR 44679), we issued a comment solicitation on intensive outpatient mental health treatment, including SUD treatment furnished by IOPs, to collect information regarding whether there are any gaps in coding that may be limiting access to needed levels of care for treatment of mental health disorders or SUDs for Medicare beneficiaries, and specific information about IOP services, such as the settings of care in which these programs typically furnish services, the range of services typically offered, and the range of practitioner types that typically furnish these services.

In addition, in the same CY 2024 OPPS/ASC final rule with comment period, we explained that along with the requirements for IOP mandated by the CAA, 2023, we took into consideration the 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 OPPS. Thus, we analyzed a broader set of data that included both PHP and non-PHP days with three or more services in order to calculate proposed payment for PHP services. 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.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81833), we established a policy of applying the 4-service day 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 four or more services. For days with three or fewer services, we apply the 3-service day 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). As we noted in the CY 2024 OPPS/ASC final rule with comment period, 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.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94269), for beneficiaries in a PHP or IOP, we maintained the payment rate methodology finalized in the CY 2024 OPPS/ASC final rule with comment period.

In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53774 through 53775), we explained that the calculated CY 2026 geometric mean per diem cost for CMHC PHP and IOP providers would result in an inversion (that is, the CMHC three-service geometric mean per diem costs were greater than the CMHC four-service geometric mean per diem costs). We stated that we believed the inverted geometric mean per diem costs were influenced by the small number of CMHCs that bill Medicare for PHP and IOP services, as well as CMHCs with low costs that first began billing Medicare for services in CY 2024. We remedied this cost inversion and preserved our longstanding payment policy of appropriately reflecting the observed cost differences between the CMHC and hospital settings by applying the 40 percent MPFS Relativity Adjuster to the hospital-based PHP and IOP costs to calculate the PHP and IOP payment rates for CMHCs.

2. CY 2027 Payment Rate Methodology for PHP and IOP

For CY 2027, we proposed to maintain our current methodology of calculating separate rates for hospitals and CMHCs. For the four hospital-based PHP and IOP APCs (that is, APCs 5861, 5862, 5863, and 5864), we proposed 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 2025 OPPS claims to update the payment rates. We explained that this proposal was consistent with the overall proposed use of cost data for the OPPS, which is discussed in section II.A.1.a. of the CY 2027 OPPS/ASC proposed rule (91 FR 41740).

In accordance with the methodology finalized in the CY 2024 OPPS/ASC final rule with comment period, we proposed to base the payment rate for each hospital-based PHP APC on the geometric mean per diem cost for days with three services and four or more services. We proposed to use the broader set of OPPS data to calculate the geometric mean costs for hospital outpatient departments, and we proposed to apply the same trims and exclusions consistent with the OPPS. We also proposed to set the payment rates for the hospital-based IOP APCs based on the geometric mean per diem cost for PHP days with three services and four or more services.

For the four CMHC PHP and IOP APCs (that is, APCs 5851, 5852, 5853, and 5854), we proposed to calculate the CY 2027 geometric mean per diem costs based on 40 percent of the corresponding hospital-based PHP and IOP APCs (APCs 5861, 5862, 5863, and 5864, respectively), in keeping with the methodology established in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53775 and 53776). We implemented this change in methodology for calculating the four CMHC PHP and IOP APCs to avoid possible future cost inversions (that is, the cost for 3-service days being greater than the cost for 4-service days). We explained in the CY 2026 OPPS/ASC final rule with comment period that we believe this methodology would continue to be generally appropriate for estimating CMHC costs and aligns with the methodology that is used for other nonexcepted OPPS services furnished by a nonexcepted off-campus hospital outpatient department (90 FR 53775 through 53776). For additional information on our analyses of the data used for setting the PHP and IOP payment rates for CY 2026 and application of the 40 percent MPFS Relativity Adjuster, we refer readers to sections VIII.C.2. and VIII.C.3. of the CY 2026 OPPS/ASC final rule with comment period (90 FR 53774 through 53779).

Lastly, we proposed that if more recent hospital cost data subsequently became available after the publication of the CY 2027 OPPS/ASC proposed rule (91 FR 41904), we would consider using such updated data as appropriate to determine the CY 2027 payment rates for the four hospital-based PHP and IOP APCs.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comments: Several commenters supported our proposal to maintain the current methodology of calculating hospital-based and CMHC-based PHP and IOP payment rates for 3 services per day and 4 services per day.

Response: We thank commenters for their support.

Comment: A commenter expressed concern that CY 2027 PHP and IOP rates were set based on cost data that was several years old and no longer representative of the cost of furnishing hospital-based PHP and IOP services.

Response: We refer readers to the discussion of the use of cost data for the OPPS in section II.A.1.a. of this CY 2027 OPPS/ASC final rule with comment period. We note that our proposal for CY 2027 was to use the most recent available cost and claims data to set PHP and IOP payment rates and that the OPPS payment rates are adjusted annually for inflation.

Comment: A commenter stated that CMS proposed no increase in current payment rates for PHP and IOP services.

Response: The proposed and final CY 2027 geometric mean costs for hospital and CMHC-based PHP and IOP services for 4 or more services per day represent an increase over CY 2026. We refer readers to Table 118 in the CY 2026 OPPS/ASC final rule with comment

period (90 FR 53779) and Table 78 in this final rule with comment period. We remind readers that due to the OPPS budget neutrality adjustments and the application of the final market basket update for CY 2027, the final APC payment rates may be higher or lower than their estimated APC geometric mean costs.

Comment: Multiple commenters stated that CMHC cost estimates do not reflect the actual costs of providing PHP and IOP and that the resources involved are comparable to those required for hospital-based programs. Commenters stated that CMS' policy of paying separate rates for hospitals and CMHCs creates arbitrary incentives for PHP and IOP services in settings other than CMHCs.

Response: We disagree with the commenters who believe CMS policy creates an incentive for PHP and IOP services in settings other than CMHCs. As discussed earlier in this section and in the CY 2027 OPPS/ASC proposed rule (91 FR 41902), our longstanding payment policies reflect the cost differences between the CMHC and hospital settings, based on our observation of CMHCs incurring significantly different costs than hospitals in the provision of PHP services. As we explained in the CY 2026 OPPS/ASC final rule, we observed that on average, the CY 2024 and CY 2025 geometric mean costs for the CMHC PHP and IOP APCs were 40 percent of the CY 2024 and CY 2025 geometric mean costs for the hospital-based PHP and IOP APCs (90 FR 53778). We believe that the stark difference between hospital and CMHC costs for PHP and IOP services that we continue to observe in the data reflects the actual cost structure differences between facility types.

Furthermore, we have observed sustained increases in the number of Medicare PHP and IOP days billed by CMHCs. In CY 2024, CMHCs billed for approximately 92,000 PHP days and approximately 9,000 IOP days, making up around 38.2 percent of total PHP and IOP days billed under the OPPS in that year. By contrast, in CY 2025, CMHCs billed for approximately 145,000 PHP days and approximately 41,000 IOP days, growing to around 42.4 percent of total PHP and IOP days billed under the OPPS. We believe this trend indicates that the level of payment appropriately supports access to these services at CMHCs. We will continue to monitor changes in the provision of PHP and IOP and will take these comments into consideration to potentially inform future policy.

Comment: Multiple commenters urged CMS to implement a site-neutral payment for CMHCs and hospital-based providers for PHP and IOP services. Some commenters stated that CMHCs are entitled under sections 1832(a)(2)(J) and 1833(a)(2)(B)(iii) of the Act to receive payment for PHP/IOP under the same methodology as hospital outpatient departments. A few commenters cited 1833(t)(2)(B) of the Act and stated that CMS has the discretion to create APC groups for different classes of services, but not to create distinct APC groups based on where a service is provided. Some commenters supported site neutrality more generally across Medicare payment systems.

Response: It has been our longstanding policy since CY 2011 to pay separate PHP APC per diem payment rates for CMHCs and hospital-based PHPs. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71992), we stated that section 1833(t)(9)(A) of the Act requires the Secretary to ''review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.'' We stated that we believe we have authority to revise the groups and relative payment weights and to make other adjustments to the payment rates for PHP services, including basing rates on hospital-based PHP data only, combined hospital-based PHP and CMHC data, or CMHC data only, to take into account relevant information and factors that would allow us to more appropriately pay providers for the resource costs associated with providing PHP services. Accordingly, we finalized separate PHP APC per diem payment rates for hospital OPDs and CMHCs, and we have maintained that structure for payment since CY 2011. Beginning in CY 2024, we applied this payment structure to IOP because we expected (and subsequently have observed) differences in resource use between CMHCs and hospital OPDs for the provision of both PHP and IOP services.

In response to the commenters who cited to section 1833(t)(2)(B) of the Act, we believe we have authority to create APC groups as shown by our longstanding methodology for PHP and IOP. CMS data shows that PHP and IOP services furnished at hospital OPDs differ with respect to the use of resources from PHP and IOP services furnished at CMHCs; therefore, payment rates that recognize these resource differences are consistent with the statutory requirements under section 1833(t) of the Act.

We also disagree that paying CMHCs at the same higher rate as hospitals for these services would have a negligible impact on the Medicare program. Despite the small number of CMHCs billing Medicare, the volume of PHP and IOP services that they provide is significant. Our data from CY 2025 OPPS claims shows that CMHCs furnished approximately 42 percent of all PHP and IOP days that were paid under the OPPS. If we were to increase payment for these PHP and IOP days by 150 percent (from 40 percent of the hospital-based payment rate to 100 percent of the hospital-based payment rate), as commenters have suggested, it would cause a significant increase in the total amount of PHP and IOP payments, both from the Medicare program and from Medicare beneficiaries in the form of coinsurance payments.

Comment: Some commenters stated that, given inflation and increased labor costs, the proposed rate is too low for CMHCs to effectively and appropriately staff and deliver PHPs and IOPs. The commenters stated that applying the 40 percent relativity adjuster could reduce CMHC payment rates compared to the hospital-based PHP and IOP payment rates.

Response: We appreciate the commenters' concerns; however, we disagree that the proposed rates are inadequate. We note that the OPPS payment rates are adjusted annually for inflation and that CMHC payment rates reflect those annual updates. We refer readers to the CY 2026 OPPS/ASC final rule with comment period for more extensive analysis of how CMHC costs align with the application of the 40 percent MPFS Relativity Adjuster to the hospital-based PHP and IOP costs (90 FR 53777 through 53778).

Comment: Some commenters stated that 40-percent methodology for determining CMHC rates is arbitrary and capricious under the Administrative Procedure Act because the data is inadequate to support the rate. Some of these commenters additionally stated that two of CMS's rationales were contradictory: the 40-percent adjuster had become necessary due to unstable CMHC cost data that resulted in a cost inversion, yet that same unstable data was used to support the 40-percent adjuster as we explained that CMHC geometric mean costs were on average 40 percent of hospital-based PHP and IOP geometric mean costs.

Response: Application of the 40 percent MPFS Relativity Adjuster

allows CMS to set CMHC payment rates based on the best available data, consistent with section 1833(t)(9)(A) of the Act. The fact that CMHC cost data is less stable than desired for ratesetting does not mean, however, that it gives us no range indicating where CMHC costs fall in relation to hospital costs. When we tested the 40 percent adjuster against several years of CMHC and hospital cost data, effectively increasing the CMHC dataset by adding years of cost reports, examining the ratio of CMHC costs to hospital costs per year, and taking an average to smooth out anomalies, we found that the 40 percent MPFS Relativity Adjuster provides stability and accuracy for CMHC PHP and IOP rates, both important elements in our payment methodologies. Our analysis indicates that the appropriateness of the CMHC payment methodology relative to patients' needs is fully supported by cost data and the rulemaking record. We refer readers to the extensive analysis and discussion in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53774 through 53778).

Final Decision: After consideration of the public comments, we are finalizing the CY 2027 PHP and IOP payment rate methodology for hospitals and CMHCs as proposed. Table 78 shows the final calculated geometric mean per diem costs for hospital-based PHP and IOP APCs, and the final geometric mean per diem costs for CMHC PHP and IOP APCs based on the application of the 40 percent MPFS Relativity Adjuster for this CY 2027 OPPS/ASC final rule with comment period. Additional information about the data trims, data exclusions, and CCR adjustments applicable to the data used for the CY 2027 OPPS/ASC proposed rule can be found online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*[2]

TABLE 78: FINAL CY 2027 PHP AND IOP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2027 APC	Group Title	Final PHP and IOP APC Geometric Mean Per Diem Costs
5851	Intensive Outpatient (3 services per day) for CMHCs	$123.94
5852	Intensive Outpatient (4 or more services per day) for CMHCs	$202.96
5853	Partial Hospitalization (3 services per day) for CMHCs	$123.94
5854	Partial Hospitalization (4 or more services per day) for CMHCs	$202.96
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	$309.85
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	$507.39
5863	Partial Hospitalization (3 services per day) for hospital-based PHPs	$309.85
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	$507.39

D. Outlier Policy for CMHCs

For CY 2027, we proposed 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 (91 FR 41904). We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 81834 through 81836) for more details on CMHC outlier policies, and to section II.G. of this final rule with comment period for our general policies for hospital outpatient outlier payments.

1. Background

As discussed in the CY 2004 OPPS/ASC final rule with comment period (68 FR 63469 and 63470), we created a separate outlier policy specific to the estimated costs and OPPS payments provided to CMHCs. We designated a portion of the estimated OPPS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs.

2. CMHC Outlier Percentage

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 and 59268), we described the current outlier policy for hospital outpatient payments and CMHCs. We note that we also discussed our outlier policy for CMHCs in more detail in section VIII.C. of that same final rule with comment period (82 FR 59381). We set our projected target for all OPPS aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS (82 FR 59267). This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61350), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082). We did not propose any changes to the CMHC outlier percentage policy for CY 2027.

3. Cutoff Point and Percentage Payment Amount

Also described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59381), our policy has been to pay CMHCs for outliers if the estimated cost of the day exceeds a cutoff point. In CY 2006, we set the cutoff point for outlier payments at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year (70 FR 68551). For CY 2018, the highest CMHC PHP APC payment rate was the payment rate for CMHC PHP APC 5853. In addition, in CY 2002, the final OPPS outlier payment percentage for costs above the multiplier threshold was set at 50 percent (66 FR 59889). In CY 2018, we continued to apply the same 50 percent outlier payment percentage that applies to hospitals to CMHCs and continued to use the existing cutoff point (82 FR 59381). Therefore, for CY 2018, we continued to pay for partial

hospitalization services that exceeded 3.4 times the CMHC PHP APC payment rate at 50 percent of the amount of CMHC PHP APC geometric mean per diem costs over the cutoff point. This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996 and 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 and 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). In the CY 2024 OPPS/ASC final rule with comment period, we extended this policy to intensive outpatient services. We did not propose any changes to the cutoff point and payment amount policy for CY 2027.

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 apply to all hospitals and CMHCs paid under the OPPS. We initiated steps to ensure that outlier payments appropriately account for the financial risk when providing an extraordinarily costly and complex service but are only being made for services that legitimately qualify for the additional payment.

For a comprehensive description of outlier reconciliation, we refer readers to the CY 2023 OPPS/ASC and CY 2019 OPPS/ASC final rules with comment period (83 FR 58874 and 58875 and 81 FR 79678 through 79680, respectively). We did not propose any changes to the outlier reconciliation policy for CY 2027.

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 costs from three CMHCs that accounted for 98 percent of all CMHC outlier payments that year and received outlier payments that ranged from 104 percent to 713 percent of their total per diem payments. To balance our concern about disadvantaging CMHCs with our interest in protecting the benefit from excessive outlier payments and to mitigate potential inappropriate outlier billing vulnerabilities, we finalized the CMHC outlier payment cap at 8 percent of the CMHC's total per diem payments (81 FR 79694 and 79695) to limit the impact of inflated CMHC charges on outlier payments. This cap was established after detailed analysis of claims data, which showed that a cap set at 8 percent would effectively address excessive outlier payments while minimally impacting CMHCs with legitimate high-cost cases. The cap applies to each CMHC's total per diem payments, which include both the Medicare payment portion and the beneficiary cost-sharing amount. The 8 percent cap continues to be calculated and applied on a calendar year basis, with outlier payments monitored throughout the year to ensure compliance with the cap.

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 did not propose any changes to the outlier payment cap for CY 2027.

Comment: A commenter indicated general support for the CMHC outlier cap while requesting that CMS evaluate whether requiring documentation that PHP and IOP services furnished followed a published behavioral health clinical pathway would better protect program integrity than a fixed outlier cap.

Response: We appreciate the commenter's perspective and will take it into consideration to potentially inform future program monitoring and research efforts.

6. Fixed-Dollar Threshold

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 and 59268), for the hospital outpatient outlier payment policy, we set a fixed-dollar threshold in addition to an APC multiplier threshold. Fixed-dollar thresholds are typically used to drive outlier payments for very costly items or services, such as cardiac pacemaker insertions. Currently, for CY 2026, 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), the CY 2024 OPPS/ASC final rule with comment period (88 FR 81836), the CY 2025 OPPS/ASC final rule with comment period (89 FR 94271), and the CY 2026 OPPS/ASC final rule with comment period (90 FR 53780). We did not propose any changes to the fixed-dollar threshold policy for CY 2027 and did not receive any public comments on this provision.

IX. Services That Will Be Paid Only as Inpatient Services

A. Background

The Inpatient Only (IPO) list was established in rulemaking as part of the initial implementation of the Outpatient Prospective Payment System (OPPS) in 2000, pursuant to the Secretary's authority under section 1833(t)(1)(B)(i) of the Act (65 FR 18455) to determine the services covered and paid for under the OPPS. The IPO list was created to identify services excluded from payment under the OPPS by designating certain procedures as ''inpatient only'' and therefore payable only when furnished in the inpatient hospital setting under Medicare Part A (65 FR 18442). Services included on the IPO list were those determined to require inpatient care because of the invasive nature of the procedures, the underlying physical condition of the Medicare 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 creation of the IPO list was based on the premise (rooted in the practice of medicine at that time) that Medicare should not pay for procedures furnished as outpatient services when those procedures were being performed on an inpatient basis virtually all of the time for the Medicare population because performing these procedures on an

outpatient basis was not safe or appropriate, and therefore not reasonable and necessary under Medicare rules (86 FR 63671; 63 FR 47571). Designation of a service as inpatient only does not preclude the service from being furnished in a hospital outpatient setting but 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 absence of a procedure from the list should not be interpreted as identifying that procedure as appropriately performed only in the hospital outpatient setting (70 FR 68696). Rather, from the beginning, we have emphasized our expectation that, in every case, the physician or surgeon and hospital will exercise their professional judgment and assess the risk of the procedure or service to the individual patient, taking into account the site of service and act in that patient's best interest (65 FR 18456). We have also previously stated that for procedures that are not included on the inpatient list, we rely on the practitioner's judgment to determine on a patient-by-patient basis whether or not a particular procedure would be most appropriately performed in the inpatient setting (70 FR 68698).

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86084 through 86088), we finalized a policy to eliminate the IPO list over the course of 3 years (85 FR 86093). We revised our regulation at 42 CFR 419.22(n) to state that, effective January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition. As part of the first phase of this elimination of the IPO list, we removed 298 codes, including 266 musculoskeletal-related services, from the list beginning in CY 2021.

In the CY 2022 OPPS/ASC final rule with comment period, we halted the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021 as part of the first phase of eliminating the IPO list, we returned most services removed from the IPO list in 2021 back to the IPO list beginning in CY 2022 (86 FR 63671 through 63736). We amended the regulation at § 419.22(n) to remove the reference to the elimination of the list of services and procedures designated as requiring inpatient care through a 3-year transition (86 FR 63676). We also finalized our proposal to codify the following five longstanding criteria for determining whether a service or procedure should be removed from the IPO list in the regulation at § 419.23 (86 FR 63672):

- Most outpatient departments are equipped to provide the service or procedure to the Medicare population.
- The simplest service or procedure described by the code may be performed in most outpatient departments.
- The service or procedure is related to codes that CMS has already removed from the Inpatient Only list.
- CMS determines that the service or procedure is being performed in numerous hospitals on an outpatient basis.
- CMS determines that the service or procedure can be appropriately and safely performed in an ambulatory surgical center, and is specified as a covered ambulatory surgical procedure, or CMS has proposed to specify it as a covered ambulatory surgical procedure.

For CY 2023 through CY 2025, we maintained the IPO list and continued to evaluate services brought forth by interested parties for removal using the five longstanding criteria (87 FR 72004 through 72012; 88 FR 81858 through 81863; and 89 FR 94271 through 94275).

In the CY 2026 OPPS/ASC final rule with comment period, we again finalized a policy to eliminate the IPO list over the course of three years, beginning by removing 285 mostly musculoskeletal procedures for CY 2026 (90 FR 53780 through 53802). As we stated in that rule, since the creation of the IPO list, there have been many new technologies and advances in surgical techniques and surgical care protocols, including the use of minimally invasive surgical procedures such as laparoscopy, improved perioperative anesthesia, expedited rehabilitation protocols, as well as significant enhancements to postoperative processes such as improvements in pain management, that have reduced the inpatient length of stay and the need for postoperative care following a surgical service. We also recognize that since we previously considered elimination of the IPO list in the CY 2021 OPPS/ASC final rule with comment period, there have also been other innovations in the practice of medicine; for example, innovations in infection control spurred by the COVID–19 PHE. Additionally, we believe that there are a number of safety mechanisms that will continue to ensure the safety of our beneficiaries and the quality of care, including physician judgment, State and local regulations, accreditation requirements, medical malpractice laws, hospital conditions of participation, and other CMS initiatives (90 FR 53857). Given the significant number of services on the list and that we would establish new reimbursement rates for those services under the OPPS, we recognized that interested parties may need time to adjust to the removal of procedures from the list. Providers may need time to prepare to furnish newly removed procedures on an outpatient basis, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the IPPS or OPPS. Therefore, we finalized our proposal to transition services off the IPO list over a 3-year period (90 FR 53783). We also refer readers to the CY 2026 OPPS/ASC final rule with comment period for further discussion on operational and beneficiary considerations, including the continuation of 2-midnight exemptions for services removed from the IPO list, effects on beneficiary cost-sharing, and implications on the 3-day stay requirement for skilled nursing facilities (90 FR 53786 through 53788). After consideration of the comments received and the issues discussed, in the CY 2026 OPPS/ASC final rule with comment period, we finalized our proposal eliminating the criteria for removing procedures from the IPO list as it was then codified at § 419.23 and amended § 419.22(n) to state that, effective on January 1, 2026, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition period, with the list eliminated in its entirety by January 1, 2029 (90 FR 53788 to 53789 and 54086; 91 FR 8384). For further discussion on the elimination of the IPO list, please refer to section IX. of the CY 2026 OPPS/ASC final rule with comment period (90 FR 53780 through 53802).

B. Final CY 2027 Changes to IPO List

Currently, there are 1,438 services remaining on the IPO list. For CY 2027, we proposed to remove approximately half of the remaining IPO services as the second phase of the elimination of the IPO list. Therefore, we proposed to remove 637 services from the following clinical families: auditory, digestive, endocrine, female genital, hemic and lymphatic systems, integumentary, male genital, maternity care and delivery, mediastinum and diaphragm, respiratory, and urinary. As stated in the proposed rule, if we finalize our proposal to remove these services for CY 2027, the majority of remaining services are more complicated in nature, and we believe the services in these clinical families may require a lengthier review process and potential changes to our current APCs in order to determine an appropriate APC assignment. For example, some of the remaining

procedures for removal in CY 2028 would be from the neurological family, cardiovascular family, solid organ, intestinal, and islet cell transplants and related services. We believe these services require additional considerations due to their complex clinical nature and resources required. We expect that these remaining clinical families and services would be removed from the IPO list for CY 2028, during the third and final phase of the elimination.

The clinical families proposed for the second phase of the elimination of the IPO list were selected based on interested parties feedback and concerns regarding proper APC placement. In the CY 2026 OPPS/ASC proposed rule, we solicited comment on the order of removal of additional clinical families of services, and/or specific services, for each of the CY 2027 and CY 2028 rulemaking cycles (90 FR 33669). We received comments requesting that we wait to remove certain invasive procedures involving craniectomy, craniotomy, and/or burr holes and cardiovascular procedures until the last phase, and we stated we would take the suggestions into consideration in future rulemaking (90 FR 53788). After further consideration, we agreed with the commenters that we should wait to remove these more clinically complex and unique procedures, including the neurological and cardiovascular procedures, until the final phase. We believe that the complicated nature of the services in these clinical families may require a lengthier review process and potential changes to our current APCs to determine an appropriate APC assignment. Additionally, the clinical families listed above and proposed for removal in CY 2027 include multiple procedures that have been previously recommended by interested parties for removal from the IPO list. Based on our review, we also believe that the procedures in these clinical families require less adjustment to existing APCs compared to those clinical families we proposed to remove in CY 2028, including the neurological and cardiovascular clinical families, meaning, they have clinical similarities and resource needs similar to that of existing procedures payable under the OPPS. As these groups of services are the next most clinically similar families, they are the natural next step in the phase out of the IPO. Therefore, we proposed to remove selected less-complex services in the auditory, digestive, endocrine, female genital, hemic and lymphatic systems, integumentary, male genital, maternity care and delivery, mediastinum and diaphragm, respiratory, and urinary clinical families from the IPO list for CY 2027 and proposed to maintain the remaining clinical families for CY 2027. If we finalize our policy as proposed, we expect to address all of the remaining clinical families and their removal during CY 2028 rulemaking.

As we have previously stated, when removing a service from the IPO list, we assign the service to an APC and include it as a payable procedure under the OPPS (67 FR 66740). As stated in previous rulemaking, services that are no longer included on the IPO list are payable in either the inpatient or hospital outpatient setting subject to the general coverage rules requiring that any procedure be reasonable and necessary, and payment should be made pursuant to the otherwise applicable payment policies (86 FR 63675). We determined 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 reviewing the Medicare Severity Diagnosis Related Groups (MS–DRG) rate for the service under the IPPS. It should be noted, however, that 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 (67 FR 66740). Additionally, sought comment and continue to seek comments on whether we should restructure or create any new APCs or C–APCs to allow for efficient OPPS payment for services that are removed from the IPO list to account for this significant increase in services that will now be eligible for OPPS payment.

In summary, we proposed to remove 637 services from the IPO list for CY 2027 as the second phase of the elimination of the IPO list (91 FR 41907). These services and their proposed status indicators and APC assignments (if applicable) are listed in the public use file titled ''Proposed Procedures for Removal from the IPO List for CY 2027'', which is available on the CMS website. The services proposed for removal from the IPO list for CY 2027 and their proposed status indicators and APC assignments (if applicable) were also included in Addendum B of the CY 2027 OPPS/ASC proposed rule. The complete list of codes that describe services that are proposed to be paid by Medicare in CY 2027 as Inpatient Only services was included as Addendum E to the CY 2027 OPPS/ASC proposed rule.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for our proposal to continue the elimination of the IPO list and remove 637 services for CY 2027. Commenters supported increasing flexibility for site-of-service determinations and increasing access and physician autonomy. Commenters stated that site-of-service determinations are best informed by the patient's physicians.

Commenters also expressed support for the removal of certain procedures from the IPO list. Several commenters supporting the removal of bariatric and metabolic services described by CPT codes 43644, 43645, 43775, 43843, 43845, 43847, 43848, and 43860. A commenter supported removing integumentary procedures, stating that continuing to provide these services primarily in the inpatient setting would increase the cost without a corresponding clinical benefit.

Response: We thank the commenters for their support.

Comment: Many commenters opposed our proposal to continue the elimination of the IPO list with the removal of 637 procedures, with patient safety continuing to be a main concern. Some commenters requested that CMS reverse its decision to eliminate the IPO list and reinstate the prior five criteria. Others suggested alternatives to removing all of the procedures from the IPO list, including individually reviewing each procedure for appropriateness in the outpatient setting or creating criteria based on factors such as average length of stay, peer-reviewed literature, patient comorbidities, clinical complexity, and infrastructure needed to safely furnish the procedure in the outpatient setting. Commenters also suggested creating criteria that would allow physicians to override an IPO designation and still receive payment for furnishing the procedure in the outpatient setting when appropriate to allow physicians more flexibility while still maintaining the IPO list. Some commenters stated they understood CMS's goal to increase site-of-service flexibility but were concerned at the pace of which procedures were being removed from the IPO list. Commenters recommended that CMS wait to remove additional, more complex procedures until the effects of the CY 2026 removals are assessed. Commenters also asserted that the large number of codes coming off the IPO list over the 3-year elimination period could expose hospitals to increased audits and claims denials and not provide enough time for hospitals

and physicians to establish clinical pathways and protocols.

Response: We thank the commenters for their input. As we previously stated in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86087), we continue to believe that physicians can and should use their clinical knowledge and judgment to appropriately determine whether a procedure can be performed in a hospital outpatient setting or whether inpatient care is required for the beneficiary based on the beneficiary's specific needs and preferences, subject to the general coverage rules requiring that any procedure be reasonable and necessary, and that payment should be made pursuant to the otherwise applicable payment policies. We believe that patient safety and quality of care will be safeguarded by the physician's assessment of the risk of a procedure or service to the individual beneficiary and their selection of the most appropriate setting of care based on this risk, as well as State and local licensure requirements, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and our quality and monitoring initiatives and programs. We also continue to believe that there have been significant developments in the practice of medicine that have allowed numerous services that were previously provided on an inpatient basis to now be provided safely and effectively in the outpatient setting. Therefore, we continue to believe it is not necessary for us to maintain an IPO list, nor do we currently believe that it is necessary to require specific HCPCS codes to remain payable only when furnished in the inpatient setting. Additionally, for these same reasons, we believe it is not necessary to adopt another method of revising the IPO list, such as reviewing individual procedures against a new set of criteria.

Regarding the length of the phase-out period, as we stated in the CY 2026 OPPS/ASC final rule with comment period, we believe that gradually removing services from the IPO list over the 3-year phase-out period will allow for adequate time for providers to prepare to furnish newly removed procedures on an outpatient basis, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the IPPS or OPPS (90 FR 53788). Additionally, we believe that our policy to exempt procedures that have been removed from the IPO list from certain medical review activities to assess compliance with the 2-midnight rule until the Secretary determines that the service or procedure is more commonly performed in the Medicare population in the outpatient setting will prevent hospitals from the burden of audits and denials due to furnishing former IPO procedures in the inpatient setting.

Comment: Many commenters requested that CMS emphasize that the removal of codes from the IPO list does not imply that the hospital outpatient setting is automatically the most appropriate site-of-service for these procedures.

Response: As we have stated in previous rulemaking (82 FR 59384; 84 FR 61354; 90 FR 53784), the removal of a service from the IPO list does not require the service to be performed only on an outpatient basis. Rather, it allows for payment under the OPPS when the service is performed in an outpatient setting. Services that are removed from the IPO list can be and are performed on individuals who are admitted as inpatients (as well as individuals who are registered hospital outpatients), based on the physician's clinical knowledge and judgment.

Comment: Several commenters expressed concern that the removal of the proposed services and elimination of the IPO list could cause shifts in the site-of-care availability and cost impacts. One commenter was concerned that these changes may lead to increased reliance on Medicare Part B services and reduced access to Medicare Part A post-acute care benefits, such as SNF care. Commenters were also concerned that the continued elimination of the IPO list could lead to increased pressure on physicians to furnish former IPO list services in the lowest cost setting, even if not clinically appropriate for that patient.

Many commenters expressed concern that Medicare Advantage (MA) plans and commercial payors may not follow CMS's lead that the absence of a procedure from the IPO list does not mean it is always appropriately performed in the outpatient setting, leading to denials for inpatient care or pressure for hospitals to provide these procedures in lower cost settings. Commenters requested that CMS continue to emphasize that MA plans must comply with general coverage and benefit conditions included in Traditional Medicare laws, including coverage criteria that governs inpatient admissions. Commenters also requested that CMS issue guidance to MA plans to ensure that they do not create internal policies that inpatient admissions are no longer appropriate for procedures coming off the IPO list or override a physician's determination that inpatient care is needed, apply prior authorizations in a limited manner, and appropriately follow CMS's 2-midnight rule.

Response: As many of the procedures coming off the IPO list are complex procedures that are not currently regularly performed in the hospital outpatient setting, we do not anticipate to see large shifts in site-of-care due to the elimination of the IPO list, nor do we anticipate that this will cause cost effects that would limit access to Medicare Part A services. We anticipate that procedures that do see significant increases in being performed in the outpatient setting will likely be procedures that are less complex and are already being performed regularly in the outpatient setting in the general population.

We consider discussions regarding MA plans to be out of scope of this OPPS/ASC rule, however, as we have previously stated, MA plans are required to comply with the 2-midnight benchmark. This is stated in the April 12, 2023 rule titled ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.'' In this rule, we codified that MA plans must comply with ''General coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans. This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare.'' These criteria include ''payment criteria for inpatient admissions at 42 CFR 412.3'' and ''services and procedures that the Secretary designates as requiring inpatient care under 42 CFR 419.22(n).'' (88 FR 22328). These requirements mean that MA plans must comply with the 2-midnight rule and may not treat removal from the IPO list as requiring those procedures to be performed in the outpatient setting. We will take the commenters' request for additional guidance into consideration for future rulemaking.

Regarding changes made by commercial insurance providers and site selection for outpatient services as a result of us eliminating the IPO list, while we believe that these comments are outside the scope of the OPPS/ASC proposed rule, we note that commercial providers establish their own rules regarding payment for services. We also refer readers to our discussion below regarding CMS's limitations on interfering with the practice of medicine and our belief that the specific decision

about the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs.

Comment: Several commenters made requests regarding data monitoring and additional guidance. Commenters recommended that CMS monitor the effects of removing procedures from the IPO list, including factors such as hospital length of stay, readmissions, patient outcomes, and emergency department visits. Commenters requested that CMS provide guidance on patient selection criteria for performing these procedures in the hospital outpatient setting. Commenters also requested additional education from CMS regarding the exemptions from 2-midnights claims review for procedures removed from the IPO list, including identifying which procedures are exempt, citing that some hospitals were unaware of these exemptions. Additionally, commenters requested that CMS educate beneficiaries on potential higher cost-sharing for procedures performed in the outpatient setting, which some commenters expressed as a factor for opposing our proposal.

Response: We thank the commenters for their feedback. Annually, through rulemaking, we assess, monitor, and reevaluate hospital claims data, the clinical environment, and our overall payment policies to inform our proposals and final policies. We would welcome and use any data, analyses, or recommendations that interested parties would like to share with us to help inform IPO decision-making going forward. We will take these recommendations into consideration for future rulemaking and are open to receiving any relevant data in the interim.

Regarding providing additional guidance on patient selection criteria and site-of-service determinations, as we have previously stated (86 FR 63675), we note the balance between several factors on this important issue, namely, the prohibition on us interfering with the practice of medicine in section 1801 of the Act, the need to provide clear information about our billing and payment rules that ensure hospitals, physicians, and other interested parties can understand and operate within them, and our belief that the specific decision about the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary.

Regarding requests for additional education on the exemptions from 2-midnights claims review for procedures removed from the IPO list, we remind commenters that procedures removed from the IPO list on or after January 1, 2021, are indefinitely exempted from site-of-service claim denials, initial medical review contractor referrals to RACs, and RAC reviews for ''patient status'' (that is, site-of-service) until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting than the inpatient setting. For the exemption to end for a specific procedure, in a single calendar year we would need to have Medicare claims data indicating that the procedure was performed more than 50 percent of the time in the outpatient setting. We noted that the end of the exemption period for each procedure removed from the IPO list on or after January 1, 2021 would be announced via rulemaking. During the exemption period, Medicare review contractors have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-midnight rule, but claims identified as noncompliant are not denied with respect to the site-of-service under Medicare Part A. Information gathered by the Medicare review contractor when reviewing procedures as they are newly removed from the IPO list can be used for educational purposes but will not result in a claim denial during the exemption period.

We also refer commenters to the full discussion on these exemptions in section X.D. of the CY 2026 OPPS/ASC final rule with comment period (90 FR 53827 through 53832). We will take the request for further education into consideration for future implementation. As stated previously, services included on the IPO list tend to be surgical procedures that, if performed on an outpatient basis, would typically be the focus of the hospital outpatient stay and would likely be assigned to a comprehensive APC (C–APC) when they are removed from the IPO list. As such, these services would likely be considered a single episode of care with one payment rate and one copayment amount. In most instances, we expect that beneficiaries will not be responsible for multiple copayments for individual ancillary services associated with services removed from the IPO list, because the primary service will generally be assigned to a C–APC and the inpatient deductible cap will apply to the entire hospital claim, which is paid as a comprehensive service. Also, as stated previously, in the event there are separately payable OPPS services included on a claim with a service assigned to a C–APC, OPPS cost-sharing for an individual service is capped at the applicable Part A hospital inpatient deductible amount for that year for each service.

Comment: Many commenters provided recommendations on the methodology for assigning procedures coming off the IPO list to APCs. Commenters provided various methodologies, including crosswalking the CPT codes to ICD–10 PCS codes and establishing payment rates from corresponding IPPS short-stay claims, applying our universal low-volume policy to procedures coming off the IPO list, allowing MACs to use contractor pricing to determine the payment rate, and placing the procedures in New Technology APCs. A few commenters also recommended that CMS wait to assign the remaining IPO procedures to APCs until the final year of the phase-out period or to extend the phase-out period to ensure that CMS does not assign procedures to inappropriate APCs just to meet the timeline. One commenter recommended that former IPO list procedures are included in the annual assessment of the two-times rule, regardless of claims volume for the first four years following removal from the IPO list, stating this would give CMS a structured and data-driven mechanism to assess, monitor, and manage the significant migration of complex procedures into the outpatient setting.

Some commenters recommended that CMS create new APCs and C–APCs to accommodate the services coming off the IPO list, including establishing additional levels in the Abdominal/Peritoneal/Biliary and Related Procedures, Laparoscopy and Related Procedures, and Gynecologic Procedures families and creating thoracic procedures APCs. A commenter also recommended that CMS establish a policy for code combinations that qualify for complexity adjustment but have no higher level in its APC family.

Response: We thank the commenters for their recommendations. Further discussion on how we assign former IPO procedures to APCs is included in our response to commenters' APC reassignment requests later in this section. We will take commenters' recommendations regarding APC assignment methodology and complexity adjustments into consideration for future rulemaking. At this time, we are not finalizing any additional APC levels for CY 2027 as a result of these comments. However, we

will take the commenters' recommendations into consideration and continue to monitor claims data to identify any potential need to create new APCs.

Comment: Some commenters shared recommendations regarding the procedures and clinical families that were proposed to remain on the IPO list for CY 2027, with commenters encouraging CMS to propose new and higher APC levels for CY 2028 where appropriate. A commenter requested that for CY 2028, we assign the mechanical thrombectomy code described by CPT code 61645 to an APC based on its clinical and resource characteristics instead of an existing endovascular APC that may not be homogeneous to its resource use. Ae commenter also recommended creating additional Endovascular Procedures APCs to accommodate the procedures that will come off the IPO list. A commenter supported keeping cardiovascular codes on the IPO list for CY 2027 and recommend that CMS issue proposed APC assignments for these procedures and amendments to the APCs and C–APCs to accommodate the removal of cardiovascular procedures as an RFI in the CY 2028 OPPS/ASC proposed rule to inform final proposals in the CY 2029 OPPS/ASC proposed rule. Another commenter recommended that we create a Level 6 Neurostimulator and Related Procedures APC to accommodate the neurostimulation procedures that will eventually be removed from the IPO list and require APC assignments.

A commenter requested that CMS also remove CPT codes 0235T (Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; visceral artery (except renal), each vessel), 0345T (Transcatheter mitral valve repair percutaneous approach via the coronary sinus), 0483T (Transcatheter mitral valve implantation/replacement (tmvi) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed), 0484T (Transcatheter mitral valve implantation/replacement (tmvi) with prosthetic valve; transthoracic exposure (eg, thoracotomy, transapical)), and 33440 (Replacement, aortic valve; by translocation of autologous pulmonary valve and transventricular aortic annulus enlargement of the left ventricular outflow tract with valved conduit replacement of pulmonary valve (ross-konno procedure)). The commenter stated that these procedures are recognized nationally for being safely performed on the same day and would be appropriate to furnish in the outpatient setting.

Response: We thank the commenters for their recommendations and will take them into consideration for future rulemaking. Regarding the recommendation to remove CPT codes 0235T, 0345T, 0483T, 0484T, and 33440 from then IPO list for CY 2027, we are not accepting this recommendation. We plan to remove these procedures in future rulemaking with procedures in their clinical families, which will allow us to review and make adjustments to the related APCs as necessary.

Comment: A commenter requested clarification on if CPT codes 0569T, 0570T, 0646T, 33710, 59514, 59525, and 59620 will be removed from the IPO list for CY 2027, as they were not listed as being proposed for removal or in Addendum E.

Response: CPT codes 0569T, 0570T, 0646T, 33710, 59514, 59525, and 59620 were not proposed for removal as these codes are being deleted by the AMA. They will no longer be effective starting in CY 2027.

Comment: Several commenters disagreed with certain proposed APC assignments for procedures proposed to be removed from the IPO list, requesting that these procedures be placed in higher APC levels or different APC families to better reflect the resource costs and clinical complexity of these procedures. Commenters also requested greater transparency regarding how CMS assigned these procedures to APCs. The services for which we received APC reassignment requests are listed in Table 79.

Response: We thank the commenters for their input. As we have previously stated, 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 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. After further clinical review and review of the limited available claims data for these procedures, we have reassigned some of the procedures recommended by commenters. The proposed and final APC and status indicator assignments for procedures for which commenters requested APC reassignments are listed in Table 79 below.

After consideration of public comments received, we are finalizing our proposal to remove 637 services from the IPO list for CY 2027 as the second phase of the elimination of the IPO list. We continue to believe that there are a number of safety mechanisms that will continue to ensure the safety of our beneficiaries and the quality of care, including physician judgment, State and local regulations, accreditation requirements, medical malpractice laws, hospital conditions of participation, and other CMS initiatives. These services and their final status indicators and APC assignments (if applicable) are listed in the public use file titled ''Final Procedures Removed from the IPO List for CY 2027'', which is available on the CMS website. The complete list of codes that describe services that are finalized to be paid by Medicare in CY 2027 as inpatient only services is included as Addendum E to this CY 2027 OPPS/ASC final rule with comment period, which is available on the CMS website.

TABLE 79: CY 2027 PROPOSAL AND FINAL APC ASSIGNMENTS FOR PROCEDURES RECOMMENDED FOR APC REASSIGNMENT BY COMMENTERS

CPT Code	Long Descriptor	CY 2027 Proposed SI	CY 2027 Proposed APC	CY 2027 Final SI	CY 2027 Final APC
11004	Debridement of skin, subcutaneous tissue, muscle and fascia for necrotizing soft tissue infection; external genitalia and perineum	T	5053	T	5054
11005	Debridement of skin, subcutaneous tissue, muscle and fascia for necrotizing soft tissue infection; abdominal wall, with or without fascial closure	T	5053	T	5054
11006	Debridement of skin, subcutaneous tissue, muscle and fascia for necrotizing soft tissue infection; external genitalia, perineum and abdominal wall, with or without fascial closure	T	5053	T	5054
19364	Breast reconstruction; with free flap (eg, ftram, diep, siea, gap flap)	J1	5092	J1	5092
19367	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (tram) flap	J1	5092	J1	5092
32440	Removal of lung, pneumonectomy	J1	5182	J1	5184
32480	Removal of lung, other than pneumonectomy; single lobe (lobectomy)	J1	5182	J1	5183
32482	Removal of lung, other than pneumonectomy; 2 lobes (bilobectomy)	J1	5182	J1	5183
32484	Removal of lung, other than pneumonectomy; single segment (segmentectomy)	J1	5182	J1	5183
32486	Removal of lung, other than pneumonectomy; with circumferential resection of segment of bronchus followed by broncho-bronchial anastomosis (sleeve lobectomy)	J1	5182	J1	5184
32663	Thoracoscopy, surgical; with lobectomy (single lobe)	J1	5362	J1	5362
32666	Thoracoscopy, surgical; with therapeutic wedge resection (eg, mass, nodule), initial unilateral	J1	5362	J1	5362
32669	Thoracoscopy, surgical; with removal of a single lung segment (segmentectomy)	J1	5362	J1	5362
39503	Repair, neonatal diaphragmatic hernia, with or without chest tube insertion and with or without creation of ventral hernia	J1	5342	J1	5342
39540	Repair, diaphragmatic hernia (other than neonatal), traumatic; acute	J1	5342	J1	5342
39541	Repair, diaphragmatic hernia (other than neonatal), traumatic; chronic	J1	5342	J1	5342
43107	Total or near total esophagectomy, without thoracotomy; with pharyngogastrostomy or cervical esophagogastrostomy, with or without pyloroplasty (transhiatal)	J1	5163	J1	5165
43332	Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; without implantation of mesh or other prosthesis	J1	5163	J1	5342
43333	Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; with implantation of mesh or other prosthesis	J1	5163	J1	5342
43334	Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except	J1	5163	J1	5342

CPT Code	Long Descriptor	CY 2027 Proposed SI	CY 2027 Proposed APC	CY 2027 Final SI	CY 2027 Final APC
	neonatal; without implantation of mesh or other prosthesis				
43335	Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except neonatal; with implantation of mesh or other prosthesis	J1	5163	J1	5342
43336	Repair, paraesophageal hiatal hernia, (including fundoplication), via thoracoabdominal incision, except neonatal; without implantation of mesh or other prosthesis	J1	5163	J1	5342
43337	Repair, paraesophageal hiatal hernia, (including fundoplication), via thoracoabdominal incision, except neonatal; with implantation of mesh or other prosthesis	J1	5163	J1	5342
43500	Gastrotomy; with exploration or foreign body removal	T	5301	T	5301
43501	Gastrotomy; with suture repair of bleeding ulcer	T	5301	J1	5302
43502	Gastrotomy; with suture repair of pre-existing esophagogastric laceration (eg, mallory-weiss)	T	5301	J1	5302
43520	Pyloromyotomy, cutting of pyloric muscle (fredet-ramstedt type operation)	T	5301	T	5301
43605	Biopsy of stomach, by laparotomy	T	5301	T	5301
43610	Excision, local; ulcer or benign tumor of stomach	T	5301	J1	5302
43611	Excision, local; malignant tumor of stomach	T	5301	J1	5302
43620	Gastrectomy, total; with esophagoenterostomy	T	5301	J1	5342
43621	Gastrectomy, total; with roux-en-y reconstruction	T	5301	J1	5342
43622	Gastrectomy, total; with formation of intestinal pouch, any type	T	5301	J1	5342
43631	Gastrectomy, partial, distal; with gastroduodenostomy	T	5301	J1	5342
43632	Gastrectomy, partial, distal; with gastrojejunostomy	T	5301	J1	5342
43633	Gastrectomy, partial, distal; with roux-en-y reconstruction	T	5301	J1	5342
43634	Gastrectomy, partial, distal; with formation of intestinal pouch	T	5301	J1	5342
43640	Vagotomy including pyloroplasty, with or without gastrostomy; truncal or selective	T	5301	T	5301
43641	Vagotomy including pyloroplasty, with or without gastrostomy; parietal cell (highly selective)	T	5301	T	5301
43800	Pyloroplasty	T	5301	T	5301
43810	Gastroduodenostomy	T	5301	J1	5303
43820	Gastrojejunostomy; without vagotomy	T	5301	J1	5303
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty	J1	5303	J1	5303
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)	J1	5303	J1	5303
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption	J1	5303	J1	5303

CPT Code	Long Descriptor	CY 2027 Proposed SI	CY 2027 Proposed APC	CY 2027 Final SI	CY 2027 Final APC
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)	J1	5303	J1	5303
43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy	J1	5303	J1	5303
44120	Enterectomy, resection of small intestine; single resection and anastomosis	J1	5303	J1	5303
44125	Enterectomy, resection of small intestine; with enterostomy	J1	5303	J1	5303
44130	Enteroenterostomy, anastomosis of intestine, with or without cutaneous enterostomy (separate procedure)	J1	5303	J1	5303
44140	Colectomy, partial; with anastomosis	J1	5341	J1	5341
44141	Colectomy, partial; with skin level cecostomy or colostomy	J1	5341	J1	5341
44143	Colectomy, partial; with end colostomy and closure of distal segment (hartmann type procedure)	J1	5341	J1	5341
44144	Colectomy, partial; with resection, with colostomy or ileostomy and creation of mucofistula	J1	5341	J1	5341
44145	Colectomy, partial; with coloproctostomy (low pelvic anastomosis)	J1	5341	J1	5341
44146	Colectomy, partial; with coloproctostomy (low pelvic anastomosis), with colostomy	J1	5341	J1	5341
44147	Colectomy, partial; abdominal and transanal approach	J1	5341	J1	5342
44150	Colectomy, total, abdominal, without proctectomy; with ileostomy or ileoproctostomy	J1	5341	J1	5342
44151	Colectomy, total, abdominal, without proctectomy; with continent ileostomy	J1	5341	J1	5342
44155	Colectomy, total, abdominal, with proctectomy; with ileostomy	J1	5341	J1	5342
44156	Colectomy, total, abdominal, with proctectomy; with continent ileostomy	J1	5341	J1	5342
44157	Colectomy, total, abdominal, with proctectomy; with ileoanal anastomosis, includes loop ileostomy, and rectal mucosectomy, when performed	J1	5341	J1	5342
44158	Colectomy, total, abdominal, with proctectomy; with ileoanal anastomosis, creation of ileal reservoir (s or j), includes loop ileostomy, and rectal mucosectomy, when performed	J1	5341	J1	5342
44160	Colectomy, partial, with removal of terminal ileum with ileocolostomy	J1	5341	J1	5341
44204	Laparoscopy, surgical; colectomy, partial, with anastomosis	J1	5361	J1	5361
44205	Laparoscopy, surgical; colectomy, partial, with removal of terminal ileum with ileocolostomy	J1	5361	J1	5361
44206	Laparoscopy, surgical; colectomy, partial, with end colostomy and closure of distal segment (hartmann type procedure)	J1	5361	J1	5361

CPT Code	Long Descriptor	CY 2027 Proposed SI	CY 2027 Proposed APC	CY 2027 Final SI	CY 2027 Final APC
44207	Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis)	J1	5361	J1	5361
44210	Laparoscopy, surgical; colectomy, total, abdominal, without proctectomy, with ileostomy or ileoproctostomy	J1	5361	J1	5362
44211	Laparoscopy, surgical; colectomy, total, abdominal, with proctectomy, with ileoanal anastomosis, creation of ileal reservoir (s or j), with loop ileostomy, includes rectal mucosectomy, when performed	J1	5361	J1	5362
44212	Laparoscopy, surgical; colectomy, total, abdominal, with proctectomy, with ileostomy	J1	5361	J1	5362
44316	Continent ileostomy (kock procedure) (separate procedure)	J1	5341	J1	5341
44625	Closure of enterostomy, large or small intestine; with resection and anastomosis other than colorectal	J1	5341	J1	5341
44626	Closure of enterostomy, large or small intestine; with resection and colorectal anastomosis (eg, closure of hartmann type procedure)	J1	5341	J1	5341
44640	Closure of intestinal cutaneous fistula	J1	5341	J1	5341
44650	Closure of enteroenteric or enterocolic fistula	J1	5341	J1	5341
44660	Closure of enterovesical fistula; without intestinal or bladder resection	J1	5341	J1	5341
44661	Closure of enterovesical fistula; with intestine and/or bladder resection	J1	5341	J1	5342
44800	Excision of meckel's diverticulum (diverticulectomy) or omphalomesenteric duct	J1	5341	J1	5341
45119	Proctectomy, combined abdominoperineal pull-through procedure (eg, colo-anal anastomosis), with creation of colonic reservoir (eg, j-pouch), with diverting enterostomy when performed	J1	5342	J1	5342
45126	Pelvic exenteration for colorectal malignancy, with proctectomy (with or without colostomy), with removal of bladder and ureteral transplantations, and/or hysterectomy, or cervicectomy, with or without removal of tube(s), with or without removal of ovary(s), or any combination thereof	J1	5342	J1	5342
45136	Excision of ileoanal reservoir with ileostomy	J1	5342	J1	5342
45397	Laparoscopy, surgical; proctectomy, combined abdominoperineal pull-through procedure (eg, colo-anal anastomosis), with creation of colonic reservoir (eg, j-pouch), with diverting enterostomy, when performed	J1	5342	J1	5362
45400	Laparoscopy, surgical; proctopexy (for prolapse)	J1	5341	J1	5361
45402	Laparoscopy, surgical; proctopexy (for prolapse), with sigmoid resection	J1	5341	J1	5362
47120	Hepatectomy, resection of liver; partial lobectomy	J1	5341	J1	5341
47122	Hepatectomy, resection of liver; trisegmentectomy	J1	5341	J1	5341
47125	Hepatectomy, resection of liver; total left lobectomy	J1	5341	J1	5341

CPT Code	Long Descriptor	CY 2027 Proposed SI	CY 2027 Proposed APC	CY 2027 Final SI	CY 2027 Final APC
47130	Hepatectomy, resection of liver; total right lobectomy	J1	5341	J1	5341
47380	Ablation, open, of 1 or more liver tumor(s); radiofrequency	J1	5341	J1	5342
48140	Pancreatectomy, distal subtotal, with or without splenectomy; without pancreaticojejunostomy	J1	5341	J1	5342
48145	Pancreatectomy, distal subtotal, with or without splenectomy; with pancreaticojejunostomy	J1	5341	J1	5342
48146	Pancreatectomy, distal, near-total with preservation of duodenum (child-type procedure)	J1	5341	J1	5342
48150	Pancreatectomy, proximal subtotal with total duodenectomy, partial gastrectomy, choledochoenterostomy and gastrojejunostomy (whipple-type procedure); with pancreatojejunostomy	J1	5341	J1	5342
48152	Pancreatectomy, proximal subtotal with total duodenectomy, partial gastrectomy, choledochoenterostomy and gastrojejunostomy (whipple-type procedure); without pancreatojejunostomy	J1	5341	J1	5342
48153	Pancreatectomy, proximal subtotal with near-total duodenectomy, choledochoenterostomy and duodenojejunostomy (pylorus-sparing, whipple-type procedure); with pancreatojejunostomy	J1	5341	J1	5342
48154	Pancreatectomy, proximal subtotal with near-total duodenectomy, choledochoenterostomy and duodenojejunostomy (pylorus-sparing, whipple-type procedure); without pancreatojejunostomy	J1	5341	J1	5342
48155	Pancreatectomy, total	J1	5341	J1	5342
49215	Excision of presacral or sacrococcygeal tumor	J1	5073	J1	5073
49596	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated	J1	5342	J1	5342
49616	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated	J1	5342	J1	5342
49617	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible	J1	5342	J1	5342
49618	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total	J1	5342	J1	5342

CPT Code	Long Descriptor	CY 2027 Proposed SI	CY 2027 Proposed APC	CY 2027 Final SI	CY 2027 Final APC
	length of defect(s); greater than 10 cm, incarcerated or strangulated				
49621	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including implantation of mesh or other prosthesis, when performed; reducible	J1	5342	J1	5342
49622	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including implantation of mesh or other prosthesis, when performed; incarcerated or strangulated	J1	5342	J1	5342
57305	Closure of rectovaginal fistula; abdominal approach	J1	5414	J1	5414
57308	Closure of rectovaginal fistula; transperineal approach, with perineal body reconstruction, with or without levator plication	J1	5414	J1	5415
58943	Oophorectomy, partial or total, unilateral or bilateral; for ovarian, tubal or primary peritoneal malignancy, with para-aortic and pelvic lymph node biopsies, peritoneal washings, peritoneal biopsies, diaphragmatic assessments, with or without salpingectomy(s), with or without omentectomy	J1	5415	J1	5416
58950	Resection (initial) of ovarian, tubal or primary peritoneal malignancy with bilateral salpingo-oophorectomy and omentectomy;	J1	5415	J1	5416
58951	Resection (initial) of ovarian, tubal or primary peritoneal malignancy with bilateral salpingo-oophorectomy and omentectomy; with total abdominal hysterectomy, pelvic and limited para-aortic lymphadenectomy	J1	5415	J1	5416
58952	Resection (initial) of ovarian, tubal or primary peritoneal malignancy with bilateral salpingo-oophorectomy and omentectomy; with radical dissection for debulking (ie, radical excision or destruction, intra-abdominal or retroperitoneal tumors)	J1	5415	J1	5416
58953	Bilateral salpingo-oophorectomy with omentectomy, total abdominal hysterectomy and radical dissection for debulking;	J1	5415	J1	5416
58954	Bilateral salpingo-oophorectomy with omentectomy, total abdominal hysterectomy and radical dissection for debulking; with pelvic lymphadenectomy and limited para-aortic lymphadenectomy	J1	5415	J1	5416
58956	Bilateral salpingo-oophorectomy with total omentectomy, total abdominal hysterectomy for malignancy	J1	5415	J1	5416
58958	Resection (tumor debulking) of recurrent ovarian, tubal, primary peritoneal, uterine malignancy (intra-abdominal, retroperitoneal tumors), with omentectomy, if performed, with pelvic lymphadenectomy and limited para-aortic lymphadenectomy	J1	5415	J1	5416

X. Nonrecurring Policy Changes

A. Method To Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)

1. Background

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015), we adopted a method to control unnecessary increases in the volume of clinic visit services furnished in excepted off-campus provider-based departments (PBDs). We refer readers to the CY 2019 OPPS/ASC final rule with comment period for a detailed discussion of the background, legislative provisions, and payment policies we developed to address unnecessary increases in the volume of covered outpatient department (OPD) services. Later in this section of the preamble we discuss the policy we finalized in the CY 2019 OPPS/ASC final rule with comment period and its expanded application under the OPPS in subsequent years.

In the CY 2019 OPPS/ASC final rule with comment period, we finalized a policy to use our authority under section 1833(t)(2)(F) of the Act to adopt a method to control unnecessary increases in the volume of covered OPD services. We applied an amount equal to the site-specific Medicare Physician Fee Schedule (PFS) payment rate for non-excepted items and services furnished by a non-excepted off-campus PBD (the PFS 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 (departments that bill the modifier ''PO'' on claim lines). However, we phased in the application of the reduction in payment for the clinic visit service described by HCPCS code G0463 in the excepted provider-based department setting over 2 years. For CY 2019, the payment reduction was phased-in by applying 50 percent of the total reduction in payment that would have applied if these departments were paid the site-specific PFS rate for the clinic visit service. The PFS-equivalent rate was 40 percent of the OPPS payment for CY 2019 (that is, 60 percent less than the OPPS rate). We provided for a 2-year phase-in of this policy under which one-half of the total 60 percent payment reduction (a 30 percent reduction) was applied in CY 2019. These departments were paid approximately 70 percent of the OPPS rate (100 percent of the OPPS rate minus the 30 percent payment reduction that was applied in CY 2019) for the clinic visit service in CY 2019.

For CY 2020, the second year of the 2-year phase-in, we stated that we would apply the total reduction in payment that is applied if these departments (departments that bill the modifier ''PO'' on claim lines) are paid the site-specific PFS rate for the clinic visit service described by HCPCS code G0463. For CY 2020 and subsequent years, the PFS-equivalent rate was 40 percent of the proposed OPPS payment (that is, 60 percent less than the OPPS rate).

In addition, as we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013), we implemented this policy in a non-budget neutral manner. We did so to ensure that our method for controlling the unnecessary growth in the volume of clinic visits furnished by excepted off-campus PBDs did not simply increase other unnecessary expenditures within the OPPS, thus driving different utilization-distorting decisions.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71748), we finalized a policy which provided that off-campus 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 2024 and subsequent years, we continued to exempt excepted off-campus PBDs of rural SCHs from the clinic visit payment policy.

In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53448), we finalized a policy to use our authority under section 1833(t)(2)(F) of the Act to adopt a method to control unnecessary increases in the volume of covered OPD services for additional services. We finalized a policy for CY 2026 and subsequent years to apply an amount equal to the site-specific PFS payment rate for non-excepted items and services furnished by a non-excepted off-campus PBD (the PFS-equivalent payment rate) for any HCPCS codes assigned to the drug administration services APCs, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier ''PO'' on claim lines) (90 FR 53821). In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53824), we also finalized a policy which provided that off-campus PBDs (departments that bill the modifier ''PO'' on claim lines) of rural SCHs, as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, are exempt from the volume control method policy for drug administration services that applies a PFS-equivalent payment rate for the drug administration services APCs (5691–5694), when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For the full discussion of both policies, we refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 53802 through 53824).

We noted in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53810 through 53812) that section 1833(t)(2)(F) of the Act provides authority to implement this policy. The U.S. Court of Appeals for the District of Columbia Circuit held in *American Hospital Ass'n* v. *Azar* (*AHA* v. *Azar*) that a service-specific, non-budget-neutral reduction of the reimbursement rate for OPD services ''qualifies as a 'method for controlling unnecessary increases in the volume of covered [outpatient] services'' under that provision. 964 F.3d 1230, 1245 (D.C. Cir. 2020) (quoting section 1833(t)(2)(F) of the Act, 42 U.S.C. 1395l(t)(2)(F)) (brackets in original), *cert. denied sub nom. Am. Hosp. Ass'n* v. *Becerra,* 141 S. Ct. 2853 (2021) (No. 20–1113). The D.C. Circuit reasoned in part that ''[t]he lower the reimbursement rate for a service, the less the incentive to provide it, all else being equal[,]'' and ''[r]educing the reimbursement rate . . . is naturally suited to addressing unnecessary increases in the overall volume of a service provided by hospitals.'' *Id.* at 1241. It ultimately concluded that the policy ''falls comfortably within the plain text'' of section 1833(t)(2)(F) of the Act, *id.* at 1241, ''and 'fits the design of the statute as a whole . . . and its object and policy,'' *id.* at 1245 (quoting *Good Samaritan Hosp.* v. *Shalala,* 508 U.S. 402, 418 (1993)). We noted in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53810) that we continue to believe that our interpretation of the Act is the best one, and that this policy falls well within the Act's delegation to the Secretary to ''develop a method for controlling unnecessary increases in the volume of covered OPD services.''

2. Expanding the Method To Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments

As described in the CY 2019 OPPS/ASC final rule with comment period, we found that earlier rulemaking efforts were insufficient to control the unnecessary growth of certain covered OPD services and as a result we implemented a method to control for unnecessary growth in covered OPD services by adjusting the payment rate for clinic visits in excepted off-campus PBDs to the PFS-equivalent rate rather than the higher OPPS rate. While this regulatory change has had a positive impact, we noted in the CY 2026 OPPS/ASC proposed rule that there is evidence of continued unnecessary growth in the volume of OPD services driven by site-of-service payment differentials rather than clinical need for other service families.

We continue to be concerned that beneficiaries are being driven into higher-cost settings of care because of financial incentives when they could safely receive care in a lower-cost setting. This creates greater financial burden both for Medicare and for beneficiaries in the form of increased coinsurance. Volume increases that seek to take advantage of financial incentives created by payment policy rather than clinical need are unnecessary and therefore warrant policy changes to address these increases. As the D.C. Circuit explained, ''[i]t is reasonable to think that Congress . . . would have wanted the agency to avoid causing unnecessary volume growth with its own reimbursement practices.'' *AHA* v. *Azar,* 964 F.3d at 1245. Accordingly, for CY 2026, we finalized a policy to remove this differential for drug administration services delivered in excepted PBDs. We are continuing to study and identify services that we believe have experienced unnecessary growth in volume driven by site-of-service payment differentials rather than clinical need.

In the CY 2026 OPPS/ASC proposed and final rules, we indicated we are particularly concerned about the services within the imaging without contrast APCs (APCs 5521–5524). Imaging without contrast services are often high-volume, low-intensity services that can be provided in OPDs or freestanding offices. In the CY 2026 OPPS/ASC proposed rule, we stated that we are concerned that these services have experienced unnecessary growth and that a volume control method may be appropriate to apply in the future (90 FR 33690). Additionally, we solicited comments on whether it might be appropriate to apply a volume control method to the imaging without contrast APCs in the future.

Many healthcare services can be performed in multiple settings. Even when there is little variation in the service provided across settings, the Federal Supplementary Medical Insurance Trust Fund and Medicare beneficiaries typically pay more when that service is performed in an OPD than when the same service is performed in a freestanding physician office. That payment differential creates an incentive for providers to shift the care of beneficiaries to an OPD rather than a freestanding physician office or ASC, even if the services can be safely performed in the freestanding physician office or an ASC. Generally, 20 percent of any increased payment is the responsibility of the beneficiary in the form of coinsurance. Taking into account that any payment differential occurs across millions of claims for a variety of services each year, this threatens to create a significant source of unnecessary spending both by Medicare beneficiaries in the form of unnecessarily high copayments and by Medicare in the form of unnecessarily high Medicare payments for services that are being performed in an OPD because of the site-of-care payment difference.

In the CY 2019 OPPS/ASC final rule with comment period, we discussed vertical consolidation and the practice of hospitals purchasing freestanding physician practices and converting the billing from the PFS to higher paying OPD visits. These conversions shift market share from freestanding physician offices to OPDs. We stated that we believed there was a correlation among the increasing volume of OPD clinic visits, vertical integration, and the higher OPPS payment rates for clinic visits. More favorable reimbursement for hospital-owned sites compared to physician-owned sites has been shown to encourage hospitals' acquisition of physician practices.[145] [146] Once a practice is acquired and designated as an OPD, physician services can be billed at higher hospital-based rates. This type of consolidation has been associated with higher Medicare spending and more intense treatment patterns.[147] [148] [149]

The impact of vertical integration and the increases in volume of outpatient services extends to multiple clinic families. Studies have shown that, after vertical integration, the number of imaging tests performed in hospital sites of care increased while the number of procedures performed in nonhospital sites of care decreased.[150]

Our policy in the CY 2019 OPPS/ASC final rule with comment period to pay for clinic visits in excepted off-campus PBDs at the PFS-equivalent rate addressed the financial incentive for only one type of service in one outpatient setting. However, the share of other ambulatory services billed under the OPPS has continued to increase. We built upon this policy in the CY 2026 OPPS/ASC proposed rule to address the unnecessary growth in drug administration services. Like with clinic visit and drug administration services, we believe the difference in payment between OPDs and freestanding offices creates a strong incentive for providers to shift imaging without contrast services to the higher-cost setting.

For the CY 2027 proposed rule, we examined the growth in imaging without contrast services provided in excepted PBDs. Imaging without contrast services are diagnostic imaging procedures that do not require the administration of contrast agents and instead rely on standard imaging modalities such as X-ray, ultrasound, computed tomography (CT), magnetic resonance imaging (MRI), and dual-energy X-ray absorptiometry scans (DXA) to produce clinically meaningful images. These services are generally low- to moderate-complexity and are routinely used to evaluate a wide range of conditions, including musculoskeletal injuries, organ structure, and disease screening. Imaging without contrast services can be safely and effectively furnished in multiple settings, including freestanding physician offices and hospital OPDs, without compromising diagnostic quality or patient safety.

For example, in 2023, for transthoracic echocardiograms (HCPCS 93306), a high-volume imaging without contrast service frequently provided in both OPDs and freestanding physician offices, Medicare paid 294 percent more for services in an OPD than in a

[145] *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0830.*

[146] *https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.13613.*

[147] *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2463591.*

[148] *https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01183.*

[149] *https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.14172.*

[150] *https://pmc.ncbi.nlm.nih.gov/articles/PMC9924392/.*

freestanding office.[151] HCPCS code 77080, which describes a DXA scan measuring bone density at the axial skeleton (hips, pelvis, spine), is the most frequently billed imaging without contrast code in excepted PBDs. In 2025, this service had a freestanding physician office payment rate of around $30 and an OPPS payment rate of approximately $106, making the same scan more than three times as expensive in the OPD than in the freestanding physician office. Based on our claims data analysis, the volume of this service has grown by over 55 percent in excepted PBDs between 2016 and 2025. Conversely, from 2016 through 2024, the volume of HCPCS code 77080 has only grown by 2 percent in the freestanding physician office setting. This service can be and routinely is safely performed in either setting, but there is a clear financial incentive to perform this service in excepted PBDs due to substantially higher payment in the outpatient setting compared to the freestanding physician office setting.

For the CY 2027 OPPS/ASC proposed rule, we estimated that 70 HCPCS codes account for over 95 percent of the volume of imaging without contrast services provided in excepted PBDs (91 FR 41909). These codes comprise the overwhelming majority of imaging without contrast services provided in excepted PBDs. From 2016 to 2025, the provision of these services grew over 38 percent. From 2016 to 2025, these increases in volume have resulted in a 33 percent increase in spending, corresponding to approximately $126 million in additional spending in CY 2025. We believe this growth in the volume of imaging without contrast services in excepted PBDs can largely be attributed to the financial incentive to furnish low-complexity imaging services in OPDs rather than freestanding physician offices.

We considered whether other factors, such as coding changes, updates to clinical practice guidelines, or shifts in beneficiary case mix, might explain this growth. However, we believe these alternative explanations are unlikely to account for the observed patterns. Our analysis focuses on a stable set of high-volume HCPCS codes that consistently represent the vast majority of imaging without contrast services over time, limiting the likelihood that coding changes are driving the increase. In addition, we are not aware of any broad changes in clinical guidelines during this period that would warrant substantial increases in the use of routine, low- to moderate-complexity imaging services across these modalities. Finally, although there may be some variation in beneficiary characteristics over time, the magnitude of the growth in utilization, particularly when considered alongside declining fee-for-service enrollment and relatively stable or modest volume growth in freestanding physician offices, suggests that changes in case mix are not the primary driver of growth in excepted PBDs. Taken together, these considerations support the conclusion that site-of-service payment differentials, rather than clinical or coding factors, are a principal contributor to the observed increases in volume.

We stated in the CY 2026 OPPS/ASC proposed rule that we believe that financial incentives have driven volume from the freestanding office setting to the higher paying OPD setting, creating unnecessary increases in the volume of OPD services. We also stated that we believe that this problem is pervasive and exists across a number of service families. Section 1833(t)(2)(F) of the Act directs the Secretary to ''develop a method for controlling unnecessary increases in the volume of covered OPD services,'' and CMS has previously interpreted this provision to permit payment adjustments that address financial incentives contributing to such increases. Consistent with this authority, CMS may implement a volume control method for imaging without contrast services furnished in excepted off-campus PBDs, where evidence demonstrates increases in utilization and that increase is disproportionately concentrated in higher-paid hospital outpatient settings. Because these services are commonly furnished in physician offices and do not generally require hospital-level resources, higher OPPS payment rates may incentivize shifts in site of care and increased utilization that are not clinically driven. As CMS established in the CY 2019 OPPS/ASC final rule with comment period and reaffirmed in subsequent rulemaking, including the CY 2026 OPPS/ASC final rule with comment period, and as the D.C. Circuit held in *AHA* v. *Azar,* 964 F.3d 1230 (D.C. Cir. 2020), aligning payment rates across settings for clinically comparable services is an appropriate ''method'' to mitigate these incentives. Accordingly, applying a PFS-equivalent payment rate to imaging without contrast services in excepted PBDs represents a reasonable approach to controlling unnecessary increases in OPD service volume.

Any time a service is provided in the higher cost OPD when it could be provided safely in the freestanding physician office but is not because of financial incentives, it potentially represents unnecessary utilization of the OPD setting. In CY 2019, we started by addressing a pervasive problem with the clinic visit provided in excepted PBDs. In that case, it was practical to address only a single code, G0463, the clinic visit. For CY 2026, we finalized a policy to address drug administration services provided at excepted PBDs. We chose to address payment for these services across the APC family, meaning all codes assigned to these APCs, as we believe this volume control method should apply to all drug administration services at excepted PBDs. For CY 2027, we again proposed addressing services across an APC family.

Our authority under section 1833(t)(2)(F) of the Act to adopt a method to control unnecessary increases in the volume of covered OPD services authorizes us to address real-world effects of these payment inequalities. Given these continued disparities, we stated we believed it was necessary to further examine and refine our volume control method by identifying additional covered OPD services that we believe are being shifted to the hospital setting based on financial incentives rather than medical necessity. We conducted an analysis of imaging without contrast services paid under the OPPS and present our findings from the CY 2027 OPPS/ASC proposed rule on the utilization and payment of these services in the sections discussed later in this section of the preamble.

3. Utilization of Imaging Without Contrast Services

The high volume of imaging without contrast services and the magnitude of rate differences between the freestanding physician office and OPD settings make it a family of services likely to migrate to a higher paying setting of care. Imaging without contrast services can be performed in either freestanding physician offices or OPDs. In the OPPS, imaging without contrast services are categorized into four levels of complexity. Payments are set at a category level, called an Ambulatory Payment Classification (APC). The APCs for imaging without contrast service are 5521 (Level 1 Imaging Without Contrast), 5522 (Level 2 Imaging Without Contrast), 5523 (Level 3 Imaging Without Contrast), and 5524 (Level 4 Imaging Without Contrast). For 2026, 337 Healthcare Common Procedure Coding System (HCPCS) codes make up the four levels of the

[151] *https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf.*

imaging without contrast APCs. Although there are 337 HCPCS codes in the four imaging without contrast APCs, we estimated that 70 HCPCS codes account for over 95 percent of the volume of imaging without contrast services provided in excepted PBDs. This trend extends to non-excepted PBDs, where 70 HCPCS codes also make up over 95 percent of claims volume. There is an approximate 90 percent overlap of the top 70 most frequently billed imaging without contrast codes in excepted and non-excepted PBDs. HCPCS codes that are similar in terms of cost and clinical attributes are placed in the same APC. All HCPCS codes in the same APC have the same OPPS payment rate. The individual HCPCS and APC assignments are available in Addendum B to this final rule with comment period.

We evaluated the growth in volume and spending for multiple families of APCs in OPDs across multiple years of claims data. If commenters wished to replicate any of our analyses, the CMS website included information about obtaining the ''Limited Data Set,'' *https://www.cms.gov/data-research/files-for-order/data-disclosures-and-data-use-agreements-duas/limited-data-set-lds* through which OPPS claims data are available for purchase. Additionally, we made publicly available a file containing the 70 HCPCS codes that we estimated account for more than 95 percent of the volume of imaging without contrast services provided in excepted PBDs.

The PO modifier was established to identify services furnished in off-campus PBDs and became mandatory following implementation of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74). CMS finalized this requirement in the CY 2016 OPPS/ASC final rule with comment period, requiring hospitals to report the PO modifier for services provided in excepted off-campus PBDs beginning January 1, 2016. We subsequently established the PN modifier to identify services furnished in non-excepted off-campus PBDs, which are paid under the PFS-equivalent rate rather than the full OPPS rate. Hospitals were required to begin reporting the PN modifier starting January 1, 2017. The mandatory use of the PO and PN modifiers has enabled CMS, MedPAC, and the hospital industry to track utilization patterns.

We found that there has been an increase in the volume of services paid through the imaging without contrast APCs (5521–5524) over time, which indicates that there has been migration of these services to the OPD setting. From 2016 to 2025, the volume of the 70 HCPCS codes which account for over 95 percent of imaging without contrast services provided in excepted PBDs grew over 38 percent. From 2016 to 2025, these increases in volume have resulted in a 33 percent increase in spending, corresponding to approximately $126 million in additional spending in CY 2025. This growth persisted even with the introduction of the PFS-equivalent rate for PBDs subject to section 603 of the Bipartisan Budget Act of 2015 starting in 2017. The COVID–19 Public Health Emergency (PHE) did impact utilization across the OPPS, but we have seen the volume of imaging without contrast services rebound and return to this pattern of unnecessary volume growth. Between 2016 and 2025, we have seen increases in the volume of imaging without contrast services provided in OPDs utilized per beneficiary.[152] Between 2016 and 2025, for the top 70 most frequently billed imaging without contrast HCPCS codes provided in excepted PBDs, there has been an over 67 percent increase in utilization per beneficiary. This upward trend persists despite a declining Part B FFS population. During this same time, for example, FFS enrollment decreased by approximately 17 percent, indicating that imaging services are being used more frequently on a per-beneficiary basis rather than growth being driven by enrollment.

In addition to looking at the growth in volume and spending at the APC level for imaging without contrast services provided at excepted PBDs, we also examined the growth in volume at the HCPCS code level. Analysis of HCPCS-level utilization trends from 2016 through 2025 indicates that several imaging without contrast services experienced particularly pronounced growth in volume, with increases far exceeding overall Medicare enrollment growth. Several codes experienced growth in the excepted PBDs that outpaced growth in the freestanding physician office setting.

HCPCS code 77080, which describes a DXA scan measuring bone density at the axial skeleton (hips, pelvis, spine), is the most frequently billed imaging without contrast code in excepted PBDs. In 2025, this service had a freestanding physician office payment rate of around $30 and an OPPS payment rate of approximately $106, making the same scan more than three times as expensive in the OPD compared to the freestanding physician office. Based on our claims data analysis, the volume of this service has grown by over 55 percent in excepted PBDs between 2016 and 2025. In contrast, from 2016 to 2025, utilization of this code in the freestanding physician office setting declined modestly, by less than half a percent. HCPCS code 71045, which describes a simple chest x-ray, was created in 2018 as part of the 2018 CPT/HCPCS code restructuring for chest radiography. In 2025, this service had a physician office payment rate of around $17 and an OPPS payment rate of approximately $88, making the same scan 417 percent more expensive in the OPD than in the freestanding physician office. Based on our claims data analysis, the volume of this service has grown by over 92 percent in excepted PBDs between 2018 and 2025. From 2018 to 2025, this code decreased in volume by 33 percent in the freestanding physician office setting.

The volume for HCPCS 71250, which describes a CT scan of the chest performed without contrast dye, increased roughly 72 percent in the excepted PBD setting between 2016 and 2025. In contrast, the freestanding physician office setting experienced a comparatively modest increase of 33 percent over the same time period. In 2025, this service has a freestanding physician office payment rate of around $83 and an OPPS payment rate of approximately $106, making the same CT scan 27 percent more expensive in the OPD than in the freestanding physician office.

Similarly, HCPCS 70551, which describes an MRI scan of the brain, including the brainstem, performed without contrast material grew by 41 percent between 2016 and 2025 at excepted PBDs. From 2016 to 2025, this code only grew by 14 percent in the freestanding physician office setting. In 2025, this service had a freestanding physician office payment rate of around $127 and an OPPS payment rate of approximately $243, making the same scan 91 percent more expensive in the OPD than in the freestanding physician office.

HCPCS 76536, which describes an ultrasound of the head and neck, had excepted PBD volume increase 48 percent from 2016 to 2025. The same code only experienced a 4 percent increase in volume in the freestanding physician office setting during the same time period. In 2025, this service had a physician office payment rate of around $82 and an OPPS payment rate of approximately $106, making the same scan 29 percent more expensive in the OPD than in the freestanding physician office.

[152] Based on our analysis of claims data and Medicare FFS enrollment.

Breast imaging services also demonstrated substantial increases, with the volume of ultrasound breast complete (HCPCS 76641) increasing 52 percent in the excepted PBD setting from 2016 to 2025. From 2016 to 2025, this code decreased in volume by 25 percent in the freestanding physician office setting. In 2025, this service had a freestanding physician office payment rate of around $66 and an OPPS payment rate of approximately $106, making the same scan 60 percent more expensive in the OPD than in the freestanding physician office.

These services are generally low- to moderate-complexity imaging procedures that can be safely performed in multiple settings, and their growth in volume in excepted PBDs suggests increased utilization intensity beyond what would be expected based solely on growth in the Medicare population. We stated in the proposed rule that we believed that the financial incentives created by payment policy rather than clinical need are a significant factor in shifting these services to OPDs. If there was not a material difference in payment rates, we stated we believed fewer of these services would have shifted to OPDs and the corresponding increase in Medicare payments and beneficiary cost-sharing would not have occurred (91 FR 41911).

We also examined trends across excepted and non-excepted PBDs, alongside the freestanding physician office setting. There are approximately four times as many providers billing with the PN modifier (non-excepted PBDs) as compared to the PO modifier (excepted PBDs) (91 FR 41911). This substantial difference suggests that non-excepted PBD services are distributed across a much broader provider base, while volume in excepted PBDs remains concentrated among a smaller group of providers.

Excepted PBDs continue to account for the overwhelming share of imaging without contrast volume, even as non-excepted PBDs have grown steadily in recent years. Across the highest-volume services, the gap remains substantial: in 2025, excepted PBDs furnished roughly 4 to 5 times the volume of non-excepted PBDs for key services, accounting for about 75–82 percent of total combined PBD volume. For example, excepted PBDs represent approximately 81 percent of volume for HCPCS 77080 (DXA bone density scan), 79 percent for HCPCS 71046 (chest x-ray, 2 views), 79 percent for HCPCS 93306 (complete transthoracic echocardiography), and 83 percent for HCPCS 71250 (CT thorax without contrast). In the freestanding physician office setting, in comparison, these same services show relatively stable or modest growth over time rather than rapid expansion. Importantly, these are routine imaging services that rely on widely available equipment and standardized protocols and they are clinically comparable regardless of setting, meaning they can be safely and effectively performed in freestanding physician offices, non-excepted PBDs, or excepted PBDs without meaningful differences in patient acuity or quality.

For example, in its 2023 report, MedPAC examined APCs where such potentially unnecessary payment differentials exist.[153] To identify appropriate APCs, MedPAC compared the volume of services in each APC that was provided in OPDs, ASCs, and freestanding offices over the period of 2016 through 2021, but omitted 2020 because the COVID–19 PHE affected the volume of care in ambulatory settings. If freestanding offices had the highest volume for an APC, MedPAC concluded that the services in that APC could be provided safely in freestanding offices for most beneficiaries and that beneficiaries would be able to access the services in that APC. Therefore, for those services, it would be reasonable to align the OPPS payment rates with the PFS payment rates. MedPAC found that all four of the imaging without contrast APCs had higher volume in freestanding facilities than in OPDs, indicating that these services can be safely provided to beneficiaries in a lower cost setting of care.

We stated we believed MedPAC's analysis aligns well with the rationale CMS adopted in the CY 2019 OPPS/ASC final rule with comment period: we consider OPPS utilization potentially unnecessary if the beneficiary can safely receive the same services in a lower-cost setting but instead receives care in the hospital outpatient setting because of site-of-service payment differentials.

In our review of the utilization of imaging without contrast services in excepted PBDs, we found increases in the volume of services over time, increases in the volume of services provided per beneficiary, and significant volume growth for some individual HCPCS codes within the imaging without contrast APC family. We believed that these changes represent unnecessary increases in the volume of covered OPD imaging without contrast services and, therefore, we proposed to apply our volume control method to these services under section 1833(t)(2)(F) of the Act.

[153] *www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf.*

4. Payment for Imaging Without Contrast Services at PBDs

As discussed in the CY 2017 OPPS/ASC interim final rule with comment period (81 FR 79726), we established a Medicare PFS relativity adjuster that is applied to the OPPS rate for the billed non-excepted items and services furnished in a non-excepted off-campus PBD to calculate payment rates under the PFS. The PFS relativity adjuster reflects the estimated overall difference between the payment that would otherwise be made to a hospital under the OPPS for the non-excepted items and services furnished in non-excepted off-campus PBDs and the resource-based payment under the PFS for the technical aspect of those services with reference to the difference between the facility and nonfacility (office) rates and policies under the PFS. The PFS relativity adjuster, as discussed in the CY 2018 PFS final rule, is set at 40 percent of the amount that would have been paid under the OPPS (82 FR 53028). Non-excepted PBDs are required to use the modifier ''PN'' so that the PFS relativity adjuster is applied to the payment of their claim. Excepted PBDs use the modifier ''PO'' on their claims to indicate that the service was provided at an excepted off-campus PBD and that payment should generally be made at the OPPS rate.

In the CY 2019 OPPS/ASC final rule with comment period, we stated that we consider the shift of services from the freestanding physician office to the hospital OPD unnecessary if the beneficiary can safely receive the same services in a lower-cost setting but is instead receiving services in the higher paid setting (83 FR 59006). To better understand the migration of services to off-campus OPDs, we analyzed claims data for imaging without contrast services to assess whether increases in volume and spending could be driven by payment incentives. We examined the top 70 most frequently billed HCPCS codes in the imaging without contrast APC family at both excepted and non-excepted off-campus PBDs. These 70 HCPCS codes account for over 95 percent of the volume of imaging without contrast services in off-campus PBDs. We found that over 90 percent of these codes in the imaging without contrast APCs were in the top 70 most frequently billed codes at both excepted and non-excepted off-campus PBDs with slight variations in the order based on volume. We therefore concluded that the majority of HCPCS codes in the imaging without contrast APCs were being billed with both the ''PO'' and ''PN'' modifiers, indicating that these

imaging without contrast services were safely being provided in both excepted and non-excepted PBDs.

We also compared OPPS and PFS payment rates by using PFS payment rates for the most frequently billed imaging without contrast HCPCS codes by excepted PBDs (departments that bill the modifier ''PO'' on claim lines) and volume-weighing them to create a PFS proxy average APC payment rate for all imaging without contrast services. Using this approach, we found that, on average, OPPS payment rates for excepted off-campus PBDs are approximately 2.5 times higher than PFS rates, while non-excepted PBD rates are closely aligned with the PFS. At the APC level, PFS payments range from about 31 percent to 54 percent of OPPS payments, confirming a substantial and consistent payment differential. A similar pattern is observed for beneficiary cost-sharing, where average cost-sharing in excepted PBDs is more than double that in freestanding physician offices, while cost-sharing for services provided in non-excepted PBDs is closely aligned with cost-sharing in freestanding physician offices.

We stated that we believed that the differential in our payment rates created a payment incentive that led to unnecessary growth for the services in the imaging without contrast APCs. We consider the shift of services from the physician office to the hospital OPD unnecessary if the beneficiary can safely receive the same services in a lower-cost setting but is instead receiving services in the higher paid setting due to payment incentives. We believed the OPPS payment rate for the imaging without contrast APCs being several times greater than the PFS rate created such a payment incentive and that the growth in imaging without contrast services at excepted PBDs was therefore unnecessary.

We did not believe that the imaging payment limitation established under section 5102 of the Deficit Reduction Act (DRA) of 2005 (Pub. L. 109–171), codified at section 1848 of the Act, constrained our ability to implement a volume control method for imaging without contrast services furnished in excepted off-campus PBDs. The DRA provision applies specifically to services paid under the PFS and limits payment to the lesser of the PFS or OPPS amount, but it does not directly affect payment for services furnished in PBDs. The DRA functions as a ceiling on PFS payments, ensuring they do not exceed OPPS rates, while the PFS relativity adjuster is used to scale payments appropriately when applied in the PBD setting. As a result, using PFS-equivalent rates for imaging without contrast services in excepted PBDs aligns excepted PBD payment rates under the OPPS with payment rates for these services under the PFS and therefore would not conflict with the DRA.

5. Patient Severity and Cost of Care

In comments to the CY 2019 OPPS/ASC proposed rule and subsequent rulemaking, we heard from commenters that the higher payments for services in hospital outpatient settings are justified by the level of care patients need, the higher costs of providing care in hospitals, and the costs of maintaining emergency care and standby capacity. We recognize that OPDs serve unique patient populations and provide services to medically complex beneficiaries; however, we believed that there was no evidence to demonstrate the need for higher payment for services provided in OPDs that could also be provided in lower-cost settings. This was particularly relevant for imaging without contrast services, which are generally low- to moderate-complexity diagnostic procedures, such as standard CT, MRI, ultrasound, radiography, and bone density testing, that do not require the administration of contrast agents or the associated monitoring and infrastructure. These services can be safely and effectively furnished in multiple settings, including freestanding physician offices, without compromising quality or patient safety.

In general, despite marked differences in payment rates for a range of services, identical services are being delivered to very similar patients across physicians' offices, hospital OPDs, and ASCs.[154] [155] Moreover, a 2023 literature review found no peer-reviewed evidence that shows differences in the quality of services delivered across hospital OPDs and freestanding physicians' offices.[156] In their 2023 report, MedPAC evaluated risk scores from the CMS hierarchical condition category (CMS–HCC) risk-adjustment model to compare the medical complexity of OPD patients with patients in freestanding offices. They found that, on average, OPD patients have higher risk scores, which suggests that OPD patients are potentially more medically complex than those in physician offices. However, they also found substantial overlap in the CMS–HCC risk scores of patients in these two settings, which suggests that the difference in patient severity between settings is small. Their analysis showed that the effects of patient severity on cost of care for the aligned services is not statistically significant as the services, like imaging without contrast services, are generally of low complexity. In addition, if there is a need to bill for more complex cases, under the OPPS, providers can often bill separately for additional services that a patient might need such as prolonged observation, emergency medications, or additional diagnostic testing furnished in response to a complication or change in the patient's condition during the outpatient encounter. Accordingly, we continued to believe that higher OPPS payment rates for imaging without contrast services were not justified by differences in patient complexity or resource needs and may instead contribute to unnecessary increases in utilization in higher-cost settings.

6. Impact of Unnecessary Increases in Volume on the OPPS

Our concern with unnecessary increases in the volume of imaging without contrast services was tied to the health and sustainability of the OPPS. As described in Table 80 in the CY 2019 OPPS/ASC final rule with comment period, we found that the mean and median annual increases in the volume and intensity of hospital outpatient services were about 5.5 percent and 5.4 percent, respectively, from 2011 to 2019. Over that period, the estimated increase in aggregate annual hospital incurred payments through Medicare FFS Part B was $28.2 billion.[157]

More recent data indicated that this trend has persisted and accelerated. As shown in Table 80, from 2019 through 2027, hospital outpatient costs per FFS enrollee are projected to grow at a mean annual rate of approximately 7.7 percent and a median annual rate of 9.2 percent.[158] After a temporary decline in 2020, annual growth rebounded sharply to 19.7 percent in 2021. From 2022 through 2027, the projected year-over-year annual growth rates are expected to range from 4.7 percent to 9.5 percent annually. As seen in Table 81, over this period outpatient hospital spending per FFS enrollee is projected to increase from $1,738 in 2019 to $3,238 in 2027, an increase of about 86 percent.[159] This translates to an increase of

[154] *https://tobin.yale.edu/sites/default/files/2023-10/Site-Neutral%20Payment%20Literature%20Review%2010302023.pdf.*

[155] *https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf.*

[156] *https://tobin.yale.edu/sites/default/files/2023-10/Site-Neutral%20Payment%20Literature%20Review%2010302023.pdf.*

[157] Available in Table IV.B6. at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2019.pdf.*

[158] *https://www.cms.gov/oact/tr/2025.*

[159] *https://www.cms.gov/oact/tr/2025.*

approximately $35 billion in aggregate annual incurred reimbursements for hospital outpatient services between 2019 and 2027. This level of growth exceeds that observed in other categories of Part B services in dollar terms and occurs despite relatively stable or declining FFS enrollment over much of the period.

When looking at this time period it is important to note that PHE likely contributed significantly to the increase in claims volume in 2021. During the acute phase of the pandemic in 2020, many outpatient services were delayed or deferred as beneficiaries postponed routine care and providers limited non-urgent services. As these restrictions eased in 2021, utilization rebounded sharply as providers worked through substantial backlogs of postponed services and beneficiaries returned for deferred evaluations and treatment. This pent-up demand for outpatient care likely contributed to the pronounced increase in year-over-year outpatient hospital cost growth observed in 2021.

TABLE 80: GROWTH IN HOSPITAL OUTPATIENT COSTS PER FEE-FOR-SERVICE ENROLLEE[160]

Calendar Year	Percent Increase
2019	5.2
2020	-5.8
2021	19.7
2022	4.7
2023	8.4
2024	9.4
2025	9.4
2026 (Estimated)	9.2
2027 (Estimated)	9.5

TABLE 81: OUTPATIENT HOSPITAL SPENDING PER FEE-FOR-SERVICE ENROLLEE[161]

Calendar Year	Outpatient Hospital Spending Per Fee-For-Service Enrollee
2019	$1,738.46
2020	$1,663.57
2021	$2,021.31
2022	$2,072.33
2023	$2,230.61
2024	$2,450.22
2025	$2,700.77
2026 (Estimated)	$2,952.52
2027 (Estimated)	$3,237.60

Taken together, the sustained acceleration in per-enrollee spending and aggregate expenditures suggests that factors beyond underlying beneficiary need, such as increases in service volume and intensity, are contributing to spending growth in the hospital outpatient setting. Continued increases in the volume of imaging without contrast services raise concerns about potentially unnecessary utilization. Such trends have implications for Medicare program expenditures and beneficiary cost-sharing, as well as for the financial sustainability of the OPPS.

As we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59018), there is evidence that increased volume and intensity of certain covered OPD services is likely driven by financial incentives to furnish services in hospitals in order to receive higher reimbursement, rather than making site-of-service decisions based on medical necessity. We continue to be concerned with the rate of increase in program expenditures under the OPPS for several reasons. The OPPS was originally designed to manage Medicare spending growth by replacing a cost-based system with a prospective payment system. Contrary to this Congressional purpose, the OPPS has continued to be one of the fastest growing sectors of Medicare payments out of all payment systems under Medicare Parts A and B.[162] Furthermore, we are concerned that the persisting rate of growth relative to other payment systems suggests that payment incentives, rather than patient acuity or medical necessity, continue to affect site-of-service decision-making. This site-of-service selection has an impact on not only the Medicare program, but also on Medicare beneficiary out-of-pocket spending. Our authority to implement volume control methods is an important tool in combating unnecessary OPPS utilization. We have seen success in stemming unnecessary growth in the

[160] Available in Table IV. B3. at *https://www.cms.gov/oact/tr/2025.*

[161] Available in Table IV. B4. at *https://www.cms.gov/oact/tr/2025.*

[162] *https://www.gpo.gov/fdsys/pkg/FR-2018-11-21/pdf/2018-24243.pdf.*

volume of clinic visits at excepted PBDs. Since 2019, when we began phasing in our volume control method, there has been a 25 percent decrease in the volume of clinic visit services performed in excepted PBDs. Since 2023, the volume of clinic visit services at excepted PBDs has stayed relatively steady. We believed that imaging without contrast services provided at excepted PBDs were in need of similar treatment.

7. Multiple Procedure Discounts

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 86569), we finalized a policy that, effective January 1, 2009, we make 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. 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 82 of this final rule with comment period.

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 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 (non-composite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. As discussed in section XA. of this final rule with comment period, for CY 2027 we proposed to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology.

The multiple imaging composite APC policy reflects the efficiencies that hospitals can achieve when furnishing multiple imaging procedures within the same imaging family during a single session. A similar principle underlies the multiple procedure payment reduction (MPPR) policy for diagnostic imaging services under the PFS. Under the MPPR policy, when multiple diagnostic imaging procedures are furnished to the same patient in the same session, payment for the technical component of the subsequent procedures is reduced to reflect efficiencies associated with the preparation of the patient, positioning, and other clinical and administrative activities that do not need to be repeated for each additional imaging procedure. Both the OPPS multiple imaging composite APC policy and the PFS MPPR policy recognize that furnishing multiple imaging services during the same encounter generally requires fewer resources than furnishing those services separately. Consistent with other services furnished in non-excepted PBDs, when multiple imaging procedures are performed at a non-excepted PBD and paid through one of the multiple imaging composite APCs, providers are required to report modifier ''PN,'' and the PFS relativity adjuster is applied to the composite APC payment.

As discussed later in this section, we proposed to apply our volume control methodology to the imaging without contrast APCs (5521–5524). We believed it was also appropriate to apply the volume control methodology to APCs 8004 (Ultrasound Composite), 8005 (CT and CTA without Contrast Composite), and 8007 (MRI and MRA without Contrast Composite). APCs 8004, 8005, and 8007 are comprised of HCPCS codes assigned to the imaging without contrast APCs that would be subject to the volume control methodology when paid separately. In other words, the underlying imaging without contrast services that qualify a claim for payment under APCs 8004, 8005, and 8007 are the same imaging procedures for which we proposed to apply the volume control methodology under the standard APC payment structure.

Accordingly, excluding APCs 8004, 8005, and 8007 from the volume control methodology would result in different payment treatment for the same underlying imaging procedures based solely on whether those procedures were paid separately or through a multiple imaging composite APC. We do not believe such differential treatment would be appropriate. Moreover, because APCs 8004, 8005, and 8007 are comprised of HCPCS codes assigned to the imaging without contrast APCs that would be subject to the volume control methodology when paid separately, excluding these composite APCs would allow a portion of the same imaging services that contribute to the volume concerns identified previously to be paid outside the volume control methodology when furnished in excepted PBDs. Further, because these composite APCs are already subject to the PFS relativity adjuster when furnished at non-excepted PBDs, excluding them from the volume control methodology in excepted PBDs could create inconsistent payment incentives across settings and undermine the effectiveness of the volume control methodology. Therefore, we proposed to apply the volume control methodology to APCs 8004, 8005, and 8007.

8. Payment for Imaging Without Contrast Services for CY 2027 and Subsequent Years

As we stated in the CY 2019 OPPS/ASC final rule with comment period, we consider the shift of services from the freestanding physician office to the hospital OPD unnecessary if the beneficiary can safely receive the same services in a lower-cost setting but is instead receiving services in the higher paid setting due to payment incentives (83 FR 59006). We believe the increase in the volume of imaging without contrast services is due to the payment incentive that exists to provide this service in the higher-cost setting. Because these services could generally be safely provided in a lower-cost setting, we believe that the growth in imaging without contrast services paid under the OPPS is unnecessary. Further, we believe that paying for imaging without contrast services provided at excepted off-campus PBDs at the PFS-equivalent rate could be an effective method to control the unnecessary increase in the volume of these services because the payment differential that is driving the site-of-service decision will be removed. We believe this method will control unnecessary volume increases both in terms of the number of covered OPD services furnished and costs associated with those services.

Therefore, given the unnecessary increases in the volume of imaging without contrast services in hospital

OPDs, we proposed to apply the PFS-equivalent payment rate to HCPCS codes assigned to the imaging without contrast APCs and to services paid through APCs 8004 (Ultrasound Composite), 8005 (CT and CTA without Contrast Composite), and 8007 (MRI and MRA without Contrast Composite) when furnished at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill modifier ''PO'' on claim lines). Under our authority in section 1833(t)(2)(F) of the Act, we would implement this proposal by applying an amount equal to the site-specific PFS payment rate for non-excepted items and services furnished by a non-excepted off-campus PBD (the PFS-equivalent payment rate). Table 82 shows the specific APCs that we would identify for this proposal, which are APCs 5521 through 5524, 8004, 8005, and 8007. Off-campus PBDs that are not excepted from section 603 (departments that bill the modifier ''PN'') already receive a PFS-equivalent payment rate for any HCPCS codes assigned to the imaging without contrast APCs.

TABLE 82: PROPOSED APCS NEWLY PAID THE PFS-EQUIVALENT RATE FOR SERVICES PROVIDED AT EXCEPTED OFF-CAMPUS PBDS FOR CY 2027

APC	APC Description
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
8004	Ultrasound Composite
8005	CT and CTA without Contrast Composite
8007	MRI and MRA without Contrast Composite

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013), we finalized our method to address the unnecessary increases in utilization of clinic visits in the OPD setting in a non-budget neutral manner. In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53448), we likewise finalized an expansion of our method to address the unnecessary increases in utilization of drug administration services in the OPD setting in a non-budget neutral manner. For CY 2027, we proposed to implement this proposed method to address the unnecessary increases in utilization of imaging without contrast services in the OPD setting in a non-budget neutral manner. We continued to believe that, while section 1833(t)(9)(B) of the Act requires that certain changes made under the OPPS be made in a budget neutral manner, this section does not apply to the volume control method under section 1833(t)(2)(F) of the Act. In particular, section 1833(t)(9)(A) of the Act, titled ''Periodic review,'' provides, in part, that the Secretary must annually review and revise the groups, ''the relative payment weights, and *the wage and other adjustments* described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors'' (emphasis added). Section 1833(t)(9)(B) of the Act, titled ''Budget neutrality adjustment'' provides that if ''the Secretary makes *adjustments* under subparagraph (A), then the *adjustments* for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made'' (emphasis added). However, a volume-control method under section 1833(t)(2)(F) of the Act is not an ''adjustment'' under paragraph (2). Unlike the wage adjustment under section 1833(t)(2)(D) of the Act and the outlier, transitional pass-through, and equitable adjustments under section 1833(t)(2)(E) of the Act, section 1833(t)(2)(F) of the Act refers to a ''method'' for controlling unnecessary increases in the volume of covered OPD services, not an ''adjustment.'' Likewise, sections 1833(t)(2)(D) and (E) of the Act also explicitly require the adjustments authorized by those subparagraphs to be budget neutral, while the volume control method authority at section 1833(t)(2)(F) of the Act does not. Therefore, the volume control method proposed under section 1833(t)(2)(F) of the Act is not one of the adjustments under section 1833(t)(2) of the Act that is referenced under section 1833(t)(9)(A) of the Act that must be included in the budget neutrality adjustment under section 1833(t)(9)(B) of the Act. Moreover, section 1833(t)(9)(C) of the Act specifies that if the Secretary determines under methodologies described in subparagraph (2)(F) that the volume of services paid for under this subsection increased *beyond* amounts established through those methodologies, the Secretary *may* appropriately adjust the update to the conversion factor otherwise applicable in a *subsequent* year. We therefore continue to interpret this provision to mean that the Secretary can implement a volume control method under section 1833(t)(2)(F) of the Act in a non-budget neutral manner in the year in which the method is implemented, and that the Secretary may then make further adjustments to the conversion factor in a subsequent year to account for volume increases that are *beyond* the amounts estimated by the Secretary under the volume control method (see 83 FR 59009).

We stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59010) that we believe implementing a volume control method in a budget neutral manner would not appropriately reduce the overall unnecessary volume of covered OPD services, and instead would simply shift the movement of the volume within the OPPS system in the aggregate, a concern similar to the one we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613). We believe that concern applies to imaging without contrast services just the same. The estimated payment impact for various provider classifications is displayed in Table 112: CY 2027 Changes for Services Provided in the Hospital Outpatient Prospective Payment System of this final rule with comment period. For CY 2027, the estimated savings were $260 million, with $190 million of the savings accruing to Medicare, and $70 million saved by Medicare beneficiaries in the

form of reduced beneficiary coinsurance. And beginning in 2028, the savings from the proposed policy would begin to flow into the baseline for Medicare Advantage rates, thus resulting in a significant increase in savings in subsequent years. For 2027, the Medicare Advantage rates had already been calculated at the time of this final rule with comment period and thus the 2027 Medicare Advantage rates are not impacted by the proposed policy. From 2027–2036 we estimated that this policy would lower net Part B spending by $7.2 billion. The 10-year estimated payment impact is displayed in Table 111: Estimated Effect of Changes to Imaging without Contrast Services when Furnished at Excepted Off-Campus Providers. To effectively establish a method for controlling the unnecessary growth in the volume of imaging without contrast services furnished by excepted off-campus PBDs that did not simply reallocate expenditures that are unnecessary within the OPPS, we believed that this method must be adopted in a non-budget neutral manner. The impact associated with this proposal is further described in section XXVII. of this final rule with comment period.

While we are refining our method to control for unnecessary increases in the volume of hospital OPD services, we continue to recognize the importance of not impeding development or beneficiary access to new innovations. We solicited public comments on other ways or other services for which we should exercise the Secretary's statutory authority under section 1833(t)(2)(F) of the Act.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Numerous commenters, including organizations representing private health insurance plans, physicians and independent physician practices, outpatient imaging providers, consumer organizations, and individual Medicare beneficiaries, supported the proposal to apply our volume control method to imaging without contrast services furnished in excepted off-campus PBDs. Commenters agreed that this method would help control unnecessary increases in the volume of imaging services furnished in excepted off-campus PBDs when beneficiaries can generally safely receive the same services in a lower-cost setting but instead receive care in a higher-cost setting due to payment incentives. Commenters stated that higher payments to OPDs for imaging services that can be safely furnished in lower-cost settings increase costs for Medicare beneficiaries and taxpayers and may encourage care to shift toward higher-paid OPDs.

Several commenters highlighted the substantial differences in Medicare payment for imaging services furnished in hospital outpatient departments compared to freestanding physician offices and other freestanding settings. Commenters provided examples of imaging services for which Medicare payment in the hospital outpatient setting is substantially higher than payment for the same service in a freestanding physician office. For example, commenters noted that a bone density scan may be paid at nearly three times the freestanding physician office rate when furnished in a hospital outpatient department and cited substantial payment differences for ultrasound, x-ray, CT, and other diagnostic imaging services. Commenters stated that these payment differences increase both Medicare program expenditures and beneficiary cost sharing without corresponding differences in the imaging service furnished or the quality of care provided. Several commenters emphasized that higher out-of-pocket costs can create a barrier to obtaining medically necessary diagnostic care, particularly for beneficiaries living on fixed incomes or those who require repeated imaging services. Commenters stated that beneficiaries may delay or forgo clinically appropriate imaging because of these costs, potentially delaying diagnosis and treatment. One physician commenter described patients who had delayed essential imaging and follow-up care because of hospital-based charges and facility fees.

Commenters generally agreed that imaging without contrast services can be routinely and safely furnished in lower-cost ambulatory settings. Several commenters stated that routine imaging services furnished in hospital outpatient departments and freestanding settings use the same or similar equipment, standardized protocols, technologists, and interpreting physicians. Commenters stated that hospital ownership does not itself result in a clinically different service or higher quality of care and that payment for comparable services should reflect the resources required to furnish the service rather than the ownership or billing designation of the facility.

Several commenters also agreed with our concern that payment differentials between the OPPS and PFS contribute to hospital acquisition of physician practices and independent imaging facilities and the migration of imaging services to higher-cost hospital outpatient settings. Commenters stated that these payment differences may encourage consolidation, reduce competition from independent practices and imaging facilities, and increase costs for Medicare and its beneficiaries.

Commenters also highlighted the utilization trends presented in the proposed rule as support for the proposal, including the growth in the volume of imaging without contrast services furnished in excepted off-campus PBDs and growth in utilization per beneficiary. Some commenters also noted that non-excepted off-campus PBDs already receive PFS-equivalent payment for these services and have continued to furnish imaging services under that payment methodology.

Several commenters also supported implementing the proposed policy in a non-budget neutral manner. Commenters stated that doing so would allow Medicare and beneficiaries to realize savings from controlling unnecessary volume rather than redistributing those savings to other services paid under the OPPS.

Response: We appreciate the commenters' support. As discussed in the CY 2027 OPPS/ASC proposed rule (91 FR 41734), we share the commenters' concerns regarding the effect of payment incentives on site of service decision-making and the downstream effects created by these payment disparities. As we noted in the CY 2019 OPPS/ASC proposed rule by quoting a MedPAC report (83 FR 37140), ''[a] large source of growth in spending on services furnished in hospital outpatient departments (HOPDs) appears to be the result of the unnecessary shift of services from (lower cost) physician offices to (higher cost) HOPDs.'' We continue to believe that these shifts in site of service are unnecessary if the beneficiary can safely receive the same services in a lower-cost setting but instead receives care in a higher-cost setting due to payment incentives.

In addition to the concern that the difference in payment is leading to unnecessary increases in the volume of covered outpatient department services, we remain concerned that this shift in care setting increases beneficiary cost-sharing liability because Medicare payment rates for the same or similar services are generally higher in hospital outpatient departments than in freestanding physician offices. Higher beneficiary cost sharing is not only a financial concern. We are also concerned that higher out-of-pocket costs may discourage beneficiaries from obtaining clinically appropriate services

or cause them to delay necessary diagnostic care. This concern may be particularly significant for beneficiaries who require repeated imaging services and beneficiaries with limited financial resources. Reducing unnecessary differences in payment across settings therefore has the potential to both reduce beneficiary cost-sharing liability and reduce financial barriers to receiving needed care. For example, as discussed in the CY 2027 OPPS/ASC proposed rule (91 FR 41909), in 2025, the freestanding physician office payment rate for a DXA scan described by HCPCS code 77080 was approximately $30, compared to approximately $106 under the OPPS. Similarly, the freestanding physician office payment rate for a chest x-ray described by HCPCS code 71045 was approximately $17, compared to approximately $88 under the OPPS. Because beneficiaries are generally responsible for 20 percent of the Medicare payment amount through coinsurance, these payment differences can translate into meaningfully higher out-of-pocket costs for the same or similar service simply because it is furnished in the higher-paid setting. For beneficiaries living on fixed incomes, particularly those who require repeated diagnostic imaging, these differences can accumulate and may create a financial barrier to obtaining timely care.

We also agree with commenters that the substantial differences in payment for imaging without contrast services across settings create a financial incentive to furnish these services in the higher-paid OPD setting. Imaging without contrast services are routinely furnished in freestanding physician offices and other lower-cost ambulatory settings. We continue to believe that to the extent similar services can be safely provided in more than one setting, it is not prudent for the Medicare program to pay more for these services in one setting than another solely because of the site in which the service is furnished.

As discussed in the CY 2027 OPPS/ASC proposed rule (91 FR 41910 through 41912), our review of imaging without contrast services found increases in the volume of these services over time and increases in the volume of services provided per beneficiary. We believe that these changes represent unnecessary increases in the volume of covered outpatient department imaging without contrast services and that it is appropriate to apply our volume control method to these services.

We further agree that our experience with non-excepted off-campus PBDs is relevant to our assessment of this policy. Imaging without contrast services are furnished in both excepted and non-excepted off-campus PBDs, even though non-excepted off-campus PBDs generally receive the PFS-equivalent payment rate. As discussed in the proposed rule, there are approximately four times as many providers billing the ''PN'' modifier as providers billing the ''PO'' modifier. The continued furnishing of these services in non-excepted off-campus PBDs supports our conclusion that imaging without contrast services can continue to be furnished in an off-campus hospital setting under the PFS-equivalent payment methodology.

We appreciate the comments supporting the implementation of this policy in a non-budget neutral manner. As we stated in the CY 2027 OPPS/ASC proposed rule and consistent with our discussion in the CY 2019 and CY 2026 OPPS/ASC rulemakings, we believe implementing a volume control method in a budget neutral manner would not appropriately reduce the overall unnecessary volume of covered OPD services and instead would simply shift the volume of services within the OPPS system in the aggregate.

Comment: In its comment letter, the Medicare Payment Advisory Commission (MedPAC) supported expanding the PFS-equivalent payment rate to imaging without contrast services furnished in excepted off-campus PBDs. MedPAC highlighted its June 2023 Report to the Congress, in which it recommended more closely aligning payment rates across ambulatory settings for selected services that are safe and appropriate to provide in all ambulatory settings when doing so does not pose a risk to beneficiary access. MedPAC noted that its report included an illustrative framework that could be helpful in identifying services for which it might be safe and appropriate to align payment rates and encouraged CMS to consult with clinicians, industry, and other interested parties when determining which services to choose. MedPAC further noted that its June 2023 recommendation was not limited to off-campus PBDs and recommended applying site-neutral payment rates for selected services furnished in both off-campus and on-campus hospital outpatient departments.

MedPAC stated that payment alignment between the OPPS and PFS should not adversely affect hospitals' ability to be available 24/7 for emergency care, with particular attention paid to safety-net and rural providers. Additionally, MedPAC recommended maintaining the packaging of ancillary items in the OPPS.

MedPAC reiterated a point from its June 2023 Report to the Congress in which it noted some benefits of making budget-neutral adjustments for some OPPS services in conjunction with site-neutral payments. For example, MedPAC stated that applying a budget-neutral payment adjustment with a site-neutral policy would increase OPPS payment rates for other services, including emergency department visits, which would support hospitals' emergency care and standby capacity.

Response: We thank MedPAC for its comment and support of this policy. We continue to find MedPAC's work valuable as we identify services that may have experienced unnecessary increases in volume in the OPPS. As discussed in the CY 2027 OPPS/ASC proposed rule (91 FR 41912), MedPAC's framework for identifying services that can safely and appropriately be furnished in lower-cost ambulatory settings informed our consideration of imaging without contrast services. We agree that beneficiary access and the ability to safely furnish a service in alternative settings are important considerations when determining whether application of our volume control method is appropriate.

We note that imaging without contrast services are routinely furnished in freestanding physician offices. As discussed in the CY 2027 OPPS/ASC proposed rule (91 FR41912), MedPAC found that all four imaging without contrast APCs had higher volume in freestanding facilities than in OPDs. We believe this supports our conclusion that these services can generally be safely furnished to beneficiaries in lower-cost settings of care and aligns well with the rationale CMS adopted in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015): we consider OPPS utilization unnecessary if the beneficiary can safely receive the same services in a lower-cost setting but instead receives care in the hospital outpatient setting because of payment differentials that result in the unnecessary provision of OPD services.

We also acknowledge MedPAC's recommendation to align payment rates for selected services furnished in on-campus as well as off-campus OPDs. The policy finalized in this rule for CY 2027 and subsequent years is limited to imaging without contrast services furnished in excepted off-campus PBDs. We appreciate MedPAC's recommendation regarding on-campus OPDs and may take this recommendation into consideration in future rulemaking.

We also appreciate MedPAC's comments regarding rural providers and hospitals' emergency and standby capacity. As discussed later in this section, we are finalizing our proposal to exempt rural Sole Community Hospitals from the expanded volume control method. We do not believe that our volume control method will adversely impact hospitals' ability to provide 24/7 emergency care. We are applying our volume control method to a limited set of services provided in a limited set of OPD departments and do not believe that the financial impact of this provision will significantly impact hospitals' ability to provide 24/7 emergency care. Our final policy will only impact imaging without contrast services furnished in excepted off-campus PBDs and billed with the ''PO'' modifier.

We understand that MedPAC's June 2023 recommendation proposed to make some site-neutral adjustments in a budget neutral manner. However, we are using our authority under section 1833(t)(2)(F) of the Act to implement a volume control method to control unnecessary increases in the volume of imaging without contrast services. Under sections 1833(t)(2)(F) and (9)(C) of the Act, we are not required to budget neutralize the volume control method here, and as we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013), we believe implementing a volume control method in a budget neutral manner would not reduce the overall unnecessary volume of covered OPD services and instead would simply shift services within the OPPS system because of payment incentives rather than medical necessity.

Comment: Numerous commenters who supported our proposal also encouraged CMS to expand the volume control method to additional services that can safely and routinely be furnished in lower-cost settings. Commenters stated that the payment incentives that have contributed to unnecessary increases in the volume of clinic visits, drug administration services, and imaging without contrast services may exist for other covered OPD services and encouraged CMS to continue identifying services for which payment differentials may influence site-of-service decisions.

Several commenters recommended that CMS use MedPAC's work identifying services appropriate for payment alignment as a starting point for future policies. Commenters cited MedPAC's identification of 66 clinical services, including 57 APCs for which services are most commonly furnished in freestanding physician offices, and stated that these services may be appropriate candidates for future application of the volume control method. Some commenters recommended that CMS develop a more systematic approach for identifying additional services, considering factors such as whether services can safely and routinely be furnished in lower-cost settings, the magnitude of payment differences across settings, trends in utilization and site of service, and evidence that payment differences may be contributing to shifts toward hospital outpatient departments.

Some commenters specifically recommended expanding the volume control method to additional imaging services, including imaging with contrast, nuclear medicine, cardiac perfusion imaging, and other ambulatory imaging services that commenters stated can safely be furnished in lower-cost settings. Other commenters encouraged CMS to continue evaluating oncology-related imaging and other outpatient services commonly furnished in freestanding physician practices. Commenters also identified a range of other services and procedures for potential future consideration, including certain skin procedures, urology services, nerve injections, diagnostic and minor procedures, cardiology services, gastroenterology procedures, ophthalmology procedures, orthopedic procedures, and otolaryngology services.

Several commenters also recommended that CMS expand the volume control method to services furnished in on-campus hospital outpatient departments, including clinic visits. Commenters stated that the rationale for addressing payment incentives that encourage shifts to higher-cost OPDs may also apply to services furnished in on-campus departments when those services can safely be furnished in freestanding physician offices or other lower-cost settings. Commenters stated that expanding the policy to on-campus departments could further reduce Medicare spending and beneficiary cost sharing and reduce incentives for provider consolidation.

Some commenters recommended that CMS proceed cautiously with any future expansion and consider beneficiary access, patient complexity, quality and safety, geographic availability of alternative sites of care, hospital infrastructure and emergency capabilities, and provider readiness. Commenters recommended that CMS use a data-driven approach and provide opportunities for interested parties' input before applying the volume control method to additional services or settings.

Response: We thank commenters for their recommendations regarding additional services and settings that may be appropriate for application of our volume control method. As discussed in the CY 2027 OPPS/ASC proposed rule, we continue to believe that the financial incentives created by differences in payment across settings are not limited to the services currently subject to our volume control method. We continue to believe that shifts in site of service are unnecessary if the beneficiary can safely receive the same services in a lower-cost setting but instead receives care in a higher-cost setting due to payment incentives.

We appreciate commenters' specific recommendations regarding additional imaging services, clinic visits furnished in on-campus hospital outpatient departments, and other clinical service families. We appreciate the analyses and recommendations commenters provided regarding factors that could be considered when evaluating additional services and settings, as well as commenters' recommendations regarding beneficiary access, patient complexity, quality and safety, and the availability of alternative sites of care.

Given the wide array of information presented through this public comment process, we may take the technical recommendations and other detailed feedback provided regarding other services and settings into consideration in future notice-and-comment rulemaking.

We received several comments arguing that CMS lacks the statutory authority to reduce payments to excepted off-campus PBDs, particularly in a non-budget neutral manner. We discuss these comments below.

Comment: Commenters suggested that legal developments since the D.C. Circuit's decision in *AHA* v. *Azar,* 964 F.3d 1230 (D.C. Cir. 2020), which upheld the agency's invocation of its authority under section 1833(t)(2)(F) of the Act, undermine the agency's reliance on section 1833(t)(2)(F) of the Act for the proposed volume-control methodology. Commenters stated that the D.C. Circuit in *AHA* v. *Azar* reviewed HHS' interpretation under the two-step framework of *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984), but *Chevron* has since been overruled by *Loper Bright Enterprises* v. *Raimondo,* 603 U.S. 369 (2024). Commenters noted that, following *Loper Bright,* courts may not defer to an agency statutory

interpretation simply because a statute is ambiguous. Commenters therefore contended that the agency's reading of section 1833(t)(2)(F) of the Act is not the best interpretation of the law.

Commenters contended that section 1833(t)(2)(F) of the Act does not authorize HHS to lower payments only for certain services performed by certain providers, including those excepted under section 1833(t)(21) of the Act. Commenters stated that CMS' interpretation would allow the agency to supersede the payment system established by Congress and make non-budget-neutral reductions to particular services based on a general statutory direction to develop a method for controlling unnecessary increases in volume.

Some commenters also cited *Bridgeport Hospital* v. *Becerra,* 108 F.4th 882 (D.C. Cir. 2024), and stated that the decision further supports their view that CMS may not rely on general statutory authority to depart from a more specific, congressionally prescribed Medicare payment methodology.

Response: We continue to believe that section 1833(t)(2)(F) of the Act gives the Secretary authority to develop a method for controlling unnecessary increases in the volume of covered OPD services, including a method that controls unnecessary volume increases by removing a payment differential that is driving site-of-service decisions and, as a result, is unnecessarily increasing service volume.

As an initial matter, the Supreme Court in *Loper Bright* expressly disclaimed that its opinion should alter the holdings of past cases. ''By [overruling *Chevron*],'' the Supreme Court explained, ''we do not call into question prior cases that relied on the *Chevron* framework. The holdings of those cases that specific agency actions are lawful . . . are still subject to statutory *stare decisis* despite our change in interpretive methodology.'' *Loper Bright,* 603 U.S. at 412.

Prior to *Loper Bright,* the D.C. Circuit upheld CMS's invocation of our authority under section 1833(t)(2)(F) of the Act whereby we adopted a method to control for unnecessary increases in the volume of the relevant service in a manner nearly identical to that at issue here. *See AHA* v. *Azar,* 964 F.3d at 1241–45. *Loper Bright* does not change that result. The D.C. Circuit's holding that our volume-control methodology complies with section 1833(t)(2)(F) of the Act therefore is still good law. *See also Agendia Inc.* v. *Kennedy,* No. 24–5180, 2025 WL 1467116, at *3 (D.C. Cir. May 22, 2025) (''The Supreme Court's intervening decision in *Loper Bright* . . . does not alter the consequences of claim preclusion.'').

Moreover, the best reading of section 1833(t)(2)(F) of the Act, which states ''the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services,'' is that it delegates significant discretionary authority to the Secretary. *See Loper Bright,* 603 U.S. at 395 (explaining that the ''best reading of a statute [may be] that it delegates discretionary authority to an agency''). Because, as the D.C. Circuit explained, our policy ''falls comfortably within the plain text of subparagraph (2)(F)'' and is further supported by the broader statutory context, *AHA* v. *Azar,* 964 F.3d at 1241, our policy does not fall outside the ''outer statutory bounds'' of the delegation, as discussed in *Loper Bright.* This is especially true when one considers that section 1833(t)(2)(F) of the Act was enacted against the backdrop of the Secretary's longstanding rulemaking authority under sections 1102(a) and 1871(a) of the Act, *cf. Cboe Global Mkts., Inc.* v. *SEC,* 155 F.4th 704, 715 (D.C. Cir. 2025) (finding similar statutory rulemaking authority supported conclusion that Congress delegated significant discretion to agency), and in the context of a statute (section 1833(t) of the Act) that repeatedly delegates significant discretionary authority to the Secretary to design the manner in which OPPS payments will be calculated.

As we noted in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58818) and in our decision to complete the two-year phase of this policy in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61366), ''[a] large source of growth in spending on services furnished in hospital outpatient departments (HOPDs) appears to be the result of the shift of services from (lower cost) physician offices to (higher cost) HOPDs.'' We continue to believe that these shifts in the sites of service are unnecessary if the beneficiary can safely receive the same services in a lower-cost setting but instead receives care in a higher-cost setting due to payment incentives. We continue to believe that the difference in payment is leading to unnecessary increases in the volume of covered outpatient department services, and we remain concerned that this shift in care setting increases beneficiary cost-sharing liability because Medicare payment rates for the same or similar services are generally higher in hospital outpatient departments than in freestanding physician offices. We continue to believe that our method addresses the concerns described in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59005).

As we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013), we believe implementing a volume control method in a budget neutral manner would not appropriately reduce the overall unnecessary volume of covered OPD services and instead would simply shift services within the OPPS system because of payment rather than medical necessity. We also outlined in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013) that while section 1833(t)(9)(B) of the Act requires that certain changes made under the OPPS be made in a budget neutral manner, this section does not apply to the volume control method under section 1833(t)(2)(F) of the Act.

Here, as in *AHA* v. *Azar,* we have identified an unnecessary increase in volume in a set of OPPS payment codes based on payment differentials between the OPPS and the PFS. As in *AHA* v. *Azar,* CMS has tailored a methodology to eliminate that unnecessary volume increase by eliminating its cause. And as the D.C. Circuit already found in *AHA* v. *Azar,* that falls comfortably within the agency's delegated authority under section 1833(t)(2)(F) of the Act.

The D.C. Circuit's decision in *Bridgeport Hospital* does not undermine the precedential value of the D.C. Circuit's earlier decision in *AHA* v. *Azar. See LaShawn A. v. Barry,* 87 F.3d 1389, 1395 (D.C. Cir. 1996) (en banc) (explaining that when a prior panel in the same circuit has decided an issue, the law-of-the-circuit doctrine precludes reconsideration of that decision). Moreover, *Bridgeport Hospital* addressed a completely different payment policy promulgated under a completely different statute. The *Bridgeport* panel concluded that a particular wage-index policy applied under the Inpatient Prospective Payment System (IPPS) exceeded the Secretary's authority under sections 1886(d)(3)(E) and 1886(d)(5)(I)(i) of the Act. *See* 108 F.4th at 887–91. In doing so, the *Bridgeport* panel focused on the specificity and length of section 1886(d)'s wage-index provision and section 1886(d) as a whole, concluding that it did not give the Secretary discretion to change the wage-index values produced within the statutory formula. *See id.* at 889 n.3 (observing that the IPPS ''section on inpatient reimbursement formulas'' is ''longer than many books'').

Here, in contrast, section 1833(t)(2) of the Act (entitled ''System requirements'') expressly gives the Secretary significant discretion by

instructing in subparagraph (F) that ''the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services.'' The statute does this in the context of a statutory payment scheme (OPPS) where Congress has delegated to the Secretary significant discretion to design the particulars of that payment system. For example, in contrast to the IPPS statute's wage-index language in section 1886(d)(3)(E) of the Act, section 1833(t)(2)(D) of the Act delegates to the Secretary authority to ''determine a wage adjustment factor [for OPPS] 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'' in the context of a statute that expressly precludes judicial review of such determinations—and numerous others related to OPPS, including the Secretary's development of volume control methods under section 1833(t)(2)(F)—in section 1833(t)(12) of the Act.

Finally, as we stated in the FY 2026 IPPS/LTCH PPS final rule (90 FR36853), we respectfully disagree with the D.C. Circuit's decision in *Bridgeport.*

Comment: Commenters stated that the D.C. Circuit in *AHA* v. *Azar* failed to account for section 603 of the Bipartisan Budget Act of 2015 (BBA of 2015), which enacted section 1833(t)(21) of the Act. Commenters stated that the BBA of 2015 created two categories of provider-based departments (PBDs): (1) those established before November 2, 2015, and (2) those established after that date. For those PBDs in existence prior to November 2, 2015, commenters stated that the Congress required CMS to continue paying off-campus PBDs, referred to in the statute as excepted off-campus PBDs, under the OPPS; however, for post-November 2, 2015 PBDs, the Congress required CMS to pay PBDs under another applicable Part B payment system. Commenters believed that the Congress reinforced this policy choice by providing that certain ''mid-build'' PBDs should receive the same payment treatment as existing, pre-November 2, 2015 off-campus PBDs in section 1833(t)(21)(B)(v) of the Act.

Some commenters noted that section 603 of the BBA of 2015 represents Congress' thoughtful consideration of recommendations to eliminate differences in payment between hospital outpatient departments and freestanding physicians' offices in certain circumstances, and that CMS's proposal undermines the balance struck by Congress. Commenters stated that the agency cannot rely solely on *AHA* v. *Azar* and must instead address why the text and history of section 603 of the BBA of 2015 do not foreclose the agency's authority to apply the proposed volume control method to imaging without contrast services furnished in excepted off-campus PBDs.

Response: As we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59008), we continue to believe the changes required by section 603 of the BBA of 2015 made in section 1833(t) of the Act had the effect of addressing some of the concerns related to shifts in settings of care and overutilization of services in the hospital outpatient setting for new off-campus PBDs that began billing Medicare for OPPS services after November 1, 2015. In enacting section 603 of the BBA of 2015, Congress addressed the specific circumstances that lead to the proliferation of new off-campus provider-based departments. As we stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79711), with section 603 of the BBA of 2015, we believe Congress may have been trying to address the incentive for hospitals to purchase physician's offices and convert them to OPDs without changing their location or patient population. In this final rule with comment period, we are addressing new and separate circumstances: the over utilization of imaging without contrast services in the OPPS.

We disagree with commenters that by enacting legislation that does not reference section 1833(t)(2)(F) of the Act, Congress meant to circumscribe our authority under that preexisting statutory provision. As the D.C. Circuit explained when rejecting the same claim in *AHA* v. *Azar:* ''Nothing in the text of section 603 [of the BBA of 2015] indicates that preexisting off-campus PBDs are forever exempt from adjustments to their reimbursement. Rather, the text of the law exempts those providers from the change mandated by section 603 itself, leaving the exempted providers subject to all the provisions of the OPPS statute, including subparagraph (2)(F).'' 964 F.3d at 1246.

Additionally, as the D.C. Circuit there explained, even assuming that section 603 of the BBA of 2015 could be read to judge increases in volume at preexisting off-campus PBDs are not ''unnecessary'' under section 1833(t)(2)(F) of the Act, that judgment would extend only to 2015 and ''would not mean that Congress considered acceptable the continued volume increases later taking place'' in other years. *Id.*

Finally, the commenters are also wrong that *Loper Bright* undermines the D.C. Circuit's analysis of section 603 of the BBA of 2015 in *AHA* v. *Azar.* Nothing in the appellate court's analysis of section 603 of the BBA of 2015 suggests that the court found the provision ambiguous or incorrectly deferred to the agency's interpretation of it. *See id.* And contrary to the commenters' suggestion, the court fully considered any impact of section 603 of the BBA of 2015 on the agency's authority under the OPPS statute, even if it characterized the section 603 argument as an ''alternative'' argument made by the plaintiffs in that case.

Comment: Commenters reiterated their objections from prior rulemaking that the proposed payment reductions constitute ''adjustments'' that are subject to the budget neutrality requirements set forth in section 1833(t)(9)(B) of the Act and urged CMS to implement any volume control method in a budget neutral manner.

Commenters stated that section 1833(t)(9)(A) of the Act refers to the groups, relative payment weights, wage adjustments, and ''other adjustments described in paragraph (2),'' and therefore encompasses a payment reduction implemented under section 1833(t)(2)(F) of the Act. Commenters stated that characterizing the policy as a ''method'' rather than an ''adjustment'' does not change the fact that the policy reduces payment rates for particular OPD services.

Some commenters also disagreed with CMS's interpretation of section 1833(t)(9)(C) of the Act. Commenters stated that this provision provides a specific mechanism for responding to volume that exceeds amounts established through methodologies under section 1833(t)(2)(F) of the Act—an adjustment to the update to the conversion factor in a subsequent year—and does not authorize CMS to implement service-specific payment reductions in a non-budget neutral manner.

Response: As we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59009), we believe that while section 1833(t)(9)(B) of the Act does require that many changes made under the OPPS be made in a budget neutral manner, this provision does not apply to the volume control method under section 1833(t)(2)(F) of the Act as outlined through our proposals in CY 2019, CY 2026, and CY 2027 rulemakings. As we noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37138 through 37143), unlike the wage adjustment under section 1833(t)(2)(D) of the Act and the outlier, transitional pass-through, and equitable adjustments

under section 1833(t)(2)(E) of the Act, section 1833(t)(2)(F) of the Act refers to a ''method'' for controlling unnecessary increases in the volume of covered OPD services, not an adjustment. Likewise, sections 1833(t)(2)(D) and (E) of the Act also explicitly require the adjustments authorized by those paragraphs to be budget neutral, while the volume control method authority at section 1833(t)(2)(F) of the Act does not include such a requirement. Therefore, we continue to believe that the volume control method proposed under section 1833(t)(2)(F) of the Act is not one of the adjustments under section 1833(t)(2) of the Act that is referenced under section 1833(t)(9)(A) of the Act that must be included in the budget neutrality adjustment under section 1833(t)(9)(B) of the Act.

Moreover, section 1833(t)(9)(C) of the Act specifies that if the Secretary determines under methodologies described in paragraph (2)(F) of section 1833(t) of the Act that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year. We continue to interpret this provision to mean that the Secretary will have implemented a volume control method under section 1833(t)(2)(F) of the Act in a non-budget neutral manner in the year in which the method is implemented. Further, as we stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37138 through 37143), we believe that implementing a volume control method in a budget neutral manner would not appropriately reduce the overall unnecessary volume of covered OPD services and instead would simply shift the volume within the OPPS system in the aggregate.

In addition, the D.C. Circuit in *AHA* v. *Azar* held not only that budget neutrality is not required under a volume control method, but that making that method budget neutral would be contrary to the purpose and intent of the Medicare statute. For example, the appellate court emphasized that subparagraph (2)(F) of the Act ''says nothing about budget-neutrality,'' and specifically rejected the plaintiffs' claim that volume-control methods must be budget neutral. 964 F.3d at 1241. After all, it would be ''anomalous'' for the statute to require a rate cut made for purposes of volume control to be ''implemented budget-neutrally'' because, if we were required ''to redistribute the costs traceable to the provision of unnecessary services throughout the OPPS,'' the result would be ''no net savings to Medicare,'' ''largely negating the point of reducing reimbursement in the first place.'' *Id.* at 1241–42. This common-sense interpretation is thus supported by the text and structure of the OPPS statute, as both we (see 83 FR 37142 through 37143) and the D.C. Circuit have explained.

Comment: Several commenters raised concerns regarding the timeframe and data CMS used to evaluate changes in the volume of imaging without contrast services furnished in excepted off-campus PBDs. Commenters questioned CMS's use of CY 2016 as a baseline, noting that 2016 was the first year hospitals were required to report the informational ''PO'' modifier for services furnished in excepted off-campus PBDs and stating that first-year reporting may have been incomplete or inconsistent. Commenters recommended that CMS test its findings using alternative baseline years, such as CY 2017 or CY 2018.

Some commenters also recommended that CMS place greater weight on more recent utilization trends. Commenters stated that the period analyzed by CMS spans implementation of section 603 of the BBA of 2015 and the mid-build exception and therefore captures growth associated with the acquisition, construction, and development of off-campus PBDs. Commenters stated that more recent data show relatively stable utilization in excepted off-campus PBDs and stated that CMS should focus on utilization following implementation of section 603 when determining whether there is currently an unnecessary increase in volume. Other commenters stated that CMS should consider a sufficiently long historical period because relying only on recent utilization could include prior shifts from freestanding physician offices to OPDs into the baseline and obscure the effects of consolidation and site-of-service payment differentials.

Several commenters also questioned CMS's use of the 70 HCPCS codes that accounted for more than 95 percent of imaging without contrast volume in excepted off-campus PBDs in CY 2025 to evaluate historical utilization. Commenters stated that these codes represented a smaller proportion of imaging without contrast volume in earlier years and that changes in HCPCS coding during the analysis period make comparisons using a fixed set of current codes potentially misleading. Commenters noted that analyses accounting for predecessor and successor codes and including the full set of imaging without contrast services produced substantially less growth than CMS's analysis. Commenters also stated that a significant portion of the growth identified by CMS was attributable to codes that did not exist or had no reported volume in the baseline year and recommended that CMS account for coding changes when evaluating historical utilization.

Several commenters also requested that CMS make available additional information regarding the data and methodology used to conduct its utilization analysis. Commenters stated that providing the underlying claims analysis, including information regarding the HCPCS codes, claims fields, settings of care, and methodology used to calculate changes in utilization, would allow interested parties to reproduce CMS's analysis and more fully evaluate the basis for the proposed policy.

Response: We thank the commenters for their input. Based on these comments, we conducted additional analyses to determine whether using alternative baseline periods or the full set of imaging without contrast services would change our conclusion that these services have experienced unnecessary increases in volume.

We first considered commenters' concerns regarding the use of CY 2016 as the baseline year. Using CY 2017 as the baseline, total utilization increased by approximately 5 percent through CY 2025, while utilization per FFS beneficiary increased by approximately 26 percent. Similarly, using CY 2018 as the baseline, total utilization increased by approximately 6 percent through CY 2025, while utilization per FFS beneficiary increased by approximately 26 percent. Even when examining the more recent period from CY 2021 through CY 2025, total utilization increased by approximately 9 percent and utilization per FFS beneficiary increased by approximately 20 percent. We therefore do not believe that our conclusion depends on the selection of CY 2016 as the baseline year.

We also considered commenters' concerns regarding the 70 HCPCS codes examined in the proposed rule. We acknowledge that these codes represented a smaller proportion of imaging without contrast services in the earlier years of our analysis than in more recent years. Specifically, these 70 HCPCS codes represented approximately 75 percent of imaging without contrast volume in excepted off-campus PBDs in CYs 2016 and 2017, compared with approximately 94 percent in CY 2018 and more than 95 percent in CY 2025. We therefore also examined historical utilization using the full set of HCPCS codes identified as

imaging without contrast services based on CY 2025 claims data, rather than limiting our analysis to the 70 high-volume HCPCS codes discussed in the proposed rule.

Our analysis of historical utilization for this full set of imaging without contrast HCPCS codes continues to demonstrate growth in utilization in excepted off-campus PBDs. Total volume increased from approximately 2.79 million claims in CY 2016 to approximately 3.03 million claims in CY 2025, an increase of approximately 9 percent. Moreover, after accounting for changes in Medicare FFS enrollment, utilization per FFS beneficiary increased by approximately 31 percent over this period. We therefore do not believe that our conclusion depends on limiting our analysis to the 70 HCPCS codes discussed in the proposed rule.

We also do not believe that it would be appropriate to examine only data from more recent years. In our CY 2027 OPPS/ASC proposed rule analysis, we started our claims review in CY 2016 to examine what volume looked like during and following the period of consolidation and growth of excepted PBDs and in subsequent years. Rather than a reason to exclude these data, we believe fully understanding how the growth of excepted off-campus PBDs affected the volume of imaging without contrast services is important in examining unnecessary increases in the volume of outpatient services.

Looking only at data from more recent years removes the context for the changes that occurred in the OPPS over the longer historical period. Even if utilization for a particular service has leveled off in recent years, that does not mean that earlier unnecessary increases in volume are no longer reflected in current utilization. If utilization increased unnecessarily in earlier years and subsequently remained at that higher level, examining only the more recent period would include that earlier increase into the baseline and could obscure the extent of the historical growth. Accordingly, we believe it is appropriate to consider utilization over a longer period when evaluating whether there have been unnecessary increases in the volume of covered OPD services.

We also acknowledge commenters' requests for additional information regarding the data and methodology underlying our analysis. In the CY 2027 OPPS/ASC proposed rule, we described the data, time period, settings of care, and HCPCS codes used in our analysis and presented the utilization trends on which our proposal was based. We believe the information provided in the proposed rule was sufficient to allow interested parties to obtain the raw data and conduct analyses intended to replicate or test our analysis. Several commenters submitted their own analyses of utilization trends using Medicare claims data and the parameters described in the proposed rule, including analyses using alternative sets of HCPCS codes, baseline years, and settings of care. These analyses allowed commenters to identify specific methodological concerns and alternative interpretations of the data, which we have considered and addressed in this final rule with comment period.

Based on our review of the proposed-rule data and these additional analyses, we continue to believe that imaging without contrast services have experienced unnecessary increases in the volume of covered OPD services and that it is appropriate to apply our volume control method to these services.

Comment: Several commenters stated that CMS's analysis does not support applying the volume control method to all HCPCS codes assigned to the four imaging without contrast APCs. Commenters noted that the proposed policy would apply to more than 300 HCPCS codes, while CMS's proposed rule utilization analysis focused on 70 high-volume codes. Commenters stated that the remaining codes encompass a broad range of imaging modalities and clinical circumstances and stated that CMS should identify unnecessary increases in volume at the individual HCPCS code level before applying the volume control method to a service.

Commenters further stated that some HCPCS codes subject to the proposed policy had little or no utilization in excepted off-campus PBDs during the period examined by CMS. Commenters stated that CMS cannot control an unnecessary increase in volume for a service for which there has been no utilization or no demonstrated increase in utilization. Commenters similarly identified services with little or no utilization in freestanding physician offices and stated that these services do not support CMS's premise that the affected services are being shifted from freestanding physician offices to OPDs because of payment incentives. Commenters therefore recommended that CMS limit the policy to individual services for which the agency has demonstrated unnecessary increases in OPD volume and meaningful utilization in lower-cost settings.

Response: We thank the commenters for their input. We disagree that we must demonstrate an unnecessary increase in volume independently for every individual HCPCS code assigned to the imaging without contrast APCs before applying our volume control method at the APC level. As we explained in the CY 2026 OPPS/ASC final rule with comment period in response to similar comments regarding drug administration services (90 FR 53815), we have evaluated unnecessary utilization at the APC level and intentionally chosen to apply the volume control method at the APC level rather than at the individual service level.

We continue to believe this approach is consistent with the structure of the OPPS established under section 1833(t) of the Act. Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered OPD services, and section 1833(t)(2)(B) of the Act provides for the establishment of groups of covered OPD services within that classification system so that the services within each group are comparable clinically and with respect to the use of resources. Consistent with these provisions, we group services under the OPPS into APCs and generally establish payment at the APC level. We therefore believe it is appropriate to evaluate unnecessary increases in volume and apply our volume control method to groups of clinically and resource-similar services at the APC level rather than requiring each individual HCPCS code within an APC to independently demonstrate the same utilization pattern.

In the CY 2027 OPPS/ASC proposed rule, we examined the 70 most frequently billed HCPCS codes for imaging without contrast services, which accounted for more than 95 percent of imaging without contrast volume furnished in excepted off-campus PBDs in CY 2025. As discussed previously, in response to comments regarding our use of these 70 HCPCS codes, we conducted an additional analysis of historical utilization using the full set of imaging without contrast HCPCS codes identified based on CY 2025 claims data. That additional analysis does not change our conclusion that imaging without contrast services have experienced unnecessary increases in volume.

We acknowledge that some individual HCPCS codes assigned to these APCs have little or no utilization in excepted off-campus PBDs or freestanding physician offices. However, as we explained in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53815), the fact that some less frequently used codes within an APC

are rarely utilized in either setting does not detract from the larger finding of unnecessary increases in volume for the services in the APCs as a whole. A code with no utilization in an excepted off-campus PBD also contributes no volume to the utilization trends on which our APC-level finding is based.

Consistent with our approach to the drug administration APC family, we believe applying the methodology to the imaging without contrast APCs is a practical and appropriate way to control unnecessary increases in the volume of this family of services. Accordingly, the fact that some less frequently used codes within these APCs are rarely utilized in either the OPD or freestanding physician office setting does not detract from our APC-level finding or our conclusion that application of the volume control method to the imaging without contrast APCs is appropriate.

Comment: Several commenters stated that the utilization trends for individual imaging without contrast services do not consistently support CMS's conclusion that payment differences are causing services to shift from physician offices to excepted off-campus PBDs. Commenters identified services for which utilization increased in both settings, remained stable in physician offices, or increased more rapidly in freestanding physician offices than in excepted off-campus PBDs. Commenters stated that these varying trends undermine the conclusion that a common payment incentive is responsible for increased utilization across imaging without contrast services.

Commenters also stated that observed increases in excepted off-campus PBD utilization may reflect factors other than shifts from freestanding physician offices attributable to payment incentives. Commenters cited shifts from inpatient to outpatient care, changes in clinical practice and screening recommendations, advances in imaging technology, changes in disease prevalence and beneficiary demographics, physician referral patterns, hospital investments in imaging capacity, and closures or acquisitions of independent imaging facilities as potential explanations for changes in utilization.

Several commenters also questioned CMS's reliance on increases in utilization per Medicare FFS beneficiary. Commenters stated that increased enrollment in Medicare Advantage may have changed the composition of the remaining FFS population, potentially leaving a population that is older or more clinically complex and requires more imaging services. Commenters stated that accounting for changes in the composition of the FFS population would reduce the measured increase in per-beneficiary utilization and recommended that CMS account for beneficiary case mix when evaluating utilization trends. Commenters also requested that CMS disclose whether its per-beneficiary analysis adjusts for changes in the composition of the Medicare FFS population, including changes associated with increasing enrollment in Medicare Advantage.

Response: We thank the commenters for their input. We acknowledge that utilization patterns vary across individual imaging without contrast services and that not every service demonstrates the same pattern of utilization across settings. However, we do not believe that an increase in utilization in the freestanding physician office setting, including an increase that occurs at the same time as growth in excepted off-campus PBDs, demonstrates that there is no unnecessary utilization in the excepted PBD setting. As we explained in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53814), taking individual utilization trends out of their full historical context does not provide an accurate gauge of the actual growth of services in excepted PBDs.

We also reviewed the specific utilization trends identified by commenters. Our review continues to show substantial increases in the volume of several high-volume imaging without contrast services furnished in excepted off-campus PBDs. For example, between CY 2016 and CY 2025, utilization in excepted off-campus PBDs increased by approximately 72 percent for HCPCS code 71250, 56 percent for HCPCS code 77080, 52 percent for HCPCS code 76641, 48 percent for HCPCS code 76536, and 41 percent for HCPCS code 70551. These increases occurred notwithstanding differing utilization trends for these services in freestanding physician offices. We therefore do not believe that differing utilization patterns for individual services demonstrate that payment differences are not a substantial cause of unnecessary increases in volume across the imaging without contrast APCs.

We also do not believe that the existence of other factors that may contribute to increased utilization, such as changes in clinical practice, screening recommendations, technology, beneficiary characteristics, referral patterns, or the availability of imaging capacity, demonstrates that the payment differential between the OPPS and PFS does not constitute a substantial cause of unnecessary increases in OPD volume. Our determination does not depend on a finding that payment differences are the sole cause of increased utilization. Rather, as we have explained in prior rulemaking, we consider shifts in the site of service unnecessary if the beneficiary can safely receive the same service in a lower-cost setting but instead receives care in a higher-cost setting due to the payment incentives created by the difference in payment amounts.

We specifically considered commenters' assertion that increases in utilization in excepted off-campus PBDs may reflect shifts from the inpatient to outpatient setting. We agree that shifts from inpatient to outpatient care may partially explain changes in utilization for particular services. However, this does not explain why services that can appropriately migrate from the inpatient setting are furnished in excepted off-campus PBDs rather than in freestanding physician offices or other lower-cost ambulatory settings. A decline in inpatient utilization accompanied by an increase in outpatient utilization demonstrates that the site of care has changed, but it does not establish what the distribution of that outpatient volume would have been absent the payment differential between the OPPS and PFS.

Once a service can safely be furnished outside of the inpatient setting, the payment differential between outpatient settings remains relevant. To the extent the same service can safely be furnished in a freestanding physician office or other lower-cost setting, the higher payment available in an excepted off-campus PBD creates a significant incentive for some portion of that volume to remain in or shift to the higher-paid OPD setting. Commenters did not demonstrate how much of the observed increase in excepted off-campus PBD utilization would have occurred absent that payment differential. Accordingly, evidence of an inpatient-to-outpatient shift does not demonstrate that the resulting increase in excepted off-campus PBD volume is necessary or that payment incentives do not contribute to the setting in which those services are ultimately furnished.

We also considered commenters' concerns regarding changes in the composition of the Medicare FFS population. We clarify that our per-beneficiary utilization analysis accounts for changes in the number of Medicare FFS beneficiaries by dividing utilization by Medicare Part B FFS enrollment for

the applicable year. The analysis does not adjust for changes in the demographic characteristics, health status, or clinical risk of the FFS beneficiary population over time. We do not believe that such an adjustment is necessary or appropriate for purposes of this analysis. The purpose of examining utilization per FFS beneficiary is to determine whether changes in aggregate utilization can be explained by changes in the size of the FFS population, rather than to estimate the amount of imaging that would be clinically necessary for a particular beneficiary population. Developing a case-mix adjustment for this purpose would require determining which beneficiary characteristics should be expected to affect utilization of the broad range of imaging services included in these APCs and the extent to which those characteristics should affect expected utilization. We do not believe commenters provided a sufficiently supported methodology for making such an adjustment. Moreover, even if such an adjustment could estimate the portion of increased imaging utilization attributable to changes in beneficiary characteristics, it would not establish the setting in which those medically necessary services needed to be furnished.

Moreover, even if changes in the composition of the FFS population explain some portion of the increase in imaging services per beneficiary, that would not demonstrate that the resulting increase in services furnished in excepted off-campus PBDs is necessary. Beneficiaries with greater clinical needs may appropriately require more imaging services, but that does not mean those services must be furnished in the higher-paid OPD setting. As discussed previously, our concern is not whether the underlying imaging service is medically necessary. Rather, we consider increases in covered OPD services unnecessary when a beneficiary can safely receive the same medically necessary service in a lower-cost setting but instead receives it in the higher-paid OPD setting due to payment incentives. Our policy does not prevent a physician from determining that an OPD is the appropriate setting for a particular beneficiary based on the beneficiary's clinical needs.

Based on our review of the proposed-rule data, our additional analyses, and the information provided by commenters, we continue to believe that the payment differential between the OPPS and PFS is a significant driver of unnecessary increases in the volume of imaging without contrast services furnished in excepted off-campus PBDs. The fact that individual services may exhibit different utilization patterns, or that factors other than payment may also affect utilization, does not change our conclusion.

Comment: Several commenters stated that utilization trends in non-excepted off-campus PBDs undermine CMS's conclusion that the payment differential between the OPPS and PFS contributes to unnecessary increases in the volume of imaging without contrast services. Commenters noted that non-excepted off-campus PBDs already receive the PFS-equivalent payment rate and stated that utilization of imaging without contrast services in these departments has nevertheless increased substantially, in some cases more rapidly than in excepted off-campus PBDs. Commenters stated that this growth suggests that eliminating the payment differential may reduce Medicare expenditures without affecting where services are furnished.

Commenters also stated that CMS had not established an appropriate counterfactual for determining what utilization would have been in the absence of the OPPS payment differential. Commenters stated that growth in non-excepted off-campus PBD utilization may reflect factors such as growth in the number of these departments, hospital consolidation and referral patterns, beneficiary case mix, geography, and changes in the availability of independent imaging facilities.

Conversely, other commenters cited an analysis of Maryland, where hospitals operate under a global budget model, showing that the share of imaging without contrast services furnished in OPDs declined relative to the rest of the country. Commenters stated that this comparison provides evidence that payment incentives may influence the setting in which imaging services are furnished.

Response: We thank the commenters for their input. We disagree that growth in imaging without contrast services furnished in non-excepted off-campus PBDs demonstrates that the OPPS/PFS payment differential does not contribute to unnecessary increases in volume. Under section 603 of the BBA of 2015, new off-campus PBDs generally enter the Medicare program as non-excepted departments. Accordingly, growth in aggregate utilization in non-excepted off-campus PBDs reflects, at least in part, growth in the number of departments subject to that payment methodology and does not provide a direct comparison of how excepted and non-excepted PBDs respond to different payment rates.

We also cannot observe what utilization in non-excepted off-campus PBDs would have been had those departments instead received the higher OPPS payment. The fact that utilization increased under the PFS-equivalent payment methodology therefore does not establish that utilization would not have been greater in the absence of that methodology. More fundamentally, our concern is not that imaging utilization should never increase under PFS-equivalent payment. Rather, our concern is whether the higher payment available under the OPPS creates an additional incentive for services that can safely be furnished in a lower-cost setting to instead be furnished in the higher-paid OPD setting.

We also note that non-excepted off-campus PBDs continue to furnish substantial volumes of imaging without contrast services while receiving the PFS-equivalent payment rate. We believe the continued furnishing of these services at significant volume demonstrates that imaging without contrast services can be furnished in an off-campus hospital setting under the PFS-equivalent payment methodology.

We also considered the analysis submitted by commenters comparing utilization in Maryland, where hospitals operate under a global budget model, with the rest of the country. The analysis found that from CY 2017 through CY 2024, the regression-adjusted share of imaging without contrast services furnished in OPDs declined from approximately 32 percent to 24 percent in Maryland, while remaining approximately 50 percent outside Maryland.[163]

We recognize that Maryland's payment system differs from those applicable in other States and that this comparison does not establish what utilization in excepted off-campus PBDs would have been absent the OPPS/PFS payment differential. Nevertheless, because Maryland's global budget model creates different incentives regarding the volume of hospital outpatient services, we believe the differing utilization patterns provide additional evidence consistent with our conclusion that payment incentives can affect site of service.

For these reasons, we continue to believe that growth in non-excepted off-campus PBD utilization does not undermine our conclusion that the OPPS/PFS payment differential is a substantial cause of unnecessary increases in the volume of imaging

[163] *https://assets.arnoldventures.org/uploads/PDFs/Site-Neutrality-Impact-of-Payment-Differentials-and-Updated-Savings-Estimates.pdf.*

without contrast services furnished in excepted off-campus PBDs.

Comment: A few commenters stated that CMS cannot determine that there have been unnecessary increases in the volume of imaging without contrast services without first identifying a necessary level or rate of growth. Commenters stated that CMS has not established what level of utilization would be considered necessary and therefore has no basis for determining what portion of the observed growth is unnecessary. Some commenters recommended that CMS establish a benchmark for expected utilization and monitor volume against that benchmark before applying a payment reduction.

Some commenters also stated that CMS appears to conflate unnecessary increases in the volume of covered OPD services with medically unnecessary imaging. Commenters stated that the fact that an imaging service could potentially be furnished in a lower-cost setting does not establish that the underlying service was medically unnecessary or clinically inappropriate.

Commenters also recommended that CMS consider other methods for addressing unnecessary or inappropriate imaging utilization, including medical-necessity requirements, claims review, prior authorization or other utilization management policies, clinical practice guidelines, and appropriate use criteria. Some commenters specifically recommended that CMS reconsider or modernize the Medicare Appropriate Use Criteria program for advanced diagnostic imaging as an alternative to the proposed payment policy.

Response: We disagree that section 1833(t)(2)(F) of the Act requires us to establish a specific level or rate of necessary volume growth before determining that there have been unnecessary increases in the volume of covered OPD services. As we explained in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53815), because site-of-service payment differentials affect utilization throughout the OPPS, it would be extremely difficult to determine, at the HCPCS or APC level, the precise amount of volume that would have occurred absent that influence. We do not believe that establishing a retrospective benchmark would materially improve our ability to identify unnecessary increases in volume and, as discussed in prior rulemaking, such an approach could raise concerns similar to those associated with prior benchmark-based volume control methodologies.

We also clarify that our use of the term ''unnecessary'' does not mean that the underlying imaging service was medically unnecessary for the beneficiary. Our concern under section 1833(t)(2)(F) of the Act is with unnecessary increases in the volume of covered OPD services. As we have explained in prior rulemaking, we consider a shift in site of service unnecessary when a beneficiary can safely receive the same medically necessary service in a lower-cost setting but instead receives it in the higher-paid OPD setting because of the payment incentive created by the difference in payment amounts. Accordingly, determining whether an individual imaging service satisfies Medicare medical-necessity requirements would not resolve the site-of-service issue addressed by this policy.

We appreciate commenters' recommendations regarding other approaches to addressing unnecessary utilization, including medical-necessity review, prior authorization, utilization management, clinical practice guidelines, and appropriate use criteria. As discussed in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53825), we previously solicited public comment on other methods that may be warranted to control unnecessary increases in the volume of outpatient services besides changes to payment rates, including prior authorization and other utilization management policies. We continue to appreciate interested parties' input regarding these alternative approaches and may consider these recommendations in future rulemaking.

For purposes of the policy finalized in this rule, however, we continue to believe that applying the PFS-equivalent payment rate to imaging without contrast services furnished in excepted off-campus PBDs is an appropriate method to address the site-of-service payment differential that is a substantial cause of unnecessary increases in the volume of covered OPD services. We will continue to monitor the effects of this policy on utilization, as we have done for our clinic visit and drug administration volume control policies.

Comment: Commenters reiterated concerns raised in response to prior rulemaking that OPDs are more likely to serve Medicare patients who are sicker, more clinically complex, and more likely to be disabled or living in poorer, rural communities than patients treated in independent physician offices. In support of these concerns, commenters again cited studies prepared for the American Hospital Association that were also cited in comments on the CY 2026 OPPS/ASC proposed rule and discussed in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53819 through 53820).

Commenters again cited a study finding that, compared to beneficiaries treated in independent physician offices, beneficiaries receiving care in OPDs were more likely to be:

- Under age 65 and disabled,
- Reside in a rural county,
- Be dually eligible for Medicare and Medicaid,
- Have serious chronic conditions, and
- Have recently used hospital care, including emergency department and inpatient hospital services.

Commenters also again cited a related study comparing beneficiaries with cancer treated in OPDs to beneficiaries with cancer treated in freestanding physician offices, which similarly found that beneficiaries receiving cancer care in OPDs were more likely to be disabled, reside in rural areas, be dually eligible, have multiple serious chronic conditions, and have recently used emergency department or inpatient hospital services. We discussed these same studies and commenters' concerns regarding differences in the patient populations served by OPDs and physician offices in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53819 through 53820).

Commenters also provided additional analyses specific to the imaging without contrast services included in the CY 2027 proposal. One commenter stated that, based on 2025 Medicare claims data, beneficiaries receiving imaging without contrast services in OPDs were 51 percent more likely than beneficiaries receiving the same services in independent physician offices to be dually eligible for Medicare and Medicaid, 64 percent more likely to be disabled, and 58 percent more likely to have end-stage renal disease. The commenter also stated that OPD beneficiaries receiving these services had greater clinical complexity, including being 50 percent more likely to have five or more complications or comorbidities and 92 percent more likely to have five or more major complications or comorbidities.

Commenters further stated that imaging without contrast services furnished in OPDs may be part of broader, coordinated episodes of care, including pre-operative evaluation, treatment planning, serial imaging for patients receiving complex therapies or cancer treatment, and multispecialty care. Commenters stated that OPDs may provide additional staff, specialized equipment, emergency response capabilities, and immediate access to laboratory, advanced imaging, surgical,

and other services that may be important for medically complex beneficiaries. Commenters also noted that physicians may refer higher-risk patients to OPDs because those settings can more readily manage complications or escalation of care.

Commenters noted that these differences demonstrate that OPDs and physician offices are not interchangeable for all beneficiaries and that higher-acuity patients may require additional time, staffing, coordination, and hospital-level resources. Commenters therefore stated that reducing payment for imaging without contrast services in OPDs could adversely affect access to care for medically complex beneficiaries.

Response: We appreciate commenters reiterating their concerns regarding differences in the patient populations served by OPDs and freestanding physician offices and providing additional information specific to imaging without contrast services. As we explained in response to similar comments in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53820), we appreciate that OPDs serve unique patient populations and provide services to medically complex beneficiaries. However, the data provided by commenters do not demonstrate how these factors necessitate a higher payment for all imaging without contrast services provided in OPDs. While commenters indicate that these patients are more frequently treated in OPDs and, in some cases, may require additional coordination or support, they do not show that OPDs alone are clinically capable of furnishing imaging without contrast services to medically complex patients or that freestanding physician offices and other lower-cost ambulatory settings would be unequipped to safely furnish these same services when clinically appropriate.

As we stated in the CY 2019 OPPS/ASC final rule with comment period (90 FR 53820), we continue to believe shifts in the sites of service described in the preceding paragraphs are inherently unnecessary if the beneficiary can safely receive the same services in a lower-cost setting but instead receives care in a higher-cost setting due to the payment incentives created by the difference in payment amounts. Our policy does not prevent a physician from determining that an OPD is the appropriate setting for a particular beneficiary based on the beneficiary's clinical needs.

Further, the OPPS contains mechanisms to increase payment to providers for complex care. Hospitals can receive outlier payments to help hospitals mitigate financial risks associated with complex and costly procedures that exceed the normal payment amount. We also use complexity adjustments to provide increased payment for certain comprehensive services.

Comment: Some commenters stated that the proposed policy does not appropriately account for the role of physicians in determining whether an imaging service is medically necessary and the appropriate site of service. Commenters stated that physicians, rather than hospitals or outpatient departments, generally order imaging services and that hospitals therefore have limited ability to control the volume of imaging services furnished in their outpatient departments. Commenters stated that reducing payment to the hospital may penalize the facility for utilization that is largely driven by physician clinical judgment.

Commenters further stated that physicians may determine that an OPD is the appropriate site of service for particular beneficiaries based on clinical complexity, comorbidities, availability of specialized equipment or personnel, or the potential need for other hospital resources. Commenters expressed concern that the proposed policy could interfere with or create incentives inconsistent with physicians' clinical judgment regarding the most appropriate setting for their patients.

Response: We thank the commenters for their input. We agree that physicians should determine whether an imaging service is medically necessary and should consider the medical needs of the beneficiary when determining the appropriate setting in which that service should be furnished. We believe that payment should have no influence on what setting of care a physician decides is most appropriate for their patient. Our policy does not limit a physician's ability to order a medically necessary imaging service or prevent a beneficiary from receiving that service in an OPD when that setting is clinically appropriate.

We also disagree that the role of physicians in ordering imaging services makes application of the volume control method to excepted off-campus PBDs inappropriate. Our concern is not with the physician's decision regarding whether a beneficiary requires a particular imaging service. Rather, our concern is with the financial incentives that may affect the setting in which that service is ultimately furnished. The fact that a physician determines that an imaging service is medically necessary does not establish that the service must be furnished in an excepted off-campus PBD or that the higher OPPS payment rate is necessary for that service.

We also do not believe that application of the volume control method depends on an individual hospital having direct control over a physician's decision to order a particular imaging service. The method is intended to address the broader payment structure that creates a systemic financial incentive for services that can safely be furnished in lower-cost ambulatory settings to be furnished in the higher-paid OPD setting and that we believe is a significant driver of unnecessary increases in covered OPD services over time. By aligning payment for the affected services furnished in excepted off-campus PBDs with the PFS-equivalent payment methodology applicable to non-excepted off-campus PBDs, we are addressing the underlying payment differential that contributes to these site-of-service incentives rather than seeking to influence individual physicians' clinical ordering decisions.

As discussed previously, imaging without contrast services are routinely furnished in freestanding physician offices and non-excepted off-campus PBDs. Where a beneficiary can safely receive the same medically necessary service in a lower-cost setting but instead receives the service in a higher-paid OPD setting because of payment incentives, we consider the resulting increase in covered OPD services unnecessary for purposes of section 1833(t)(2)(F) of the Act. Applying the PFS-equivalent payment rate removes the payment differential while leaving physicians free to determine, based on the beneficiary's clinical needs, whether the hospital outpatient setting is appropriate.

Comment: Several commenters noted that CMS failed to adequately consider other explanations for increases in the volume of imaging without contrast services furnished in hospital outpatient departments. Commenters disagreed that higher OPPS payments are necessarily responsible for hospital acquisitions of physician practices and independent imaging facilities or resulting increases in OPD utilization. Commenters stated that correlation between payment differentials, consolidation, and increased OPD utilization does not establish that the payment differential caused the observed increase.

Similar to comments received in response to the CY 2026 OPPS/ASC proposed rule, commenters stated that physician practices may seek acquisition by or affiliation with hospitals because of financial and operational pressures unrelated to OPPS

payment rates. Commenters cited increasing practice expenses, regulatory and administrative burden, workforce shortages, physician burnout, payer mix, and declines in Medicare physician payment as factors contributing to physicians leaving independent practice. Commenters also stated that entities other than hospitals, including commercial insurers and private equity firms, have acquired physician practices and stated that broader consolidation trends cannot be attributed solely to Medicare site-of-service payment differences.

Commenters also identified other factors that may affect imaging utilization and site-of-service patterns, including changes in clinical practice and technology, beneficiary needs, physician referral patterns, hospital investment in imaging capacity, and changes in the availability of independent imaging facilities. Commenters recommended that CMS account for these factors before concluding that payment differences contribute to unnecessary increases in OPD volume.

Response: We thank the commenters for their input. As discussed earlier in this section, we recognize that multiple factors may affect changes in imaging utilization and the settings in which imaging services are furnished. However, the existence of other factors that may contribute to consolidation or changes in utilization does not mean that the substantial difference between OPPS and PFS payment rates does not also create an incentive to furnish services in the higher-paid setting.

As we explained in response to similar comments in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53819), hospitals did, in large quantities, acquire physician practices and convert them into PBDs, and a financial incentive to make these conversions existed. While physician practices may also be acquired by private equity firms, commercial insurers, or other entities, only acquisition by a hospital can result in services that were previously paid under the PFS being paid at the higher OPPS rate as a result of conversion to a provider-based department. We therefore do not believe that evidence of other causes of physician-practice consolidation eliminates the Medicare payment incentive created by the difference between OPPS and PFS payment rates.

We also acknowledge commenters' concerns regarding financial and operational pressures faced by freestanding physician practices that may encourage association with hospitals and a shift to OPD settings. However, as we stated in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53819), the OPPS was intended to pay for services provided in the hospital outpatient setting; it has no mandate to subsidize care or the cost of providing that care as a result of broader economic forces or the perceived inadequacy of other forms of payment. To the extent that commenters may believe payment under the PFS is inadequate, as discussed elsewhere in this section, such concerns do not provide a basis for maintaining a higher OPPS payment for services that can safely be furnished in lower-cost settings.

We similarly recognize that changes in clinical practice, technology, beneficiary needs, referral patterns, and the availability of imaging capacity may affect utilization of particular imaging services. However, our determination does not depend on a finding that the OPPS/PFS payment differential is the sole cause of changes in imaging utilization or consolidation. As discussed previously, our additional analyses continue to demonstrate increases in imaging without contrast services furnished in excepted off-campus PBDs, including increases in utilization per FFS beneficiary, and we have considered commenters' specific concerns regarding the timeframe of our analysis, coding changes, individual service trends, changes in the FFS population, inpatient-to-outpatient migration, utilization in non-excepted PBDs, and available counterfactual evidence.

After considering these alternative explanations, we continue to believe that the substantial payment differential between the OPPS and PFS creates a significant financial incentive to furnish imaging without contrast services in the higher-paid OPD setting and is a significant factor contributing to unnecessary increases in the volume of these services furnished in excepted off-campus PBDs. Even if multiple factors affect where imaging services are furnished, we continue to believe that payment should have no influence on what setting of care is selected when a beneficiary can safely receive the same service in a lower-cost setting. Our policy removes the payment incentive that we believe is a substantial cause of unnecessary increases in covered OPD services while preserving the ability of physicians and beneficiaries to use the hospital outpatient setting when clinically appropriate.

Comment: Some commenters raised concerns regarding the direct comparison between OPPS and PFS payment rates for imaging without contrast services. Commenters stated that the OPPS and PFS reflect fundamentally different approaches to valuing and paying for services and stated that there is no basis for substituting payment rates developed under one payment system for rates under the other. Similar to comments received in response to the CY 2026 OPPS/ASC proposed rule, commenters stated that hospital outpatient departments incur costs and maintain capabilities that are not reflected in physician office payment rates, including regulatory and accreditation requirements, staffing and equipment, emergency and standby capacity, and other hospital infrastructure. Commenters stated that these differences make direct comparisons between OPPS and PFS payment rates inappropriate.

Commenters also stated that imaging services furnished in OPDs may require resources that differ from those reflected in PFS payment rates. Commenters cited differences in equipment acquisition and maintenance costs, staffing, quality and safety requirements, and the resources necessary to serve medically complex patients. Commenters stated that OPDs may maintain imaging capacity and specialized staff that allow them to furnish services to higher-acuity patients and respond to complications or other clinical needs. Commenters stated that these additional costs are not adequately reflected in PFS payment rates and that reducing OPPS payment based on PFS rates could adversely affect hospitals' ability to maintain imaging capacity and beneficiary access to care.

Other commenters questioned whether PFS payment rates themselves provide an appropriate benchmark for determining payment under the OPPS. Commenters stated that physician practices have experienced increasing practice expenses and reductions in inflation-adjusted Medicare payment and expressed concern that aligning hospital payment with PFS rates could extend payment inadequacies in the PFS to the hospital outpatient setting. Commenters also cited negative Medicare hospital margins and stated that further reductions in OPPS payment would exacerbate hospitals' existing financial pressures and could impair their ability to support emergency, standby, and other hospital capabilities. Some commenters stated that site-neutral payment should account for the actual resources required to furnish services across ambulatory settings rather than simply

reduce payment to the amount paid in the lowest-cost setting.

Response: We appreciate the commenters' concerns regarding comparisons between OPPS and PFS payment rates. As we stated in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53817), to the extent that similar services can be safely provided in more than one setting, we do not believe it is prudent for the Medicare program to pay more for these services in one setting than another. We believe that differences in payment for the same or similar services can create a payment incentive to provide those services in the higher-cost setting. Because these services can be safely provided in a lower-cost setting, we believe that growth in services paid under the OPPS that results from this payment incentive is unnecessary. Further, we believe that setting OPPS payment at a PFS-equivalent rate is an effective method to control the unnecessary increase in the volume of these services because the payment differential that is driving the site-of-service decision would be removed.

As discussed in the CY 2027 OPPS/ASC proposed rule (91 FR 41912), we also compared OPPS and PFS payment rates using PFS payment rates for the most frequently billed imaging without contrast HCPCS codes furnished by excepted off-campus PBDs and volume-weighted those rates to create a PFS proxy average APC payment rate for imaging without contrast services. Using this approach, we found that, on average, OPPS payment rates for imaging without contrast services furnished in excepted off-campus PBDs were approximately 2.5 times higher than PFS payment rates, while payment rates for these services furnished in non-excepted off-campus PBDs were closely aligned with PFS payment rates. At the APC level, PFS payments ranged from approximately 31 percent to 54 percent of OPPS payments. We believe these findings demonstrate a substantial payment differential between the OPPS and PFS for the imaging without contrast services subject to this policy.

We observed a similar pattern for beneficiary cost sharing. Average beneficiary cost sharing for imaging without contrast services furnished in excepted off-campus PBDs was more than twice the amount for these services when furnished in freestanding physician offices, while beneficiary cost sharing for services furnished in non-excepted off-campus PBDs was closely aligned with beneficiary cost sharing in freestanding physician offices. These differences further support our concern that the payment differential not only creates an incentive to furnish services in the higher-paid setting but also results in higher costs for Medicare beneficiaries.

We appreciate that some hospital outpatient departments may incur costs that physician offices do not. We note that applying the PFS-equivalent payment methodology to these services does not eliminate payment to the hospital for furnishing the service. The hospital continues to receive payment for the facility component of the service under the applicable PFS-equivalent methodology, while the physician or other practitioner may receive separate payment under the PFS for the professional services furnished. Thus, the payment methodology continues to recognize a facility payment for services furnished in the off-campus PBD, although at a lower amount than would otherwise be paid under the OPPS. However, the issue we are addressing here is whether the difference between OPPS payment rates and PFS payment rates for imaging without contrast services distorts the market and incentivizes providers to shift volume to the higher-paying setting unnecessarily. The aspects of the OPD setting identified by commenters, including staffing and equipment, licensing and accreditation requirements, emergency and standby capacity, and the resources associated with caring for medically complex patients, do not change the fact that a specific imaging without contrast service provided in an off-campus provider-based department of a hospital is clinically similar to the provision of that same imaging service when provided in a freestanding physician office. We believe that imaging without contrast services included in this policy can generally be safely performed in the freestanding physician office setting and note that freestanding physician offices also incur costs to adhere to regulatory and safety standards and ensure that they are appropriately equipped to provide these services. While some hospital outpatient departments may have additional costs that freestanding physician offices do not, hospitals may also have efficiencies that freestanding physician offices do not, such as greater purchasing power, that may offset some of the additional costs identified by commenters. This is consistent with our response to similar comments regarding drug administration services in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53819).

We also acknowledge commenters' concerns regarding the adequacy of payment rates under the PFS. As we stated in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53817), the overall amount of Medicare payments to physicians and other entities made under the PFS is determined by the PFS statute, and the rates for individual services are determined based on the resources involved in furnishing these services relative to other services paid under the PFS. To the extent commenters believe that the PFS rate for a particular service is misvalued relative to other PFS services, commenters may nominate the service for review as a potentially misvalued service under the PFS.

We similarly do not believe that commenters' concerns regarding overall Medicare hospital margins demonstrate that the higher OPPS payment rate must be maintained for the imaging without contrast services subject to this policy. As discussed in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53819), the OPPS was intended to pay for services provided in the hospital outpatient setting; it has no mandate to subsidize care or the cost of providing that care as a result of broader economic forces or the perceived inadequacy of other forms of payment. Our volume control method addresses the payment incentive associated with the particular services subject to the policy rather than the overall financial condition of an individual hospital or the adequacy of Medicare payment across all hospital services.

We therefore continue to believe that applying the PFS-equivalent payment methodology to imaging without contrast services furnished in excepted off-campus PBDs is appropriate. Doing so directly addresses the payment differential that we believe is a significant driver of unnecessary increases in OPD volume while preserving physicians' ability to determine the clinically appropriate setting for each beneficiary.

Comment: Some commenters raised concerns related to the use of the 40-percent PFS relativity adjuster for the proposed volume control method. Commenters stated that the relativity adjuster does not necessarily produce the payment amount that would otherwise apply under the PFS for individual imaging services. Commenters presented analyses comparing 40 percent of the applicable OPPS payment amount with the PFS technical component payment and stated that, for some imaging services, application of the 40-percent relativity adjuster would result in payment below the applicable PFS technical component amount, while for other services it would result in payment above the PFS technical component amount. Commenters stated that these

differences demonstrate that the 40-percent factor does not consistently approximate PFS payment for imaging without contrast services.

Commenters also raised concerns regarding application of the relativity adjuster to imaging services paid through the multiple imaging composite APCs. Commenters stated that the composite APC methodology already reflects payment for multiple imaging services furnished during the same encounter and stated that applying the 40-percent relativity adjuster to the composite APC payment could result in an additional or duplicative payment reduction. Commenters also stated that comparisons between OPPS and PFS payment amounts should account for differences in packaging and other payment policies between the two systems.

Some commenters further stated that certain imaging services under the PFS are subject to the imaging payment cap established by the Deficit Reduction Act of 2005 (DRA) and codified at section 1848(b)(4) of the Act. Commenters stated that the DRA imaging payment cap may contribute to differences between the applicable PFS technical component payment and the payment produced by applying the 40-percent PFS relativity adjuster and recommended that CMS account for these differences when establishing payment for imaging without contrast services under the volume control method.

Several commenters recommended that CMS modify the methodology so that payment would be no less than the applicable PFS technical component amount. Commenters suggested, for example, that CMS pay the greater of 40 percent of the OPPS payment amount or the applicable PFS technical component payment. Commenters stated that such a floor would ensure that hospitals are not paid less for an imaging service than would be paid for the technical component of the same service under the PFS.

Response: We appreciate commenters' concerns regarding the relationship between the 40-percent PFS relativity adjuster and the payment amounts that would otherwise apply under the PFS for particular imaging services. We note, however, that the PFS relativity adjuster itself was established through separate rulemaking and was not proposed for modification in this rulemaking. In the CY 2018 PFS final rule (82 FR 52976), we finalized a PFS relativity adjuster of 40 percent for purposes of establishing payment under the PFS for non-excepted items and services furnished by non-excepted off-campus PBDs. In doing so, we explained that the adjuster was intended to approximate the overall relativity between OPPS and PFS payment rather than reproduce the applicable PFS payment amount for each individual HCPCS code.

As we explained in the CY 2018 PFS final rule (82 FR 53023), the comparison between OPPS and PFS payment varies considerably across services, reflecting, among other things, differences in packaging, bundling, multiple procedure payment reductions, and the mix of services furnished in off-campus PBDs. We therefore recognized that an across-the-board relativity adjuster would necessarily be imprecise and that the actual difference between OPPS and PFS payment for an individual service may be higher or lower than the amount produced by application of the adjuster. We also recognized that PFS payment for some individual services may be lower or higher than the payment amount calculated using the PFS relativity adjuster.

When finalizing the 40-percent factor for CY 2018, we considered an updated analysis showing that the utilization-weighted applicable PFS payment amount for the most frequently billed services in off-campus PBDs was approximately 35 percent of the corresponding OPPS payment amount. Because we were unable at that time to fully account for differences in packaging between the OPPS and PFS, we finalized a 40-percent relativity adjuster as an upward adjustment to that 35-percent estimate. Thus, the 40-percent factor was not intended to establish exact code-specific PFS payment amounts.

For the CY 2027 imaging policy, our analysis similarly demonstrates variation in the relationship between OPPS and PFS payment across the affected services. As discussed in the CY 2027 OPPS/ASC proposed rule (91 FR 41912), at the APC level, PFS payments for imaging without contrast services ranged from approximately 31 percent to 54 percent of OPPS payments. We believe that this range is consistent with the service-level variation that we anticipated when establishing an overall relativity adjuster. Accordingly, the fact that application of the 40-percent factor may result in payment above the applicable PFS technical component amount for some services and below it for others does not, by itself, demonstrate that use of the existing PFS relativity adjuster is inappropriate for purposes of the volume control method finalized in this rule.

We also disagree that application of the PFS relativity adjuster to imaging services paid through the multiple imaging composite APCs results in an inappropriate duplicative payment reduction. As discussed in the CY 2018 PFS final rule (82 FR 53024), when establishing payment for non-excepted items and services furnished by non-excepted off-campus PBDs, we included applicable OPPS packaging and payment policies, including comprehensive APCs, conditionally and unconditionally packaged items and services, and applicable multiple procedure payment reductions. We explained that retaining these OPPS payment policies was necessary to maintain the integrity of the PFS relativity adjuster because the adjuster is intended, in part, to account for methodological differences between the OPPS and PFS. Accordingly, where imaging services are paid through an applicable multiple imaging composite APC, the composite APC payment amount represents the OPPS payment amount to which the relativity adjuster applies. The methodology was not designed to reconstruct, on a service-by-service basis, the amount that would be paid under the PFS for each individual service comprising the composite.

We also considered commenters' concerns regarding the DRA imaging payment cap under section 1848(b)(4) of the Act. We recognize that the applicable PFS payment for certain imaging services may be affected by statutory payment limitations and that this may contribute to differences between the applicable PFS technical component payment and the payment produced by applying the 40-percent PFS relativity adjuster. However, this does not alter the purpose or design of the PFS relativity adjuster. As discussed previously, the relativity adjuster was intended to approximate the overall relationship between OPPS and PFS payment and may produce payment amounts that are higher or lower, on a code-by-code basis, than the payment that would otherwise apply under the PFS.

Several commenters recommended that, at a minimum, CMS establish the applicable PFS technical component payment as a floor, such that payment would equal the greater of 40 percent of the OPPS payment amount or the applicable PFS technical component amount. We appreciate commenters' recommendation. However, the PFS relativity adjuster itself was not proposed for modification in this rulemaking. Rather, the proposed volume control method relied on the existing site-specific PFS payment methodology applicable to non-excepted off-campus PBDs, including

the existing 40-percent PFS relativity adjuster.

Accordingly, we are not establishing a PFS technical component floor or otherwise modifying the PFS relativity adjuster in this final rule. However, we appreciate commenters' input regarding the relationship between the relativity-adjusted payment amount and the applicable PFS technical component payment. We believe commenters have raised important considerations regarding the continued use and design of the PFS relativity adjuster, including the variation between relativity-adjusted payment amounts and applicable PFS payment amounts for individual services. We intend to continue evaluating whether refinements to the PFS relativity adjuster, or the development of alternative relativity adjusters, may be appropriate and may consider such changes in future rulemaking.

Comment: Several commenters expressed concern that applying the volume control method to imaging without contrast services could adversely affect beneficiary access to preventive and screening services. Commenters identified several screening services assigned to the imaging without contrast APCs, including low-dose CT for lung cancer screening, CT colonography, abdominal aortic aneurysm (AAA) screening, and DXA bone density testing. Commenters stated that reductions in payment for these services could affect provider capacity and availability and create barriers to beneficiary participation in recommended screening. Some commenters recommended that CMS exempt imaging services that receive an A or B recommendation from the United States Preventive Services Task Force (USPSTF) or are recommended by medical specialty societies, while other commenters recommended that CMS monitor payment adequacy and beneficiary access to preventive imaging following implementation of the policy.

Several commenters raised particular concerns regarding bone mass measurement services. Commenters stated that DXA is an important preventive service used to identify beneficiaries at risk for osteoporosis and fracture and noted that the USPSTF recommends osteoporosis screening for certain populations. Commenters noted that DXA is already underutilized and cited analyses indicating that utilization of DXA among Medicare beneficiaries has declined over the longer term. Commenters stated that reductions in Medicare payment for office-based DXA have contributed to reductions in the number of physician offices furnishing the service and stated that the increase in hospital-based DXA utilization may reflect migration of services from physician offices rather than unnecessary increases in the overall volume of DXA testing. Commenters further stated that reduced access to screening could result in beneficiaries remaining undiagnosed and untreated until after experiencing a fracture, potentially resulting in greater downstream Medicare expenditures.

Commenters also cited prior CMS rulemaking concerning payment for DXA services. Commenters noted that in the CY 2017 OPPS rulemaking CMS proposed to assign CPT code 77080 to a lower-paying APC but did not finalize that proposal after commenters raised concerns regarding beneficiary access to bone density testing. Commenters stated that although the payment policy proposed for CY 2027 differs from the policy considered in that prior rulemaking, similar concerns regarding the effects of reduced payment on access to preventive bone density screening remain relevant.

Commenters raised similar concerns regarding other preventive imaging services. For example, commenters stated that AAA screening is a preventive service for which increased utilization may be clinically appropriate and cautioned against treating increases in the volume of such screening as unnecessary solely because the service is furnished in an off-campus PBD. Commenters generally stated that CMS should distinguish medically appropriate increases in recommended screening from increases attributable to site-of-service payment incentives.

Response: We appreciate commenters' concerns regarding the application of the volume control method to preventive services, including bone mass measurement, abdominal aortic aneurysm screening, and lung cancer screening services. We recognize the important role that preventive services play in identifying disease at an earlier stage and improving health outcomes for Medicare beneficiaries. However, we do not believe that the preventive nature of a service, by itself, warrants exclusion from the volume control method. The policy finalized in this rule does not change Medicare coverage of these preventive services, applicable eligibility or frequency requirements, or the clinical criteria for determining when these services are appropriate.

We also do not interpret increases in the utilization of preventive services in excepted off-campus PBDs to mean that clinically appropriate screening or preventive care is itself unnecessary. Rather, consistent with the volume control method finalized in this rule, our concern is with an unnecessary increase in the volume of covered OPD services when a clinically appropriate service that can safely be furnished in a lower-cost setting is instead furnished in the higher-paid OPD setting because of the payment incentive created by the difference in payment amounts.

The preventive and screening nature of these services also does not, in itself, indicate that they require the hospital outpatient setting. Preventive services are generally planned ambulatory services and are frequently ordered or furnished as part of routine physician and primary care. Encouraging beneficiaries to obtain appropriate preventive care does not require Medicare to maintain a higher payment when that care is furnished in an excepted off-campus PBD. We are concerned that substantial differences in Medicare payment across settings may create incentives for preventive services that can safely and appropriately be furnished in freestanding physician offices or other lower-cost ambulatory settings to migrate to the higher-paid OPD setting.

We considered commenters' concerns regarding historical trends in the availability and utilization of DXA services. We recognize that commenters cited evidence of declines in DXA utilization and in the number of freestanding physician offices furnishing DXA over longer historical periods. However, the information submitted by commenters does not demonstrate that maintaining the higher OPPS payment rate for DXA services furnished in excepted off-campus PBDs is necessary to preserve beneficiary access to these services. DXA remains a frequently furnished outpatient service. For example, CPT code 77080 had more than 1.2 million single-frequency claims used in the CY 2027 OPPS rate-setting process, and the number of such claims has exceeded 1.1 million in each of the past five OPPS rate-setting years.

Moreover, our utilization analysis demonstrates a substantial shift in the site of service for CPT code 77080. Between CY 2016 and CY 2025, utilization of CPT code 77080 in excepted off-campus PBDs increased by more than 55 percent, while utilization in freestanding physician offices remained relatively stable. We acknowledge commenters' view that some of this change may reflect historical reductions in physician-office capacity and recognize that multiple factors may contribute to changes in site of service. However, the existence of other factors does not demonstrate that the OPPS/PFS payment differential has

no effect on where DXA services are furnished. As discussed previously, acquisition of a physician practice or imaging facility by a hospital uniquely permits services that otherwise would be paid under the PFS to receive the higher OPPS payment when furnished in an excepted off-campus PBD. We therefore do not believe these historical trends support maintaining a higher OPPS payment simply because DXA is a preventive service.

We also considered commenters' discussion of the CY 2017 OPPS rulemaking regarding the APC assignment for CPT code 77080. In the CY 2017 OPPS/ASC proposed rule, we proposed to assign CPT code 77080 to APC 5521, which would have reduced the OPPS payment for the service from $100.69 in CY 2016 to $63.33 in CY 2017. In response to public comments, we reconsidered the proposed APC assignment. In the CY 2017 OPPS/ASC final rule (81 FR 79629), we assigned CPT code 77080 to APC 5522 based on our analysis of its geometric mean cost and its resource comparability to other services within the imaging APCs. Specifically, we noted that CPT code 77080 had a geometric mean cost of $91.08 and that its assignment to APC 5521 increased the probability of a violation of the 2 times rule when compared with other significant procedures assigned to that APC. We therefore assigned CPT code 77080 to APC 5522, with a final CY 2017 payment rate of $112.69.

That determination addressed a different payment question from the policy finalized in this rule. APC assignments establish the relative payment for services within the OPPS based on the applicable OPPS classification and ratesetting methodology, including the clinical characteristics and relative resource costs of services grouped within an APC. The determination of the appropriate APC assignment for a service is not based on whether the resulting OPPS payment approximates the payment that would otherwise be made for the service under the PFS. Here, we are not reconsidering the appropriate APC assignment for CPT code 77080. Rather, under section 1833(t)(2)(F) of the Act, we are applying a method to control unnecessary increases in the volume of covered OPD services by addressing the payment differential between excepted off-campus PBDs and lower-cost settings in which these services can safely be furnished.

Application of the volume control method also does not preclude us from reevaluating the APC assignment for CPT code 77080 in future rulemaking. We review APC groups and relative payment weights annually and may revise APC assignments based on changes in medical practice, technology, new cost data, and other relevant information and factors. Accordingly, if future OPPS claims data or other relevant information support a different APC assignment for CPT code 77080, we may consider such a change through future OPPS rulemaking.

For these reasons, we do not believe that preventive services, including DXA and other imaging without contrast services that qualify as Medicare preventive services, should be excluded from the volume control method finalized in this rule.

Comment: Several commenters expressed concern that applying the volume control method to imaging without contrast services could adversely affect beneficiary access to care. Commenters stated that payment reductions could cause hospitals to reduce imaging capacity, discontinue certain services, close off-campus imaging locations, or limit investments in imaging equipment and staffing. Commenters stated that these effects could be particularly significant in rural, low-income, medically underserved, and other communities where freestanding physician offices or freestanding imaging facilities may not have sufficient capacity or may not offer comparable services. Commenters also stated that reduced hospital outpatient imaging capacity could result in longer wait times or travel distances, delayed diagnosis, greater fragmentation of care, and increased reliance on emergency departments or other higher-cost settings.

Some commenters further stated that off-campus PBDs may improve access by locating imaging services closer to where beneficiaries live while maintaining integration with the hospital and other physicians involved in the beneficiary's care. Commenters noted that freestanding physician offices and independent imaging facilities may lack the capital, equipment, workforce, or operational capacity to absorb imaging services currently furnished in hospital outpatient departments. Commenters therefore recommended that CMS reconsider the proposal, adopt additional access protections, or closely monitor the effects of the policy on service availability, wait times, travel distances, and beneficiary access.

Response: We appreciate commenters' concerns regarding beneficiary access to imaging services. We agree that maintaining access to clinically appropriate imaging is important, particularly in communities where alternative sources of care may be limited. However, we do not believe that the information provided by commenters demonstrates that applying the PFS-equivalent payment rate to imaging without contrast services furnished in excepted off-campus PBDs will generally result in the loss of access to these services.

As discussed previously, imaging without contrast services are routinely furnished in physician offices, freestanding facilities, and non-excepted off-campus PBDs. Our experience with non-excepted off-campus PBDs is particularly relevant because these departments already receive the PFS-equivalent payment rate for applicable services. We also believe that non-excepted off-campus PBDs are relevant to commenters' concerns that some beneficiaries may benefit from receiving imaging in a hospital-affiliated setting with access to hospital clinical resources. The choice of setting is not limited to an excepted off-campus PBD receiving the full OPPS payment rate or a freestanding physician office. Non-excepted off-campus PBDs are also hospital departments and furnish imaging without contrast services while receiving the PFS-equivalent payment rate.

As discussed in the CY 2027 OPPS/ASC proposed rule (91 FR 41911), there are approximately four times as many providers billing the ''PN'' modifier for non-excepted off-campus PBDs as providers billing the ''PO'' modifier for excepted off-campus PBDs. Nevertheless, excepted off-campus PBDs continue to account for the substantial majority of combined off-campus PBD volume for many of the highest-volume imaging without contrast services. In CY 2025, excepted off-campus PBDs accounted for approximately 81 percent of combined PBD volume for HCPCS code 77080, 79 percent for HCPCS code 71046, 79 percent for HCPCS code 93306, and 83 percent for HCPCS code 71250. We believe these patterns are relevant because they demonstrate that, despite a substantially broader base of non-excepted off-campus PBDs furnishing services under the PFS-equivalent payment methodology, utilization of these high-volume services remains disproportionately concentrated in the smaller group of excepted off-campus PBDs receiving the higher OPPS payment.

We recognize that section 603 of the BBA of 2015 established different payment treatment for excepted and non-excepted off-campus PBDs, and the policy finalized in this rule does not alter that statutory framework. Rather,

as discussed previously, we are exercising our separate authority under section 1833(t)(2)(F) of the Act to develop a method to control unnecessary increases in the volume of covered OPD services. For purposes of addressing commenters' access concerns, we believe the continued furnishing of imaging without contrast services in non-excepted off-campus PBDs is relevant evidence that these services can be furnished in a hospital-affiliated off-campus setting under the PFS-equivalent payment methodology. Thus, maintaining access to hospital affiliation and hospital clinical resources does not, by itself, demonstrate that the higher OPPS payment applicable to an excepted off-campus PBD is necessary for these services.

We also note that, consistent with our approach in prior rulemaking, we have taken specific access concerns into account in determining the scope of this policy. As discussed later in this section, we are finalizing an exemption for rural SCHs because of their historical treatment under the OPPS, documented additional resource costs, and importance in maintaining access to care in rural communities. In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53822), we similarly recognized that rural SCHs are often the only source of care in their communities and that rural beneficiaries may have fewer alternative sites of care.

We acknowledge that particular communities may differ in the availability of alternative imaging providers and that individual hospitals may make operational decisions in response to changes in Medicare payment. However, commenters did not demonstrate that freestanding physician offices, freestanding imaging facilities, and non-excepted off-campus PBDs generally lack the capacity to furnish imaging without contrast services or that maintaining the higher OPPS payment rate for all affected services is necessary to preserve beneficiary access. Moreover, our policy does not prevent a beneficiary from receiving imaging in an OPD when that setting is clinically appropriate and does not restrict a physician's ability to determine the appropriate setting of care based on the beneficiary's medical needs.

We will continue to monitor the effects of this change in Medicare payment policy, including changes in the volume and availability of imaging without contrast services and beneficiary access to care. If future data indicate that the policy is creating significant access concerns, we may consider whether additional refinements are appropriate in future rulemaking.

Comment: Several commenters recommended that, if CMS finalizes the volume control method for imaging without contrast services, CMS phase-in the payment reduction, delay implementation, or otherwise provide a transition period. Commenters stated that immediately applying the full PFS-equivalent payment rate could result in a significant reduction in payment for affected services and could give hospitals insufficient time to adjust staffing, equipment, contracts, referral arrangements, and other operational considerations. Some commenters recommended that CMS initially apply a less significant payment reduction and transition to the PFS-equivalent rate over multiple years.

Other commenters recommended that CMS establish hardship protections or other mechanisms to address providers that may experience significant financial or access impacts as a result of the policy. Commenters stated that transition or hardship protections could reduce the risk of service reductions or disruptions in beneficiary access while allowing CMS to evaluate the effects of the policy before fully implementing the payment reduction.

Response: We appreciate commenters' recommendations regarding a phase-in, delayed implementation, or other transition or hardship protections. We do not believe that a phase-in or delay is necessary for the volume control method finalized in this rule. The policy applies to a defined set of imaging without contrast services furnished in excepted off-campus PBDs, and these same services are routinely furnished in freestanding physician offices and other lower-cost ambulatory settings.

We also believe our experience with non-excepted off-campus PBDs supports implementation of the PFS-equivalent payment rate without a phase-in. Non-excepted off-campus PBDs already receive the PFS-equivalent payment rate for applicable services and continue to furnish imaging without contrast services at substantial volume. We believe this experience demonstrates that imaging without contrast services can continue to be furnished in an off-campus hospital setting under the PFS-equivalent payment methodology.

As discussed later in this section, we are finalizing an exemption for rural SCHs based on their historical treatment under the OPPS, documented additional resource costs, and importance in maintaining access to care in rural communities.

Moreover, a phase-in would continue, during the transition period, the payment differential that we have determined contributes to unnecessary increases in the volume of covered OPD services. The purpose of the volume control method is to remove that payment incentive by applying the PFS-equivalent payment rate to the affected services. We therefore believe that implementing the PFS-equivalent payment rate beginning in CY 2027 is appropriate.

We will continue to monitor the effects of this change in Medicare payment policy, including the volume and availability of imaging without contrast services and beneficiary access to care, and may consider whether additional refinements are appropriate in future rulemaking.

Comment: Some commenters questioned whether the proposed reduction in payment would actually control unnecessary increases in volume. Commenters stated that reducing the payment amount for individual services could create an incentive for hospitals to increase the number of services furnished in off-campus PBDs to offset the reduction in revenue. Commenters stated that CMS therefore had not demonstrated that reducing payment for imaging without contrast services would result in a reduction in volume rather than simply lower Medicare payment for the same volume or potentially lead to additional utilization.

Commenters pointed to CMS's experience with the sustainable growth rate methodology and other prior discussions of volume control as evidence that reducing unit payment does not necessarily result in lower utilization. Commenters therefore stated that the proposed methodology is not reasonably designed to control unnecessary increases in volume as required under section 1833(t)(2)(F) of the Act.

Response: We thank the commenters for their input. We disagree that the possibility that a provider could respond to a reduction in payment by increasing volume means that our volume control method is not reasonably designed to control unnecessary increases in volume. As we explained in the CY 2026 OPPS/ASC final rule with comment period in response to similar comments (90 FR 53811), our volume control method is specifically designed to address unnecessary increases in OPD volume that result from site-of-service payment differentials. By applying a PFS-equivalent payment rate, the method removes the payment differential that creates an incentive to furnish a service in the higher-paid OPD setting when the

same service can safely be furnished in a lower-cost setting.

We recognize that changes in payment may affect provider behavior in different ways. However, the relevant incentive addressed by this policy is the additional Medicare payment available when an imaging without contrast service is furnished in an excepted off-campus PBD rather than in a physician office or non-excepted off-campus PBD. Once payment for the service furnished in the excepted off-campus PBD is aligned with the PFS-equivalent payment applicable in the lower-paid setting, the financial incentive to furnish the service in the excepted off-campus PBD solely because of the higher OPPS payment is removed. We therefore continue to believe that applying the PFS-equivalent payment rate is an appropriate method to control the unnecessary increase in volume attributable to that payment differential.

We also do not believe that commenters' references to the sustainable growth rate (SGR) methodology lead to a different conclusion. The SGR established an aggregate spending target under the PFS and adjusted physician payment updates based on whether aggregate expenditures exceeded that target. Our volume control method does not establish an aggregate expenditure target or reduce payment in response to providers exceeding a predetermined volume benchmark. Rather, it prospectively addresses a specific payment differential that we have determined is a substantial cause of unnecessary increases in covered OPD services by eliminating that differential for the affected services.

We will continue to monitor utilization following implementation of this policy, as we have done for our clinic visit and drug administration volume control policies. We continue to believe that prospectively applying the PFS-equivalent payment rate to imaging without contrast services furnished in excepted off-campus PBDs is an appropriate method under section 1833(t)(2)(F) of the Act to control unnecessary increases in the volume of covered OPD services.

Comment: Several commenters requested additional information and implementation guidance regarding how the volume control method for imaging without contrast services would be operationalized. Commenters requested that CMS clearly identify the HCPCS codes subject to the policy and explain how changes in HCPCS coding or APC assignments would affect application of the volume control method in future years.

Commenters also requested clarification regarding the treatment of imaging services paid through the multiple imaging composite APCs and encounters involving multiple imaging services. Commenters requested CMS to clarify how the PFS-equivalent payment methodology would apply when imaging without contrast services are furnished together with other imaging services, including services that may not otherwise be subject to the volume control method, and how the policy would interact with existing OPPS packaging and composite payment policies.

Some commenters also requested sufficient implementation guidance and lead time for hospitals to update billing, claims-processing, financial, and other operational systems before the policy takes effect.

Response: We appreciate commenters' requests for additional implementation guidance. As finalized in this rule, the volume control method applies to imaging without contrast services assigned to APCs 5521 through 5524, as well as imaging without contrast services paid through the applicable multiple imaging composite APCs (APCs 8004, 8005, and 8007), when furnished by an off-campus PBD excepted from section 1833(t)(21) of the Act and billed with the ''PO'' modifier. We identify the applicable HCPCS codes and their APC assignments through the applicable OPPS Addenda, consistent with our usual process for publishing annual OPPS payment information.

We also clarify that this policy does not change the existing OPPS packaging or composite APC policies. Where an imaging without contrast service is otherwise paid through a composite APC under the OPPS, the existing requirements for determining whether the composite payment applies will continue to apply. When the applicable imaging without contrast composite APC is paid for a service furnished by an excepted off-campus PBD, the payment for that composite APC will be subject to the volume control method finalized in this rule. Similarly, existing OPPS packaging rules will continue to determine whether other items and services furnished during the encounter are separately payable or packaged.

The volume control method does not change hospitals' existing requirements for reporting the ''PO'' modifier for services furnished in excepted off-campus PBDs. Rather, the modifier will continue to identify services furnished by these departments for purposes of applying the appropriate payment methodology. Services furnished in other settings or not otherwise within the scope of the volume control method will continue to be paid under the applicable Medicare payment methodology.

We appreciate commenters' concerns regarding implementation and the need for hospitals to update their billing and operational systems. The policy will be implemented through the annual OPPS payment system and associated claims-processing instructions, consistent with our established processes for implementing annual OPPS payment changes. We believe these existing mechanisms provide an appropriate framework for communicating the HCPCS and APC information necessary to implement the policy.

After consideration of public comments, we are finalizing our proposal to use our authority under section 1833(t)(2)(F) of the Act to apply an amount equal to the site-specific PFS payment rate for non-excepted items and services furnished by a non-excepted off-campus PBD (the PFS payment rate) for HCPCS codes assigned to the imaging without contrast APCs or paid through the imaging without contrast composite APCs, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier ''PO'' on claim lines) without modification. In addition, we are finalizing our proposal to implement this policy in a non-budget neutral manner without modification. We will monitor the impacts of this policy to ensure that beneficiaries continue to have access to quality care.

9. Exemption for Rural Sole Community Hospitals

As stated previously, we proposed to expand our method to control unnecessary increases in the volume of covered OPD services by paying a PFS-equivalent payment rate for imaging without contrast services furnished in excepted off-campus PBDs. We believe that this policy is an appropriate method for controlling unnecessary volume of imaging without contrast services in excepted off-campus PBDs because beneficiaries can generally safely receive these same services in a lower-cost setting but instead may receive care in a higher-cost setting due to payment incentives. In these cases, we maintain that, similar to the clinic visit volume control policy established in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015) and the drug administration volume control policy established in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53806 through 53821), to the extent

similar services can be safely provided in more than one setting, we do not believe it is appropriate for the Medicare program to pay more for these services in one setting than another. We continue to believe the difference in payment for these services is a significant factor in the shift in services from the freestanding physician's office setting to the hospital OPD.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051) and the CY 2026 OPPS/ASC final rule with comment period (90 FR 53821 through 53824), we finalized exemptions to our clinic visit and drug administration volume control policies for PBDs of rural SCHs. Under these exemptions, we pay the full OPPS payment rate, rather than the PFS-equivalent rate, when the clinic visit or drug administration service is furnished in excepted PBDs of rural SCHs. In those rules, we explained that rural SCHs have historically received special payment treatment to account for their higher costs and the disproportionately harmful impact that payment reductions could have on them. Because we proposed a volume control payment policy for imaging without contrast services, we have additionally considered whether a similar policy for rural SCHs or other provider types would be appropriate.

a. Special Payment Treatment for Rural SCHs

Across the various Medicare payment systems, CMS has established several special payment provisions for rural providers to ensure access to high quality care for beneficiaries in rural areas. CMS administers several statutory hospital payment designations in which rural or isolated hospitals that meet specified eligibility criteria receive higher reimbursement for hospital services than they otherwise would receive under Medicare's standard payment methodologies. A rural hospital may qualify as a Critical Access Hospital (CAH),[164] Sole Community Hospital (SCH),[165] Rural Emergency Hospital (REH),[166] or Medicare Dependent Hospital [167]—each of which has different eligibility criteria and payment methodologies. With the exception of CAHs, rural hospitals may also qualify as Low Volume Hospitals[168] and Rural Referral Centers (RRCs),[169] which qualify these hospitals for additional payments or exemptions. Not all rural or isolated hospitals receive special payment treatment under the OPPS. For instance, CAHs are not paid under the OPPS and are reimbursed at 101 percent of reasonable costs for outpatient services.

Rural SCHs are a hospital type that has received special payment treatment under the OPPS to account for their higher costs and the disproportionately harmful impact that payment reductions could have on them. In the CY 2006 OPPS final rule with comment period (70 FR 68556 through 68561), we finalized a payment increase for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, items paid at charges reduced to costs, and devices paid under the pass-through payment policy. This policy was adopted under section 1833(t)(13)(B) of the Act, which required the Secretary, by January 1, 2006, to provide for an appropriate adjustment under subparagraph (t)(2)(E) to reflect the higher costs of hospitals in rural areas if the Secretary determined, pursuant to a study required by section 1833(t)(13)(A) of the Act, that the costs to rural hospitals by APC exceeded those costs for hospitals in urban areas. Our analysis revealed that rural SCHs had significantly higher costs per unit than urban hospitals. We have continued to adjust payments for rural SCHs by 7.1 percent each year since 2006. As discussed in section II.E. of this final rule with comment period, for CY 2027 we proposed to continue the current policy of utilizing a 7.1 percent payment adjustment for rural SCHs.

As noted previously, in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72051), we finalized an exemption for clinic visits to our policy to pay the PFS-equivalent rate for the clinic visit service at excepted off-campus PBDs to control unnecessary increases in the volume of covered OPD services. Commenters were generally supportive of this proposal and noted that rural SCHs are typically the chief, if not sole, source of community outpatient care for rural residents and stated that this exemption would be vital to ensuring continued access to the care they need. Some commenters stated that the exemption should be extended to other types of hospitals, including urban SCHs. In that rule, we explained that our analysis did not find that urban SCHs had the additional resource costs for covered OPD services that rural SCHs have and only finalized applying the clinic visit policy exemption to rural SCHs (87 FR 72049).

Similarly, in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53824), we finalized an exemption for rural SCHs to our policy to pay the PFS-equivalent rate for drug administration services at excepted off-campus PBDs to control unnecessary increases in the volume of covered OPD services. Commenters were again generally supportive of the proposal and emphasized that rural SCHs have higher costs and are important for access in rural areas. Some commenters suggested extending the exemption to other types of hospitals such as urban SCHs, Medicare Dependent Hospitals (MDHs), urban and rural safety-net hospitals, REHs, FQHCs, and all rural hospitals. However, because our historical analysis did not demonstrate that these facilities had the additional resource costs that rural SCHs do, we did not finalize any exemptions beyond our exception for rural SCHs (90 FR 53823).

b. Exemption to Volume Control Payment Policy for Imaging Without Contrast Services Furnished in Off-Campus Provider-Based Departments of Rural SCHs

Earlier in this section, where we proposed the volume control method policy for imaging without contrast services, we stated that to the extent there are lower-cost sites of service available, beneficiaries and the physicians treating them should be able to choose the appropriate care setting and not be encouraged to receive or provide care in settings for which payment rates are higher solely for financial reasons. However, as we have previously noted, many rural providers, and rural SCHs in particular, are often the only source of care in their communities,[170] which means beneficiaries and providers are not choosing between a higher paying off-campus PBD of a hospital and a lower paying freestanding physicians' office setting. The closure of inpatient departments of hospitals and the shortage of primary care providers in rural areas likely further drives utilization to off-campus PBDs in areas where rural SCHs are located.

As with clinic visits and drug administration services, we do not believe that rural SCH site-of-service decisions for imaging without contrast services are being driven by differences in payment rates. As we have previously observed, rural areas often experience lower availability of health care professionals and hospitals than urban

[164] 42 CFR 485.601 through 485.647.

[165] 42 CFR 412.92.

[166] 42 CFR 419.91.

[167] 42 CFR 412.108.

[168] 42 CFR 412.101.

[169] 42 CFR 412.96.

[170] *https://www.shepscenter.unc.edu/wp-content/uploads/dlm_uploads/2017/11/SCHs_Differences_in_Community_Characteristics.pdf.*

areas.[171] Hospital closures in rural communities are associated with lower access to health care and worse health outcomes.[172] Access to outpatient services, particularly in rural areas, is vital to keeping beneficiaries from being admitted as an inpatient because beneficiaries in rural settings face unique challenges that impact their health. In the CY 2023 OPPS/ASC final rule with comment period, we explained that we believe that exempting rural SCHs from the clinic visit policy would help to maintain access to care in rural areas by ensuring rural providers are paid for clinic visit services provided at off-campus PBDs at rates comparable to those paid at on-campus departments (87 FR 72049). We extended this exemption to drug administration in the CY 2026 OPPS/ASC final rule with comment period on the same basis (90 FR 53822), and we proposed to extend it to our proposed imaging without contrast policy for similar reasons. Specifically, we proposed to exempt rural SCHs from payment of the site-specific PFS-equivalent payment for imaging without contrast services, as described by APCs 5521 through 5524, 8004, 8005, and 8007, when furnished at an off-campus PBD exempted from section 1833(t)(21) of the Act (departments that bill the modifier ''PO'' on claim lines). Under the proposed policy, a rural SCH would continue to bill services in APCs 5521 through 5524, 8004, 8005, and 8007 with the ''PO'' modifier for CY 2027 and the payment rate for such services would continue to be the full OPPS payment without the PFS relativity adjuster.

This exemption would result in higher payments to excepted off-campus PBDs of rural SCHs compared to if rural SCHs were subject to the proposed volume control method. By exempting rural SCHs, the Medicare payments for these services would remain at the OPPS level. We note, however, that these figures do not represent increases in costs to Medicare or the beneficiaries above the current policy, as our proposed exemption would maintain current payment rates at excepted off-campus PBDs of rural SCHs of 107.1 percent of the OPPS payment rate for these services. These figures are solely for the purpose of comparing potential savings from this policy.

We invited comments on all aspects of the proposed exemption for rural SCHs from the method to control unnecessary volume of imaging without contrast services. Specifically, we requested comments on whether such an exemption was appropriate for rural SCHs; what the impact on SCHs would be, should we finalize the method without an exemption for rural SCHs; and whether we should consider any other hospital types for an exemption to any of the three policies to control unnecessary volume of outpatient services at off-campus PBDs. Additionally, we requested comments on whether the current exemptions for rural SCHs from the method to control unnecessary volume of clinic visit and drug administration services remained appropriate.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters supported our proposal to exempt rural Sole Community Hospitals (rural SCHs) from payment of the site-specific Medicare PFS-equivalent payment for any HCPCS codes assigned to the imaging without contrast APCs or paid through the imaging without contrast composite APCs, when furnished at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier ''PO'' on claim lines). Several commenters opposed the volume control method generally but stated that should CMS finalize the policy, CMS should also finalize the proposed exemption for rural SCHs. Commenters stated that rural SCHs have higher costs, operate with limited financial and workforce resources, and are important for maintaining access to care in rural areas where alternative sources of imaging services may be limited. Commenters also stated that applying the volume control method to rural SCHs could result in reduced service availability or require beneficiaries to travel greater distances for care. One commenter opposed a broad exemption for all rural SCHs and recommended that CMS instead target the exemption to independent rural hospitals or hospitals that demonstrate greater financial vulnerability. The commenter stated that some rural SCHs are affiliated with large health systems and may be better positioned to absorb payment reductions than independent hospitals.

Response: We thank the commenters for their support of the proposed exemption for rural SCHs. As discussed in the CY 2027 OPPS/ASC proposed rule (91 FR 41918), and consistent with our historical analysis that indicated rural SCHs have higher costs, we agree that their financial health is vital to ensure continued access to care in rural areas. We acknowledge the nuanced perspective that many commenters took in supporting the proposed exemption while disagreeing with the volume control methodology overall.

We appreciate the commenter's recommendation that any exemption be targeted to independent rural hospitals or hospitals demonstrating greater financial vulnerability. However, as we stated in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53823), we believe the rural SCH designation generally indicates that a hospital has additional costs and is vital for access in rural areas. We do not believe that the exemption should be limited to independent hospitals, as rural SCHs that are part of larger health systems may also face similarly heightened costs. We continue to believe that these considerations support exempting rural SCHs from the volume control method. We intend to continue to monitor costs at rural SCHs and to ensure that this exemption continues to be warranted for our volume control policies.

Comment: Several commenters supported the proposed rural SCH exemption but recommended that CMS extend the exemption to additional types of hospitals and providers. Commenters recommended exemptions for, among others, all rural hospitals, Critical Access Hospitals (CAHs), Rural Emergency Hospitals (REHs), Medicare Dependent Hospitals (MDHs), Rural Referral Centers, low-volume hospitals, safety-net hospitals, hospitals serving Health Professional Shortage Areas or Medically Underserved Areas, Qualifying Disadvantaged Hospitals, children's hospitals, and other geographically isolated or essential providers. Commenters generally stated that hospitals other than rural SCHs may face similar financial, workforce, and geographic challenges and may likewise be important for maintaining beneficiary access to imaging services in communities where alternative sites of care are limited.

Some commenters also recommended exempting hospitals that have reclassified as rural. Other commenters recommended exempting children's hospitals, noting their generally limited Medicare utilization and expressing concern regarding the potential effects of the policy on pediatric access.

Response: We appreciate commenters' recommendations regarding additional types of hospitals and providers for which they believe further exemptions would be warranted. We note that CAHs

[171] *https://www.gao.gov/assets/gao-21-93.pdf.*

[172] Mills CA, Yeager VA, Unroe KT, Holmes A, Blackburn J. The impact of rural general hospital closures on communities—A systematic review of the literature. *J Rural Health.* 2024; 40:238–248. *https://doi.org/10.1111/jrh.12810.*

and REHs are not subject to the volume control method finalized in this rule, and therefore an exemption for these hospital types is not necessary.

We also appreciate commenters' discussion of rural reclassifications and clarify that the exemption for rural SCHs includes SCHs that have reclassified as rural, consistent with our rural SCH exemptions from the clinic visit and drug administration volume control methods.

We appreciate commenters' recommendation to exempt children's hospitals based on their generally limited Medicare utilization and concerns regarding pediatric access. We recognize the unique role that children's hospitals play in furnishing specialized pediatric care and appreciate commenters' interest in ensuring that Medicare payment policies do not adversely affect access to these services. We also recognize that children's hospitals generally have limited Medicare utilization, which may limit the overall impact of this policy on these hospitals. Based on the information available to us, we do not believe that a separate exemption for children's hospitals is necessary at this time. As discussed previously, the policy does not prevent a physician from determining that the hospital outpatient setting is clinically appropriate for a particular beneficiary. We will continue to consider the effects of our volume control policies on different types of hospitals and beneficiary access to care and may consider whether additional exemptions are appropriate in future rulemaking.

With respect to the other hospital types suggested by commenters, as we discussed in the CY 2027 OPPS/ASC proposed rule and in prior rulemaking (90 FR 53823), our historical analysis has found that rural SCHs have higher costs, which we believe is appropriate to consider when developing a payment policy such as this. Rural SCHs have historically received special treatment under the OPPS due to these higher costs. As we stated in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051), we believe exempting rural SCHs, which have demonstrated additional resource costs, is appropriate to ensure these hospitals can remain open to serve the beneficiaries who rely on them for their care.

We proposed a narrow exemption largely based upon the historical treatment and documented additional resource costs of rural SCHs under the OPPS. We continue to believe in the underlying principles of the volume control method, and that same rationale continues to justify application of the volume control method for imaging without contrast services to other hospitals subject to this policy. Where differences in payment lead to unnecessary increases in the volume of covered outpatient department services, we remain concerned that shifts in the site of care increase beneficiary cost-sharing liability because Medicare payment rates for the same or similar services are generally higher in hospital outpatient departments than in physician offices.

We share commenters' concerns about maintaining access to care in rural and medically vulnerable communities, including concerns regarding pediatric access. However, we do not believe that commenters provided sufficient reasoning or data to demonstrate that the other hospital types subject to this policy have the additional resource costs that our historical analysis has demonstrated for rural SCHs and therefore should also be exempted from this OPPS payment policy. We will continue to study access and costs to determine whether further exemptions to the volume control policy are appropriate in future rulemaking.

Comment: Some commenters recommended that CMS use criteria other than hospital type in determining whether a provider should qualify for an exemption. Commenters suggested considering factors such as geographic isolation, the availability of alternative imaging providers, beneficiary travel times, financial vulnerability, local workforce shortages, and the role of a hospital in maintaining access to essential services. Some commenters recommended that CMS monitor the effects of the policy on beneficiary access, including changes in imaging availability, wait times, travel distances, and service volumes, particularly in rural and underserved communities.

Response: We appreciate commenters' thoughtful suggestions regarding alternative criteria for determining whether an exemption may be appropriate. As discussed previously, for purposes of this policy we believe that the rural SCH designation provides an appropriate basis for the exemption because of the historical treatment and documented additional resource costs of rural SCHs under the OPPS. We are not adopting additional exemption criteria at this time. We will, however, consider commenters' suggestions as we continue to evaluate the effects of our volume control policies and whether additional exemptions may be appropriate in future rulemaking.

We also appreciate commenters' concerns regarding beneficiary access. Consistent with our approach to the clinic visit and drug administration volume control policies, we will continue to monitor the effects of this change in Medicare payment policy, including the volume of these types of OPD services and beneficiary access to care, including for beneficiaries with disabilities, and may revisit the policy in future rulemaking.

Comment: Some commenters recommended that CMS exempt certain imaging services or clinical circumstances from the volume control method based on the type of service furnished or the needs of the patient. Several commenters recommended exempting preventive and screening imaging services from the volume control method based on concerns regarding beneficiary access to recommended screening and early detection services. As discussed previously in this section, commenters specifically identified certain preventive and screening services included in the imaging without contrast APCs and recommended that CMS exclude these services from the policy.

Other commenters recommended exemptions for certain oncology-related imaging services. One commenter requested that CMS exempt diagnostic and procedural imaging directly associated with planned or same-day interventional oncology procedures, including pre- and post-procedural imaging used for treatment planning, procedural guidance, or assessment following a procedure. Other commenters recommended exemptions or other protections for imaging furnished to high-acuity oncology patients or imaging that is integrated with specialty oncology care, stating that these services may require hospital-level clinical infrastructure, specialized staff, immediate access to other hospital resources, or coordination with other services furnished as part of the patient's treatment.

Some commenters also raised concerns that applying the volume control method to imaging without contrast services, while imaging services furnished with contrast or an enhancing agent would not be subject to the policy, could create a payment incentive affecting the use of contrast or enhancing agents. Commenters specifically noted that ultrasound enhancing agents may be clinically appropriate for certain echocardiography services but stated that the decision to use an enhancing agent should be based on the clinical needs of the patient rather than differences in payment. Commenters expressed concern that increased use of

enhancing agents in response to payment differences could also increase costs associated with the agent, intravenous access, nursing, and other related resources.

Some commenters more generally recommended exempting imaging furnished as part of a medically complex diagnostic workup, imaging integrated with same-day procedures requiring hospital-level resources, or services that rely on hospital infrastructure or specialty resources. Commenters stated that these circumstances may involve medically-complex beneficiaries or additional resources that are not available in freestanding imaging facilities or physician offices.

Response: We appreciate the commenters' thoughtful suggestions regarding exemptions for particular imaging services or clinical circumstances. As we stated in the CY 2026 OPPS/ASC final rule with comment period in response to similar recommendations regarding drug administration services (90 FR 53824), we are concerned that exempting a small subset of services from the volume control methodology could inadvertently incentivize an increase in the provision of those services in the higher cost setting of care. Furthermore, we do not believe that commenters have provided a clear clinical justification for exempting certain imaging without contrast services while leaving other imaging without contrast services non-exempted. We believe it would be most transparent to propose any service-specific exceptions through notice-and-comment rulemaking.

We address commenters' recommendations regarding preventive and screening imaging services in detail previously in this section. As discussed there, we recognize the important role that preventive services play in identifying disease at an earlier stage and improving health outcomes for Medicare beneficiaries, but we do not believe that the preventive nature of a service, by itself, warrants exclusion from the volume control method.

We also appreciate commenters' concerns regarding the potential for differences in payment to affect the use of contrast or enhancing agents. We agree that the decision to use a contrast or enhancing agent should be based on the clinical needs of the beneficiary and not on differences in Medicare payment. The volume control method finalized in this rule does not change the clinical criteria for determining when the use of a contrast or enhancing agent is appropriate. As discussed previously, our policy is intended to remove a payment incentive that we believe contributes to unnecessary increases in the volume of covered OPD services, not to influence clinical decisions regarding how an imaging service should be furnished. We will monitor utilization following implementation of this policy and may consider changes in utilization patterns, including the use of contrast or enhancing agents, as part of our evaluation of the effects of the volume control method.

With respect to commenters' recommendations regarding imaging furnished to high-acuity or medically complex patients, imaging furnished in connection with planned or same-day procedures, or imaging furnished as part of integrated oncology care or other complex episodes of care, we appreciate that OPDs serve unique patient populations and provide services to medically complex beneficiaries. However, we do not believe that these circumstances demonstrate the need for higher payment for all imaging without contrast services furnished to these beneficiaries or in connection with these episodes of care. The fact that an imaging service is furnished on the same day as, or in connection with, another hospital service also does not necessarily establish that the imaging service itself requires the hospital outpatient setting or should be excluded from the volume control method. Our policy does not prevent a physician from determining that an OPD is the appropriate setting for a particular beneficiary based on the beneficiary's clinical needs.

We also are not certain how we would reliably identify the particular patients, services, or clinical circumstances suggested by commenters for purposes of administering an exemption. We appreciate commenters' input and may consider these suggestions in future rulemaking.

Comment: Several commenters discussed the impact of the proposed method to control volume for imaging without contrast services on PPS-exempt cancer hospitals. Commenters noted that payments to PPS-exempt cancer hospitals are subject to the cancer hospital payment adjustment based on a payment-to-cost ratio and stated that reducing OPPS payment for imaging without contrast services could indirectly affect payments to these hospitals through the payment-to-cost ratio methodology.

Response: We appreciate commenters' discussion of the impact of this policy on PPS-exempt cancer hospitals. We note that any reduction in the initial OPPS payment to a PPS-exempt cancer hospital as a result of this policy would lower the hospital's payment-to-cost ratio and would result in a corresponding increase in the cancer hospital payment adjustment at cost report settlement. We therefore do not believe that the application of the volume control method to imaging without contrast services warrants a separate exemption for PPS-exempt cancer hospitals.

We also recognize that this policy may affect the target payment-to-cost ratio used in determining the cancer hospital payment adjustment because the target payment-to-cost ratio is based on the payment-to-cost ratios of hospitals paid under the OPPS other than PPS-exempt cancer hospitals. We believe the effect of this policy on the target payment-to-cost ratio, through its effect on non-cancer hospitals' payment-to-cost ratios, would be relatively small. Moreover, because we believe the reduced payment for imaging without contrast services furnished by non-cancer hospitals subject to this policy is appropriate, we likewise believe that any resulting effect on the target payment-to-cost ratio is appropriate.

After consideration of public comments, we are finalizing our proposal to exempt rural Sole Community Hospitals (rural SCHs) from payment of the site-specific Medicare PFS-equivalent payment for any HCPCS codes assigned to the imaging without contrast APCs or paid through the imaging without contrast composite APCs, when furnished at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier ''PO'' on claim lines). We believe that exempting rural SCHs from the volume control policy for imaging without contrast services will help to maintain access to care in rural areas by ensuring rural providers are paid for imaging without contrast services provided at off-campus PBDs at the same rate paid when the service is furnished in on-campus departments. Finalizing this policy also aligns with the special payment treatment rural SCHs receive under the OPPS. We will continue to monitor the effects of this change in Medicare payment policy.

B. OPPS Payments for SaMS Diagnostic Services

1. Payment for Software as a Medical Service (SaMS)

In recent years, there have been rapid developments in the use of software-based technologies with novel functionalities to support clinical decision-making in the outpatient and physician office settings. New clinical software, which includes clinical

decision support software, clinical risk modeling, and computer aided detection (CAD), is becoming increasingly available to providers. These technologies often perform data analysis of diagnostic images from patients, relying on complex algorithms or statistical predictive modeling to aid in the diagnosis or treatment planning of a patient's condition. In previous rulemaking, we have referred to these algorithm-driven services that assist practitioners in making clinical assessments or diagnoses as Software as a Service (SaaS). Unlike prescription digital therapeutics (PDTs), for example PDTs that provide cognitive behavioral therapy to treat substance disorders or chronic insomnia, SaaS technologies as we refer to them do not currently treat illnesses or patient injuries. SaaS is also separate from remote patient monitoring (RPM) and remote therapeutic monitoring (RTM), which are digital healthcare tools for tracking patient data outside traditional office settings (90 FR 49394). For CY 2027, we proposed-a change in terminology. We noted that we now understand that in other industries, the existing SaaS terminology is used for general cloud-based computing service models outside of a health care context, which may cause confusion as we are using it to describe specific services that provide a medical function for purposes of OPPS/ASC Medicare payment policy. To dispel any ambiguity and clarify that distinction, we proposed to change our terminology from SaaS to Software as a Medical Service (SaMS) to refer to software-based technologies that support clinical decision making through algorithmic analysis, including those that provide clinical or diagnostic functionality. We welcomed public comments on the proposed change in terminology.

CMS has been evaluating how to develop a comprehensive and consistent approach to SaMS payment for several years with the novel and evolving nature of these technologies. We have sought public input through two comment solicitations (87 FR 72035 through 87 FR 72036, 89 FR 94129 through 89 FR 94131) and expressed our objective to seek a payment strategy that aligns with our agency's mission to increase quality, improve health, reduce costs, and strengthen the healthcare system. However, questions remain regarding how best to structure payment for these services. One challenge is that current Medicare Part B payment systems for SaMS, including in the OPPS, are primarily designed to pay for services that rely on material resources, rather than technologies whose value is driven by proprietary algorithms and scalable, non-material costs. This creates difficulties in establishing appropriate valuation methodologies, as the current cost-based system often offers only limited transparency into underlying costs and may not effectively constrain pricing. Another challenge is determining how to account for the various ways in which these technologies are acquired and billed by hospital OPDs, particularly in cases with subscription- or license-based arrangements, as well as per-use or ''per-click'' fees, which raises concerns regarding program integrity.

As coding for SaMS continues to rapidly increase and technologies evolve, establishing a consistent and timely payment methodology for these services is a priority. New SaMS technologies are continuing to be introduced to the market, each often accompanied by unique CPT codes reflecting their proprietary algorithms or specific characteristics. Interested parties are frequently seeking Medicare payment and coding for SaMS technologies through the new technology APC process or requesting clinical APC assignments. As a result, CMS is continuously assessing and evaluating payment for SaMS through different pathways. As we consider this policy, we want to ensure that we are moving toward a more standardized approach that reduces payment rate variation across similar technologies.

Given the growing need for a comprehensive and tailored payment methodology, as we work to gather additional data to better understand and more fully address the inherent payment challenges in this area, we proposed an interim payment policy for SaMS for CY 2027 while we examine a range of approaches to payment for these kinds of technologies. Specifically, we proposed to assign SaMS technologies to new technology APCs for CY 2027. We propose*d* to designate 36 HCPCS codes as SaMS services and reassign the proposed designated SaMS services that are currently paid separately (assigned to status indicator ''S'') under clinical APCs, to new technology APCs that closely align with their current CY 2026 payment rates. We proposed to assign the separately paid SaMS technologies to new technology APCs because we believed that the existing clinical APC structure did not adequately accommodate SaMS. We believed that the new technology APCs were more appropriate to accommodate SaMS on a temporary basis, as there have historically been placements under the OPPS that allow us to provide consistent payment for new procedures that are not yet reflected in our claims data or for which we lack sufficient clinical information and cost data until we can identify an appropriate clinical APC. In certain circumstances, we have also assigned some services to new technology APCs through rulemaking, even when they have not met the specific regulatory criteria (66 FR 59897 through 59903) or have not applied for new technology APC assignment through the subregulatory process. For example, we have assigned certain services to new technology APCs in special cases where an appropriate clinical APC to which to assign the service does not exist. In the CY 2026 OPPS/ASC final rule with comment period, we maintained the new technology APC assignment for HCPCS codes G2082 and G2083 because we did not believe there was an appropriate clinical APC to which to assign the service (90 FR 53551). This proposed approach of assigning SaMS services to the same APC series would allow CMS to take the first step towards standardization and applying a consistent payment methodology across these services as we consider more comprehensive long-term approaches, including those that may better align payment with clinical outcomes.

We also believed it was important to distinguish SaMS technologies from other services that are assigned to new technology APCs because not all new services assigned to new technology APCs are SaMS technologies. Therefore, we proposed to create a new status indicator under OPPS specifically for SaMS technologies. For CY 2027, we proposed to create status indicator ''O1'' (Software as a Medical Service, Paid under OPPS; separate APC payment) and assign all services that we proposed to designate as SaMS to status indicator ''O1.'' Functionally, we proposed for status indicator ''O1'' to have the same payment specifications as status indicator ''S,'' to allow for separate payment. We requested public comment on this proposal. We also requested public comment regarding whether a new status indicator with the same specification as status indicator ''T'' (Procedure or service subject to multiple procedure discounting) would provide more appropriate payment for these services while addressing any potential program integrity concerns.

For CY 2027, we proposed to designate the HCPCS codes listed in Table 83 as SaMS technologies. Of these, we proposed to assign 21 HCPCS codes to new technology APCs from clinical APCs, maintaining approximate

payment rate continuity with CY 2026 payment, and status indicator ''O1''. Table 84 provides the list of HCPCS codes and proposed new technology APC and status indicator assignments for CY 2027. For SaMS that are already assigned to new technology APCs for CY 2026, we proposed to continue to assign these services to new technology APCs for CY 2027 while proposing to update the status indicator assignment to ''O1'' to designate these technologies as SaMS. We refer readers to section III.C. of the proposed rule-(91 FR 41803 through 91 FR 41807) for a discussion on our proposals for SaMS technologies that are currently assigned to new technology APCs for CY 2026.

We note that there are a small number of technologies we consider to be SaMS that are currently paid under the OPPS and assigned to an OPPS status indicator of ''Q1'' (STV-Packaged Codes; Paid under OPPS), indicating that the service is conditionally packaged. Services assigned to an OPPS status indicator of ''Q1'' will receive packaged payment when furnished with a significant procedure but will be separately paid when the service appears on the claim without a significant procedure. Because services assigned to new technology APCs are exempt from C–APC packaging policies, we did not believe it would be appropriate to propose to assign SaMS HCPCS codes that are currently conditionally packaged for CY 2026 to new technology APCs with status indicator ''S'' (Procedure or Service, Not Discounted When Multiple) to indicate separate payment. As an alternative, we considered unconditionally packaging SaMS services that are currently assigned to status indicator ''Q1'' by proposing to assign the services a status indicator of ''N'' (Items and Services Packaged into APC Rates). However, we stated that we believe proposing to unconditionally package payment for CY 2027 for SaMS technologies that are currently conditionally packaged under the OPPS may have resulted in interruptions to patient access. Given that we intended for this policy to be a first step towards more comprehensive payment policy changes and sought to minimize disruption, we believed it was more appropriate to propose to maintain the clinical APC and status indicator assignments for these codes. Therefore, for CY 2027, we proposed to maintain the clinical APC and status indicator assignments for SaMS that are currently conditionally packaged under the OPPS.

Similarly, there are other HCPCS codes that describe SaMS assigned to status indicator ''E1'' (Items, codes, and services not covered by any Medicare outpatient benefit category; statutorily excluded; not reasonable and necessary), status indicator ''N'' (Items or services packaged into APC rates), or status indicator ''M'' (Items and services not billable to the FI or MAC). Since these are not separately paid services under the OPPS for CY 2026, for CY 2027, we proposed to maintain the OPPS status indicators to which they are currently assigned.

We provided a table with the various SaMS HCPCS codes that were impacted by our proposals. Table 83 provides the proposed CY 2027 APC and status indicator assignments for codes we proposed to designate as SaMS services and that are currently assigned to clinical APCs or are not separately paid under the OPPS for CY 2026. We referred readers to section III.C. of the proposed rule for a discussion on the proposed CY 2027 payment rates for SaMS codes that are currently assigned to new technology APCs for CY 2026. In addition, we referred readers to Addendum B of the proposed rule for proposed CY 2027 OPPS payment rates and status indicators for HCPCS codes that we proposed to designate as SaMS. We requested comment on our proposals, including the list of HCPCS codes we proposed to designate as SaMS and that we proposed to reassign to new technology APCs for CY 2027, including whether there were any additional HCPCS codes we should consider.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed terminology change from SaaS to SaMS. One commenter explained that the proposed terminology would clarify the distinction between clinical algorithms and generic cloud tooling. A commenter requested that we clarify whether the transition to SaMS is intended solely as a naming convention or whether it reflects broader distinctions regarding the scope, classification, valuation or payment treatment of these technologies.

Response: We thank the commenters for their support. The terminology change from SaaS to SaMS seeks to clarify, as one commenter explained, the distinction between clinical algorithms used to furnish these services and generic cloud tooling.

Based on the comments received, for CY 2027, we are finalizing our proposal to change the terminology for these algorithm-based software services that are paid under Medicare from ''SaaS'' to ''SaMS.''

Comment: Many commenters requested clarification regarding the types of services that would be considered SaMS for purposes of this policy. For example, commenters asked whether remote care delivery or non-device clinical decision support (CDS) would be considered SaMS for purposes of separate payment. Similarly, we received comments regarding how CMS will distinguish separately paid software that supports clinical decision making from software that provides broader operational, administrative, or business functions. One commenter specifically requested that we expand our scope of services that we designate as SaMS to include those that perform analyses on structured clinical data conforming to recognized interoperability standards such that super intelligence-enabled comprehensive clinical trial eligibility analysis would be payable under the OPPS.[173]

Response: We thank the commenters for their interest in better understanding the scope of our policy. Regarding whether we would consider remote care delivery services as SaMS for purposes of this policy, we refer the commenter to our proposal where we specified that SaMS is separate from RPM and RTM, which are digital health tools for remotely tracking patient data. Furthermore, software that includes broader operational, administrative, or business functions, including clinical trial eligibility analysis, would not be considered SaMS under current policy. These kinds of software services can provide operational efficiencies but would not have a Medicare benefit category to allow for separate payment under OPPS.

We also appreciate commenters' input regarding whether CMS would consider non-device CDS as SaMS. The 36 services that we proposed to designate as SaMS, and that we previously referred to as SaaS, are regulated by the FDA as devices and therefore would not be considered non-device CDS. We note that although SaMS described in this section of this final rule with comment period (section X.B.1.), are required to have FDA marketing authorization to receive Medicare payment, ''SaMS analyses performed on laboratory tests,'' which are described in the following section of this final rule with comment period (section X.B.2.), currently do not require FDA marketing authorization in order to receive payment. As the CY

[173] The term ''Super Intelligence'' is used herein to refer to what was formerly called Artificial Intelligence or AI. See Exec. Order No. 14434, Inaugurating the Era of Super Intelligence, 91 FR 63,129 (Oct. 2, 2026).

2027 SaMS policy is an interim policy that seeks to maintain payment for CY 2027, we are declining to expand the scope of our policy to include non-device CDS at this time, although we note that there are existing non-device CDS services assigned to clinical APCs for CY 2026. We will consider expanding and further clarifying the scope of the SaMS policy for future rulemaking.

Comment: We received several comments requesting information on CMS's process for identifying the 36 proposed HCPCS codes to be designated as SaMS. Commenters requested that we adopt, in the future, specific criteria that CMS will use to determine whether a service is payable as a SaMS under OPPS. For example, a commenter requested that we include the definitions and criteria from the recently updated Appendix S, effective June 2026, available via the AMA's website to identify SaMS codes. Other commenters requested that we identify SaMS codes based on functionality rather than input modality. We also received comments requesting that CMS align its clinical or diagnostic functionality criteria with the definitions that are used by the Food and Drug Administration (FDA) for their review of indications for use and device descriptions in their guidance documents and clearance processes.

Response: We appreciate the comments. To identify the 36 proposed SaMS CPT codes, we examined all CPT codes currently paid under the OPPS to determine which codes aligned with the SaMS terminology provided in the CY 2027 OPPS/ASC proposed rule, specifically ''software-based technologies that support clinical decision making through algorithmic analysis, including those that provide clinical or diagnostic functionality'' as a framework. We excluded RTM, RPM, non-device CDS, and services that we did not believe would fall under a Medicare benefit category, including those that are administrative in function. For instance, software that serves as the infrastructure that the provider uses to furnish another separately paid service.

Given the interim nature of the proposed policy, we will take the criteria concerns raised by the commenters, including establishing specific criteria for SaMS service for purposes of payment under the OPPS, into consideration for future rulemaking. We welcome public engagement from interested parties on these issues, including whether there are services that should be designated as SaMS in the future.

Comment: We received a significant number of comments and requests from various interested parties regarding the proposed APC and status indicator assignments for certain SaMS services. Some of the requests included services that we did not identify as SaMS for the proposed rule and interested parties requested that they be added to the SaMS list. Others requested to maintain the clinical APC assignments for specific services we identified as SaMS versus assigning them to new technology APCs. A third category of requests included services that we identified as SaMS and assigned to new technology APCs, but interested parties requested different new technology APC assignments. We also received several comments requesting for certain services to be designated as SaMS and assigned to status indicator ''O1'' for CY 2027. A summary of the SaMS APC Specific requests and our responses are below.

We also note that since the CY 2027 proposed rule was published, the AMA revised their 'release and effective date' calendar for new category III CPT codes. The new category III CPT codes that were going to be effective January 1, 2027, became effective October 1, 2026. New category III CPT codes with January 1, 2027, effective dates that we had designated as SaMS for the proposed rule, were assigned to clinical APCs and status indicators for the October 2026 update.

We received several comments requesting for certain services to be designated as SaMS and assigned to status indicator ''O1'' for CY 2027.

a. Biomechanical Computed Tomography (BCT) Analysis, CPT Code 0554T

Biomechanical Computed Tomography (BCT) analysis involves the use of a previous CT scan that is used by a computer software program to measure both the bone strength and bone mineral density of the hip or spine region. These services are described by CPT codes 0554T, 0555T, 0556T, 0557T, 0558T, and 0743T. CPT code 0554T is currently assigned to status indicator 'M' (Items and Services Not Billable to the MAC. Not paid under OPPS). We received public comment on this service.

Comment: A commenter requested we designate CPT code 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)* as a SaMS. The commenter stated that since the other BCT codes (0555T, 0556T, 0557T, 0558T, 0743T) were designated as SaMS, it may be appropriate to designate CPT code 0554T as SaMS, although the commenter noted that the payment for CPT code 0554T is the sum of the payment for CPT codes 0555T–0557T.

Response: We thank the commenter for their input. For CPT code 0554T, we note that the current payment assignment is 'M'. As we conveyed in the proposed rule, this interim payment policy is a step toward a more standardized approach that reduces payment rate variation across similar technologies. We believe that it is important to either maintain current payment rates (*i.e.,* by maintaining a service's new technology APC assignment) or assign new technology APCs that are closely aligned with current CY 2026 payment rates. We believe that because CPT code 0554T is not payable under OPPS, we should maintain the current status indicator. We are finalizing the status indicator assignment for CPT code 0554T as proposed. Please refer to Addendum B to this final rule with comment period, which is available on the CMS website, for the final CY 2027 payment rates.

b. Cardiosense Solution, CPT Code 1036T

The Cardiosense Solution, which is composed the CardioTag™ wearable sensor and the PCWP Analysis Software™, estimates a patient's pulmonary capillary wedge pressure (PCWP) noninvasively to aid providers in the management of heart failure. CPT code 1036T (*Noninvasive hemodynamic assessment with pulmonary pressures and ejection fraction when performed, including passive acquisition of acoustic and electrical signals, augmentative algorithmic analysis, and generation of a clinical report with review, interpretation, and clinical integration by a physician or other qualified health care professional*) is currently assigned to status indicator 'E1' (Not covered by any Medicare outpatient benefit category; Statutorily excluded by Medicare; Not reasonable and necessary; Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) and receives no payment under OPPS. We received public comment on this service.

Comment: A commenter indicated that the devices in this service have recently received FDA marketing authorization (510(k) clearance for the CardioTag™ and De Novo authorization for the PCPW Analysis Software™) and

requested that we designate CPT code 1036T as a SaMS. The commenter requested that we assign it to APC 1503 and status indicator O1 using the following CPT codes as possible crosswalks:

- 1104T—*Noninvasive cardiopulmonary assessment, including quantitative parameters, respectively predictive of significant epicardial coronary artery disease, pulmonary hypertension, and/or elevated pulmonary capillary wedge pressure, derived by augmentative algorithmic analysis of orthogonal voltage gradient and photoplethysmography signals, with automated report;*
- 0962T—*Assistive algorithmic analysis of acoustic and electrocardiogram recording for detection of cardiac dysfunction (eg, reduced ejection fraction, cardiac murmurs, atrial fibrillation), with review and interpretation by a physician or other qualified health care professional;*
- 0764T—*Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (eg, low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to concurrently performed electrocardiogram (List separately in addition to code for primary procedure);* and
- 0765T—*Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (eg, low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to previously performed electrocardiogram.*

Response: We thank the commenter for their input. We agree with the commenter that, since these products recently received FDA marketing authorization, CPT code 1036T should be designated as a SaMS and paid under this final policy, as it describes an augmentative algorithmic analysis. We note that although SaMS described in this section of this final rule with comment period (section X.B.1.), such as CPT code 1036T, are required to have FDA marketing authorization to receive Medicare payment, ''SaMS analyses performed on laboratory tests,'' which are described in the following section of this final rule with comment period (section X.B.2.), currently do not require FDA marketing authorization in order to receive payment. We also agree with the commenter's choice of crosswalk codes, particularly CPT code 1104T. In summary, we are finalizing CPT code 1036T to APC 1503 (New Technology—Level 3 ($101–$200)) with a payment rate of $150.50. See Table 83 for the list of services designated as SaMS and their CY 2027 payment assignments.

c. DeepView AI® System, CPT Code 0972T

The DeepView AI® System (DeepView) is a non-invasive medical imaging platform used to evaluate burn wounds and predict their healing potential. This service is described by CPT 0972T *(Assistive algorithmic classification of burn healing (ie, healing or nonhealing) by noninvasive multispectral imaging, including system set-up and acquisition, selection, and transmission of images, with automated generation of report)* and is currently assigned to status indicator 'E1' (Not covered by any Medicare outpatient benefit category; Statutorily excluded by Medicare; Not reasonable and necessary; Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)). We received public comment on this service.

Comment: A commenter has requested that we designate this service as a SaMS and reassign CPT 0972 to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50, noting that DeepView received De Novo marketing authorization in May of 2026.

Response: We thank the commenter for their input. We agree with the commenter that this service should no longer be assigned to status indicator 'E1' as the device utilized for this service has received De Novo marketing authorization and agree that this service should be designated as a SaMS. We disagree, however, with the commenter regarding the APC assignment and payment rate requested. We note that the commenter requested an APC assignment with a payment rate of $2,750.50 stating that this would cover the cost of the software. After review of the service and input from our medical advisors, we believe CPT 0992T *(Noninvasive assessment of cardiac risk derived from augmentative software analysis of perivascular fat without concurrent computed tomography (CT) scan of the heart, including patient-specific clinical factors, with interpretation and report by a physician or other qualified health care professional)* is an appropriate crosswalk because both services are utilizing imaging data with their software to obtain additional information for the clinician. We are assigning CPT 0972T to APC 1504 (New Technology—Level 4 ($201–$300)) with a payment of $250.50 and a status indicator of 'O1'. See Table 83 below for the list of services designated as SaMS and their final CY 2027 APC assignments.

d. CureMatch, CPT Code 0794T

CPT code 0794T (*Patient-specific, assistive, rules-based algorithm for ranking pharmaco-oncologic treatment options based on the patient's tumor-specific cancer marker information obtained from prior molecular pathology, immunohistochemical, or other pathology results which have been previously interpreted and reported separately*) is currently assigned to APC 5733 (Level 3 Minor Procedures) and status indicator 'S'. We received public comment on this code.

Comment: A commenter requested that we designate this service as a SaMS consistent with our request for comment on additional codes that should be designated as SaMS.

Response: We thank the commenter for their input. We note that this service is considered a non-device CDS, and as explained earlier in this section, we are declining to expand the scope of our policy to include non-device CDS. In summary, we are finalizing the APC assignment for CPT code 0794T as proposed. Please refer to Addendum B to this final rule with comment period, which is available on the CMS website, for the final CY 2027 payment rates.

e. MuscleSound, CPT Codes 0689T, 0690T

CPT codes 0689T *(Quantitative ultrasound tissue characterization (non-elastographic), including interpretation and report, obtained without diagnostic ultrasound examination of the same anatomy (e.g. organ, gland, tissue, target structure)) and 0690T (Quantitative ultrasound tissue characterization (non-elastographic), including interpretation and report, obtained with diagnostic ultrasound examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure))* became effective January 1, 2022. For CY 2026, CPT code 0689T is assigned to APC 5521 (Level 1 Imaging without Contrast) with a status indicator 'S' (Procedure or Service, Not Discounted When Multiple, Paid under OPPS; separate APC payment) and CPT 0690T is assigned to status indicator 'N' (Items and Services Packaged into APC Rates; Paid under OPPS; payment is packaged into payment for other services). We received public comment on these codes.

Comment: A commenter requested that we designate these services as SaMS and assign these codes to an appropriate new technology APC and a status indicator of 'O1'.

Response: We thank the commenter for their input. We believe the services described by these codes are similar enough to a non-device CDS software, that we are not persuaded to designate them as SaMS at this time. Therefore, for CY 2027, we are finalizing CPT codes 0689T and 0690T as proposed. Please refer to Addendum B to this final rule with comment period, which is available on the CMS website, for the final CY 2027 payment rates.

f. NeuroMatch, CPT Code 1041T

CPT code 1041T *(Augmentative algorithmic analysis of encephalographic waveforms to identify the source and propagation of epileptiform activity, including artifact reduction with analysis of 3D localization of spike sources throughout the examination, 3D animations over time of high-amplitude event locations, high-frequency activity locations, and temporal relationships among locations, with interpretation and report by physician or other qualified health care professional, related to a previously performed electroencephalogram (EEG))* became effective July 1, 2026 and was assigned to APC 5734 (Level 4 Minor Procedures) and status indicator 'S'. We received public comment on this code.

Comment: A commenter requested that we assign CPT code 1041T to new technology APC 1513 (New Technology—Level 13 ($1101—$1200)) with a payment of $1,150.50 citing resource costs and designate this service as SaMS (status indicator assignment of 'O1').

Response: We thank the commenter for their input. We agree with the commenter that CPT code 1041T should be designated as a SaMS and assigned to status indicator of 'O1'. However, we note that CPT code 1041T is currently assigned to APC 5734 (Level 4 Minor Procedures) with a payment rate of approximately $152. As we stated in our proposed rule, we cross walked services that were assigned to clinical APCs to new technology APCs that were aligned in payment. Therefore, for CY 2027, we are assigning CPT code 1041T to APC 1503 (New Technology—Level 3 ($101–$200)) with a payment of $150.50. See Table 83 below for the list of services designated as SaMS and their CY 2027 payment assignments.

g. MeRT, CPT Code 1105T

The MeRT system utilizes an augmentative super intelligence algorithm that analyzes eyes-closed, resting state EEG and single-lead ECG recordings to algorithmically derive each patient's personalized stimulation pulse rate for Transcranial Magnetic Stimulation (TMS) to treat obsessive-compulsive disorder and major depressive disorder. This device received 510(k) clearance June 3, 2026 and the service utilizing the device is described by CPT code 1105T *(Personalized neurostimulation pulse rate derived by augmentative algorithmic analysis of data from electroencephalogram (EEG) and electrocardiogram (ECG), including acquisition of EEG and single-lead ECG, with automated report).* This code is currently assigned to a status indicator of 'E1' because we believed the service did not have FDA marketing authorization. We received public comment on this code.

Comment: A commenter requested that we assign CPT 1105T (placeholder code X647T) to a payable status indicator ('S') and APC 5722 (Level 2 Diagnostic Tests and Related Services) or if we finalize our interim SaMS policy, assign CPT code 1105T to APC 1504 and status indicator 'O1' using CPT code 90867 *(Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management)* as a crosswalk code.

Response: We thank the commenter for their input. After review of the service and input from our medical advisors, we agree with the commenter and believe that CPT code 1105T should be designated as a SaMS and assigned to status indicator of 'O1'. We also agree that CPT code 90867 is a good crosswalk for this service. Therefore, for CY 2027, we are assigning CPT code 1105T to APC 1504 (New Technology—Level 4 ($201–$300)) with a payment rate of $250.50 and a status indicator of O1. See Table 83 below for the list of services designated as SaMS and their CY 2027 APC assignments.

Comment: We received comments on certain services that opposed our proposal to designate those services as SaMS and assign those services to new technology APCs that would maintain CY 2026 payment rates. Various commenters have requested that CMS maintain existing clinical APC assignments for the following services (noted by their HCPCS code and long descriptor):

- C9793—*3d predictive model generation for pre-planning of a cardiac procedure, using data from cardiac computed tomographic angiography and/or magnetic resonance imaging with report*
- CPT code 0764T—*Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (e.g., low ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to concurrently performed electrocardiogram (List separately in addition to code for primary procedure)*
- CPT code 0765T—*Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (e.g., low ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy)*
- CPT code 92229—*Imaging of retina for detection or monitoring of disease; point-of-care autonomous analysis and report, unilateral or bilateral*
- CPT code 75580—*Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional*

Comment: Commenters cited various reasons as to why these services should stay in their clinical APCs. Commenters believe that established services should be allowed to remain in their existing clinical APC to continue gathering claims data, noting that some of these services have accumulated sufficient claims and cost data to support their clinical APC assignment. They believe that utilizing the new technology APCs in a manner outside of our ''normal'' use of new technology APCs will introduce payment instability without a benefit to the interested parties or signal to payers that we consider some of these SaMS services as experimental or investigational.

Several commenters requested that we refrain from reassigning these services from clinical APCs until the new payment framework and policy has been defined to avoid unnecessary disruption for hospital outpatient departments. Several commenters cited a reduction in payment for CPT code 75580, requesting that, if we are reassigning this service to a new technology APC, we reassign it to a higher APC to reflect the cost of the service.

Several commenters noted that CPT code 75580 describes a diagnostic test and moving it to a new technology APC during this interim period results in payment rates that do not reflect the true costs of these services.

Response: We appreciate the commenters' feedback and their concerns. As we stated in the proposed rule, this is an interim policy or a first step towards a more comprehensive payment policy. We proposed these changes to minimize payment disruption. We cross walked the clinical APCs to new technology APCs

maintaining payment rate continuity with CY 2026 payment rates. We understand that reassigning APCs from clinical APC families to new technology APCs may result in slight payment changes. However, we believe that it is important to consistently assign all designated SaMS to new technology APCs and not make exceptions for some services because they have been utilized for a longer period of time compared to newer services.

We do not believe that the reassignment to new technology APCs that maintain CY 2026 payment rates will cause payment instability or signal to other payers that these services are new or experimental. For CY 2027, we are finalizing our proposal for these services without modification. See Table 83 at the end of this section for the list of services designated as SaMS and their final CY 2027 APC assignments.

We received a number of comments requesting APC reassignments to higher APCs for various services that we proposed to designate as SaMS. Table 83 provides the proposed, requested, and final APC and status indicator assignments for those services for CY 2027. Our collective response follows.

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TABLE 83: PROPOSED, REQUESTED, AND FINAL APC AND SI ASSIGNMENTS FOR SERVICES REQUESTING ALTERNATIVE APCS FOR CY 2027

Service Name	HCPCS Code	Descriptor	Proposed CY 2027 APC, SI	Commenter Requested CY 2027 APC, SI	Final CY 2027 APC, SI
Bone Strength and Vertebral Fracture Risk Assessment	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)	APC 1504 (New Technology - Level 4 ($201 - $300), O1	APC 1505 (New Technology - Level 5 ($301 - $400)), O1	APC 1504 (New Technology - Level 4 ($201 - $300), O1
3D Image Generation Used in Surgical Planning and Navigation for Placement Implants and Devices (BoneMRI)	G0566	3D radiodensity-value bone imaging, algorithm derived, from previous magnetic resonance examination of the same anatomy	APC 1503 (New Technology - Level 3 ($101 - $200)), O1	APC 1504 (New Technology - Level 4 ($201 - $300)), O1	APC 1503 (New Technology - Level 3 ($101 - $200)), O1
3D Anatomical Segmentation Imaging Software Service	C8001	3d anatomical segmentation imaging for preoperative planning, data preparation and transmission, obtained from previous diagnostic computed tomographic or magnetic resonance examination of the same anatomy	APC 1503 (New Technology - Level 3 ($101 - $200)), O1	APC 1506 (New Technology - Level 6 ($401 - $500)) or APC 1507 (New Technology - Level 7 ($501 - $600))	APC 1503 (New Technology - Level 3 ($101 - $200)), O1
FibreSolve	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	APC 1508 (New Technology - Level 8 ($601 - $700)), O1	APC 1524 (New Technology - Level 24 ($3001-$3500), O1	APC 1508 (New Technology - Level 8 ($601 - $700)), O1
FibreSolve	0878T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease;	APC 1508 (New Technology - Level 8 ($601 - $700)), O1	APC 1524 (New Technology - Level 24 ($3001-$3500), O1	APC 1508 (New Technology - Level 8 ($601 - $700)), O1

Service Name	HCPCS Code	Descriptor	Proposed CY 2027 APC, SI	Commenter Requested CY 2027 APC, SI	Final CY 2027 APC, SI
		obtained with concurrent CT examination of the same structure)			
MindMotion GO Neurorehabilitative Remote Therapy Service	0733T	Remote real-time, motion capture-based neurorehabilitative therapy ordered by a physician or other qualified health care professional; supply and technical support, per 30 days	APC 1505 (New Technology - Level 5 ($301 - $400)),O1	APC 1510 (New Technology - Level 10 ($801 - $900)), O1	APC 1505 (New Technology - Level 5 ($301 - $400)),O1
Noninvasive Arterial Plaque Analyses	0712T	Noninvasive arterial plaque analysis using software processing of data from non-coronary computerized tomography angiography; quantification of the structure and composition of the vessel wall and assessment for lipid-rich necrotic core plaque to assess atherosclerotic plaque stability	APC 1504 (New Technology - Level 4 ($201 - $300)), O1	APC 1511 (New Technology - Level 11 ($901 - $1000)), O1	APC 1504 (New Technology - Level 4 ($201 - $300)), O1
Coronary Fractional Flow From Coronary Angiography Data (QFR)	1086T	Intraprocedural estimate of coronary fractional flow derived by augmentative algorithmic analysis of data from real-time coronary angiography, with creation of functional map of coronary circulation, when performed, with review and interpretation (List separately in addition to code for primary procedure)	APC 1510 (New Technology - Level 10 ($801 - $900)), O1	APC 1522 (New Technology - Level 22 ($2001-$2500))	APC 1510 (New Technology - Level 10 ($801 - $900)), O1
Coronary Fractional Flow From Coronary Angiography Data (QFR)	1087T	Estimate of coronary fractional flow derived by augmentative algorithmic analysis of data from previously acquired coronary angiogram, with creation of functional map of coronary circulation, when performed, with automated result	APC 1510 (New Technology - Level 10 ($801 - $900)), O1	APC 1522 (New Technology - Level 22 ($2001-$2500))	APC 1510 (New Technology - Level 10 ($801 - $900)), O1
Algorithmic Analysis for Lesion Monitoring(TRAQInform)	1085T (placeholder code X567T)	Assistive algorithmic analysis for identification of new lesions and determination of inter-lesion heterogeneity of change in metabolic activity and volume for advanced metastatic cancer, data sets from 2 or more previously acquired positron emission tomography (PET) and/or PET computed tomography (CT) (PET/CT) studies	APC 1510 (New Technology - Level 10 ($801 - $900)), O1	APC 1511 (New Technology - Level 11 ($901 - $1000))	APC 1510 (New Technology - Level 10 ($801 - $900)), O1

Service Name	HCPCS Code	Descriptor	Proposed CY 2027 APC, SI	Commenter Requested CY 2027 APC, SI	Final CY 2027 APC, SI
Computational Electrocardiogram (ECG) Analysis System (vMap)	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	APC 1510 (New Technology - Level 10 ($801 - $900)), O1	APC 1516 (New Technology - Level 16 ($1401 - $1500))	APC 1510 (New Technology - Level 10 ($801 - $900)), O1

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Response: We appreciate the input and feedback from commenters. Once again, we emphasize that this is an interim first step to a broader payment policy for SaMS. We intended to preserve current payment rates for these services as much as possible for CY 2027 while assigning these services to new technology APCs. Many commenters claimed resources costs for these services are higher than the proposed payment rates and that they are concerned about beneficiary access to these clinical meaningful services. We are committed to developing a comprehensive and consistent approach for these technologies and our objective remains to have this new payment strategy align with CMS's mission to increase quality, improve health, reduce costs, and strengthen the healthcare system. We proposed to maintain current payment rates as much as possible for these services that we designated as SaMS as we moved them to new technology APCs and we continue to believe that that is the right approach. We thank the commenters again for their input and we will consider this feedback as part of our deliberations regarding our long-term payment methodology for SaMS.

Comment: Commenters were very supportive of the proposed new ''O1'' status indicator for SaMS. Commenters opposed mirroring the payment specifications of the new ''O1'' status indicator using ''T,'' which would apply multiple procedure discounting to SaMS. Several commenters explained that the rationale behind multiple-procedure discounting does not apply to SaMS because, unlike other non-software based services which share physical resources, and therefore, subsequent procedures are less expensive, SaMS do not rely on shared resources. Commenters noted that algorithmic services do not rely on these shared resources: when two distinct algorithms are run on a single claim, each represents an independent service with its own development, validation, and computational costs, not a marginal add-on to a shared setup. Commenters further explained that separate payment is appropriate because SaMS tests are distinct diagnostic services that are separately ordered, performed after specimen collection or after or concurrently with an imaging scan, and reported to inform subsequent treatment planning. Commenters also believed it would not be appropriate to address program integrity concerns through the status indicator specifications and thought they would be better addressed through the claims-level tracking that the ''O1'' status indicator itself enables, together with medical-necessity review.

Response: We agree with commenters, at this time, that these services are currently furnished as separate, independent services and that payment should reflect that for our interim maintenance policy. Therefore, we are creating the proposed new status indicator ''O1'' and use the same payment specifications as status indicator ''S'' to allow for separate payment without multiple procedure discounting.

Comment: A commenter requested that CMS state that SaMS designation is a payment-category designation and does not itself establish coverage or medical necessity.

Response: We appreciate the comment. As we have consistently stated in past OPPS/ASC final rules with comment period (see, for example, 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. Therefore, SaMS designation and assignment to status indicator ''O1'' and a new technology APC does not imply coverage.

Comment: A few commenters requested that we revise the status indicator of certain HCPCS codes that we proposed to continue to always or conditionally packaged (assigned to ''N'' or ''Q1'', respectively) for CY 2027 to status indicator ''O1''. For example, we received comments that did not support our proposal to maintain assignment to status indicator ''Q1'' for CPT codes 92227, 92228, 0902T, 0904T, and 9044T. Commenters explained that conditionally packaging these services risks providing inadequate or no separate payment for technologies that CMS has itself determined warrant recognition as a distinct category of medical services.

Response: We thank the commenters for their input. As provided in our proposal, our intention behind this policy is to provide an interim policy that minimizes payment disruption for CY 2027. Because these codes are currently assigned to status indicator ''Q1,'' we do not believe that finalizing to maintain the status indicator assignments for CY 2027 would cause payment disruptions. As such, we are finalizing the status indicators of the HCPCS codes we proposed to assign to Q1 or N as proposed. We refer readers to Table 84 for the clinical APC assignments and status indicators for the relevant HCPCS codes. The final CY 2027 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this final

rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

Comment: We received a comment seeking clarification regarding the process for technologies that receive FDA clearance outside of the rulemaking cycle to become designated as a SaMS and assigned to status indicator ''O1''.

Response: SaMS that receive FDA clearance for their devices outside of the rulemaking cycle would receive the same treatment as other services that receive FDA clearance for their associated devices outside of the rulemaking cycle; CMS would use our normal quarterly coding processes for these services. We note that although the services we have designated as SaMS in this section of this final rule with comment period (section X.B.1.), are required to have FDA marketing authorization to receive Medicare payment, ''SaMS analyses performed on laboratory tests,'' which are described in the following section of this final rule with comment period (section X.B.2.), currently do not require FDA marketing authorization in order to receive payment.

Comment: We received many comments with ideas and information for us to consider while developing a proposed longer-term methodology for future rulemaking. Below is a brief summary of several ideas we received. Many commenters urged CMS to establish a permanent, predictable, and distinct reimbursement pathway for SaMS, cautioning that inadequate reimbursement could push practices toward less precise, outdated treatment planning approaches. To support this longer-term work, several commenters recommended that CMS act now to build better data infrastructure, particularly by creating a dedicated cost center and revenue code so that hospitals can accurately report SaMS-related costs, such as licensing, implementation, training, and other fees, rather than folding them into existing departmental cost centers designed for other purposes, including imaging. Commenters also called for ongoing transparency and collaboration between CMS, physician specialty societies, and industry interested parties throughout the policy development process, along with clearer communication about the expected timeline for a more comprehensive framework.

On payment design, some suggested differentiating SaMS by clinical function (*e.g.,* computer-aided detection, diagnosis, or triage) using objective criteria such as FDA clearance, clinical validation, and peer-reviewed evidence of impact on patient management. Many commenters discussed the types of costs we should consider for payment and emphasized that any methodology must account for the full cost of safe deployment, including integration, cybersecurity, monitoring, and clinician oversight, not just vendor licensing fees. Commenters were divided on using the new technology APC pathway as a longer-term solution, with some advocating for new technology APC assignment for at least five years, while others noted this approach may not adequately address the unique, market-driven pricing dynamics of SaMS. Finally, several commenters offered perspectives on value-based payment approaches, with some encouraging CMS to weigh demonstrated clinical outcomes and others cautioning that reliable outcome-based payment requires stronger claims-level tracking and verification of human oversight rather than assumptions about its effectiveness.

Response: We appreciate the commenters' thoughtful discussion and ideas. We will consider the comments received as we prepare potential policy proposals for CY 2028. We welcome continued engagement from interested parties regarding future payment methodologies. Future payment methodologies for SaMS would go through the annual rulemaking process to ensure proper engagement with the public.

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TABLE 84: PROPOSED AND FINAL APC AND SI ASSIGNMENTS FOR SAMS FOR CY 2027

HCPCS Code	Long Descriptor	CY 2027 Proposed APC, SI	CY 2027 Final APC, SI
92229	Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral	APC 1502 (New Technology - Level 2 ($51 - $100)), O1	APC 1502 (New Technology - Level 2 ($51 - $100)), O1
0932T	Noninvasive detection of heart failure derived from augmentative analysis of an echocardiogram that demonstrated preserved ejection fraction, with interpretation and report by a physician or other qualified health care professional	APC 1505 (New Technology - Level 5 ($301 - $400)), O1	APC 1505 (New Technology - Level 5 ($301 - $400)), O1
75580	Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional	APC 1510 (New Technology - Level 10 ($801 - $900)), O1	APC 1510 (New Technology - Level 10 ($801 - $900)), O1
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	APC 1493 (New Technology - Level 1C ($21-$30)), O1	APC 1493 (New Technology - Level 1C ($21-$30)), O1
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	APC 1504 (New Technology - Level 4 ($201 - $300)), O1	APC 1504 (New Technology - Level 4 ($201 - $300)), O1
0615T	Automated analysis of binocular eye movements without spatial calibration, including disconjugacy, saccades, and pupillary dynamics for the assessment of concussion, with interpretation and report	APC 1503 (New Technology - Level 3 ($101 - $200)), O1	APC 1503 (New Technology - Level 3 ($101 - $200)), O1
0712T	Noninvasive arterial plaque analysis using software processing of data from noncoronary computerized tomography angiography; quantification of the structure and composition of the vessel wall and assessment for lipid-rich necrotic core plaque to assess atherosclerotic plaque stability	APC 1504 (New Technology - Level 4 ($201 - $300)), O1	APC 1504 (New Technology - Level 4 ($201 - $300)), O1
0731T	Augmentative AI-based facial phenotype analysis with report	APC 1502 (New Technology - Level 2 ($51 - $100)), O1	APC 1502 (New Technology - Level 2 ($51 - $100)), O1
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	APC 1504 (New Technology - Level 4 ($201 - $300)), O1	APC 1504 (New Technology - Level 4 ($201 - $300)), O1

HCPCS Code	Long Descriptor	CY 2027 Proposed APC, SI	CY 2027 Final APC, SI
	fractures, with overall fracture-risk assessment, interpretation and report		
0764T	Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (eg, low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to concurrently performed electrocardiogram (List separately in addition to code for primary procedure)	APC 1503 (New Technology - Level 3 ($101 - $200)), O1	APC 1503 (New Technology - Level 3 ($101 - $200)), O1
0765T	Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (eg, low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to previously performed electrocardiogram	APC 1503 (New Technology - Level 3 ($101 - $200)), O1	APC 1503 (New Technology - Level 3 ($101 - $200)), O1
0865T	Quantitative magnetic resonance image (MRI) analysis of the brain with comparison to prior magnetic resonance (MR) study(ies), including lesion identification, characterization, and quantification, with brain volume(s) quantification and/or severity score, when performed, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the brain during the same session	APC 1504 (New Technology - Level 4 ($201 - $300)), O1	APC 1504 (New Technology - Level 4 ($201 - $300)), O1
0866T	Quantitative magnetic resonance image (MRI) analysis of the brain with comparison to prior magnetic resonance (MR) study(ies), including lesion detection, characterization, and quantification, with brain volume(s) quantification and/or severity score, when performed, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the brain (List separately in addition to code for primary procedure)	APC 1504 (New Technology - Level 4 ($201 - $300)), O1	APC 1504 (New Technology - Level 4 ($201 - $300)), O1
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	APC 1510 (New Technology - Level 10 ($801 - $900)), O1	APC 1510 (New Technology - Level 10 ($801 - $900)), O1
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	APC 1510 (New Technology - Level 10 ($801 - $900)), O1	APC 1510 (New Technology - Level 10 ($801 - $900)), O1

HCPCS Code	Long Descriptor	CY 2027 Proposed APC, SI	CY 2027 Final APC, SI
0992T	Noninvasive assessment of cardiac risk derived from augmentative software analysis of perivascular fat without concurrent computed tomography (CT) scan of the heart, including patient-specific clinical factors, with interpretation and report by a physician or other qualified health care professional	APC 1504 (New Technology - Level 4 ($201 - $300)), O1	APC 1504 (New Technology - Level 4 ($201 - $300)), O1
0993T	Noninvasive assessment of cardiac risk derived from augmentative software analysis of perivascular fat with concurrent computed tomography scan of the heart, and including patient-specific clinical factors, with interpretation and report by a physician or other qualified health care professional (List separately in addition to code for primary procedure)	APC 1504 (New Technology - Level 4 ($201 - $300)), O1	APC 1504 (New Technology - Level 4 ($201 - $300)), O1
C8001	3D anatomical segmentation imaging for preoperative planning, data preparation and transmission, obtained from previous diagnostic computed tomographic or magnetic resonance examination of the same anatomy	APC 1503 (New Technology - Level 3 ($101 - $200)), O1	APC 1503 (New Technology - Level 3 ($101 - $200)), O1
C9793	3d predictive model generation for pre-planning of a cardiac procedure, using data from cardiac computed tomographic angiography and/or magnetic resonance imaging with report	APC 1510 (New Technology - Level 10 ($801 - $900)), O1	APC 1510 (New Technology - Level 10 ($801 - $900)), O1
G0183	Quantitative software measurements of cardiac volume, cardiac chambers volumes and left ventricular wall mass derived from CT scan(s) data of the chest/heart (with or without contrast)	APC 1502 (New Technology - Level 2 ($51 - $100)), O1	APC 1502 (New Technology - Level 2 ($51 - $100)), O1
G0566	3D radiodensity-value bone imaging, algorithm derived, from previous magnetic resonance examination of the same anatomy	APC 1503 (New Technology - Level 3 ($101 - $200)), O1	APC 1503 (New Technology - Level 3 ($101 - $200)), O1
1036T	Noninvasive hemodynamic assessment with pulmonary pressures and ejection fraction when performed, including passive acquisition of acoustic and electrical signals, augmentative algorithmic analysis, and generation of a clinical report with review, interpretation, and clinical integration by a physician or other qualified health care professional	E1	APC 1503 (New Technology - Level 3 ($101 - $200)), O1
0972T	Assistive algorithmic classification of burn healing (ie, healing or nonhealing) by noninvasive multispectral imaging, including system set-up and acquisition, selection, and transmission of images, with automated generation of report	E1	APC 1504 (New Technology - Level 4 ($201 - $300)), O1
1041T	Augmentative algorithmic analysis of encephalographic waveforms to identify the source and propagation of epileptiform activity, including artifact reduction with analysis of 3D localization	APC 5734 (Level 4 Minor Procedures), S	APC 1503 (New Technology - Level 3 ($101 - $200)), O1

HCPCS Code	Long Descriptor	CY 2027 Proposed APC, SI	CY 2027 Final APC, SI
	of spike sources throughout the examination, 3D animations over time of high-amplitude event locations, high-frequency activity locations, and temporal relationships among locations, with interpretation and report by physician or other qualified health care professional, related to a previously performed electroencephalogram (EEG)		
1105T (X647T)	Personalized neurostimulation pulse rate derived by augmentative algorithmic analysis of data from electroencephalogram (EEG) and electrocardiogram (ECG), including acquisition of EEG and single-lead ECG, with automated report	E1	APC 1504 (New Technology - Level 4 ($201 - $300)), O1
1087T (X669T)	Estimate of coronary fractional flow derived by augmentative algorithmic analysis of data from previously acquired coronary angiogram, with creation of functional map of coronary circulation, when performed, with automated result	APC 1510 (New Technology - Level 10 ($801 - $900)), O1	APC 1510 (New Technology - Level 10 ($801 - $900)), O1
1104T (X658T)	Noninvasive cardiopulmonary assessment, including quantitative parameters, respectively predictive of significant epicardial coronary artery disease, pulmonary hypertension, and/or elevated pulmonary capillary wedge pressure, derived by augmentative algorithmic analysis of orthogonal voltage gradient and photoplethysmography signals, with automated report	APC 1503 (New Technology - Level 3 ($101 - $200)), O1	APC 1503 (New Technology - Level 3 ($101 - $200)), O1
1086T (X668T)	Intraprocedural estimate of coronary fractional flow derived by augmentative algorithmic analysis of data from real-time coronary angiography, with creation of functional map of coronary circulation, when performed, with review and interpretation (List separately in addition to code for primary procedure)	APC 1510 (New Technology - Level 10 ($801 - $900)), O1	APC 1510 (New Technology - Level 10 ($801 - $900)), O1
1085T (X567T)	Assistive algorithmic analysis for identification of new lesions and determination of inter-lesion heterogeneity of change in metabolic activity and volume for advanced metastatic cancer, data sets from 2 or more previously acquired positron emission tomography (PET) and/or PET computed tomography (CT) (PET/CT) studies	APC 1510 (New Technology - Level 10 ($801 - $900)), O1	APC 1510 (New Technology - Level 10 ($801 - $900)), O1
G0685	Algorithm-based assessment of likelihood of autism spectrum disorder (asd), derived from validated analysis of eye-gaze data or other technology	n/a – code became effective October 1, 2026.	APC 1503 (New Technology - Level 3 ($101 - $200)), O1

HCPCS Code	Long Descriptor	CY 2027 Proposed APC, SI	CY 2027 Final APC, SI
92227	Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral	APC 5733 (Level 3 Minor Procedures), Q1	APC 5733 (Level 3 Minor Procedures), Q1
92228	Imaging of retina for detection or monitoring of disease; with remote physician or other qualified health care professional interpretation and report, unilateral or bilateral	APC 5732 (Level 2 Minor Procedures), Q1	APC 5732 (Level 2 Minor Procedures), Q1
0902T	QTc interval derived by augmentative algorithmic analysis of input from an external, patient-activated mobile ECG device	APC 5734 (Level 4 Minor Procedures), Q1	APC 5734 (Level 4 Minor Procedures), Q1
0944T	3D contour stimulation of target liver lesion(s) and margin(s) for image-guided percutaneous microwave ablation.	APC 5523 (Level 3 Imaging without Contrast), Q1	APC 5523 (Level 3 Imaging without Contrast), Q1
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	N/A, M	N/A, M
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	N/A, N	N/A, N
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	N/A, M	N/A, M
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)	N/A, E1	N/A, E1
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)	N/A, E1	N/A, E1
0903T	Electrocardiogram, algorithmically generated 12-lead ECG from a reduced-lead ECG; with interpretation and report	N/A, M	N/A, M

HCPCS Code	Long Descriptor	CY 2027 Proposed APC, SI	CY 2027 Final APC, SI
0905T	Electrocardiogram, algorithmically generated 12-lead ecg from a reduced-lead ecg; interpretation and report only	N/A, M	N/A, M
C8937	Computer-aided detection, including computer algorithm analysis of breast mri image data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation (list separately in addition to code for primary procedure)	N/A, N	N/A, N
0174T	Computer-aided detection (cad) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation (list separately in addition to code for primary procedure)	N/A, N	N/A, N
0175T	Computer-aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation	N/A, N	N/A, N

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2. SaMS Analyses Performed on Laboratory Tests

In recent years, we have seen an increase in laboratory tests that combine laboratory analyses, such as genomic sequencing or immunoassays, with computer algorithms to produce a clinical test result. The AMA CPT Editorial Panel created a category called Multi-Analyte Assays with Algorithmic Analysis (MAAA's), to categorize test codes that combined laboratory analyses with computer algorithms to generate clinical information. More recently, however, we are seeing the development of distinct algorithmic analyses alone with distinct CPT codes.

For example, when the genomic sequencing of an individual is performed, this sequencing will likely only need to be performed once by a laboratory. However, once the genomic sequence has been generated, the subsequent algorithmic analyses of that sequence data can be performed an infinite number of times to produce a wide range of results and/or diagnostic or risk-related information. These secondary analyses of original genomic sequences can be proprietary and unique to a single laboratory but could also be conducted at a range of settings. For purposes of this final rule with comment period, we are referring to subsequent stand-alone algorithmic analyses as ''SaMS analyses performed on laboratory tests''.

As discussed in the proposed rule, currently, certain SaMS analyses performed on laboratory tests are treated as clinical diagnostic laboratory tests (CDLTs) and paid under the Clinical Laboratory Fee Schedule (CLFS) (91 FR 41925). Section 1861(s) of the Act specifies items and services included as ''medical and other health services'' under Part B, including diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests as described in section 1861(s)(3) of the Act. Sections 1833(h) and 1834A of the Act and the implementing regulations at 42 CFR part 414, subpart G, set forth the CLFS rate setting methodologies for CDLTs. We stated in the proposed rule that we do not believe it is appropriate to consider these secondary algorithmic analyses, when performed alone, to be CDLTs or establish CLFS payment rates for these analyses because we believe these secondary algorithmic analyses may not currently require laboratory services or entities, regulated by CLIA, to perform them. Our position is that the secondary analyses, which have distinct CPT codes,[174] are ''other diagnostic tests'' under section 1861(s)(3) of the Act as opposed to ''diagnostic laboratory tests.'' As noted previously, Medicare will not pay for CDLTs on the CLFS unless they are furnished by laboratories that meet applicable certification requirements. Tests that examine materials derived from the human body are assigned to and paid under the CLFS only when furnished by such certified laboratories in accordance with 42 CFR 410.32(d). Because SaMS analyses performed on laboratory tests are downstream evaluations of the data generated by a prior laboratory test, which are described by distinct CPT codes, an entity that performs only algorithmic analyses of previously

[174] We note that the AMA has created Category III CPT codes that describe secondary algorithmic analyses performed on laboratory tests. *https://www.ama-assn.org/system/files/cpt-category3-codes-long-descriptors.pdf.*

sequenced data may not meet the definition of a ''laboratory'' under 42 CFR 493.2 or qualify for payment under CLFS. We believe SaMS that evaluate data generated by a prior laboratory test should not be treated as CDLTs for Medicare payment purposes.

As discussed in the proposed rule, we are also concerned that paying for these analyses based on existing CLFS payment methodologies may create significant vulnerabilities for the Medicare program, due to the lack of data transparency and CDLTs not being subject to beneficiary cost-sharing or budget neutrality. 42 CFR 414.508 outlines the rate setting methodologies CMS uses to set payment rates for new tests on the CLFS. Under § 414.508(b), CMS determines the payment amount based on either crosswalking or gapfilling methodologies until applicable information is available to establish a payment amount under the methodology described in § 414.507(b). Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code. Gapfilling is used when no comparable existing CDLT is available. Public consultation for payment for a new clinical diagnostic laboratory test is required in determining payment amounts, receiving public comments and recommendations (and data on which the recommendations are based) as well as recommendations from the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLTs) per § 414.506. A significant challenge to the rate setting process for CMS is receiving transparent data from laboratories outlining resource costs of a test, particularly for the algorithmic portions of tests that are combined with other analytes. In the past, laboratories have explained to CMS that the algorithmic components of laboratory tests are highly proprietary and details cannot be shared. Thus, CMS has worked with the limited information available on the details of methods or resources for the algorithmic portions of tests or analyses and has thus far relied on other laboratory methods provided in the CPT descriptor (*i.e.,* NGS sequencing, RT–PCR, or DNA methylation analysis). As CMS has gathered more information on SaMS analyses performed on laboratory tests, we now believe that since these analyses are entirely computer-based, comparison based on laboratory methodologies is not appropriate. We believe that these analyses are substantially similar to other SaMS already paid under the OPPS. Additionally, in contrast to the OPPS, the CLFS generally does not include beneficiary cost-sharing or budget neutrality adjustments, which limits transparency regarding pricing and creates challenges for ensuring appropriate valuation of these services.

CMS has an interest in ensuring that services that are fundamentally similar are paid for and treated in the same way, regardless of the setting of care in which the service is furnished. Since we believe SaMS perform algorithmic analyses on previously generated data, we believe SaMS analyses performed on laboratory tests are substantively similar to other SaMS technologies that are currently paid under the OPPS. Accordingly, we believe that whether the SaMS performs algorithmic analyses of an imaging test (*e.g.* CT scan) or whether it performs an algorithmic analysis on data generated from a laboratory test, all algorithmic analyses should be treated consistently from a payment perspective. We believe that this uniform approach for SaMS technologies would promote stability and predictability in payment for similar services.

Finally, we note that CMS and CDC issued a Request for Information (RFI) on July 16, 2026, regarding CLIA regulations, the results of which may be used to help inform the agencies as to what types of action, if any, should be taken to update the existing CLIA regulations through future comment and rulemaking (91 FR 43586). The RFI closed for comments on September 15, 2026. CMS may refine SaMS payment and policies based on RFI responses and make changes in future rulemaking.

For CY 2027, as an interim first step to address concerns described above, we proposed to assign 10 HCPCS codes describing various SaMS analysis performed on laboratory tests to new technology APCs under the OPPS, using the latest available CLFS data to crosswalk to new technology APCs with payment rates that closely approximate the current CY 2026 CLFS payment rates for these codes. We note that SaMS analyses performed on laboratory tests would not currently require FDA marketing authorization in order to receive payment under OPPS. SaMS payment policies may be refined in future rulemaking. We explained that the proposed payment rates for SaMS performed on prior laboratory tests cannot be expected to align exactly with current CLFS payment rates because assignment to new technology APCs is based on established cost bands rather than individual test-specific payment amounts. For example, if a HCPCS code is currently paid $430.17 under the CLFS, the appropriate new technology APC assignment under this proposal would be APC 1506 (New Technology—Level 6 ($401–$500)), which has a standardized payment rate of $450.50, rather than receiving a payment rate that exactly matches the current CLFS amount. We noted that, under this proposal, SaMS analyses performed on laboratory tests would be paid separately by being assigned to new technology APCs with the newly proposed status indicator ''O1'' (Software as a Medical Service, Paid under OPPS; separate APC payment) for CY 2027. These 10 HCPCS codes were identified based on the CPT descriptor for the code. We noted that, if there were no laboratory methods included in the code descriptor, and only an algorithmic analysis was described, we identified the code as a SaMS analysis performed on a laboratory test. We invited public comment on this proposed list and any other similar analyses that should be removed from the CLFS and paid under the OPPS.

In addition, for CY 2027 and subsequent years, we proposed to assign any new SaMS analyses performed on laboratory test codes to new technology APCs for payment under the OPPS. We requested public comment on these proposals, including the list of 10 HCPCS codes that we identified as SaMS analyses performed on laboratory tests and any additional HCPCS codes that we should designate as SaMS analyses performed on laboratory tests and pay under the OPPS rather than the CLFS. We stated that CMS may finalize a policy that includes such payment for additional HCPCS codes in the final rule based on public comment.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters, including large cancer treatment centers, supported our proposal to establish a payment methodology for software-based analyses performed on laboratory tests distinct from the underlying laboratory test. These commenters supported migrating software-based analyses performed on laboratory tests from payment under the CLFS to payment under the OPPS and agreed that such analyses are better characterized as ''other diagnostic tests.'' Commenters added that this policy correctly recognizes algorithmic re-analysis of previously obtained data as a separately payable clinical service. In addition, commenters expressed support for establishing a consistent, cross-setting payment framework for algorithmic analyses, citing that this policy seeks to adapt and evolve with

changing healthcare environments. The commenters noted that it is especially critical that this payment policy evolve to reflect the value and resource costs of these technologies.

Response: We thank the commenters for their support and note that we will consider these comments as we continue to refine this payment policy.

Comment: Some commenters, including independent laboratories, supported our proposal but requested that CMS develop the payment methodology transparently, and ensure the payment for algorithm-driven services rests on evidence of clinical benefit. Commenters requested that CMS establish a payment mechanism for these services when the patient is not seen in a hospital outpatient department, noting that as proposed, the framework would leave no payment mechanism for a substantial share of medically necessary testing. Commenters also requested that CMS assign substantively comparable specimen-based algorithmic analyses to consistent new technology APCs and state the basis for APC assignment, and that CMS establish a defined, confidential process through which laboratories may submit cost and clinical outcomes data to support valuation as CMS develops a more comprehensive payment methodology. One commenter supported the proposal but requested that CMS defer changes to CLFS payment for algorithm-only laboratory analyses until the necessary coding, regulatory, and operational infrastructure has been established.

Response: We appreciate the suggestion to be transparent and thoughtful in the implementation of this policy. We believe that publicly proposing this policy in the proposed rule, inviting comments, and addressing those comments in this rule has made this process transparent. We also appreciate the recommendation to evaluate the clinical benefit of SaMS analyses performed on laboratory tests. We remind readers that our goal in this rulemaking cycle is to establish the category of SaMS analyses performed on laboratory tests and the general payment mechanism for those services under the OPPS. Regarding a request to establish a separate confidential process through which laboratories may submit cost and clinical data, we remind commenters that we are available to meet with interested parties where information may be shared with CMS. However, because payment rates are finalized through the notice-and-comment rulemaking process, which requires providing the underlying reasoning for our proposals and final policy, establishing a separate confidential process would not be compatible with the existing rulemaking process. Further, finalizing this policy would not eliminate Medicare payment for these services, or prohibit certain facilities from billing Medicare, but rather, it would define how these services would be paid under the OPPS. For the purposes of maintaining stability, particularly for the HCPCS codes we proposed to remove from the CLFS and place in an APC category, we chose to assign APC levels based on the CY 2026 CLFS payment rates to avoid any considerable payment disruption. As we continue to develop this policy, we will consider possible methods for evaluating the APC assignment for new SaMS analyses performed on laboratory tests. We do not believe that it is appropriate to delay the movement of SaMS analyses performed on laboratory tests from the CLFS to the OPPS, given the speed at which SaMS technologies are developing and the goal of having a consistent policy across payment systems for similar services. These services will be paid for under existing and well-established Medicare payment mechanisms, depending on the place of service (that is, hospital outpatient departments or physician offices).

Comment: A few commenters, specifically large laboratory associations, requested that we not finalize the policy as proposed. Commenters generally believed that CMS should engage with the laboratory community more closely prior to finalizing payment changes for SaMS analyses performed on laboratory tests. Commenters specifically expressed concerns that the proposed policy could inadvertently create duplicate or inconsistent payment pathways and fragment integrated laboratory services by separating algorithmic analyses from the laboratory responsible for validation, quality, clinical interpretation, and reporting. Several commenters expressed concerns regarding the implications of introducing beneficiary cost sharing for services that generally are not subject to cost sharing under the CLFS if this policy were to be finalized. One commenter explained that, if CMS is concerned about unregulated software vendors billing Medicare, CMS should condition Medicare payment for designated SaMS laboratory services on performance by a CLIA-certified, appropriately accredited laboratory.

Response: We acknowledge the commenters' concerns, and we will continue to consider them while we implement the policy. Regarding cost sharing, we acknowledge that while cost sharing shifts some costs to beneficiaries, it also encourages greater efficiency by providers and more economical delivery of medically necessary services, which would contain unnecessary growth in Medicare spending long-term to the benefit of both Medicare and beneficiaries.

We disagree with concerns that this final policy would fragment integrated laboratory services, as this policy would apply to HCPCS codes that already recognize a distinct SaMS analysis component. To ensure that this policy impacts HCPCS codes describing the secondary analyses only, we requested public comment on the list of HCPCS codes we proposed to designate as SaMS analyses performed on laboratory tests. As discussed further below, based on public comments received, HCPCS codes describing integrated services, meaning those codes that describe both the wet lab and SaMS secondary analyses, were not finalized for payment under this policy for CY 2027. These HCPCS codes would continue to be paid under the CLFS.

Concerns about billing and regulations regarding vendors of SaMS analyses are outside of the scope of this final rule with comment period.

While we understand the commenters' concerns, we believe that the proposed policy provides a uniform payment pathway for SaMS that should be implemented for CY 2027. We continue to maintain that paying for SaMS analyses performed on laboratory tests under the CLFS may create significant vulnerabilities for the Medicare program, due to the challenges in receiving transparent data regarding the algorithms themselves and CDLTs on the CLFS generally not being subject to beneficiary cost-sharing or budget neutrality. As mentioned above, we believe SaMS technologies generally should be treated and paid for consistently across the Medicare program because these algorithm-based services are functionally equivalent, despite differences in the type of clinical service or data. For example, both SaMS currently paid under the OPPS and SaMS analyses performed on laboratory tests perform algorithm-based analyses on existing data. We anticipate that resource costs may be similar between these kinds of services. For SaMS analyses performed on laboratory tests, assigning them to new technology APCs under the OPPS means similar algorithm-based services will be billed and paid for under the same payment system. We will continue to engage the broader laboratory community in further dialogue as we consider potential

refinements to this policy in future rulemaking.

Comment: Some commenters, especially large laboratory associations, asked CMS to not finalize its proposal to reassign SaMS analyses performed on prior laboratory tests to new technology APCs under the OPPS and to continue paying for these as CDLTs on the CLFS. A few commenters urged CMS to exempt current and future software-based laboratory tests from this proposed policy and only designate the proposed tests as SaMS analyses performed on laboratory tests.

Response: We appreciate these comments but believe it is important for SaMS-based technologies to be treated consistently across the Medicare program, rather than establishing distinct payment policies for similar SaMS depending on whether the analysis is performed on an imaging service or on a laboratory test.

Comment: Commenters generally expressed concern that the proposed framework to distinguish SaMS analyses performed on laboratory tests from other laboratory tests would be challenging to apply in practice. Commenters stated that these services have generally been classified and paid as CDLTs under the CLFS, reflecting longstanding treatment from CMS, the AMA CPT process, and the FDA. Commenters expressed concern regarding using CPT code descriptors to determine which HCPCS codes should be designated as a SaMS analyses performed on a laboratory test since descriptors do not always indicate whether activities, such as slide preparation or immunostaining, are included in the reported service. Commenters explained that although SaMS analyses performed on laboratory tests are defined as being both separate from specimen examination and entirely computer-based, several of the examples CMS identified appear to involve wet lab components, creating uncertainty regarding how the criteria would be operationalized, and that as a result, interested parties may face difficulty determining whether a given service qualifies as a purely algorithmic analysis or should continue to be treated as a laboratory test including wet lab processes. Commenters requested that CMS provide additional guidance and examples to support consistent classification and payment for these services.

Response: Medicare utilizes the description of services as provided by the HCPCS code descriptors in determining appropriate payment. For the proposed policy, we identified services listed on the CLFS that indicated algorithmic analysis in the CPT long descriptor and in the description of intraservice work (as provided by AMA in its valuation of CPT codes) and proposed to treat those services as SaMS analyses performed on laboratory tests. Specifically, we considered code descriptors that included phrases such as ''augmentative algorithmic analysis'' or ''previously established sequence,'' as we believed that these indicated that the code described SaMS analyses performed on laboratory tests. We requested public comments on the proposed list of codes, understanding that we may have inadvertently omitted certain codes or included codes that do not solely describe subsequent, computer-based analyses as intended.

We appreciate the comments regarding the proposed list of codes. In this final rule with comment period, we have removed a few HCPCS codes from the proposed list, based on an additional understanding of the code descriptors and public comments received, but we retained the HCPCS codes that contained phrases such as ''augmentative algorithmic analysis'' or ''previously established sequence'' which we discuss in further detail below. We believe that the finalized list of HCPCS codes being reassigned from the CLFS to new technology APCs under the OPPS is limited to those that are entirely computer-based secondary analyses and do not include specimen examination performed as part of the wet lab component.

Comment: Commenters requested that CMS include additional specificity into the SaMS definition to ensure that technologies and services with meaningful differences, such as algorithm-only laboratory-developed tests, laboratory Software as a Medical Device, and imaging Software as a Medical Device, are not treated as equivalent for payment purposes. One commenter proposed that CMS limit the services included in this policy to algorithmic reanalysis of a prior laboratory test's reported results, and exclude any service that examines a patient's specimen, physical or digitized, or that measures a defined analyte from that specimen.

Response: We appreciate the commenters' input. We remind readers that our goal in this rulemaking cycle is to establish the category of SaMS analyses performed on laboratory tests and the general payment mechanism for those services under the OPPS, noting that payment alignment is a priority for these technologies. Given the interim nature of the policy, we will take the definitional concerns raised by the commenters, including incorporating additional specificity regarding differences in SaMS service for purposes of Medicare payment, into consideration for future rulemaking. We welcome public engagement from interested parties on these issues, including whether there are services that should be designated as SaMS in the future.

Comment: Some commenters, particularly large laboratory associations, disagreed with the premise underlying our proposal, explaining that the diagnostic testing process as a whole, not the physical location where the final computational step occurs, is what defines a clinical diagnostic laboratory test. These commenters did not agree that the absence of a new wet lab step converts a patient-specific computational analysis of laboratory-derived data into something other than laboratory testing and argued that treating the final analytical step as severable from the laboratory service that produced the underlying data misconstrues how these tests are developed, validated, and clinically interpreted. Relatedly, these commenters requested that CMS confirm in the final rule that a test including a laboratory assay measuring an analyte from the specimen remains a CDLT paid under the CLFS, and that specimen preparation, staining, and digitization are not the ''prior laboratory test'' on which SaMS designation depends.

Response: We disagree with these commenters that the location of the final analytical step is immaterial to the payment classification of these services. While we recognize that the underlying specimen collection, sequencing, or other data-generating steps may require laboratory services, the algorithmic analysis at issue here is a separate step that is performed on data that has already been generated, and may not necessarily require access to the specimen or laboratory equipment. The fact that a service has historically been billed and paid as a single, integrated CDLT on the CLFS does not mean that each component of that service must continue to be paid as such, particularly where the analytical component is distinguishable from the data-generating component as provided by the HCPCS code descriptor, both in the resources required to perform it and in the manner in which its costs are incurred. Accordingly, we are finalizing our proposal to treat the algorithmic analysis as an ''other diagnostic test'' distinct from the underlying laboratory test for purposes of OPPS payment. We will take the definitional concerns

regarding SaMS into consideration for future rulemaking.

Comment: Several commenters urged CMS to coordinate this policy with the pending CLIA RFI issued by CMS and the CDC on July 16, 2026, regarding the appropriate level of CLIA oversight of ''dry lab'' facilities that perform computational analyses without a traditional wet-lab component, so that the two efforts do not produce conflicting outcomes.[175] Commenters noted that CMS and the CDC are actively considering, through that RFI, whether CLIA certification is required to furnish these types of services, and argued that it is premature for CMS to conclude in this rule that such services are not ''laboratory'' services for payment purposes before that RFI is complete. Commenters requested that CMS defer any changes to this OPPS payment policy pending the outcome of the CLIA RFI, given the potential for the policies under consideration there to directly conflict with the proposal at issue here. One commenter separately requested that CMS clarify that CLIA's scope includes facilities that produce and examine information obtained through analysis of materials derived from the human body.

Response: We appreciate these comments. We plan to coordinate and collaborate across the relevant agencies to ensure oversight and payment policies are consistent.

Comment: Commenters requested that CMS confirm it does not intend, in addressing the Medicare billing of SaMS analyses performed on laboratory tests, to change the regulatory structure under which laboratories and the tests they provide are governed. Commenters noted that the proposal could be read to create ambiguity on this point and requested that CMS include the following clarifying statement in the final rule: that algorithmic interpretation of specimen-derived pathology data, performed within or under arrangement with a CLIA-certified laboratory, remains subject to CLIA.

Response: This policy does not seek to make changes to the requirements governing CLIA-certified laboratories. We consider these algorithmic analyses as ''other diagnostic tests'' that are performed on an underlying laboratory test. This policy seeks to provide consistency in paying for all SaMS algorithmic analyses under new technology APCs in the OPPS. We will take the regulatory concerns raised by commenters, including incorporating additional specificity regarding SaMS services and CLIA, into consideration for future rulemaking. We welcome public engagement from interested parties on these issues.

Comment: We received comments regarding the specific list of HCPCS codes we proposed to designate as SaMS laboratory analyses. Commenters generally agreed that the following CPT codes describe algorithmic analyses and may be designated as SaMS laboratory analyses:

- 0510U—*Oncology (pancreatic cancer), augmentative algorithmic analysis of 16 genes from previously sequenced rna whole transcriptome data, reported as probability of predicted molecular subtype*
- 0512U—*Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (msi) status, formalin-fixed paraffin embedded (ffpe) tissue, reported as increased or decreased probability of msi-high (msi-h)*
- 0513U—*Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (msi) and homologous recombination deficiency (hrd) status, formalin fixed paraffin-embedded (ffpe) tissue, reported as increased or decreased probability of each biomarker*
- 0418U—*Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score*
- 0376U—*Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancer-specific mortality, includes predictive algorithm to androgen deprivation-therapy response, if appropriate*

Response: We thank the commenters for their support. We are finalizing our proposals to assign CPT codes 0510U, 0512U, 0513U, 0418U, and 0376U to new technology APCs for payment under the OPPS as SaMS analyses performed on laboratory tests. Please refer to Table 85 for the list of services we are finalizing as SaMS analyses performed on laboratory tests.

Comment: We received a comment noting that CPT codes 81417 and 81427 both describe post-sequencing data analysis but were not included in the proposed list of CPT codes to designate as SaMS analyses performed on laboratory tests for purposes of payment under the OPPS.

We also received a comment noting that CPT codes 81417 (*Exome (e.g., unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence (e.g., updated knowledge or unrelated condition/syndrome*) and 81427 (*Genome (e.g., unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (e.g., updated knowledge or unrelated condition/syndrome)*) both describe post-sequencing data analysis but were not included in the proposed list of CPT codes to designate as SaMS analyses performed on laboratory tests for purposes of payment under the OPPS.

Response: We thank the commenter for bringing these codes to our attention. We agree that CPT codes 81417 and 81427 codes should be designated as SaMS analyses performed on laboratory tests for purposes of payment under the OPPS because they provide a secondary or subsequent stand-alone algorithmic analysis of a previously obtained exome or genome sequence. Therefore, for CY 2027, we are finalizing assigning CPT code 81417 to APC 1505 (New Technology—Level 5 ($301–$400)) and 81427 to APC 1522 (New Technology—Level 22 ($2,001–$2,500)).

Comment: Some commenters asserted that certain codes that we proposed to designate as SaMS analyses performed on tests performed on laboratory tests for payment under the OPPS should not be finalized as proposed because they possess, or may possess, wet lab components. Per the commenters, the following CPT codes have wet lab components:

- 0511U—*Oncology (solid tumor), tumor cell culture in 3d microenvironment, 36 or more drug panel, reported as tumor-response prediction for each drug*
- 81416—*Exome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator exome (e.g., parents, siblings) (list separately in addition to code for primary procedure)*

Similarly, a commenter opposed finalizing CPT code 0414U (*Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (alk, braf, egfr, erbb2, met, ntrk1–3, ret, ros1), and kras g12c and pd–l1, if performed, formalin-fixed paraffin-embedded (ffpe) tissue, reported as positive or negative for each biomarker*) as a SaMS analysis

[175] *https://www.federalregister.gov/documents/2026/07/16/2026-14358/request-for-information-clinical-laboratory-improvement-amendments-of-1988-clia-regulations.*

performed on a laboratory test for payment under the OPPS because the service includes a wet lab component if performed, as designated in the descriptor. A commenter opposed similarly designating CPT code 0220U (*Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score*) as a SaMS analysis performed on a laboratory test because the code is ambiguous on whether it includes wet lab steps. One commenter pointed out that CPT code 0208U (*Oncology (medullary thyroid carcinoma), mrna, gene expression analysis of 108 genes, utilizing fine needle aspirate, algorithm reported as positive or negative for medullary thyroid carcinoma*) was deleted effective January 1, 2022, and therefore, should not be included on the final list for payment under the OPPS.

Response: We agree with commenters that CPT codes 0511U and 81416 both involve wet lab analyses as outlined in each CPT descriptor, and therefore, should not be assigned to new technology APCs for payment under the OPPS. Since the code descriptors integrate both the wet lab and secondary algorithmic analyses, rather than only the computer-based secondary analyses component, we agree to not designate CPT codes 0511U and 81416 as SaMS analyses performed on laboratory tests. These HCPCS codes would continue to be paid under the CLFS.

However, we do not agree with commenters that CPT code 0414U should be paid under the CLFS, as the descriptor characterizes the service as an augmentative algorithmic analysis. Commenters pointed out that the descriptor allows for additional analysis ''if performed,'' if, for example, a slide needs to be redone for the purpose of the analysis. However, our understanding is that the ''if performed'' language does not indicate that the algorithmic analysis is optional, but instead refers to the optional analysis of additional biomarkers. Therefore, we are finalizing assignment of CPT code 0414U to a new technology APC for payment under the OPPS as proposed.

Regarding CPT code 0220U, we similarly disagree with the commenters that the code descriptor is ambiguous on whether a wet lab component is included. The descriptor cites ''image analysis with artificial intelligence,'' which we believe is similar to other SaMS laboratory analyses of existing images or slides.

Finally, we appreciate the comment noting that CPT code 0208U was deleted and agree that it should not be included on the final list for payment under the OPPS.

Comment: We received comments regarding the proposed APC assignments for the services we proposed to designate as SaMS analyses performed on laboratory tests. Some commenters supported crosswalking codes from the CLFS to new technology APCs as proposed, maintaining CY 2026 CLFS payment rates. Some commenters disagreed with the proposed new technology APC assignment for certain HCPCS codes. For example, one commenter requested that we reassign CPT codes 1063T *(Oncology (bladder), augmentative algorithmic analysis of histomorphologic features in digitized slides from formalin-fixed paraffin-embedded (FFPE) bladder cancer tissue (high-grade, non-muscle invasive), with clinicopathologic variables entered by the qualified health care professional; algorithm-derived parameters reported as prognostic of recurrence and progression, including hematoxylin and eosin staining of tissue sections, and digitization of glass microscope slides, when performed)* and 1064T *(Oncology (bladder), augmentative algorithmic analysis of histomorphologic features in digitized slides from formalin-fixed paraffin-embedded (FFPE) bladder cancer tissue (high-grade, non-muscle invasive), with clinicopathologic variables entered by the qualified health care professional; algorithm-derived parameters reported as predictive of response to Bacillus Calmette-Guérin (BCG) therapy, including hematoxylin and eosin staining of tissue sections, and digitization of glass microscope slides, when performed)* to APC 1509 (New Technology—Level 9 ($701–$800)) rather than APC 1542 (New Technology—Level 5 ($301–$400)) based on resource costs and similarities to other services we proposed to assign to APC 1509. Commenters also requested that CMS assign substantively comparable specimen-based algorithmic analyses to consistent new technology APC bands, state the basis on which band assignments are made, and establish a mechanism for correcting assignments that are inconsistent with those made for comparable services.

Response: We thank the commenters for their input. We agree with commenters that CPT codes 1063T and 1064T are similar to CPT code 1097T, for which we proposed, and are finalizing, assignment to APC 1509. Therefore, we are finalizing assigning CPT codes 1063T and 1064T to APC 1509 (New Technology—Level 9 ($701–$800)) based on public comments received. Regarding the process for assigning and correcting assignments for comparable SaMS analyses performed on laboratory tests to new technology APCs, we remind the commenters that the notice-and-comment rulemaking is an available and appropriate process for requesting initial payment assignments and subsequent payment changes.

Comment: Commenters supported CMS's proposal to base new technology APC payment for these codes on existing CLFS payment rates, using the latest available CLFS data to crosswalk codes to new technology APCs at rates that closely approximate current CLFS payment levels.

Response: We thank the commenters for their support. We agree that CY 2026 CLFS rates for algorithmic analyses, which were the latest available CLFS rates at the time that the proposed rule was drafted, should be maintained with the implementation of this interim policy. We believe it is appropriate to use the current CLFS payment rates for CY 2026, as proposed, to align with the payment policy for SaMS described in the prior section which similarly finalized the proposed payment rates.

Comment: Commenters requested that CMS confirm that superintelligence enabled diagnostic analyses performed in CLIA-certified independent laboratories after the hospital encounter are eligible for separate payment under the OPPS framework. Commenters further requested that CMS permit laboratories to bill Medicare for these services when developed as laboratory-developed tests, noting that if such tests are not billable by laboratories under the Medicare Physician Fee Schedule, laboratories would effectively be prohibited from directly billing and receiving payment for services they perform.

Response: As we stated in the proposed rule, the services that we designate as SaMS, specifically SaMS analyses performed on laboratory tests, will be assigned to new technology APCs and a status indicator of 'O1' to indicate that these services are SaMS for payment purposes and paid for under the OPPS. We refer readers to the CY 2027 PFS final rule for discussion on how SaMS analyses performed on laboratory tests will be paid under PFS.

Comment: A commenter requested that CMS confirm the applicable date of service for algorithm-only laboratory analyses, noting that if such services are classified as ''other diagnostic tests'' rather than clinical diagnostic laboratory tests, the laboratory date of service policy would not apply.

Response: We confirm that because we are classifying SaMS analyses performed on laboratory tests as ''other diagnostic tests'' under section

1861(s)(3) of the Act, they would not be subject to the date of service policy as outlined in 42 CFR 414.510.

Comment: Regarding CMS's proposed definition of status indicator ''O1,'' a commenter requested that CMS avoid applying a multiple-procedure payment reduction to algorithm-only analyses, explaining that such services do not meet the criteria typically underlying that reduction because each algorithm is typically a distinct, independently developed and validated analytic service answering a distinct clinical question.

Response: We agree. We refer readers to the earlier discussion in this section regarding the payment specifications for status indicator ''O1,'' which we are finalizing to treat as ''S'' (Procedure or Service, Not Discounted When Multiple) to allow for separate payment without multiple procedure discounting.

After consideration of public comments, we are finalizing our proposal for CY 2027 to reassign certain HCPCS codes describing SaMS analyses performed on laboratory tests that are currently paid under the CLFS to new technology APC assignments under the OPPS. However, we are finalizing the proposed code list with certain modifications, based on public comments received. In total, for CY 2027, we are finalizing to assign 14 SaMS analyses performed on laboratory tests to new technology APCs. Additionally, we are finalizing our proposal for CY 2027 and subsequent years, to assign any new SaMS analyses performed on laboratory test codes to new technology APCs for payment under the OPPS. We note that this is an interim first step to address the concerns regarding the proliferation of SaMS analyses performed on laboratory tests. We intend to continue to engage with the laboratory community on these finalized changes, and acknowledge the definitional concerns regarding SaMS services and the applicable payment and regulatory frameworks. We will consider expanding and further clarifying the scope of the policy through future rulemaking.

Refer to Table 85 for the final new technology APC and status indicator assignments for SaMS analyses performed on laboratory tests for CY 2027. The final CY 2027 payment rates can be found in Addendum B to this final rule with comment period via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

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TABLE 85: FINAL NEW TECHNOLOGY APC AND SI ASSIGNMENTS FOR SAMS ANALYSES PERFORMED ON LABORATORY TESTS FOR CY 2027

HCPCS Code	Long Descriptor	CY 2027 Proposed New Technology APC, SI	CY 2027 Final New Technology APC, SI
0510U	Oncology (pancreatic cancer), augmentative algorithmic analysis of 16 genes from previously sequenced rna whole transcriptome data, reported as probability of predicted molecular subtype	APC 1506 (New Technology - Level 6 ($401 - $500)), O1	APC 1506 (New Technology - Level 6 ($401 - $500)), O1
0512U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (msi) status, formalin-fixed paraffin embedded (ffpe) tissue, reported as increased or decreased probability of msi-high (msi-h)	APC 1509 (New Technology - Level 9 ($701 - $800)), O1	APC 1509 (New Technology - Level 9 ($701 - $800)), O1
0513U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (msi) and homologous recombination deficiency (hrd) status, formalin fixed paraffin-embedded (ffpe) tissue, reported as increased or decreased probability of each biomarker	APC 1509 (New Technology - Level 9 ($701 - $800)), O1	APC 1509 (New Technology - Level 9 ($701 - $800)), O1
0414U	Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (alk, braf, egfr, erbb2, met, ntrk1-3, ret, ros1), and kras g12c and pd-l1, if performed, formalin-fixed paraffin-embedded (ffpe) tissue, reported as positive or negative for each biomarker	APC 1509 (New Technology - Level 9 ($701 - $800)), O1	APC 1509 (New Technology - Level 9 ($701 - $800)), O1
0418U	Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score	APC 1509 (New Technology - Level 9 ($701 - $800)), O1	APC 1509 (New Technology - Level 9 ($701 - $800)), O1
0220U	Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score	APC 1509 (New Technology - Level 9 ($701 - $800)), O1	APC 1509 (New Technology - Level 9 ($701 - $800)), O1
0376U	Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancer-specific mortality, includes predictive algorithm to androgen deprivation-therapy response, if appropriate	APC 1509 (New Technology - Level 9 ($701 - $800)), O1	APC 1509 (New Technology - Level 9 ($701 - $800)), O1
81417	Exome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence (eg, updated knowledge or unrelated condition/syndrome)	N/A, A	APC 1505 (New Technology - Level 5 ($301 - $400)), O1
81427	Genome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously	N/A, A	APC 1522 (New Technology - Level 22

	obtained genome sequence (eg, updated knowledge or unrelated condition/syndrome)		($2001-$2500)), O1
1106T (placeholder code X623T)	Oncology (breast), augmentative algorithmic analysis of histomorphologic features in digitized hematoxylin and eosin stained slides from formalin-fixed paraffin-embedded (FFPE) breast cancer tissue, algorithm-derived parameters reported as 5-year and 10-year risks of distant metastasis, including digitization of glass microscope slides and hematoxylin and eosin staining of tissue sections, when performed	APC 1509 (New Technology - Level 9 ($701 - $800)), O1	APC 1509 (New Technology - Level 9 ($701 - $800)), O1
1107T (placeholder code X624T)	Oncology (prostate), augmentative algorithmic analysis of histomorphologic features in digitized hematoxylin and eosin stained slide(s) from formalin-fixed paraffin-embedded (FFPE) prostate cancer tissue, algorithm-derived parameters reported as 10-year risk of distant metastasis and prostate cancer specific mortality, including hematoxylin and eosin staining of tissue sections and digitization of glass microscope slides, when performed	APC 1509 (New Technology - Level 9 ($701 - $800)), O1	APC 1509 (New Technology - Level 9 ($701 - $800)), O1
1097T (placeholder code X614T)	Oncology (pancreas), augmentative algorithmic analysis of histomorphologic features in digitized slides from formalin-fixed paraffin-embedded pancreatic cancer tissue, algorithm-derived parameters reported as prediction of response to fluorouracil backbone versus gemcitabine backbone chemotherapy, including hematoxylin and eosin staining of tissue sections and digitization of glass microscope slides, when performed	APC 1509 (New Technology - Level 9 ($701 - $800)), O1	APC 1509 (New Technology - Level 9 ($701 - $800)), O1
1063T (placeholder code X568T)	Oncology (bladder), augmentative algorithmic analysis of histomorphologic features in digitized slides from formalin-fixed paraffin-embedded (FFPE) bladder cancer tissue (high-grade, non-muscle invasive), with clinicopathologic variables entered by the qualified health care professional; algorithm-derived parameters reported as prognostic of recurrence and progression, including hematoxylin and eosin staining of tissue sections, and digitization of glass microscope slides, when performed	APC 1542 (New Technology - Level 5 ($301 - $400)), O1 ($350.50)	APC 1509 (New Technology - Level 9 ($701 - $800)), O1
1064T (placeholder X569T)	Oncology (bladder), augmentative algorithmic analysis of histomorphologic features in digitized slides from formalin-fixed paraffin-embedded (FFPE) bladder cancer tissue (high-grade, non-muscle invasive), with clinicopathologic variables entered by the qualified health care professional; algorithm-derived parameters reported as predictive of response to Bacillus Calmette-Guérin (BCG) therapy, including hematoxylin and eosin staining of tissue sections, and digitization of glass microscope slides, when performed	APC 1542 (New Technology - Level 5 ($301 - $400)), O1 ($350.50)	APC 1509 (New Technology - Level 9 ($701 - $800)), O1

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3. Summary of CY 2027 SaMS Final Payment Policies

In summary, for CY 2027, we are finalizing the following interim payment policies. First, we are finalizing a terminology change from SaaS to SaMS to more accurately describe algorithm-based software services. Second, we are creating a new status indicator ''O1'' (Software as a Medical Service, paid under OPPS; separate APC payment) to designate SaMS that are payable under the OPPS. Third, we are finalizing assignment of all SaMS assigned to status indicator ''O1'' to a new technology APC. For CY 2027, we are maintaining the payment rates consistent for SaMS assigned to status indicator ''O1'' from CY 2026 OPPS rates. In addition, we are finalizing our proposal to use the term ''SaMS analyses performed on laboratory tests'' to describe stand-alone algorithmic analyses of data generated by a prior laboratory test. Although the services we have designated as SaMS in section X.B.1. of the final rule with comment period are required to have FDA marketing authorization to receive Medicare payment, ''SaMS analyses performed on laboratory tests do not currently require FDA marketing authorization in order to receive payment under OPPS. While these secondary analyses are currently paid for under the CLFS as ''diagnostic laboratory tests'' under section 1861(s)(3), (16), and (17) of the Act, for CY 2027, we are finalizing our position that these services are ''other diagnostic tests'' and, therefore, will be paid under OPPS under section 1861(s)(3) of the Act. Specifically, we are finalizing payment for 14 SaMS analyses performed on laboratory tests from the CLFS to the OPPS by assigning the codes to new technology APCs that align with current CY 2026 CLFS payment rates.

C. Adjustment for Cost-of-Living in Alaska and Hawaii

We have heard from a variety of interested parties about the particularly difficult cost environment facing hospitals located in Alaska and Hawaii. These challenges stem from the unique circumstances of those geographies, including dependency on outside goods and components, remote locations and transportation challenges, and other factors inherent to providing healthcare in these non-contiguous States.

A review of the available cost report data used in OPPS ratesetting highlights these issues. We stated in the proposed rule that we observed a number of hospitals in Alaska and Hawaii with payment-to-cost ratios (PCRs) that range from 0.6 to 0.7, significantly below the average PCR for OPPS hospitals of 0.89 used as an initial target for the cancer hospital adjustment discussed in section II.F. of the proposed rule. In addition, the overall ancillary cost-to-charge ratios for several hospitals located in these States are higher than average, indicating that there are higher costs relative to what those hospitals charge for the outpatient services they provide compared to other OPPS hospitals.

Under the IPPS, section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. To account for higher non-labor-related costs for these two States in the IPPS, we apply an adjustment factor to the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii. For FY 2011 and in prior fiscal years, we used the most recent cost-of-living adjustment (COLA) factors obtained from the U.S. Office of Personnel Management (OPM) website at *https://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/nonforeign-areas/#url=COLA-Rates* to update this nonlabor portion.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by the U.S. OPM every 4 years (coinciding with the update to the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively). In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45546 through 45547), we updated the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule and Consumer Price Indices (CPIs) data through 2020. Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, we utilized these COLA factors for FYs 2022 through 2025 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii.

As we discussed in the proposed rule, in general, under the IPPS methodology, we updated the 2009 OPM COLA factors by a comparison of the growth in the CPIs for the areas of Urban Alaska and Urban Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). We used the comparison of the growth in the overall CPI relative to the growth in the CPI for those areas to update the COLA factors for all areas in Alaska and Hawaii, respectively, because BLS publishes CPI data for only Urban Alaska and Urban Hawaii. Using the respective CPI commodities index and CPI services index, and using the approximate commodities/services shares obtained from the IPPS market basket, we created reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. Lastly, we exercised our discretionary authority to adjust payments to hospitals in Alaska and Hawaii by including the statutorily mandated cap of 25 percent that was applied when determining OPM's COLA factors. (For additional information, refer to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45546 through 45547).

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule, effective for FY 2027, we proposed to adjust non-labor related costs for hospitals located in Alaska and Hawaii, using the Overseas Cost-of-Living Allowance (OCOLA) data published by the Department of Defense (DOD). Starting with the FY 2027 payment year, we also proposed to no longer cap the IPPS COLA factors at 25 percent. We refer readers to the FY 2027 IPPS/LTCH PPS proposed rule for further discussion of the proposed changes to the methodology for calculating the IPPS COLA factors for FY 2027 (91 FR 19813 through 19814).

As discussed in the FY 2027 IPPS/LTCH PPS final rule, after consideration of public comments, we finalized our proposed methodology to use the DOD OCOLAs to determine the COLA factors, to no longer cap these OCOLA-based COLA factors at 25 percent, and to continue to update the COLA factors in conjunction with the labor-related share of the IPPS market basket. However, given concerns raised by commenters, in particular that the OCOLA data may not reflect some of the high costs directly affecting Hawaii, for any locality area where the COLA factors would decrease using the DOD OCOLA data, we stated that we will maintain the COLA factors that were in place for FY 2022 through FY 2026. Therefore, we finalized the use of the DOD OCOLAs to determine the COLAs for each of the designated OPM areas in Alaska and for the designated OPM areas for County of Hawaii and County of Kauai and to no longer cap these

OCOLA-based COLA factors at 25 percent. For the areas of City and County of Honolulu and County of Maui and County of Kalawao, given that the DOD OCOLA data would result in a decrease in the COLA factor, we finalized to maintain the current COLA factors of 1.25. Table H–01 of the FY 2027 IPPS/LTCH PPS final rule lists the finalized IPPS COLA factors for FY 2027 for the OPM designated areas of Alaska and Hawaii (91 FR 50389).

While higher labor-related costs for these two States are taken into account under the OPPS through the adoption of the IPPS hospital wage index and associated wage index policies, the nonlabor portion of OPPS payment is not currently adjusted to address higher nonlabor costs in these States as is addressed in the IPPS through the COLA policy. We have historically adopted the IPPS wage index and wage index policies under the OPPS, most recently in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53494 through 53498). As discussed in section II.C of the proposed rule, we proposed to continue to adopt the IPPS wage index and wage index policies under the CY 2027 OPPS and also continue to 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. We think this same logic would apply to adopting the IPPS COLA policy for hospital outpatient services in Alaska and Hawaii, as additional nonlabor costs that apply to hospital inpatient services provided in these States likely also apply to hospital outpatient services in these States. Further, not addressing the discrepancy between the IPPS and OPPS adjustment to account for nonlabor related costs would potentially continue a disincentive to provide services in the hospital outpatient setting due to the adjustment only applying to inpatient services.

Based on our review of the costs of providing outpatient services in these States and our general practice of applying consistent policies across the inpatient and outpatient hospital settings where possible, we proposed to use the equitable adjustment authority provided by section 1833(t)(2)(E) of the Act to propose to apply the IPPS COLA factors to the nonlabor share of OPPS payment amounts for hospitals located in Alaska and Hawaii for CY 2027 and future years. We note that for OPPS payments for which there is no wage adjustable portion, we proposed to apply the COLA to the full OPPS payment, as would be the case for status indicator assignments of ''G,'' ''H,'' ''K,'' ''R,'' and ''U''.

As noted earlier in this section, in the FY 2027 IPPS/LTCH PPS proposed rule we proposed several changes to the current COLA methodology including using the OCOLA data published by the DOD for the FY 2027 factors as well as to remove the cap of 25 percent (91 FR 19813 through 19814). Consistent with our historical practice of aligning OPPS payment methodologies with those of the IPPS where appropriate, we proposed to adopt the IPPS COLA factors as finalized in the FY 2027 IPPS/LTCH PPS final rule as the CY 2027 OPPS COLA factors for hospitals located in Alaska and Hawaii. As previously discussed in this section, Table H–01 of the FY 2027 IPPS/LTCH PPS final rule lists the IPPS COLA factors finalized for FY 2027 for the OPM designated areas of Alaska and Hawaii (91 FR 50389).

Under the OPPS, section 1833(t)(2)(E) of the Act grants the Secretary the authority to establish equitable adjustments as necessary, and we proposed to use that authority to establish a COLA for outpatient hospital services provided in Alaska and Hawaii that mirrors the COLA provided for inpatient hospital services provided in these States. Associated with this proposed policy, we also proposed to add conforming regulation text changes by adding subsection (l) to § 419.43. This new subsection describes the cost-of-living adjustment to the nonlabor portion of the OPPS payment amounts for hospitals located in Alaska and Hawaii. Finally, we noted that under our authority at section 1833(t)(2)(E) of the Act this adjustment would be budget neutral, and stated that the associated budget neutrality adjustment is discussed in section II.B. of the proposed rule.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to establish a COLA for hospital outpatient services furnished in Alaska and Hawaii. Several commenters requested that CMS finalize the proposal without delay and align the outpatient adjustment with the final IPPS COLA factors.

Response: We thank the commenters for their support.

Comment: One commenter stated that the proposed rule did not clearly identify the full set of payable services to which the COLA applies. The comment asked whether the adjustment is limited to status indicators G, H, K, R, and U or also applies to H1, J1, J2, K1, P, S, T, V, and other payable indicators.

Response: We appreciate the request for clarification. For OPPS payments that include a wage-adjustable portion, the COLA would apply to the nonlabor-related portion of the payment after the applicable wage adjustment is determined. This would apply to OPPS payments associated with final status indicators ''J1,'' ''J2,'' ''O1,'' ''P,'' ''S,'' ''T,'' and ''V.''

For OPPS payments for which there is no wage-adjustable portion, including payments for services assigned status indicators ''G,'' ''H,'' ''H1,'' ''K,'' ''K1,'' ''R,'' ''S1,'' and ''U,'' the COLA would apply to the full OPPS payment amount. We are clarifying this distinction because these payments do not contain a separately identified labor-related portion to which the hospital wage index would otherwise apply.

Comment: A commenter requested that CMS implement the OPPS COLA in a manner that avoids unintended reductions for hospitals affected by the revised FY 2027 IPPS methodology. The commenter noted that, in the FY 2027 IPPS final rule, CMS maintained the existing payment levels for some of the areas in Hawaii and asked that CMS do the same the OPPS.

Response: In the FY 2027 IPPS/LTCH PPS final rule (91 FR 50389), we are maintaining the COLA factors that were in place for FY 2022 through FY 2026 for City and County of Honolulu, County of Maui, and County of Kalawao for FY 2027. Under our proposal, the same IPPS COLA factors as finalized in the FY 2027 IPPS/LTCH PPS final rule would be adopted as the CY 2027 OPPS COLA factors for hospitals located in Alaska and Hawaii. We refer readers to Table H–01 of the FY 2027 IPPS/LTCH PPS final rule, which lists the IPPS COLA factors finalized for FY 2027 for the OPM designated areas of Alaska and Hawaii (91 FR 50389). *Comment:* A commenter supported the proposed COLA but encouraged CMS to continue evaluating alternative data sources that may more accurately reflect healthcare-specific costs in Alaska and Hawaii. The commenter suggested that CMS consider state-level cost-of-living measures, healthcare-specific inflation indexes, construction costs, transportation costs, utility costs, and supply-chain measures.

Response: We appreciate the commenter's recommendations concerning potential alternative data sources. For CY 2027, we believe it is appropriate to use the COLA factors finalized under the FY 2027 IPPS because doing so provides consistency

between the inpatient and outpatient hospital payment systems.

We refer readers to the FY 2027 IPPS/LTCH PPS final rule, where we invited feedback and suggestions regarding any additional data sources that could be used to develop the COLA factors (91 FR 50388).

Comment: One commenter believed that the COLA would establish an asymmetry in which hospitals receiving low wages would contribute to financing the COLA through OPPS budget neutrality without receiving comparable recognition for their geographic circumstances. The commenter asked CMS to explain this difference or provide more substantial relief through modifying budget neutrality for the OPPS wage-index transitional exception to specifically apply to hospitals above the 75th percentile of wage indexes.

Response: We appreciate the commenter's concerns but do not agree that the COLA and wage-index policies create the asserted asymmetry. The hospital wage index and COLA apply to address different cost categories and payment portions. The wage index is used to adjust the portion of the OPPS payment that is labor-related to account for different geographic levels of hospital wage costs. The COLA is designed to adjust the portion of payments not related to labor costs, so as to account for the distinct nonlabor costs of furnishing services in Alaska and Hawaii.

The presence of a nonlabor COLA for Alaska and Hawaii thus does not indicate that the wage-index methodology is failing to recognize geographic variation in labor costs elsewhere. Hospitals outside Alaska and Hawaii continue to receive wage index and other geographic adjustments applicable to them under both the IPPS and OPPS.

Section 1833(t)(2)(E) of the Act mandates that equitable adjustments are made in a budget-neutral manner, requiring that associated changes do not affect estimated aggregate OPPS expenditures. We do not believe that it is appropriate to budget neutralize specifically to hospitals with wage indexes above the 75th percentile. Developing wage index budget neutrality in this manner would result in different wage indexes between the IPPS and OPPS, we believe that it is important to maintain alignment of the IPPS and OPPS wage indexes,

We therefore do not believe that establishing the COLA in the OPPS necessitates implementation of an additional wage index adjustment or altering the calculation of budget neutrality with regards to the wage index and its associated adjustments. For a detailed discussion of the wage index, please see section II.C. of this final rule with comment period.

Comment: Commenters agreed that circumstances in Alaska and Hawaii lead to higher non-labor costs, but stated that rural communities in other States also have geographic barriers to access care, shortages of health care workers, long travelling distances, transportation limitations, and other access limitations. One commenter stated, in general, that CMS allow for regional variation for cost-of-living.

Response: The OPPS addresses certain geographic differences through other payment policies, including application of the hospital wage index to the labor-related portion of the OPPS payment, the rural sole community hospital adjustment, geographic reclassification, and the out-migration adjustment. The OPPS COLA policy serves a narrower purpose. It recognizes the unique non-labor costs experienced by hospitals in the two non-contiguous states, Alaksa and Hawaii, and aligns the OPPS treatment of those costs with the longstanding IPPS policy.

After consideration of the public comments and for the reasons discussed, we are finalizing our proposal to apply the finalized IPPS COLA factors to the non-labor portion of OPPS payment for hospitals located in Alaska and Hawaii for CY 2027 and future years. We are also finalizing the proposed conforming regulation text changes at 42 CFR 419.43(l) and the associated budget neutrality adjustment as discussed in section II.B. of this final rule with comment period.

D. Provision of Cardiac Rehabilitation (CR), Intensive Cardiac Rehabilitation (ICR) and Pulmonary Rehabilitation (PR) Services to Hospital Outpatients in Their Homes Via Audio and Video Real-Time Communications Technology

Section 6211(a) of the Consolidated Appropriations Act, 2026 (CAA, 2026) (Pub. L. 119–75, February 3, 2026), amended section 1861(eee)(2)(A)(ii) of the Act to allow for the provision of cardiac rehabilitation (CR), intensive cardiac rehabilitation (ICR) and pulmonary rehabilitation (PR) services to hospital outpatients in their homes via audio and video real-time communications technology (excluding audio-only), through December 31, 2027.

Section 6211(b) of CAA, 2026, authorizes the Secretary to implement the amendment made by section 6211(a) via program instruction or otherwise. Consistent with that authority, we have issued sub-regulatory guidance relating to the provision of CR, ICR and PR services to hospital outpatients in their homes via audio and video real-time communications technology. This guidance is available at *https://www.cms.gov/medicare/coverage/telehealth.*

We received several comments in response to our notice of the posting of sub-regulatory guidance relating to the provision of CR, ICR and PR services to hospital outpatients in their homes via audio and video real-time communications technology.

Comment: Three commenters expressed support for the sub-regulatory guidance. One of these commenters stated that they supported policies that appropriately expand access to clinically appropriate rehabilitation services while maintaining patient safety and quality of care. Another stated that they appreciated the agency recognizing cardiac rehabilitation and related services being allowed for hospital outpatients in their homes via audio/video real-time communications through December 31, 2027 and providing clarity via the updated FAQ.

Response: We thank commenters for their support.

Comment: One commenter stated that there has been uncertainty in recent years as to whether Supervised Exercise Therapy (SET) for peripheral artery disease (PAD) continues to require direct supervision. The commenter requested that CMS clarify in the final rule whether SET for PAD is subject to direct or general supervision. If CMS's determination is that direct supervision continues to be required, the commenter urged CMS to allow the direct supervision requirement for SET to be satisfied through a virtual presence, consistent with the approach CMS has adopted for CR, PR, and ICR services.

Response: SET for PAD continues to require direct supervision. The National Coverage Determination (NCD) 20.35,[176] which is entitled Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD), requires that SET be furnished ''under the direct supervision of a physician (as defined in 1861(r)(1)), physician assistant, or nurse practitioner/clinical nurse specialist (as identified in 1861(aa)(5)) who must be trained in both basic and advanced life support techniques.'' We will take the commenter's suggestion to allow the direct supervision requirement for SET to be satisfied through virtual presence

[176] *https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=371.*

under consideration for future rulemaking.

Comment: One commenter stated that they recognized and appreciated the legislative action taken by Congress to extend authorization for the provision of telehealth pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation through December 31, 2027, and further appreciated the non-regulatory guidance and Q&A document that CMS has developed to explain appropriate billing and documentation of pulmonary rehabilitation services provided in the outpatient setting. However, the commenter expressed concern about reduced patient access to PR services resulting from ''low Medicare reimbursement levels'' and noted their comments made to previous rulemaking requesting PR services be placed in the same APC as CR (APC 5771). The commenter additionally expressed concern about some virtual only pulmonary rehabilitation programs not fully adhering to guideline-based PR recommendations and requested a meeting with CMS to ensure that ''future growth in virtual only PR follows evidence-based guidelines.''

Response: We thank the commenter for their input. As we do every year, we will monitor the claims data and reevaluate the APC assignment for PR services in the next rulemaking cycle to determine if a more appropriate APC assignment is warranted. Meetings with the Division of Outpatient Care at CMS can be requested via the OPPS mailbox at *OutpatientPPS@cms.hhs.gov.*

Comment: One commenter requested that CMS eliminate the physician supervision requirement for Certified Registered Nurse Anesthetists (CRNAs) under the critical access hospital and rural emergency hospital conditions of participation and the ambulatory surgical conditions for coverage.

Response: We thank the commenter for their input; however, this comment is out of scope for purposes of this OPPS/ASC final rule with comment period.

XI. CY 2027 OPPS Payment Status and Comment Indicators

A. CY 2027 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 2027 and subsequent years, we proposed to create a new status indicator for software as a medical service that is paid separately under the OPPS (91 FR 41929). Under the OPPS, software as a medical service that is paid separately would be assigned a status indicator of ''O1''—(Software as a Medical Service, paid under OPPS; separate APC payment). Further discussion of the final payment policy for SaMS can be found in section X.B. of this final rule with comment period.

For CY 2027 and subsequent years, we also proposed to revise the current definition of status indicator ''E2'' to comply with the drug invoice policy. Further discussion of the drug invoice payment policy can be found in section V.B.2.c. of this final rule with comment period.

We did not propose to make any other changes to the existing definitions of status indicators for 2027.

We solicited public comments on the proposed definitions of the OPPS payment status indicators for CY 2027.

We did not receive any public comments on the proposed definitions of new status indicator ''O1'' or revised status indicator ''E2'', and therefore, we are finalizing the proposed definitions of status indicators ''O1'' and ''E2'' without modification for CY 2027.

The final definitions and payment statuses of status indicators ''O1'' and ''E2'' can be found in Table 87 of this final rule with comment period.

We refer readers to section X.B of this final rule with comment period for discussion on the payment specifications for status indicator ''O1''.

TABLE 87: FINAL DEFINITIONS AND PAYMENT STATUSES OF STATUS INDICATORS O1 AND E2

Final Status Indicator	Final Descriptor	Final OPPS Payment Status
O1	Software as a Medical Service	Paid under OPPS; separate APC payment.
E2	Items and Services: For which pricing information and claims data are not available.	Not paid by Medicare when submitted on outpatient claims (any outpatient bill type). Exception: claims under drug invoice pricing policy are contractor priced.

The complete list of CY 2027 payment status indicators and their definitions is displayed in Addendum D1 to this final rule with comment period, which is available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.* The CY 2027 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this final rule with comment period, which are available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

B. CY 2027 Comment Indicator Definitions

We proposed to use four comment indicators for the CY 2027 OPPS. These comment indicators, ''CH'', ''NC'', ''NI'', and ''NP'', are in effect for CY 2026; and we proposed to continue their use in CY 2027. The CY 2027 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 2026 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, APC assignment; comments will be accepted on the APC assignment for the new code.

We solicited public comments on our proposed definitions of the OPPS comment indicators for CY 2027.

We did not receive any public comments on this provision, and therefore, we are finalizing those definitions without modification for CY 2027. The definitions of OPPS comment indicators for CY 2027 are listed in Addendum D2 to this final rule with comment period, which is available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

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 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 interested parties aware of certain MedPAC recommendations for the OPPS and ASC payment systems as discussed in its March 2026 report.

Comments received from MedPAC for other OPPS or ASC payment system policies are discussed in the applicable sections of this final rule with comment period.

A. OPPS Payment Rates Update

The March 2026 MedPAC ''Report to the Congress: Medicare Payment Policy'', recommended that the Congress update Medicare OPPS payment rates by the amount specified in current law. We refer readers to the March 2026 report for a complete discussion of this recommendation.[177] We appreciate MedPAC's recommendation and, as discussed further in section II.B. of this final rule with comment period, we are finalizing our proposal to increase the OPPS payment rates by the amount specified in current law.

B. Medicare Safety Net Index

In the March 2026 MedPAC ''Report to the Congress: Medicare Payment Policy'', MedPAC stated that their recommended update to IPPS and OPPS payment rates under current law may not be sufficient to ensure the financial viability of some Medicare safety-net hospitals with a poor payer mix. MedPAC recommended that Congress redistribute 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 recommended adding $1 billion to this MSNI pool of funds to help maintain the financial viability of Medicare safety-net hospitals and recommended to the Congress transitional approaches for an MSNI policy. The FY 2027 IPPS/LTCH final rule with comment period (91 FR 49570) provides additional information regarding statutory requirements for disproportionate share hospital and uncompensated care payments. We look forward to working with Congress on these matters.

XIII. Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background, Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 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 2026 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; 88 FR 81900 through 81961; 89 FR 94309 through 94367; and 90 FR 53834 through 53916).

B. ASC Treatment of New and Revised Codes

1. Background on Process for New and Revised HCPCS Codes

We update the lists and payment rates for covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment systems (§ 416.173; 72 FR 42535). We base ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, and we use quarterly change requests (CRs) to update services paid for under the OPPS. We also provide quarterly update CRs for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). We release new and revised Level II HCPCS codes and recognize the release of new and revised CPT codes by the American Medical Association (AMA) and make these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. We recognize the release of new and revised Category III CPT codes in the July and January CRs. We note however, that in early August of this year, the AMA updated their 'release and effective date' schedule for Category III CPT codes. The Category III CPT codes will no longer be released only twice a year. Category III CPT codes will be released April 1 with an effective date of July 1, July 1 with an effective date of October 1, and October 1 with an effective date of January 1.[178] These codes will be recognized in the July, October, 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

[177] Medicare Payment Advisory Committee. March 2026 Report to the Congress. Chapter 3: Hospital inpatient and outpatient services, pp.61–96. Available at *https://www.medpac.gov.*

[178] See the AMA's website for the complete schedule. *https://www.ama-assn.org/system/files/category-3-early-release.pdf.*

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 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 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 ASC final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes. However, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in this final rule with comment period.

We have separated our discussion later in this section of the preamble based on when the codes are released and whether we proposed to solicit public comments in the proposed rule (and respond to those comments in this CY 2027 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2027 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2028 OPPS/ASC final rule with comment period).

2. April 2026 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2026 update, there were no new CPT codes; however, there were several new Level II HCPCS codes. In the April 2026 ASC quarterly update (Transmittal 13704, dated April 7, 2026, CR 14445), we added several new Level II HCPCS codes to the list of covered ancillary services. Table 64 (New Level II HCPCS Codes for ASC Covered Surgical Procedures and Ancillary Services Effective April 1, 2026) of the CY 2027 OPPS/ASC proposed rule (91 FR 41932 through 41933), listed the new Level II HCPCS codes that were implemented April 1, 2026. These new codes that were effective April 1, 2026, were assigned to comment indicator ''NP'' in Addendum BB to the CY 2027 OPPS/ASC proposed rule to indicate that the codes were assigned to interim APC assignments. In addition, we note that the ASC addenda (AA, BB, DD1, DD2, EE, and FF) listed below, as well as other relevant addenda discussed later in this section of the preamble, are available via the internet on the CMS website, specifically, at *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices.*

- ASC Addendum AA: ASC Covered Surgical Procedures for CY 2027 (Including Surgical Procedures for Which Payment is Packaged),
- ASC Addendum BB: ASC Covered Ancillary Services Integral to Covered Surgical Procedures for CY 2027 (Including Ancillary Services for Which Payment is Packaged),
- ASC Addendum DD1: Proposed ASC Payment Indicators (PI) for CY 2027,
- ASC Addendum DD2: ASC Comment Indicators (CI) for CY 2027,
- ASC Addendum EE: Surgical Procedures to be Excluded from Payment in ASC for CY 2027, and
- ASC Addendum FF: ASC Device Offset Percentages for CY 2027, and
- Addendum O: Long Descriptors for New Category I CPT Codes, Category III CPT Codes, C-codes, and G-Codes Effective January 1, 2027.

We invited public comments on the proposed interim payment indicators for the new HCPCS codes that were recognized as ASC covered ancillary services in April 2026 through the quarterly update CRs, as listed in Table 88 (New Level II HCPCS Codes for ASC Covered Surgical Procedures and Ancillary Services Effective April 1, 2026). The new codes that were effective April 1, 2026, were assigned to comment indicator ''NP'' in ASC Addendum BB to the CY 2027 OPPS/ASC proposed rule to indicate that the codes were assigned to interim payment indicators and comments would be accepted on their interim assignments. Comments related to office-based designations or device-intensive status designations for new Level II HCPCS codes that were implemented in April 2026 can be found in sections XIII.C.3.b. and XIII.C.3.c. of this final rule with comment period. We note in prior years we included the final ASC payment indicators in the coding tables in the preamble, but because we include the same information in the ASC addenda, we have not included them in Table 88. Therefore, readers are advised to refer to the ASC addenda for the final ASC payment indicators and payment rates for all codes reported under the ASC payment system. The list of ASC payment indicators and definitions used under the ASC payment system can be found in the ASC addenda. We note that the ASC addenda (AA, BB, DD1, DD2, EE, and FF) and OPPS Addendum O are

available via the internet on the CMS website.

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TABLE 88: NEW LEVEL II HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE APRIL 1, 2026

April 2026 HCPCS Code	CY 2027 HCPCS Code	Long Descriptor
A2040	A2040	Microlyte painguard, per square centimeter
A2041	A2041	Foundation drs+ duo, per square centimeter
A2042	A2042	Foundation drs+ solo, per square centimeter
A2043	A2043	Biobrane, per square centimeter
A2044	A2044	Biobrane glove, each
A2045	A2045	Novashield or novogen wound matrix, per square centimeter
C1743	C1743	Scaffold, endovascular non-coronary, resorbable drug eluting, with delivery system (implantable)
C8007	C8007	Open implantation of hypoglossal nerve neurostimulator array and pulse generator, not requiring an insertion of a separate distal respiratory sensor electrode or electrode array
C8008	C8008	Revision or replacement of hypoglossal nerve neurostimulator array including connection to existing pulse generator
C8009	C8009	Removal of hypoglossal nerve neurostimulator array and pulse generator
C8010	1091T	Percutaneous placement of permanent common carotid embolic protection device, including all system components and imaging guidance; bilateral
C8011	C8011	Open implantation of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver, including external power source and all system components
C8012	C8012	Revision or replacement of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver
C8013	C8013	Removal of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver
C9818	C9818	Suzetrigine, oral, 1 mg
G0681	G0681	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute for a wound surface area up to 100 sq cm; first 25 sq cm or less of wound surface area
G0682	G0682	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute for a wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
G0683	G0683	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute graft for a wound surface greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
G0684	G0684	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute graft for a wound surface greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
J0463	J0463	Injection, atropine sulfate (fresenius and therapeutically equivalent), 0.01 mg

April 2026 HCPCS Code	CY 2027 HCPCS Code	Long Descriptor
J1098	J1098	Articaine ophthalmic, 8% solution, 0.4 mL
J1164	J1164	Injection, diltiazem hydrochloride in 0.72% sodium chloride, 0.5 mg
J1553	J1553	Injection, immune globulin (yimmugo), 100 mg
C9145	J8502	Injection, aprepitant (aponvie), 1 mg
J9183	J9183	Gemcitabine intravesical system, 225 mg
J9277	J9277	Injection, pembrolizumab, 1 mg and berahyaluronidase alfa-pmph
C9308	J9278	Injection, carboplatin (avyxa), 1 mg
C9307	J9601	Injection, linvoseltamab-gcpt, 1 mg
Q4418	Q4418	Biolab membrane wrap flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4419	Q4419	Biolab membrane wrap lite flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4421	Q4421	Biolab membrane wrap solo, per square centimeter (add-on, list separately in addition to primary procedure)
Q4422	Q4422	A/c wrap, per square centimeter (add-on, list separately in addition to primary procedure)
Q4423	Q4423	Biolab tri-membrane wrap flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4424	Q4424	Revive ft, per square centimeter (add-on, list separately in addition to primary procedure)
Q4425	Q4425	Revive tl, per square centimeter (add-on, list separately in addition to primary procedure)
Q4426	Q4426	Dermabind tl + or dermabind tl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4427	Q4427	Dermabind dl n or dermabind dl + or dermabind dl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4428	Q4428	Dermabind sl n or dermabind sl + or dermabind sl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4429	Q4429	Dermabind ch n or dermabind ch x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4435	Q4435	Renati membrane, per square centimeter (add-on, list separately in addition to primary procedure)
Q4436	Q4436	Renati ac membrane, per square centimeter (add-on, list separately in addition to primary procedure)
Q4437	Q4437	Revival ac, per square centimeter (add-on, list separately in addition to primary procedure)
Q4438	Q4438	Pretect, per square centimeter (add-on, list separately in addition to primary procedure)
Q4439	Q4439	Instagraft, per square centimeter (add-on, list separately in addition to primary procedure)
Q4440	Q4440	Curamatrix, per square centimeter (add-on, list separately in addition to primary procedure)
Q5162	Q5162	Injection, denosumab-nxxp (bildyos/bilprevda), biosimilar, 1 mg

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3. July 2026 HCPCS Codes Proposed Rule Comment Solicitation

In the July 2026 ASC quarterly update (Transmittal R13836, Change Request 14522, June 24, 2026), we added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and covered ancillary services. Table 65 (New HCPCS Codes for ASC Covered Surgical Procedures and Ancillary Services Effective July 1, 2026) of the CY 2027 OPPS/ASC proposed rule (91 FR 41934), displayed the new HCPCS codes that were effective July 1, 2026.

We invited public comments on the proposed payment indicators for these Level II HCPCS codes, and indicated that the proposed comment indicators, payment indicators, and payment rates for these codes were listed in Addendum AA and Addendum BB of the proposed rule. These new codes that

were effective July 1, 2026, were assigned to comment indicator ''NP'' in ASC Addendum AA and Addendum BB to the CY 2027 OPPS/ASC proposed rule to indicate that the codes were assigned to interim payment indicators and comments would be accepted on their interim assignments. We further stated that we proposed to finalize the payment indicators in this final rule with comment period. We note in prior years we included the final ASC payment indicators in the coding preamble tables, however, because the same information can be found in Addendum AA and Addendum BB, we are no longer including them in Table 89. Therefore, readers are advised to refer to the ASC addenda for the final ASC payment indicators and payment rates for all codes reported under the ASC payment system.

Comments related to office-based designations or device-intensive status designations for new CPT and Level II HCPCS codes that were added to the list of covered surgical procedures and ancillary services implemented in July 2026 can be found in sections XIII.C.3.b. and XIII.C.3.c. of this final rule with comment period.

TABLE 89: NEW HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE JULY 1, 2026

July 2026 HCPCS Code	CY 2027 HCPCS Code	Long Descriptor
0730T	0730T	Trabeculotomy by laser, including optical coherence tomography (OCT) guidance
A9574	A9574	Injection, ferumoxytol, 1 mg
C1609	C1609	Vertebral device, motion-preserving, with screw fixation
C8014	C8014	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, including use of a suction enabled ureteral access sheath, with irrigation (if performed)
C9310	C9310	Injection, leucovorin calcium (avyxa), 1 mg
J0528	J0528	Injection, fosfomycin disodium, 20 mg
J1289	J1289	Injection, narsoplimab-wuug, 1 mg
J1577	J1577	Injection, immune globulin (qivigy), 100 mg
J2361	J2361	Injection, depemokimab-ulaa, 1 mg
J2789	J2789	Riboflavin 5'-phosphate, ophthalmic solution (epioxahd/epioxa), up to 2 mL
J7176	J7176	Injection, human fibrinogen - chmt (fesilty), 1 mg
J9062	J9062	Injection, amivantamab 5 mg and hyaluronidase-lpuj
J9232	J9232	Injection, docetaxel (hospira), not therapeutically equivalent to j9171, 1 mg
Q5098	Q5098	Injection, ustekinumab-srlf (imuldosa), biosimilar, 1 mg
Q5164	Q5164	Injection, ustekinumab-hmny (starjemza), biosimilar, 1 mg
Q5165	Q5165	Injection, denosumab-mobz (oziltus), biosimilar, 1 mg
Q5166	Q5166	Injection, denosumab-desu (osvyrti/jubereq), biosimilar, 1 mg
Q5167	Q5167	Injection, denosumab-qbde (enoby/xtrenbo), biosimilar, 1 mg
Q5168	Q5168	Injection, ranibizumab-leyk (nufymco), biosimilar, 0.1 mg
Q5169	Q5169	Injection, pegfilgrastim-unne (armlupeg), biosimilar, 0.5 mg
Q5170	Q5170	Injection, aflibercept-boav (eydenzelt), biosimilar, 1 mg
Q5171	Q5171	Injection, denosumab-mobz (boncresa), biosimilar, 1 mg

4. October 2026 HCPCS Codes Final Rule Comment Solicitation

For CY 2027, consistent with our established policy, we proposed in the CY 2027 OPPS/ASC proposed rule (91 FR 41934) that the HCPCS codes that will be effective October 1, 2026, would be flagged with comment indicator ''NI'' in Addendum BB to this final rule with comment period to indicate that we have assigned the codes an interim ASC payment status for CY 2027. In the October 2026 ASC quarterly update (Transmittal 13983, Change Request 14634, dated October 8, 2026), we added separately payable Level I and II HCPCS codes to the list of covered surgical procedures and covered ancillary services. Table 90 lists the codes that were effective October 1, 2026. We are inviting public comments on this final rule with comment period on the interim payment indicators,

which will be finalized in the CY 2028 OPPS/ASC final rule with comment period. We note these codes will be subject to comment in the CY 2028 OPPS/ASC proposed rule with comment period, which will be finalized in the CY 2028 OPPS/ASC final rule with comment period.

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TABLE 90: NEW HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE OCTOBER 1, 2026

October 2026 HCPCS Code	CY 2027 HCPCS Code	CY 2027 Long Descriptor
1054T	1054T	Focused non-shock wave ultrasonic propulsion of residual stone fragment(s) post-lithotripsy, unilateral, including ultrasound guidance, fragment(s) less than or equal to 5 mm
1056T	1056T	Cochlear infusion of pharmacologic agent (ie, gene therapy vector), including mastoidectomy, labyrinthotomy, and repair of fenestrations
1062T	1062T	Artificial insemination, transcervical intratubal, unilateral or bilateral, including imaging guidance
1069T	1069T	Mechanical extremity (ie, hands and feet) cryocompression; individual glove and boot supplies with initial measurement, fitting, and therapy education
1070T	1070T	Mechanical extremity (ie, hands and feet) cryocompression; individual glove and boot placement, initiation of cooling pre-chemotherapy and continuing through chemotherapy administration
1081T	1081T	Microvascular anastomosis between a lymph node and a vein, including robot assistance, when performed; initial anastomosis
1084T	1084T	Implantation of scaffolding allograft to reinforce the suprachoroidal space
1091T	1091T	Placement of permanent common carotid artery filter, percutaneous, bilateral, including ultrasound guidance, when performed
1092T	1092T	Implantation of acellular scaffold (eg, hyaluronan), knee, single implant; into chondral defect, open
1093T	1093T	Implantation of acellular scaffold (eg, hyaluronan), knee, single implant; into a chondral or osteochondral defect, arthroscopic
A9613	A9613	Piflufolastat f 18 (pylarify truvu), diagnostic, 1 millicurie
C9311	C9311	Injection, eplontersen, 1 mg (code may be used for medicare when drug administered under the direct supervision of a physician, not for use when drug is self administered)
C9312	C9312	Injection, trabectedin (apotex), not therapeutically equivalent to J9362, 0.01 mg
C9313	C9313	Injection, pivekimab sunirine-pvzy, 0.01 mg
C9310	J0655	Injection, leucovorin calcium (avyxa), 1 mg
J0871	J0871	Injection, daptomycin (endo), not therapeutically equivalent to j0878, 1 mg
J1757	J1757	Injection, tividenofusp alfa-eknm, 1 mg
J1818	J1818	Injection, pegzilarginase-nbln, 0.05 mg
J9186	J9186	Injection, etoposide (avyxa), 1 mg
J9191	J9191	Injection, fluorouracil (avyxa), 10 mg
J9362	J9362	Injection, trabectedin, 0.01 mg
Q5172	Q5172	Injection, filgrastim-laha (filkri), biosimilar, 1 microgram
A2046	A2046	Dermisphere hdrt, per square centimeter (add-on, list separately in addition to primary procedure)
A2047	A2047	Lacertamatrix, per square centimeter (add-on, list separately in addition to primary procedure)
A2048	A2048	Puraply mz, per milligram
A2049	A2049	Theracor, per square centimeter (add-on, list separately in addition to primary procedure)
A2050	A2050	Fibrillar collagen wound dressing, per milligram
Q4207	Q4207	Carbon life, per square centimeter (add-on, list separately in addition to primary procedure)
Q4223	Q4223	Dermabind sl optic, per square centimeter (add-on, list separately in addition to primary procedure)
Q4243	Q4243	Amchomatrix, per square centimeter (add-on, list separately in addition to primary procedure)

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5. January 2027 HCPCS Codes

a. New Level II HCPCS Codes Final Rule Comment Solicitation

As has been our practice in the past, we include those HCPCS codes that are effective January 1 in this final rule with comment period, thereby updating the ASC payment system for the calendar year. In contrast, most Level II HCPCS codes effective January 1 are not released until November and therefore are not available for inclusion in the proposed rule. The G-codes listed in Addendum O to this final rule with comment period (which were also included in the proposed rule) are an exception. We assigned interim payment statuses to the Level II HCPCS codes that were not available for inclusion in the proposed rule and identify them with comment indicator ''NI'' in ASC Addendum AA and Addendum BB to this final rule with comment period to indicate that we are assigning them an interim payment status, which is subject to public comment. Therefore, as we stated in the CY 2027 OPPS/ASC proposed rule, these Level II HCPCS codes that will be effective January 1, 2027, are included in this final rule with comment period and will also be released to the public through the January 2027 ASC Update CR and the CMS HCPCS website. We are inviting public comments in this final rule with comment period on the payment indicator assignments, which would be finalized in the CY 2028 OPPS/ASC final rule with comment period. Similar to the codes effective October 1, 2026, these new Level II HCPCS codes that will be effective January 1, 2027 will be subject to comment in the CY 2028 OPPS/ASC proposed rule, which would be finalized in the CY 2028 OPPS/ASC final rule with comment period.

b. CPT Codes Proposed Rule Comment Solicitation

For the CY 2027 ASC update, we received the CPT codes that will be effective January 1, 2027, from the AMA in time to be included in this final rule with comment period; however, the AMA subsequently announced a new 'release and effective date' schedule for Category III CPT codes. As a result, the Category III CPT codes that were previously assigned a January 1, 2027 effective date by the AMA, became effective October 1, 2026.

The new, revised, and deleted CPT codes can be found in ASC Addendum AA and Addendum BB to the CY 2027 OPPS/ASC 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 the CY 2027 OPPS/ASC proposed rule to indicate that the code is new for the calendar year 2027, or the code is an existing code with substantial revision to its code descriptor in calendar year 2027 as compared to the current calendar year with a proposed payment indicator assignment. We stated that we would accept comments and finalize the payment indicators in this final rule with comment period. Further, we remind readers that the CPT code descriptors that appeared in Addendum AA and Addendum BB are short descriptors and do not describe the complete procedure, service, or item described by the CPT code. Therefore, we included the 5-digit placeholder codes and their long descriptors for the new CY 2027 CPT codes in Addendum O to the CY 2027 OPPS/ASC proposed rule (which is available via the internet on the CMS website) so that the public could comment on our proposed payment indicator assignments. The 5-digit placeholder codes were listed in Addendum O to the CY 2027 OPPS/ASC proposed rule, specifically under the column labeled ''CY 2027 OPPS/ASC Proposed Rule 5-Digit Placeholder Code.'' We also stated that we would include the final CPT code numbers in this CY 2027 OPPS/ASC final rule with comment period. Comments related to office-based designations or device-intensive status designations for new CPT codes that were added to the list of covered surgical procedures and ancillary services implemented in January 2027 can be found in sections XIII.C.3.b. and XIII.C.3.c. of this final rule with comment period.

Finally, in Table 91, we summarize our process for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the ASC payment system.

TABLE 91: 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 2026	HCPCS (CPT and Level II codes)	April 1, 2026	CY 2027 OPPS/ASC proposed rule	CY 2027 OPPS/ASC final rule with comment period
July 2026	HCPCS (CPT and Level II codes)	July 1, 2026	CY 2027 OPPS/ASC proposed rule	CY 2027 OPPS/ASC final rule with comment period
October 2026	HCPCS (CPT and Level II codes)	October 1, 2026	CY 2027 OPPS/ASC final rule with comment period	CY 2028 OPPS/ASC final rule with comment period
January 2027	CPT Codes	January 1, 2027	CY 2027 OPPS/ASC proposed rule	CY 2027 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2027	CY 2027 OPPS/ASC final rule with comment period	CY 2028 OPPS/ASC final rule with comment period

6. ASC Payment and Comment Indicators

a. Background

In addition to the payment indicators that we introduced in the August 2, 2007 ASC final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy-relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC CPL prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, NTIOLs, or qualifying nonopioid devices.

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 with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

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 the 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).

In the CY 2025 OPPS/ASC final rule with comment period, we finalized the modification of the descriptor of ASC payment indicator ''L6'' 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 (89 FR 94317). We added this code to Addendum DD1 (which is available via the internet on the CMS website).

In the CY 2026 OPPS/ASC final rule with comment period, we finalized the addition of one payment indicator, ''S2''—''Skin substitute supply group; paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate'' to describe skin substitute products paid separately in an ASC (90 FR 53843). We added this code to Addendum DD1 (which is available via the internet on the CMS website).

b. Final ASC Payment and Comment Indicators for CY 2027

For CY 2027, we proposed 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 2027 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2027, compared to the CY 2026 descriptors, are included in ASC Addenda AA and BB to this final rule with comment period and labeled with comment indicator ''NP'' to indicate that these CPT and Level II HCPCS codes were open for comment as part of the CY 2027 OPPS/ASC proposed rule.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

We refer readers to Addenda DD1 and DD2 of this final rule with comment period (which are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators finalized for the CY 2027 update. Addenda DD1 and DD2 to this final rule with comment period (which are available via the internet on the CMS website) contain the complete list of ASC payment and comment indicators for CY 2027.

C. Payment Policies Under the ASC Payment System

1. Final ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with payment indicators ''G2'' and ''A2.'' Payment indicator ''A2'' was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator ''A2'' is no longer required to identify surgical procedures

subject to transitional payment, we have retained payment indicator ''A2'' because it is used to identify procedures that are exempted from the application of the office-based designation.

As required under § 416.171(d), payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') are the lower of the amount calculated based on PFS nonfacility Practice Expense (PE) Relative Value Units (RVUs) or the amount calculated using the ASC standard rate setting methodology for the procedure. As detailed in section XIII.C.3.b. of this final rule with comment period, we update the payment amounts for office-based procedures (payment indicators ''P2,'' ''P3'', and ''R2'') using the most recent available PFS 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.

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 include the most recent device offset percentages calculated under the ASC standard ratesetting methodology, as discussed in section XIII.C.4. of this final rule with comment period.

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 generally 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 2027

We proposed to update ASC payment rates for CY 2027 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XIII.C.4. of this final rule with comment period. As the proposed OPPS relative payment weights are generally based on geometric mean costs, we proposed that the ASC payment system will generally use the geometric mean cost to determine proposed relative payment weights under the ASC standard methodology. We proposed to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2''.

We proposed to calculate payment rates for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') and device-intensive procedures (payment indicator ''J8'') according to our established policies and to identify device-intensive procedures using the methodology discussed in section XIII.C.4. of this final rule with comment period. Therefore, we proposed to update the payment amount for the service portion (the non-device portion) of the device-intensive procedures using the standard ASC ratesetting methodology and the payment amount for the device portion based on the proposed CY 2027 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. We proposed that payment for office-based procedures would be at the lesser of the proposed CY 2027 PFS nonfacility PE RVU-based amount or the proposed CY 2027 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2026, for CY 2027, we proposed to continue our policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2'') will be assigned the current ASC payment indicators associated with those procedures and will continue to be paid separately under the ASC payment system.

We did not receive public comments on our ratesetting methodology to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2''. We did not receive public comments on our ratesetting methodology 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 2027 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology and therefore, we are finalizing as proposed.

We did not receive public comments on our ratesetting methodology that payment for office-based procedures would be at the lesser of the proposed CY 2027 PFS nonfacility PE RVU-based amount or the proposed CY 2027 ASC payment amount calculated according to the ASC standard ratesetting methodology, and therefore, we are finalizing as proposed.

We did not receive public comments on 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, and therefore, we are finalizing as proposed.

c. Final Payment for ASC Add-On Procedures Eligible for Complexity Adjustments Under the OPPS

In this section, we discuss the policy to provide increased payment under the ASC payment system for combinations of certain ''J1'' service codes and add-on procedure codes that are eligible for a complexity adjustment under the OPPS.

(1) OPPS C–APC Complexity Adjustment Policy

Under the OPPS, complexity adjustments are utilized to provide increased payment for certain comprehensive services. As discussed in section II.A.2.b. of this final rule with comment period, we apply a complexity adjustment by promoting qualifying paired ''J1'' service code combinations or paired code combinations of ''J1''

services and add-on codes from the originating Comprehensive APC (C–APC) (the C–APC to which the designated primary service is first assigned) to the next higher paying C–APC in the same clinical family of C–APCs. A ''J1'' status indicator refers to a hospital outpatient service paid through a C–APC. We package payment for all add-on codes, which are codes that describe a procedure or service always performed in addition to a primary service or procedure, into the payment for the C–APC. However, certain combinations of primary service codes and add-on codes may qualify for a complexity adjustment.

We apply complexity adjustments when the paired code combination represents a complex, costly form or version of the primary service when the frequency and cost thresholds are met. The frequency threshold is met when there are 25 or more claims reporting the code combination, and the cost threshold is met when there is a violation of the 2 times rule, as specified in section 1833(t)(2) of the Act and described in section III.A.2.b. of this final rule with comment period, 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.

As previously stated, we package payment for add-on codes into the C–APC payment rate. If any add-on code reported in conjunction with the ''J1'' primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and the primary service code reported with the add-on code is not reassigned to the next higher cost C–APC. We list the final complexity adjustments for ''J1'' and add-on code combinations for CY 2027, along with all other proposed complexity adjustments, in Addendum J to this final rule with comment period (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices).*

(2) CY 2027 ASC Special Payment Policy for OPPS Complexity-Adjusted C–APCs

For CY 2027, we proposed to continue the special payment policy and methodology for OPPS complexity-adjusted C–APCs that was finalized in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72078 through 72080). We also proposed to make a minor change to the long descriptor of ASC complexity adjustment code C7570.

For those ASC complexity adjustment codes for which we have claims data, we proposed to use the claims data to calculate the code combination utilization and estimated payments for the ASC payment system budget neutrality calculations for CY 2027. Any ASC complexity adjustment budget neutrality calculations are discussed further in section XIII.H.2.a. of this final rule with comment period. The full list of the proposed ASC complexity adjustment codes, inactive ASC complexity adjustment codes, their short descriptors, long descriptors, and proposed ASC payment indicators for CY 2027 can be found in the CY 2027 proposed ASC CPX supplemental policy file, which also includes both the existing ASC complexity adjustment codes and proposed additions. The CY 2027 OPPS/ASC proposed rule ASC Addendum AA also includes our proposed active ASC complexity adjustment codes and their ASC payment rates. Both files are published on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/asc-regulations-and-notices.* Since the complexity adjustment assignments change each year under the OPPS, the proposed list of ASC complexity adjustment codes eligible for the proposed payment policy changed slightly from the previous year. Additionally, since complexity adjustment assignments may change between the proposed rule and final rule under the OPPS, the final list of ASC complexity adjustment codes eligible for this payment policy may be slightly different than the proposed list of ASC complexity adjustment codes.

We did not receive public comments on this provision, and therefore, we are finalizing the ASC special payment policy for OPPS complexity-adjusted C–APCs as proposed. Based on our review of the final CY 2027 Addendum J OPPS complexity adjustment combinations, certain add-on codes would not be reported in conjunction with the ''J1'' primary service code as the add-on code is identified as a Type 1 add-on code and the ''J1'' primary service code would not satisfy the add-on code edit. These combinations appeared as a result of a predecessor ''J1'' service code mapping to both a successor ''J1'' service code and successor add-on code and the Type 1 add-on code's primary service code was not a ''J1'' service but rather a packaged procedure. Since these code combinations could not otherwise be reported together, we are not creating ASC complexity adjustment codes for such code combinations. The final ASC complexity adjustment codes, based on the most recent data available for this final rule with comment period, can be found on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgicalcenter-asc/annual-policy-files.* Existing ASC complexity adjustment codes that do not meet our criteria for separate payment for CY 2027 because the code combination is not eligible for a complexity adjustment under the OPPS for CY 2027 will be non-payable and assigned a status indicator of ''B5''—''Alternative code may be available; no payment made''—for CY 2027. Additionally, proposed ASC complexity adjustment codes that met our criteria based on data available for the CY 2027 OPPS/ASC proposed rule but do not meet our criteria based on claims data available for this final rule with comment period have not been finalized.

d. Final Low Volume APCs and Limit on ASC Payment Rates for Procedures Assigned to Low Volume APCs

As stated in section XIII.D.1.b. of this final rule with comment period, 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. Under our policy, we expanded the low volume adjustment policy that is applied to procedures assigned to New Technology APCs to also apply to clinical and brachytherapy APCs. Specifically, a clinical APC or brachytherapy APC with fewer than 100 claims per year would be designated as a Low Volume APC. For items or services assigned to a Low Volume APC, we use up to 4 years of claims data to establish a payment rate for the APC as we currently do for low volume services assigned to New Technology APCs. The payment rate for a Low Volume APC or a low volume New Technology procedure would be based on the highest of the median cost, arithmetic mean cost, or geometric mean cost calculated using multiple years of claims data.

Based on claims data available for the CY 2027 OPPS/ASC proposed rule, we proposed to designate five brachytherapy APCs and four clinical APCs as Low Volume APCs under the ASC payment system. The four clinical APCs and five brachytherapy APCs met our criteria of having fewer than 100 single claims in the relevant claims year (CY 2025 for the CY 2027 OPPS/ASC proposed rule) and therefore, we proposed that they would be subject to our universal Low Volume APC policy and the APC cost metric would be based on the greater of the median cost, arithmetic mean cost, or geometric mean cost using up to 4 years of claims data. Eight of the nine APCs were designated as Low Volume APCs in CY 2026. Based on data for the CY 2027 OPPS/ASC proposed rule, APC 2645 (Brachytx, non-stranded, gold-198) had 87 single claims and met our criteria to be designated as a Low Volume APC.

Comment: Commenters supported our continued use of the Low Volume APC policy.

Response: We thank commenters for their support and are finalizing our methodology for determining Low Volume APCs as proposed. Based on claims data available for this final rule with comment period, we are finalizing our proposal to designate five brachytherapy APCs and four clinical APCs as Low Volume APCs under the ASC payment system. The four clinical APCs and five brachytherapy APCs met our criteria of having fewer than 100 single claims in the relevant claims year (CY 2025 for this CY 2027 OPPS/ASC final rule with comment period) and therefore, we are finalizing our proposal that they would be subject to our universal Low Volume APC policy and the APC cost metric would be based on the greater of the median cost, arithmetic mean cost, or geometric mean cost using up to 4 years of claims data. Eight of the nine APCs were designated as Low Volume APCs in CY 2026. Based on data for this final rule with comment period, APC 2645 (Brachytx, non-stranded, gold-198) had 92 single claims and we are finalizing our proposal to designate APC 2645 as a Low Volume APC.

Table 92 includes the CY 2025 claims available for ratesetting for each of the APCs we are finalizing to be designated as a Low Volume APC for CY 2027. The cost statistics for our Low Volume APCs, such as the median, arithmetic mean, and geometric mean costs, are available for download with this final rule with comment period on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/ascregulations-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 92: LOW VOLUME APCS USING STANDARD (ASC) RATESETTING METHODOLOGY FOR CY 2027

APC	APC Description	CY 2025 Claims Available for Ratesetting
2635	Brachytx, non-str, HA, P-103	29
2642	Brachytx, stranded, C-131	43
2643	Brachytx, non-stranded,c-131	80
2645	Brachytx, non-str, gold-198	92
2647	Brachytx, NS, Non-HDRIr-192	14
5244	Level 4 Blood Product Exchanges and Related Services	2
5494	Level 4 Intraocular Procedures	5
5495	Level 5 Intraocular Procedures	72
5496	Level 6 Intraocular Procedures	10

2. Final 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 proposed rule and final rule with comment period (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, 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 PFS 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 invoice 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.

In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53887 through 53888), we finalized our policy to unpackage and pay separately for certain skin substitute supplies when provided integral to a covered surgical procedure under the ASC payment system in conjunction with our policy to unpackage and pay separately for the same such items under the OPPS. We finalized the addition of a new ASC payment indicator ''S2''—''Skin substitute supply group; paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate'' to indicate a separately payable ancillary skin substitute supply when provided integral to a separately payable ASC covered surgical procedure. We finalized that payment for separately payable skin substitute supplies under the ASC payment system would be made at the same rate as is provided under the OPPS.

b. Final Payment for Covered Ancillary Items and Services for CY 2027

We proposed 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 2027 OPPS and ASC payment rates and subsequent years' payment rates. We proposed to continue to set the proposed CY 2027 ASC payment rates and subsequent years' payment rates for brachytherapy sources

and separately payable drugs, biologicals, and skin substitute supplies equal to the OPPS payment rates for CY 2027 and subsequent years' payment rates.

We did not receive public comments on this provision, and therefore, we are finalizing our proposal to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between OPPS and ASC payment systems regarding the packaged or separately payable status of services and the final CY 2027 OPPS and ASC payment rates and subsequent years' payment rates. We are also finalizing our proposal without modification to continue to set the CY 2027 ASC payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2027 and subsequent years.

Covered ancillary services and their final payment indicators for CY 2027 are listed in Addendum BB of this final rule with comment period (which is available via the internet on the CMS website). For those covered ancillary services where the payment rate is the lower of the rate under the ASC standard rate setting methodology and the PFS proposed rates (similar to our office-based payment policy), the final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the final PFS rates effective January 1, 2027. For a discussion of the PFS rates, we refer readers to the CY 2027 PFS final rule with comment period which is available on the CMS website at *https://www.cms.gov/medicare/payment/feeschedules/.*

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 recently 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 PFS 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 PFS nonfacility PE RVUs; payment based on PFS nonfacility PE RVUs); or ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later without PFS 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 PFS 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 2027 Final Office-Based Procedures

In developing the CY 2027 OPPS/ASC proposed rule, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. Historically, we also review the most recent claims volume and utilization data (CY 2025 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2026 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 2026 OPPS/ASC final rule with comment period (89 FR 94322 through 94326).

Our review of the CY 2025 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—CPT code 0102T (Extracorporeal shock wave performed by a physician, requiring anesthesia other than local, and involving the lateral humeral epicondyle) and 60660 (Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency)—that we believe meet the criteria for designation as permanently office-based. The data indicate that these procedures are performed more than 50 percent of the time in physicians' offices, and the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices.

We did not receive any public comments on our proposed permanent office-based designations and, therefore, are finalizing our proposal to permanently designate CPT codes 0102T and 60660 as office-based procedures beginning in CY 2027 as shown in Table 93.

We did not receive any public comments on our proposed permanent office-based designations and, therefore, are finalizing our proposal to no longer designate CPT code 53866 as a temporary office-based surgical procedure beginning in CY 2027 as shown in Table 94.

TABLE 93: ASC COVERED SURGICAL PROCEDURES TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2027

CPT/HCPCS Code	Long Descriptor	Final CY 2026 ASC Payment Indicator	Final CY 2027 ASC Payment Indicator*
0102T	Extracorporeal shock wave performed by a physician, requiring anesthesia other than local, and involving the lateral humeral epicondyle	G2	P2*
60660	Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency	G2	P2*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2027 PFS final rates.

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.

In Table 130 of the CY 2026 OPPS/ASC final rule with comment period, we finalized assigning temporary office-based designations to four surgical procedures for CY 2026 (90 FR 53850). We reviewed CY 2025 volume and utilization data for the four surgical procedures designated as temporarily office-based in the CY 2026 OPPS/ASC final rule with comment period. As shown in Table 94, for one of the four surgical procedures—CPT code 53866 (Catheterization with removal of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate)—there are greater than 50 claims available and the volume and utilization indicated this procedure was not performed predominantly in the office setting based on CY 2025 claims data. Therefore, we proposed to no longer designate this procedure as temporarily office-based and to designate this procedure a payment indicator of ''G2''—''Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight.'' for CY 2027.

TABLE 94: ASC COVERED SURGICAL PROCEDURES TO BE NO LONGER DESIGNATED AS TEMPORARILY OFFICE-BASED FOR CY 2027

CPT/HCPCS Code	Long Descriptor	Final CY 2026 ASC Payment Indicator	Final CY 2027 ASC Payment Indicator
53866	Catheterization with removal of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate	R2	G2

For the remaining three procedures that were designated as temporarily office-based in the CY 2026 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 number of claims to determine if the office setting was the predominant setting of care for these procedures. Therefore, as shown in Table 70 of the CY 2027 OPPS/ASC proposed rule, we proposed to continue to designate such procedures as temporarily office-based for CY 2027 and assign one of the office-based payment indicators. Additionally, for CY 2027, we did not propose to designate any new CY 2027 CPT codes for ASC covered surgical procedures as temporarily office-based.

We did not receive public comments on this provision, and therefore, we are finalizing our proposed temporary office-based designation to the procedures shown in Table 95. The procedures for which the final office-based designation for CY 2027 is temporary are also indicated by an asterisk in Addendum AA to this final rule with comment period (which is available via the internet on the CMS

website at *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/ASCPayment/ASCRegulations-and-Notices).*

TABLE 95: CY 2027 PAYMENT INDICATORS FOR NEW AND EXISTING ASC COVERED SURGICAL PROCEDURES TO BE DESIGNATED AS TEMPORARILY OFFICE-BASED

CPT/HCPCS Code	Long Descriptor	Final CY 2026 ASC Payment Indicator	Final CY 2027 ASC Payment Indicator*
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*
64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator	R2	R2*
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 2027 PFS final rates.

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.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59043), 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 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.

In the CY 2025 OPPS/ASC final rule with comment period, we finalized a modification to our policy regarding default device offset percentages for new codes that meet our criteria for device-intensive status. Under both the OPPS and ASC payment system, for new device-intensive procedures that lack claims data, or lack claims data from a predecessor code or a clinically-similar code that uses the same device, we apply the greater of the APC-wide device offset percentage or 31 percent (the previous default device offset percentage). We believe that an APC-wide average device offset percentage is, in most cases, a better reflection of device costs when the typical device costs of procedures assigned to such APC are significantly greater than 31 percent. This policy does not apply to new device-intensive procedures assigned to New Technology APCs.

In the CY 2026 OPPS/ASC final rule with comment period, we discussed the implementation of the Final Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022 rule and the impact of the OPPS conversion factor on the ASC payment system. Since most ASC payment rates for surgical procedures are constructed from OPPS relative weights or the PFS unadjusted nonfacility PE RVU-based amount, the remedy's proposed prospective offset to the OPPS conversion has a very limited impact on the ASC payment system. The only impact of the proposed reduction to the OPPS conversion factor is the payment rate for device-intensive procedures under the ASC payment system. Since the ASC payment system holds device portions constant between the two settings, the device portion is the device offset percentage multiplied by the OPPS payment rate. As we stated in that rule, we believed it would be inaccurate and inappropriate to use OPPS payment rates that have been reduced by the remedy's prospective offset since this could accumulate to have a potentially noticeable impact on ASC payment rates for certain device-intensive procedures over time. Therefore, we finalized our policy that the OPPS payment rates used for ratesetting under the ASC payment system for CY 2026 and subsequent years would not include the prospective offset to the OPPS conversion factor as a result of the 340B remedy offset that we proposed to implement in the CY 2026 OPPS/ASC proposed rule.

As discussed in section XIII.G.2.a. of this final rule with comment period, historically, the device portions of device-intensive procedures have not been scaled so that payment for device portions would remain constant between the OPPS and ASC payment system. However, due to increased utilization of orthopedic procedures in the ASC setting, ASC expenditures on device portions of device-intensive procedures represent a substantially larger share of total ASC expenditures than in prior years. For this final rule with comment period, we estimate a proposed large increase in the device portions for device-intensive procedures as a result of the proposed 340B drug payment policy which results in a large decrease in the ASC weight scaler. We solicited comment on whether our device-intensive calculation methodology should continue to exclude device portions from the ASC weight scaler, or alternatively, whether these device portions should be included in the expenditures subject to scaling through the ASC weight scaler. If we were to include device portions as subject to scaling, ASC payment rates for device-intensive procedures would decrease and ASC payment rates for non-device intensive procedures would increase. We estimated that treating device expenditures for device-intensive procedures as scalable prospective expenditures would increase the proposed ASC weight scaler from 0.809 to 0.865 in CY 2027 but would decrease the ASC payment for the device portion of device intensive procedures by approximately 14 percent.

We did not propose any changes to our device-intensive procedure policies under the ASC payment system for CY 2027, but we solicited comment on whether our device-intensive calculation methodology should continue to exclude device portions from the ASC weight scaler or whether device portions should represent scalable prospective expenditures. For the proposed CY 2027 device offset percentages, which included device offset percentages based on CY 2025 claims processed through March 31, 2026, we refer readers to Addendum FF

of the CY 2027 OPPS/ASC proposed rule. Final CY 2027 device offset percentages may differ from the proposed percentages as we rely on the most recently available claims data for the CY 2027 OPPS/ASC final rule with comment period (CY 2025 claims data processed through June 30, 2026).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported continuing to exclude the device portion of device-intensive procedures from the ASC weight scalar. The commenters stated that implantable and insertable device acquisition costs generally do not vary by site of service and that applying the scaler to device costs would reduce the device portion by approximately 14 percent, potentially making complex procedures financially infeasible in ASCs. They stated that this could impede the migration of appropriate care from hospital outpatient departments to lower-cost ASCs. The commenters requested that CMS preserve OPPS–ASC payment parity for the device component and evaluate procedure-level access effects before adopting any alternative methodology.

Response: We appreciate the commenters' feedback regarding their support for continuing to exclude the device portion of device-intensive procedures from the ASC weight scalar. As discussed in further detail in section XIII.G. of this final rule with comment period, we are finalizing our proposal to continue excluding the device portion of device-intensive procedures from the ASC weight scalar.

Comment: Several commenters requested that CMS designate CPT code 52282 (Cystourethroscopy, with insertion of permanent urethral stent) as device-intensive and establish its CY 2027 device offset using manufacturer invoice data. The commenters stated that the historical claims are not representative because no permanent prostatic urethral stent with FDA marketing authorization was commercially available in the United States for approximately a decade, making the claims that support the proposed zero percent device offset unreliable.

Response: As discussed in section III. of this final rule with comment period, we agree with the commenters that no permanent prostatic urethral stent with FDA marketing authorization had been available on the U.S. market for approximately 9 years before FDA approved such a device through the premarket approval application process in late 2025. Therefore, we believe that the CY 2025 claims data for CPT code 52282 do not accurately reflect the device and service costs associated with inserting a permanent prostatic urethral stent and are not an appropriate data source for calculating the device offset percentage for CPT code 52282. In the absence of representative CY 2025 claims data, we are accepting the commenters' recommendation to assign device-intensive status to CPT code 52282 for CY 2027. Although our policy permits temporarily assigning a higher device offset percentage in certain rare circumstances based on additional information, including manufacturer pricing data, we do not find that the information submitted warrants departing from our default device offset methodology for this procedure. We believe that applying the default methodology appropriately recognizes device costs while maintaining incentives for efficient purchasing. Therefore, we will apply our default device offset methodology to CPT code 52282 for CY 2027.

Comment: Several commenters opposed removing device-intensive status for CPT code 55882 (Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducer for delivery of thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed) for CY 2027 under the ASC payment system. The commenters stated that this procedure requires proprietary, single-use transurethral ultrasound and endorectal cooling devices that are integral to the service, contact human tissue, and are temporarily inserted into the patient. They stated that the proposed offset is distorted by incomplete device reporting, noting that the average invoice cost of $8,089 represents approximately 49 percent of the proposed $16,366 geometric mean cost. The commenters also reported that claims identifying C1889 produced offsets above the 30-percent threshold, whereas many hospitals reported little or no device cost. They requested a 49-percent device offset based on documented acquisition costs.

Response: CPT code 55882 became effective January 1, 2025. In reviewing these comments, we discovered that we had correctly assigned device-intensive status to this procedure under the ASC payment system but had inadvertently not assigned device-intensive status to this procedure under the OPPS. In general, a new CPT code that meets our criteria for device-intensive status and is separately payable in both the OPPS and ASC payment system should be designated as device-intensive under both the OPPS and the ASC payment system. (Once claims data is available, differences in the claims data available under the two systems' ratesetting methodologies may result in a procedure receiving device-intensive status under the ASC payment system but not under the OPPS.)

The incomplete reporting of devices associated with CPT code 55882 under the OPPS underscores the importance of our device edits policy for device-intensive procedures. In the absence of an applicable device edit that would have otherwise applied since we assigned CPT code 55882 as device-intensive for CY 2025, we do not believe it would be appropriate to selectively determine which claims to use to calculate the device offset percentage; instead, we believe it is appropriate to rely on a full year of claims data during which CPT code 55882 is subject to the device edits policy. Therefore, because usable CY 2025 claims data are unavailable for CPT code 55882, we are accepting the commenter's recommendation to maintain device-intensive status for the code for CY 2027 and will apply our device edits and device credits policies to the procedure beginning in CY 2027 by assigning the procedure device-intensive status for both the ASC and OPPS settings. Although our policy permits temporarily assigning a higher device offset percentage in certain rare circumstances based on additional information, including manufacturer pricing data, we do not find that the information submitted warrants departing from our default device offset methodology for this procedure. We believe that applying the default methodology appropriately recognizes device costs while maintaining incentives for efficient purchasing. Therefore, we will apply our default device offset methodology to CPT code 55882 for CY 2027.

Comment: Several commenters requested that we designate CPT code 0786T (Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed) as device intensive for CY 2027. The commenters stated that the procedure requires implantation of a single-use integrated sacral neuromodulation system and that the manufacturer-reported device cost of $18,500 represents approximately 83.5 percent of the proposed APC payment. The commenters stated that the two

claims apparently used were invalid or unrepresentative because the code had status indicator ''E1'' until the device received FDA approval in June 2025 and commercial use did not begin until after November 2025. They requested that we disregard those claims and apply the default offset for the APC, manufacturer invoice pricing, or another appropriate new technology methodology.

Response: We agree with the commenters that we should disregard CY 2025 claims for CPT code 0786T. As we stated previously, in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94214 through 94219), for purposes of determining device offset percentages, we will not use claims data from procedures that had a status indicator of ''E1''. Since CPT code 0786T was assigned a status indicator of ''E1'' for all of CY 2025, under our current policy, we will continue to assign CPT code 0786T device-intensive status for CY 2027 and will apply a device offset percentage based on our default device offset methodology.

Comment: Several commenters requested that we designate CPT code 0730T (Trabeculotomy by laser, including optical coherence tomography (OCT) guidance) as device intensive and apply a 65-percent device offset. The commenters explained that the procedure requires two proprietary, single-use optical interfaces that contact the cornea and are integral to OCT-guided imaging and laser treatment under a CMS-approved Category B IDE study. The commenters stated that the combined $3,750 acquisition cost represents approximately 65 percent of the proposed geometric mean cost for APC 5493 and therefore exceeds the 30-percent device-cost threshold.

Response: CPT code 0730T describes a minimally invasive glaucoma surgical procedure that reduces intraocular pressure by improving aqueous outflow. Specifically, CPT code 0730T describes a laser trabeculotomy procedure that noninvasively creates a channel through the trabecular meshwork, unlike other laser trabeculoplasty procedures that apply laser energy to stimulate biological changes that improve aqueous outflow. We are not accepting the commenter's recommendation to treat the patient interface system as a device for purposes of determining device-intensive status. Our criteria for device-intensive status require that a device be surgically inserted or implanted into the patient. In the CY 2006 OPPS/ASC final rule with comment period (70 FR 68629 through 68630), we explained that the surgical insertion or implantation criterion encompasses devices inserted or implanted through a natural or surgically created orifice, as well as devices inserted or implanted through a surgically created incision. We do not consider placement beneath the eyelid and against the ocular surface to constitute insertion through a natural or surgically created orifice or incision. Therefore, we do not consider the patient interface system associated with CPT code 0730T to be an insertable medical device for purposes of device-intensive status.

Comment: Several commenters requested that we expand device-intensive policy to permit CPT codes 0686T (Histotripsy (*i.e.,* non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance) and 0888T (Histotripsy (*i.e.,* non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including imaging guidance), which describe histotripsy of liver and kidney tumors, respectively, to qualify based on the cost of a nonimplantable, single-use device applied to the patient's skin. The commenters stated that the device will cost $7,500 in CY 2027 and stated that both procedures satisfy the 30-percent device-cost threshold, notwithstanding that the device is neither surgically inserted nor implanted. The commenters stated that revising the policy and increasing payment would facilitate beneficiary access to noninvasive histotripsy in the lower-cost ASC setting.

Response: While we understand the commenters' concerns regarding payment adequacy for capital-intensive procedures furnished in the ASC setting and may consider these concerns in future rulemaking, we did not propose revising the eligibility criteria for device-intensive procedures. We believe that expanding the definition of device-intensive procedures to include high-cost items that contact a patient's skin, but are not surgically implanted/inserted, could have significant unintended consequences for both the OPPS and the ASC payment system. Therefore, we are not accepting the commenters' recommendations.

Comment: A commenter opposed the proposed device offset percentage for CPT code 0885T (Colonoscopy, flexible, with initial transendoscopic mechanical dilation (*e.g.,* nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed) and requested that we continue to assign device-intensive status. The commenter stated that the three claims used to calculate the proposed offsets were erroneous because the ProTractX3 drug-coated balloon was available only through company-funded IDE trials and the facilities submitting the claims were not trial participants. The commenter requested that in the absence of sufficient claims data, the procedure should be assigned the APC-level device offset percentage under the OPPS.

Response: We rely on hospitals to accurately report device costs associated with procedures. However, based on this comment and other public comments raising concern with determining device intensive status for services with very few claims, we believe that in instances where a procedure has very few claims upon which to determine device intensive status it would be appropriate to apply a low volume methodology for device intensive status which we are finalizing for this CY 2027 OPPS/ASC final rule with comment period and which is discussed further later in this section of the preamble.

Under this low volume policy for device-intensive procedures, for procedures assigned device-intensive status in the current year with fewer than 10 claims in the ratesetting year, we will use the greater of: (1) the device offset percentage calculated from the available claims; or (2) the device offset percentage calculated under our default methodology, which is the greater of 31 percent or the device offset percentage of the APC to which the procedure is assigned.

Given the limited number of claims—three claims for this final rule with comment period—the device offset percentage of CPT code 0885T would fall under this low volume policy for device-intensive procedures and would be assigned a default device offset of 45.02 percent based on the APC-wide device offset of APC 5331 (Complex GI Procedures).

Comment: Commenters supported our proposal to designate CPT code 27486 (Revision of total knee arthroplasty, with or without allograft; 1 component) as device intensive and to continue the device-intensive designation for CPT code 31295 (Nasal/sinus endoscopy, surgical, with dilation (*e.g.,* balloon dilation); maxillary sinus ostium, transnasal or via canine fossa), noting that the associated device costs exceed the 30-percent threshold. The commenters requested that we also designate CPT codes 31296 (Nasal/sinus endoscopy, surgical, with dilation (*e.g.,* balloon dilation); frontal sinus ostium), 31297 (Nasal/sinus endoscopy, surgical, with dilation (*e.g.,* balloon dilation); sphenoid sinus ostium), and 31298 (Nasal/sinus endoscopy, surgical, with dilation (*e.g.,* balloon dilation); frontal

and sphenoid sinus ostia) as device intensive because these clinically related sinus procedures use similar balloon dilation devices; they noted that the calculated offset for CPT code 31296 exceeds 30 percent and recommended a stabilization policy for procedures such as CPT codes 31297 and 31298 that fluctuate near the threshold.

Response: We appreciate the commenters' recommendation to establish a stabilization policy for procedures with device offset percentages that fluctuate around the 30-percent device-intensive threshold and we are accepting this recommendation. We have previously heard concerns regarding payment rate volatility from device-intensive procedures that fluctuate above and below our device-intensive threshold on a year-to-year basis (87 FR 72065, 88 FR 81920, 90 FR 53853). In response to concerns regarding the reliability of limited outpatient claims data from procedures assigned to the inpatient-only list for device-intensive status, we are finalizing a low-volume device-intensive procedure policy under the OPPS. In response to such concerns and the concerns from commenters regarding the payment volatility from low-volume device-intensive procedures that fluctuate above and below our device-intensive threshold of 30 percent, we are also adopting this policy for the ASC payment system beginning in CY 2027. Therefore, under our CY 2027 low volume device-intensive procedures policy, for procedures assigned device-intensive status in the current year with fewer than 10 claims available in the ratesetting year, we will use the greater of: (1) the device offset percentage calculated from the available claims; or (2) the device offset percentage calculated under our default methodology, which is the greater of 31 percent or the device offset percentage of the APC to which the procedure is assigned.

Based on our review of the claims data available under the standard ratesetting methodology for this CY 2027 OPPS/ASC final rule with comment period, CPT codes 31295, 31296, and 31297 would be considered low-volume device-intensive procedures under our new policy. CPT code 31298 did not meet our device-intensive threshold based on our review of the claims data, nor would it be considered a low-volume device-intensive procedure under our new policy and, therefore, we are not accepting the commenter's recommendation to assign CPT code 31298 device-intensive status for CY 2027.

Comment: A commenter supported our proposal to assign device-intensive status to CPT code 52284 (Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed) and recommended finalizing the associated device offsets. The commenter explained that the procedure requires the Optilume Stricture drug-coated balloon catheter and the proposed OPPS device offset appropriately reflects the device-intensive nature of the procedure.

Response: We appreciate the commenter's support and are assigning a device offset percentage to CPT code 52284 based on the CY 2025 claims data available for this final rule with comment period.

Comment: A commenter supported our proposal to assign device-intensive status to CPT code 64728 (Decompression; median nerve at the carpal tunnel, percutaneous, with intracarpal tunnel balloon dilation, including ultrasound guidance) but requested an increase from the proposed default device offset of 31 percent. The commenter recommended a device offset of 61.69 percent under the ASC payment system.

Response: We appreciate the commenter's support of our assignment of device-intensive status to CPT code 64728. Although our policy permits temporarily assigning a higher device offset percentage in certain rare circumstances based on additional information, including manufacturer pricing data, we do not find that the information submitted warrants departing from our default device offset methodology for this procedure. We believe that applying the default methodology appropriately recognizes device costs while maintaining incentives for efficient purchasing. Therefore, we will apply our default device offset methodology to CPT code 64728 for CY 2027.

Comment: A commenter requested that we designate CPT code 52649 (Laser enucleation of the prostate with morcellation, 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)) as device intensive, stating that the procedure requires single-use, insertable devices, including a morcellator reported with HCPCS code C1782 and a laser fiber reported with C1889. The commenter stated that the proposed device offset under the ASC payment system understate the costs of these required devices.

Response: For this final rule with comment period, the CY 2025 claims data included more than 7,000 single claims for CPT code 52649 based on the standard ratesetting methodology. We rely on hospitals to accurately report device costs associated with procedures and the device offset percentage calculated from this volume of claims indicates that the device costs associated with the procedure are below the 30-percent device-intensive threshold. Therefore, we are not accepting the commenter's recommendation and are calculating the device offset percentage for CPT code 52649 using the CY 2025 claims data available for this final rule with comment period.

Comment: Several commenters requested that CMS designate CPT code 53854 (Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy) as device intensive and calculate its device offset using only claims that identify the required single-use delivery device through HCPCS code C1889 or revenue center code 0278. The commenters stated that the device is integral to the procedure, used for one patient, contacts human tissue, and is surgically inserted, thereby satisfying CMS' device criteria. They reported that only 30.84 percent of claims identified the required device, producing an all-claims offset of 17.39 percent, whereas claims identifying the device produced an offset of 45.07 percent, above the 30-percent threshold.

Response: For this final rule with comment period, the CY 2025 claims data included more than 1,000 single claims for CPT code 53854 based on the standard ratesetting methodology. We rely on hospitals to accurately report device costs associated with procedures and the device offset percentage calculated from this volume of claims indicates that the device costs associated with the procedure are below the 30-percent device-intensive threshold. Therefore, we are not accepting the commenter's recommendation and are calculating the device offset percentage for CPT code 53854 using the CY 2025 claims data available for this final rule with comment period.

Comment: Commenters requested that CMS designate CPT codes 43263 (Endoscopic retrograde cholangiopancreatography (ercp); with

pressure measurement of sphincter of oddi), 45402 (Laparoscopy, surgical; proctopexy (for prolapse), with sigmoid resection), and 47371 (Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical) as device-intensive procedures under the ASC payment system for CY 2027. The commenters noted that the device offset percentages published in Addendum FF—39.06 percent, 34.65 percent, and 41.35 percent, respectively—each exceed the 30-percent threshold, although CMS proposed payment indicator ''A2'' for CPT code 43263 and G2 for CPT codes 45402 and 47371. The commenters stated that these procedures use surgically inserted, single-use devices and that failure to apply the device-intensive methodology could understate ASC resource costs, discourage migration to lower-cost settings, and limit beneficiary access. If CMS determines that any code fails another eligibility criterion, the commenters requested a code-specific explanation reconciling that determination with the published device offsets.

Response: Based on our medical officers' review of the procedure and the associated claims data for CPT code 43263, we agree with the commenters that CPT code 43263 meets our criteria for device-intensive status for CY 2027.

We are finalizing our proposal to remove CPT code 45402 from the inpatient-only list and add this procedure to the ASC list of covered surgical procedures. Based on our medical officers' review of the procedure, we are not accepting the commenter's recommendation to assign device-intensive status to CPT code 45402 for CY 2027 as this procedure does not meet our device-intensive criteria. Specifically, we do not believe this procedure requires an insertable or implantable device.

Based on our review of the claims data associated with CPT code 47371, the device offset percentage for CPT code 47371 is below our device-intensive threshold and is therefore ineligible for device-intensive status for CY 2027.

Comment: A commenter requested that CMS grant temporary device-intensive status to CPT code 66174 (Transluminal dilation of aqueous outflow canal (*e.g.,* canaloplasty); without retention of device or stent), which requires an advanced microcatheter that is surgically inserted into the eye. The commenter stated that the procedure previously qualified as device intensive in the CY 2025 proposed rule but lost that status following changes in reported costs and cost-to-charge ratios, despite subsequent efforts to improve hospital device-cost reporting. The commenter requested that CMS calculate the device offset using only claims reporting HCPCS code C1889 or include revenue code 0272 in offset calculations.

Response: For this final rule with comment period, the CY 2025 claims data included more than 300 single claims for CPT code 66174 based on the standard ratesetting methodology. We rely on hospitals to accurately report device costs associated with procedures and the device offset percentage calculated from this volume of claims indicates that the device costs associated with the procedure are below the 30-percent device-intensive threshold. Additionally, revenue code 0272 is designated for sterile supplies associated with the operating room and would not be an applicable source of device costs under our device-intensive criteria. Therefore, we are not accepting the commenter's recommendation and are calculating the device offset percentage for CPT code 66174 using the CY 2025 claims data available for this final rule with comment period.

Comment: A commenter identified potentially inconsistent device-intensive designations within craniofacial and mandibular procedure families, noting that CPT codes 21142 (Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft) and 21195 (Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)) are designated as device intensive, while clinically similar CPT codes 21141 (Reconstruction midface, lefort i; single piece, segment movement in any direction (*e.g.,* for long face syndrome), without bone graft), 21143 (Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft), and 21196 (Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation) are not. The commenter requested that CMS clarify how the device-intensive criteria are applied across clinical families and reconsider classifications that may not accurately reflect the resources required to furnish the procedures.

Response: We apply the device-intensive criteria uniformly across procedures, including procedures within the same clinical family. However, device-intensive determinations also rely on device cost information reported on hospital outpatient claims. We rely on hospitals to report accurately the device costs associated with each procedure, and we acknowledge that limited claims volume may result in fluctuations in device offset percentages among clinically similar procedures, including the low-volume craniofacial and mandibular procedures identified by the commenter.

In this CY 2027 OPPS/ASC final rule with comment period, we are finalizing a low-volume device-intensive procedure policy. Under this policy, for a procedure assigned device-intensive status for the current year for which fewer than 10 claims are available for ratesetting, we will apply the greater of: (1) the device offset percentage calculated using the available claims; or (2) the device offset percentage calculated under our default methodology, which is the greater of 31 percent or the device offset percentage of the APC to which the procedure is assigned. We believe this policy will promote greater stability and consistency in device-intensive determinations for low-volume procedures.

Comment: A commenter requested we designate CPT code 1084T (placeholder CPT code X588T) (Implantation of scaffolding allograft to reinforce the suprachoroidal space) as device intensive under the ASC payment system. The commenter stated that the procedure requires a device that comprises two to three permanently implanted scleral allografts and a single-use delivery system with a reported acquisition cost of approximately $4,485. The commenter stated that the device, including the implanted allografts, qualifies as a device under the OPPS. Specifically, the commenter stated that the implanted allografts satisfy the criteria based on their section 361 HCT/P status. The commenter also stated that even if CMS treated the single-use delivery system, characterized as a single-use access cannula, as an excluded instrument, the reported acquisition cost of the implanted allografts would separately satisfy the cost threshold for determining device-intensive status. The commenter requested an HCPCS-specific device offset reflecting the $4,485 cost or, alternatively, application of the APC-level device offset. The commenter stated that without device-intensive status, the ASC payment would be less than the device acquisition cost, effectively limiting the procedure to the higher-cost hospital outpatient setting.

Response: To qualify as a device-intensive procedure, a procedure must involve a device that, among other criteria, has received FDA marketing authorization; has received an FDA

investigational device exemption and has been classified as a Category B device by FDA under 42 CFR 405.203 through 405.207 and 405.211 through 405.215; or qualifies for another appropriate exemption from FDA premarket review. The commenter stated that the implanted scleral allografts that are implanted with CPT code 1084T are regulated solely under section 361 of the Public Health Service Act and therefore are not subject to FDA premarket review. Although we confirmed that the product is listed in FDA's Human Cell and Tissue Establishment Registration system, FDA registration and listing do not, by themselves, establish that a product satisfies all of the criteria in 21 CFR 1271.10(a) for regulation solely under section 361 of the PHS Act. As we stated previously (90 FR 33642), FDA acceptances of an establishment registration and 361 HCT/P listing form does not constitute a determination that an establishment is compliant with applicable FDA rules and regulations, that the FDA has agreed with the manufacturer's self-determination as a 361 HCT/P, or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)). As the FDA may ultimately determine that the manufacturer's self-determination was not appropriate, we believe it would be improper for CMS to conclude that the allografts are appropriately exempt from FDA premarket review based on the self-determination of the manufacturer. The commenter did not provide additional evidence sufficient to establish that the allografts satisfy this device-intensive criterion. Therefore, in the absence of such information, we are not accepting the commenter's recommendation to assign device-intensive status to 1084T for CY 2027.

Comment: A commenter requested that CMS remove the device-intensive designation for CPT code 0621T (Trabeculostomy ab interno by laser;). The commenter questioned whether the procedure satisfies the 30-percent device-cost threshold, noting that CMS previously reported a 4.6-percent device offset and that the available claims were submitted by investigational trial sites because the ELIOS System lacks FDA marketing authorization. The commenter stated that the single-use fiber-optic laser probe used in the procedure is a disposable instrument connected to capital equipment and should be treated as a packaged surgical supply, consistent with comparable ophthalmic laser probes. The commenter stated that the designation would increase the ASC payment thereby substantially increasing beneficiary coinsurance and potentially influencing treatment selection.

Response: We appreciate the concerns raised by the commenter; however, based on our medical officer's review of the procedure and the associated device, CPT code 0621T meets our criteria for device-intensive status for CY 2027. The procedure is associated with a Category B IDE study and requires a single-use device that is surgically inserted through a surgical incision into the anterior chamber of the eye. Therefore, we are not accepting the commenter's recommendation to remove device-intensive status to CPT code 0621T.

Comment: A commenter supported CMS' proposal to continue designating CPT code 0671T (Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more) as a device-intensive procedure and calculating its ASC payment rate accordingly. The commenter explained that the procedure involves insertion of an anterior segment aqueous drainage device into the trabecular meshwork and is performed extensively in the ASC setting. The commenter stated that maintaining both the proposed assignment to APC 5493 and the device-intensive designation is necessary to provide appropriate ASC payment and preserve beneficiary access to trabecular bypass procedures.

Response: We appreciate the commenter's support of our proposal. Our final determination of device-intensive status and the final device offset percentage for CPT code 0671T is based on the CY 2025 claims data available for this final rule with comment period.

Comment: A commenter requested that CMS revise the ASC device-intensive eligibility criteria at 42 CFR 416.171(b)(2) to include qualifying medical devices applied in or on wounds or other skin lesions, consistent with the transitional pass-through criteria at 42 CFR 419.66(b)(3). The commenter stated that the current requirement that a device be surgically inserted or implanted categorically excludes procedures involving wound-applied devices, such as the RECELL System, even when device costs exceed the applicable threshold. The commenter stated that this difference could make furnishing such procedures in ASCs financially impracticable and limit beneficiaries' access to lower-cost settings. The commenter requested that CMS adopt the revision or, alternatively, acknowledge the difference between the two policies and solicit public comment in future rulemaking.

Response: We did not propose revising the eligibility criteria for device-intensive procedures. We believe that expanding the definition of device-intensive procedures to include items applied to a patient's skin could have significant unintended consequences for both the OPPS and the ASC payment system. Therefore, we are not accepting the commenters' recommendations.

After consideration of public comments, we are revising our device-intensive procedures policy to include a low volume device-intensive procedures policy for CY 2027. Under this new policy, for a procedure assigned device-intensive status for the current year for which fewer than 10 claims are available for ratesetting, we will apply the greater of: (1) the device offset percentage calculated using the available claims; or (2) the device offset percentage calculated under our default methodology, which is the greater of 31 percent or the device offset percentage of the APC to which the procedure is assigned. For final CY 2027 device offset percentages based on the claims data for this final rule with comment period, CY 2025 claims processed through June 30, 3036, we refer readers to Addendum FF of this final rule with comment period.

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted or inserted in ASCs at no cost/full credit or partial credit is set forth in § 416.179 of our regulations and is consistent with the OPPS policy that was in effect until CY 2014. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66845 through 66848) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices. ASC payment is reduced by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device.

Effective CY 2014, under the OPPS, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a device, capped at the device offset amount. Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in the CY 2014 OPPS/

ASC final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the amount of the actual credit received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

Under current ASC policy, all ASC device-intensive covered surgical procedures are subject to the no cost/full credit and partial credit device adjustment policy. Specifically, when a device-intensive procedure is performed to implant or insert a device that is furnished at no cost or with full credit from the manufacturer, the ASC appends the HCPCS ''FB'' modifier on the line in the claim with the procedure to implant or insert the device. The contractor reduces payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure furnished by the ASC.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 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 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost or receive full credit or partial credit for the device, we apply our ''FB''/''FC'' modifier policy to all device-intensive procedures.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we stated we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. In the CY 2020 OPPS/ASC final rule with comment period, we finalized continuing our existing policies for CY 2020. We noted that we inadvertently omitted language that this policy would apply not just in CY 2019 but also in subsequent calendar years. We intended to apply this policy in CY 2019 and subsequent calendar years. Therefore, we finalized our proposal to apply our policy for partial credits specified in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) in the CY 2022 OPPS/ASC final rule with comment period for CY 2022 and subsequent calendar years (86 FR 63775 through 63776). Specifically, for CY 2022 and subsequent calendar years, we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device, ASCs have the option of either: (1) submitting the claim for the device intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount.

We did not propose any changes to our policies related to no cost/full credit or partial credit devices for CY 2027.

We did not receive any comments on our policies related to no cost/full credit or partial credit devices, and we are finalizing the continuation of our existing policies for CY 2027 without modification.

D. Final Additions to ASC Covered Surgical Procedures and Covered Ancillary Services Lists

1. Final 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 interested parties.

In the CY 2019 OPPS/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 criteria established in previous years for addition to the ASC CPL.

Under our current regulations at §§ 416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2026, are surgical procedures that meet the criteria specified in § 416.166(b)(2). In the CY 2026 OPPS/ASC final rule with comment period, we finalized a policy to expand the ASC CPL by revising our criteria for adding surgical procedures to the ASC CPL (90 FR 53855 through 53886). Under the revised criteria, procedures added to the ASC CPL must be separately paid under the OPPS and are not (1) currently designated as requiring inpatient care under § 419.22(n), (2) only able to be reported using a CPT unlisted surgical procedure code, or (3) otherwise excluded under § 411.15. Additionally, we moved certain general standards and exclusions at § 416.166(b)(1) and (c), used to evaluate services for addition to the ASC CPL prior to January 1, 2026, to a new section at § 416.166(d) of the following non-binding physician considerations: (1) Is not expected to pose a significant safety risk when performed in an ASC; (2) Is one of which standard medical practice dictates the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure; (3) Generally results in extensive blood loss; (4) Requires major or prolonged invasion of body cavities; (5) Directly involves major blood vessels; (6) Is generally emergent or life- threatening in nature; and (7) commonly requires systemic thrombolytic therapy. We believe that these revised criteria are sufficient to ensure, along with appropriate patient selection and complex medical judgement of the physician, that the procedure can be performed safely on an ambulatory basis, including procedures that involve the five previous exclusion criteria. We believe that this expansion of the ASC CPL could advance the goals of increasing physician and patient choice and expanding site neutral options in conjunction with patient safety considerations. For further discussion on our policy to revise the ASC CPL criteria and expand the procedures added to the list, please refer to section XIII.D. of the CY 2026 OPPS/ASC final rule with comment period (90 FR 53855 through 53886).

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 2026 OPPS/ASC final rules with comment period (85 FR 86143 through 86145; 86 FR 63777 through 63805; 87 FR 72068 through 72076; 88 FR 81923 through 81945; 89 FR 94331 through 94334; and (90 FR 53855 through 53886).

2. Changes to the List of ASC Covered Surgical Procedures for CY 2027

Historically, we have reviewed the clinical characteristics of procedures and consulted with appropriate medical organizations, other interested parties, and our clinical advisors to determine if those procedures would meet our existing regulatory criteria under 42 CFR 416.2 and 42 CFR 416.166.

As part of our evaluation process to add procedures to the CPL, we assess potential procedures against the revised ASC CPL criteria at § 416.166(b)(2). For CY 2027, we reviewed interested parties' nominations received in the pre-proposed rule nominations process. Additionally, we reviewed procedures that are proposed to be removed from the IPO list for CY 2027, as part of the continuation of the elimination of the IPO list, as described in section IX. discussed earlier in this final rule with comment period. Based upon this review, we proposed to update the ASC CPL by adding 618 procedures that we proposed to remove from the IPO list for CY 2027. This includes four procedures that were recommended by interested parties for addition to the ASC CPL: CPT code 49596 (Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated), 49616 (Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated), 40617 (Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible), and 40618 (Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated). As stated in the proposed rule, we believe these procedures would meet the revised ASC CPL criteria under 42 CFR 416.166, if we finalize our proposal to remove these services from the IPO list for CY 2027. These procedures were listed in the public use file titled ''Proposed Additions to the List of ASC Covered Procedures for CY 2027,'' which is available on the CMS website.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to add 618 procedures proposed for removal from the IPO list to the ASC CPL for CY 2027. Commenters supported the continued expansion of the ASC CPL, and specifically supported the increased flexibility and physician autonomy to use their clinical judgment in determining the appropriate site-of-service. Some physician specialty societies stated that certain codes proposed for addition to the ASC CPL are already being performed in the ASC setting. Commenters also supported allowing procedures to be performed in lower cost settings when appropriate.

Response: We thank the commenters for their support.

Comment: Several commenters opposed our proposal to continue to expand the ASC CPL by adding 618 procedures, with patient safety being a primary concern. Commenters were especially concerned that these procedures are on the IPO list and many are associated with risks that would have previously excluded them from the ASC CPL under our previous exclusion criteria. Commenters were concerned that these procedures could be performed in the ASC setting, which may not have the same specialized capabilities or emergency care as a hospital setting. Some commenters recommended that CMS reinstate the previous exclusion criteria, with some commenters stating that the expansion of the ASC CPL removed important safety guardrails. Multiple commenters also requested that CMS review the codes individually to determine if they were appropriate to perform in the ASC setting, taking into account risk factors including the average length of stay, risk of complications, and patient profile.

Several commenters also expressed concern that we proposed to remove procedures from the IPO list and add them to the ASC CPL in the same year. Multiple commenters requested that CMS delay the addition of these codes, with recommendations ranging from a two to several year gap. Some commenters also suggested waiting to add these codes until they were performed more often in the outpatient

setting or until we are able to assess the impact of the codes added to the ASC CPL for CY 2026.

Response: We thank the commenters for their input. As we stated in the CY 2026 OPPS/ASC final rule with comment period, we believe there are sufficient safety guardrails for ASCs, including State and local regulations, Conditions for Coverage (CfCs), accreditation requirements, and medical malpractice laws, to ensure that physicians are able to prioritize patient safety when determining the site-of-service (90 FR 53857). Additionally, while the prior exclusion criteria are important considerations in determining whether a surgical procedure may be safely performed in an ASC, we believe ASCs are currently and increasingly able to safely provide services that would be covered under the current criteria when considered appropriate for a patient by their physician. Since we maintained the prior general standard and exclusionary criteria in a different section of § 416.166 as non-binding physician considerations for patient safety, we believe these criteria will still act as a roadmap for physician decision-making.

We recognize commenters' concerns regarding our proposal to add procedures to the ASC CPL that were proposed for removal from the IPO list for CY 2027 as part of the second phase of the elimination of the IPO list. As we have previously stated, we believe that concurrently adding these procedures to the ASC CPL as the IPO list is phased-out allows for greater consistency and less confusion between the two lists. We also believe that current guardrails in place mentioned previously are sufficient to ensure patient safety (90 FR 53857). Additionally, as commenters have stated, we believe some of the proposed procedures are currently being performed in the ASC setting.

Comment: Several commenters provided requests for data monitoring and guidance as CMS continues to expand the ASC CPL. Commenters requested that CMS monitor the patient safety and quality outcomes of procedures performed in the ASC setting, including hospital transfers, procedure complications. Commenters also suggested that CMS monitor the payment effects of adding these procedures to the ASC CPL. Some commenters also requested that CMS provide guidance on site-of-service selection and implementing procedures added to the ASC CPL. Additionally, multiple commenters requested that CMS make changes to strengthen the ASC CfCs in alignment with the addition of former IPO procedures being added to the ASC CPL.

Response: We thank the commenters for their recommendations. We agree with the value of monitoring quality, safety, and payment data as procedures are added the ASC CPL. As we have previously stated, we would welcome any patient outcomes data, analyses, or recommendations that interested parties would like to share (90 FR 53858). We will take these recommendations into consideration for future rulemaking.

As we stated in the CY 2026 OPPS/ASC final rule with comment period, in regards to providing further guidance, we note the balance between several factors on this important issue, namely, the need to provide clear information about CMS billing and payment rules that ensure hospitals, physicians, and other interested parties can understand and operate within them, and our belief that the specific decision about the most appropriate care setting for a given surgical procedure that preserves patient safety is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary.

Comment: Some commenters expressed concerns regarding beneficiary cost-sharing for procedures performed in the ASC setting. A commenter noted that cost-sharing in the hospital outpatient setting is capped at the Part A inpatient deductible, while ASC beneficiary cost-sharing in the ASC setting is not capped. The commenter recommended that CMS to take steps to ensure beneficiaries are informed of the cost-sharing consequences of site-of-service choice.

Response: We thank the commenters for their input. As we stated in the CY 2026 OPPS/ASC final rule with comment period, we are aware that in some limited instances beneficiaries may incur greater cost-sharing for procedures in an ASC setting that we proposed to add to the ASC CPL, but note that this is not an occurrence that is unique to these procedures. As we stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59389), section 4011 of the 21st Century Cures Act (Pub. L. 114– 255) amended section 1834 of the Act by adding a new subsection (t), which requires the Secretary to make available to the public via a searchable website, with respect to an appropriate number of items and services, the estimated payment amount for the item or service under the OPPS and ASC payment systems and the estimated beneficiary liability applicable to the item or service. We implemented this provision by providing our Outpatient Procedure Price Lookup tool available via the internet at *https://www.medicare.gov/procedure-price-lookup.* This web page allows beneficiaries to compare their potential cost-sharing liability for procedures performed in the hospital outpatient setting versus the ASC setting. We believe this tool helps inform beneficiaries of potential cost-sharing amounts for receiving a service in the ASC setting compared to the outpatient setting, and note that this tool would include a comparison of cost-sharing liability for procedures in the outpatient hospital and ASC settings in the future. Additionally, we will take these recommendations regarding beneficiary education into future consideration.

Comment: Many commenters requested that CMS clarify that if a procedure is added to the ASC CPL, it does not mean that the procedure must be performed in the ASC setting or that it is the most appropriate site-of-service for that procedure.

Response: We thank the commenters for their request. As we emphasized in the CY 2026 OPPS/ASC final rule with comment period, the fact that a procedure is added to the ASC CPL should not be interpreted to mean the procedure is only appropriately performed in ASC setting or that the ASC setting is the most appropriate setting for a beneficiary and instead defer to the clinical judgment of the physician (90 FR 53858).

Comment: Multiple commenters requested that CMS remove the criterion at § 416.166(b)(2)(ii)(B), which excludes the addition of unlisted CPT codes to the ASC CPL, stating that there is no clear safety rationale for this exclusion.

Response: We thank the commenters for their input. Under § 416.166(c)(7), covered surgical procedures do not include procedures that can only be reported using a CPT unlisted surgical procedure code. As discussed in the August 2, 2007 ASC final rule (72 FR 42485), it is not possible to know what specific procedure would be represented by an unlisted code, and therefore, it is not possible to evaluate procedures reported by unlisted CPT codes according to applicable regulatory criteria at § 416.166. Therefore, we are not accepting this recommendation.

Comment: Multiple commenters requested that CMS remove CPT code 0967T (Transanal insertion of endoluminal temporary colorectal anastomosis protection device, including vacuum anchoring component and flexible sheath connected to external vacuum source

and monitoring system) from the ASC CPL, as the technology associated with this procedure has not received FDA approval.

Response: We thank the commenters for bringing this to our attention. As the technology associated with this code has not received FDA approval, we are finalizing to reassign this procedure to status indicator ''E1'' (Not covered by any Medicare outpatient benefit category; Statutorily excluded by Medicare; Not reasonable and necessary; Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) in the OPPS. As this code will no longer be separately paid under the OPPS, a requirement for placement on the ASC–CPL, we are finalizing to remove CPT code 0967T from the ASC CPL and assigning it a nonpayable payment indicator.

Comment: Multiple commenters requested that CMS add CPT codes 97607 (Negative pressure wound therapy, (*e.g.,* vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters) and 97608 (Negative pressure wound therapy, (*e.g.,* vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters) for CY 2028, allowing CMS additional time to consider rate-setting approaches for these procedures.

Response: We thank the commenters for their recommendations. We will consider it for future rulemaking.

Comment: We received several comments requesting that we align payment for non-sheet form skin substitutes with payment for sheet-form skin substitute products.

Response: We thank the commenters for their input. After review of the comments, we are finalizing our proposal to add G0681 and G0683 to the ASC CPL in conjunction with our finalized proposal for G0681 and G0683 discussed in section V.B. of this final rule with comment period, under our established policy, we are also finalizing separate payment in CY 2027 in the ASC setting.

Comment: Multiple commenters recommended specific codes to be added to the ASC CPL including, echocardiography, electrophysiological studies, and percutaneous coronary interventions. We received 26 procedure recommendations for the CPL.

Response: We thank commenters for their recommendations. We individually assessed each of the recommended procedures to determine whether these procedures meet each of the applicable revised regulatory criteria at § 416.166. Based on our review of the clinical characteristics of the procedures and their similarity to other procedures that are currently on the ASC CPL, we believe that 1 procedure out of the 26 procedure recommendations we received meet the general requirements for covered surgical procedures for the ASC CPL as set forth in the revised § 416.166(b)(2):

- CPT code 64629 (Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (list separately in addition to code for primary procedure)).

In the upcoming section, we explain our rationale for not including the 25 recommended procedures, organized by category. We note that while we did not add these codes to the ASC CPL, we did determine some of these codes are appropriate to add to list of covered ancillary procedures, as discussed in section XIII.D.3. of this final rule with comment period.

- Two wound care procedures. As these procedures are non-surgical, they would not qualify as separately payable surgical procedures on the ASC CPL.
- 23 cardiovascular procedures, including transesophageal ecochardiography, aortography, angiography, and venography procedures. As these procedures are non-surgical, they would not qualify as separately payable surgical procedures on the ASC CPL. Sixteen of these procedures are already on the list of covered ancillary procedures. We are also adding 5 of the procedures to the list of covered ancillary procedures. The remaining two codes requested were previously deleted by the AMA.

After consideration of public comments, we are finalizing our proposal to update the ASC CPL by adding 618 procedures that we proposed to remove from the IPO list for CY 2027. Additionally, we are finalizing adding an additional code, CPT code 64629, recommended by commenters to the ASC CPL for CY 2027. These procedures, along with their long descriptor and payment indicators, are listed in the public use file titled ''Final Additions to the List of ASC Covered Procedures for CY 2027,'' which is available on the CMS website.

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 status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; (5) certain radiology services for which separate payment is allowed under the OPPS; and (6) non-opioid pain management drugs, biologicals, and medical devices as determined by CMS under § 416.174; and (7) groups of skin substitute supply products. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59062 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 OPPS and to continue this reconciliation of packaged status for subsequent calendar years. As discussed in prior rulemaking, maintaining consistency with the OPPS may result in changes to ASC payment indicators for some covered ancillary services. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2026, but will be packaged under the CY 2027 OPPS, we would also package the ancillary service under the ASC payment system for CY 2027 to maintain consistency with the OPPS. Comment indicator ''CH'' is used in Addendum BB (which is available via the internet on the CMS website) to indicate covered ancillary services for which we proposed a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2025.

In the CY 2022 OPPS/ASC final rule with comment period, we finalized our proposal to revise § 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). In the CY 2025 OPPS/ASC final rule with comment period, we revised § 416.164(b)(6) to read ''Non-opioid pain management drugs, biologicals, and medical devices as determined by CMS under § 416.174,'' as we finalized a policy to place qualifying medical devices on the ASC covered ancillary services list (89 FR 94361).

In the CY 2026 OPPS/ASC final rule with comment period, we finalized our proposal to pay separately for the provision of certain groups of skin substitute products when used during a covered surgical procedure, by revising § 416.164(b) to include groups of skin substitute products as covered ancillary items and services that are integral to a covered surgical procedure.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter requested that CMS ensure that our policy for adding procedures to the list of covered ancillary services does not lead to fragmented care because a needed ancillary service is not on the list. The commenter requested that CMS maintain a transparent process for aligning ancillary service assignments with additions to the ASC CPL.

Response: We appreciate the commenter's input. CMS reviews the list of covered ancillary procedures on a yearly basis in conjunction with its review of the ASC CPL. We also encourage interested parties to provide recommendations for covered ancillary procedures through the pre-rulemaking nomination process and comment period and notify CMS if they believe a necessary ancillary service needs to be added to the list. We believe that our current review process takes into account the need to add procedures to the list of covered ancillary procedures to prevent fragmented care. We also note that we added several procedures to the list of covered ancillary procedures in CY 2026 in conjunction with the expansion of the ASC CPL, and plan to finalize further additions for CY 2027.

Comment: Multiple commenters recommended the following codes to be added to the list of covered ancillary services for CY 2027: CPT codes 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), 1086T (Intraprocedural estimate of coronary fractional flow derived by augmentative algorithmic analysis of data from real-time coronary angiography, with creation of functional map of coronary circulation, when performed, with review and interpretation (List separately in addition to code for primary procedure)), 97610 (Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day), and 97611, previously described by placeholder code 976XX, (Real-time fluorescence wound imaging with clinical darkness to identify presence, location, load of bacteria, and measure wound size, per day).

Response: We thank the commenters for their recommendations. We agreed with the commenters that CPT code 1086T could be added to the list of covered ancillary procedures for CY 2027 as we determined the procedure described to be integral to ASC CPL procedures. However, we did not find the other recommended codes to be to be appropriate to add to the list of covered ancillary services because we did not find them to be integral to any procedures on the ASC CPL, which is a requirement for placement on the list of covered ancillary services. Therefore, we are adding one additional procedure, CPT code 1086T, recommended by commenters to the list of ASC covered ancillary services for CY 2027.

In summary, we are finalizing adding the following 6 procedures recommended by interested parties to the list of ASC covered ancillary services for CY 2027, including 5 procedures that commenters recommended for addition to the ASC CPL: CPT codes 1086T (intraprocedural estimate of coronary fractional flow derived by augmentative algorithmic analysis of data from real-time coronary angiography, with creation of functional map of coronary circulation, when performed, with review and interpretation (List separately in addition to code for primary procedure), 93313 (Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); placement of transesophageal probe only), 93314 (Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); image acquisition, interpretation and report only), 93315 (Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report), 93316 (Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only), and 93317 (Transesophageal echocardiography for congenital cardiac anomalies; image acquisition, interpretation and report only). New CPT and HCPCS codes for covered ancillary services for CY 2027 can be found in section XIII.B. of this final rule.

E. CY 2027 Non-Opioid Policy for Pain Relief Under the OPPS and ASC Payment System

1. Background

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 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.

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, paragraph (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. Paragraph (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 under this policy began on January 1, 2025. As stated in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94343 through 94344), the statute directs CMS to provide ''additional payment'', and for purposes of this policy, we interpret 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 to readers. To avoid confusion, we will continue to use ''separate payment'' throughout the rest of this section, which we believe to be synonymous with ''additional payment.'' Under section 1833(t)(2)(E) of the Act, the temporary separate payments must be made in a budget neutral manner.

For background information on the ASC Payment Policy for Non-Opioid Post-Surgery Pain Management Drugs and Biologicals prior to CY 2025, please see the summary provided in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94342 through 94343).

2. Finalized CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

In CY 2025, CMS finalized our implementation methodology for section 4135 of CAA, 2023 (hereafter referred to as ''section 4135'') (89 FR 94343 through 94361) to provide for temporary separate payments for certain non-opioid treatment for pain relief in the hospital outpatient department and ambulatory surgical center settings on a temporary basis from January 1, 2025 through December 31, 2027. CMS also finalized regulation text at 42 CFR 416.174 and 42 CFR 419.43(k), which outline the payment for non-opioid pain management drugs, biologicals, and medical devices under both the ASC payment system and OPPS, respectively.

a. 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 also meets the definition of a non-opioid treatment for pain relief at section 1833(t)(16)(G)(iv) of the Act shall receive separate payments under section 4135, subject to the payment limitation. In light of this requirement, we finalized in the CY 2025 OPPS/ASC final rule with comment period that drugs and biologicals that meet the definition of a non-opioid treatment for pain relief for purposes of section 4135 that were subject to the ASC policy for non-opioid treatments authorized by section 6082 of the SUPPORT Act in CY 2024, would instead receive separate payments, subject to the limitation, for the duration of the payment period for section 4135 (89 FR 94344).

b. 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 for a drug, biological product, or medical device and requires, in part, that such treatment does not receive transitional pass-through payment and has payment that is packaged into a payment for a covered OPD service (or group of services). In addition, 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) of the Act, it must, in part, be ''used to deliver a therapy to reduce postoperative pain, or produce post-surgical or regional analgesia''. A medical device must also, pursuant to section 1833(t)(16)(G)(iv)(II)(aa) and (bb) of the Act have both ''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''.

c. Evidence Requirement for Medical Devices

To determine whether a medical device fulfills the statutory 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 finalized in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94345) a policy 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. In CY 2025, we encouraged interested parties submitting non-opioid device recommendations to submit any relevant literature that demonstrates that the named medical device replaces, reduces, or avoids opioid use per this statutory provision with their public comments. We review any literature submitted and determine whether it meets this evidence criterion. There is no requirement 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 would not meet this evidence criterion and would not qualify for separate payment under section 4135.

d. 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 finalized a policy in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94345 through 94346) 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. We noted that products without an indication that meets this statutory requirement would not qualify. We specifically stated that products with only a general pain indication will not qualify.

As discussed in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94345 through 94346), we note that the Congress specifically included language at section 1833(t)(16)(G)(iv)(I) of the Act requiring that drugs or biologicals 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.'' Therefore, products without an indication that meets the statutory requirement will not qualify.

(2) Intended Use for Medical Devices

Regarding 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 postsurgical 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 (the FD&C Act), have been cleared for market under section 510(k) of the FD&C Act, or be exempt from the requirements of section 510(k) of the FD&C Act pursuant to section 510(l) or (m) or 520(g) of the FD&C Act. For CY 2025, for medical devices, we finalized without modification our proposal that a device must be used to deliver a therapy to reduce postoperative pain or produce postsurgical or regional analgesia to qualify for separate payment under section 4135 (89 FR 94346 through 94347). We also finalized that the medical device must have an application approved under section 515 of the FD&C Act, been cleared for market under section 510(k) of the FD&C Act, or be exempt from the requirements of section 510(k) of the FD&C Act pursuant to sections 510(l) or (m) or 520(g) of the FD&C Act (89 FR 94346 through 94347). This is consistent with the regulation text at 42 CFR 419.43(k)(2)(i) through (iv).

e. 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.

In the CY 2025 OPPS/ASC final rule with comment period, we finalized a policy to assign a payment offset of zero dollars for the qualifying drugs, biologicals, and devices for CY 2025 (89 FR 94347 through 94348). A zero dollar 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 finalized 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, we stated that the separate payment for a drug or biological would 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 finalized to be zero dollars for CY 2025. For the amount of payment for a medical device, since we are unable to reduce charges to costs for ASCs, we stated that the separate payment amount would be contractor-priced by the ASC's Medicare Administrative Contractor reduced by the portion of the otherwise applicable Medicare OPD fee schedule amount associated with the medical device, which as previously discussed, we finalized to be zero dollars for CY 2025. These separate payment amounts are all 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. Given this statutory requirement, we finalized paying the same separate payment amount for qualifying non-opioid products in both the HOPD and ASC settings starting on January 1, 2025 through December 31, 2027.

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 CY 2025, we finalized that non-opioid treatments for pain relief would not be subject to the threshold packaging policy and would also be separately paid when used during a comprehensive APC (C–APC) procedure in the HOPD setting (89 FR 94347 through 94348). See section V.B.1.a. of this final rule with comment period for more information regarding the drug packaging threshold. Section II.A.2.b. of this final rule with comment period contains further information on C–APC packaging.

f. 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.

In the CY 2025 OPPS/ASC final rule with comment period, we finalized a policy to base the 18 percent payment limitation on the volume weighted average of the payment rates of the top five primary procedures by volume into which a non-opioid treatment for pain relief would have their payment packaged, absent this policy. We also finalized applying the 18 percent payment limitation per date of service billed (89 FR 94349).

g. 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 finalized in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94350) a policy where CMS will utilize the services with which a product would be expected to be furnished and would typically be packaged absent this policy, to calculate the payment limitation based on expected clinical use patterns.

The finalized policy stated that CMS will determine the service, or group of services, to use to calculate the payment limitation through engagement with interested parties and a review by CMS Medical Officers and clinical staff during annual rulemaking. In the absence of engagement from interested parties, we will determine clinically appropriate procedures with which we would expect the drug or device to be frequently used in order to determine the payment limitation, including review of FDA approval or other marketing authorization materials, procedures identified in literature available to CMS, and other relevant materials. We noted 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.

3. Final CY 2026 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

In CY 2026, we finalized to continue the policies implemented in the CY 2025 OPPS ASC final rule (90 FR 53888 through 53909), with minor modifications to permit timely consideration of qualifying products. In that final rule we finalized to maintain a zero-dollar offset for all qualifying products regulated under the non-opioid policy, consistent with our belief that costs for some of these products may not be fully reflected yet in the cost of procedures in which they may be used. Additionally, the data used for CY 2026 ratesetting was derived from CY 2024 claims, which was prior to the effective date of this policy in CY 2025. We also finalized conforming regulatory text changes at 42 CFR 416.174(c)(1) to remove language specific to CY 2025, allowing us to consider or revise the offset amount through annual rulemaking.

We finalized a list of qualifying drugs, biologicals, and devices that meet the statutory criteria for separate payment under section 4135. Similarly, we finalized payment limitation calculations for the qualifying non-opioid products, and finalized our approach to determining those payment limitations based on the proposed procedure payment rates and utilization data available in the CY 2026 OPPS/ASC proposed rule, which we stated was the best data available at the time of writing the CY 2026 OPPS/ASC proposed rule.

In response to public comments, we finalized a modification to allow for more timely consideration of qualifying products by establishing a process to evaluate and approve additional non-opioid treatments for pain relief on a quarterly basis, rather than limiting consideration to annual rulemaking. We also made conforming regulatory text revisions at 42 CFR 419.43(k) and 416.174 to remove references tying qualification only to annual rulemaking.

4. CY 2027 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

For CY 2027, we proposed to continue the policies finalized in the CY 2026 OPPS/ASC final rule without modification (90 FR 53448), aside from a technical modification to the payment limitation calculations as described further in this section.

We continued to believe a zero-dollar offset is appropriate for all qualifying products regulated under the non-opioid 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 in the cost of procedures in which they may be used. Additionally, given the clinical nature of non-opioid treatments for pain relief, they can be used in a variety of procedures, making an APC offset impractical. A continued zero-dollar offset aligns with comment support for a zero-dollar offset as discussed in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53892).

We noted that the payment limitation calculations will now be displayed in a public use file for the proposed rule. The non-opioid payment limitation public use file is available on the CMS website under downloads for the CY 2027 OPPS proposed rule. By including the payment limitations in the public use file, we are able to use the most recently available data to calculate the payment limitations. Accordingly, the final payment limitation calculation in the CY 2027 OPPS/ASC final rule with comment period will be based on the final rule procedure payment rates and utilization data available for the final rule. Therefore, there could be slight changes between the proposed rule payment calculations and the final rule payment calculations as the payment rates and utilization data is updated between the proposed and final rules.

Given our updated policy to evaluate and approve additional non-opioid treatments for pain relief on a quarterly basis, as finalized in the CY 2026 OPPS/ASC final rule with comment period, we anticipated that we would include additional qualifying non-opioid products in the table of qualifying products in the final rule with comment period. For parties interested in submitting additional products for consideration under this policy, we referred readers to the guidance posted on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/non-opioid-treatments-pain-relief.* We stated we would review eligible products as provided in the guidance.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to continue the policies finalized in the CY 2026 OPPS/ASC final rule with comment period. Commenters supported CMS's continued implementation of separate payments for qualifying non-opioid products under section 4135. Commenters supported the proposed continued exclusion of qualifying products from C–APCs and the proposed changes to 340B drug payment policy for CY 2027. Commenters also supported the proposal to continue to apply a zero-dollar offset, as commenters believed maintaining the current payment methodology during the final year of the statute would help minimize confounding factors to allow CMS to better identify the effects of the policy.

Response: We thank the commenters for their support.

Comment: Some commenters took issue with the statutory 18 percent payment limitation, noting that the cap often results in payment below a facility's documented device cost, leaving hospitals and ASCs to absorb the difference. A commenter encouraged CMS to monitor and report the effect of the statutory 18 percent payment limitation. Another commenter requested that we reevaluate the methodology used to establish the payment limitation for qualifying non-opioid products under section 1833(t)(16)(G)(iii) of the Act. The commenter suggested that rather than relying on a volume-weighted average derived from the top five primary procedures by volume into which a given product would otherwise be packaged (which may be clinically unrelated), CMS should include device-specific cost information tied to the product's own associated CPT codes, or establish a minimum payment threshold based on documented acquisition costs already recognized through existing hospital cost reporting mechanisms.

Response: We thank the commenters for sharing their concerns. While the 18 percent limitation is a statutory requirement and, so we do not have flexibility under the current statute to remove the 18 percent cap, we agree

that the methodology for calculating the payment limitation is a matter within our discretion. At this time, we continue to believe that our existing methodology to calculate the 18 percent limitation for qualifying products is appropriate for several reasons, including that it is consistent with other methodologies, including the transitional pass-through payment methodology under section 1833(t)(6) of the Act, which similarly relies on procedure-based averaging to establish payment amounts. We also believe that by calculating the volume-weighted average across five procedures, rather than a single procedure, provides stability and predictability in payment.

As discussed in prior rulemaking (89 FR 94348), our prior analysis 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.

Additionally, we remind readers that the statute specifies the additional payment amount specified 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. Therefore, some of the suggestions mentioned by commenters, such as establishing minimum payment thresholds, are not allowable under statute. We appreciate the suggestions and will consider the commenter's suggested alternatives as part of our ongoing evaluation of the section 4135 payment methodology.

Comment: We received comments requesting that we reconsider our interpretations of the statutory criteria for qualifying products. On the criteria for devices, a commenter suggested that we consider substantial and technical equivalence when evaluating whether devices meet the clinical literature requirement. Specifically, the commenter recommended that CMS clarify that peer-reviewed evidence from technically equivalent or substantially equivalent devices may be considered when evaluating qualification under section 4135, particularly where a device shares the same mechanism of action, intended use, regulatory classification, and HCPCS category as an already recognized technology. Regarding the criteria for drug products, a commenter requested that we broaden our interpretation of the label indication to include drugs that may not have ''postoperative'' or ''postsurgical'' in the indication, explicitly.

Response: We thank the commenters for their input. Regarding devices, section 4135 requires that each medical device meets the applicable statutory and regulatory criteria to meet the definition of a non-opioid treatment for pain relief, including the clinical literature requirement. As we have explained in our assessment of products in prior rules, we believe that the device demonstrating the ability to reduce, replace, or avoid opioid use in a clinical trial or peer-reviewed journal must be the same device as the one being studied in order to qualify for separate payment under section 4135 of the CAA, 2023 (90 FR 53898). Approving a device for separate payment under section 4135 based on its similarity to another device that has independently met the criteria would effectively allow a product to qualify without its own supporting clinical evidence. Therefore, we do not believe this approach is consistent with the statute's requirement that qualification be assessed on a product-specific basis.

With regard to drugs, as we stated in prior final rules (89 FR 94246 and 90 FR 53892) we ''only approve separate payment for drug or biological products with an FDA-approved indication to reduce post-operative pain or produce post-surgical or regional analgesia. Products such as those with only a general pain indication will not qualify.'' As we explained, if there is no mention of postoperative or post-surgical use in the FDA-approved indications for the products being evaluated, they do not meet the statutory requirement. For CY 2027, we continue to believe this approach conforms with the statute. While some commenters have stated that a broad pain indication could include a more specific one we defer to the FDA to approve indications for drugs and biological products, based on the relevant statutory and regulatory authorities, and it is not within our purview to infer indications that have not been specifically finalized in the FDA's review. Therefore, while we understand the commenters' concerns, we decline to change our approach to evaluating qualification for payment under section 4135.

Comment: We received a comment requesting that we look more broadly at how other CMS policies may interact with our implementation of section 4135 in a way that could threaten patient access to non-opioid choices. The commenter specifically noted that two CMMI models, the Transforming Episode Accountability Model (TEAM) and Comprehensive Care for Joint Replacement (CJR–X), could have unintended consequences and limit the effectiveness of the policy changes in the NOPAIN Act.

Response: We thank the commenter for raising these concerns. However, we note that the comments are outside of the scope of this rulemaking.

Comment: One comment recommended that CMS consider additional evidence when evaluating whether non-opioid pain treatments qualify for separate payment, including real-world evidence on clinical outcomes, opioid utilization and overall value. Per the commenter, this approach would help ensure that reimbursable services demonstrate a meaningful impact on reducing opioid use.

Response: We thank the commenter for their suggestion. Under the statutory requirements for qualifying devices, we review submitted clinical trial data or evidence published in peer-reviewed journals to determine whether a device has demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use, or the quantity of opioids prescribed, a measure similar to the one the commenter recommends we consider in our review. Under the statutory requirements for qualifying drugs and biological products, we will only approve separate payment, under section 4135, 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 ore regional anesthesia. However, we will consider the ideas submitted by commenters as we consider payment approaches for non-opioid alternatives, as appropriate, in future rulemaking.

Comment: A commenter requested that we consider occupational therapy for separate payment under section 4135.

Response: This policy includes payment for drugs, biologicals, and medical devices; therefore, an occupational therapy service is out of scope for purposes of this final rule with comment period.

Comment: We received a comment regarding the Report to Congress that is required for HHS to complete under the NOPAIN Act by January 1, 2028. The commenter requested that we publish the report, provide a timeline for release, and include data on the effect of the 18 percent payment limitation and a recommendation regarding an extension of the policy.

Response: We thank the commenter for their suggestions. We note this

section of the statute is out of scope for purposes of this rulemaking.

Comment: We received several comments asking us to extend separate payments for qualifying products beyond the December 31, 2027, expiration of the NOPAIN Act. Commenters urged CMS to work with Congress to permanently extend or otherwise authorize a long term continuation of the policy beyond CY 2027. Commenters anticipated that adoption of qualifying products will slow with the approaching expiration. Accordingly, commenters believed that extending the separate payment window for qualifying products will allow for increased data collection over a longer period, while allowing hospitals to more clearly observe the benefits to patients and multimodal clinical strategies to manage pain without opioids. Additionally, some commenters made recommendations for the structure of a new separate payment policy after the current one expires, were we to create a new one. For example, a commenter suggested that we allow for separate payment in both the ASC and OPPS settings.

Response: We understand the commenters' concerns and the significant interest in preparing for the upcoming expiration of the NOPAIN Act. We note that the authority to extend, make permanent, or otherwise modify the duration of the NOPAIN Act rests with Congress. We will continue to implement the policy, as enacted, for the duration of the statutory period.

Comment: We received comments supporting our proposal to continue to provide separate payment for certain qualifying products under section 4135 of the CAA, 2023, including for the Iovera System (C9809), ON–Q Pump (C9804), IceMan (C9810), and Zynrelef (J0668).

Response: We thank the commenters for their support.

Comment: We received a comment requesting that we revise the top 5 primary procedures used to calculate the payment limitation for the SPRINT PNS System (HCPCS code C9807). The commenter suggested that we remove CPT code 64555 as a primary procedure, since it is used to report the implantation of the SPRINT PNS System itself, and so, per the commenter, it should not serve as the basis for calculating the separate payment intended to reimburse the cost of the qualifying non-opioid device.

Response: Section 1833(t)(16)(G)(iii) of the Act directs CMS to calculate the payment limitation based on the OPD service (or group of services) with which the non-opioid treatment is furnished. Since CPT code 64555 describes the implantation procedure through which the SPRINT PNS System is furnished to the patient, we believe continuing to include CPT code 64555 as one of the five procedures upon which to base the payment limitation for the device for CY 2027 is appropriate. Therefore, for CY 2027, we are finalizing to apply our existing methodology to qualifying non-opioid products, including finalizing the top 5 primary procedures we proposed to use to calculate the 18 percent payment limitation. However, we acknowledge that the commenter has raised an interesting point and appreciate the comment.

Comment: A commenter explained that during the first year and a half of implementation of the NOPAIN Act, facilities have struggled to get payment for the applicable products, particularly devices. The commenter mentioned that MACs require facilities to submit certain paperwork, yet still deny claims once all the paperwork has been submitted. The commenter explained that Congress intended for these products to be readily available to Medicare beneficiaries and requested that CMS clearly communicate with the MACs as to how they should facilitate implementation of the NOPAIN Act.

Response: We thank the commenter for noting their concerns. As we have stated in past OPPS/ASC final rules with comment period (see, for example, 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. Coverage of a claim where the qualifying non-opioid product is used would require an independent showing, made at the time the claim is adjudicated, that the service was reasonable and necessary for the individual beneficiary under section 1862(a)(1)(A) of the Act. CMS includes a list of qualifying products, HCPCS codes, and provides annual updates to payment limitation amounts for each qualifying product in quarterly change requests, which MACs review to aid in their review of claims. We would refer the commenter to the appropriate MAC for further questions on particular claims.

After consideration of public comments, we are finalizing our proposal to continue the policies finalized in the CY 2025 OPPS/ASC final rule with comment period with the CY 2026 OPPS/ASC final rule with comment period minor modification to permit more timely consideration of payment requests. Table 96 includes the final list of qualifying products for separate payment under section 4135.

We note that we did not receive any comments to the proposed rule requesting separate payment for a new non-opioid product. However, since the time that the proposed rule was released, we approved the Stimuplex needles as a qualifying product under our revised process to review non-opioid products for separate payment more frequently than annual rulemaking. As such, the approval is reflected in the table under revised descriptor for HCPCS code C9812.

We remind readers that the payment limitation calculations will now be displayed in a public use file for the final rule. The non-opioid payment limitation public use file is available on the CMS website under downloads for the CY 2027 OPPS final rule. By including the payment limitations in the public use file, we are able to use the most recently available data for this final rule to calculate the payment limitations. Accordingly, the final payment limitation calculation in this final rule with comment period is based on the final rule procedure payment rates and utilization data available for the final rule. Therefore, there could be slight changes between the proposed rule payment calculations and the final rule payment calculations as the payment rates and utilization data is updated between the proposed and final rules.

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TABLE 96: FINAL LIST OF QUALIFYING PRODUCTS FOR SEPARATE PAYMENT IN CY 2027 UNDER SECTION 4135 OF THE CAA, 2023

Brand Name	HCPCS Code	Long Descriptor
Exparel	J0666*	Injection, bupivacaine liposome, 1 mg
Omidria	J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml
Dextenza	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg
Zynrelef	J0668 (previously C9088**)	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg
Ketorolac tromethamine Injection	J1885	Injection, ketorolac tromethamine, per 15 mg
Journavx	C9818	Suzetrigine, oral, 1 mg
Caldolor	J1741	Injection, ibuprofen, 100 mg
ON-Q Pump	C9804	Elastomeric infusion pump (e.g., ON-Q* Pump with Bolus), including catheter and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the CAA, 2023)
SPRINT Peripheral Nerve Stimulator System	C9807	Nerve stimulator, percutaneous, peripheral (e.g., SPRINT Peripheral Nerve Stimulation System), including electrode and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the CAA, 2023)
Cryo Nerve Block Therapy	C9808	Nerve cryoablation probe (e.g., cryoICE, cryoSPHERE, cryoSPHERE MAX, cryoICE cryoSPHERE, cryoICE Cryo2), including probe and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the CAA, 2023)
ambIT Electronic Infusion Pump	C9806	Rotary peristaltic infusion pump (e.g., ambIT Pump), including catheter and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the CAA, 2023)
Iovera System	C9809	Cryoneurolysis needle (e.g., iovera System), including needle/tip and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the CAA, 2023)
IceMan	C9810	Water circulating motorized cold therapy device (e.g., IceMan) including all system components (e.g. pads, console, disposable parts), non-opioid medical device (must be a qualifying medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the cCAA 2023)
Sapphire Infusion Pump	C9811	Electronic ambulatory infusion pump (e.g. Sapphire pump), including all pump components, including disposable components , non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the CAA, 2023)
Ultrasound-visible nerve block needles	C9812	Echogenic nerve block needles (e.g. SonoPlex, SonoBlock, SonoTap, Stimuplex), non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the CAA, 2023)

Brand Name	HCPCS Code	Long Descriptor
(SonoPlex, SonoBlock, SonoTap, Stimuplex)		
Perforated continuous infusion catheter set (InfiltraLong)	C9813	Perforated continuous infusion catheter set (e.g. InfiltraLong), including all components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the CAA, 2023)
Continuous anesthesia conduction catheter sets (SonoLong, E-Cath)	C9814	Continuous anesthesia echogenic conduction catheter set (e.g. SonoLong, E-Cath), non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the CAA, 2023)
CADD-Solis infusion pump	C9815	Linear peristaltic pain management infusion pump (e.g. CADD-Solis ambulatory infusion pump), and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the CAA, 2023)
ambIT Electronic Infusion Pump (Reusable)	C9816	Rotary peristaltic infusion pump (e.g., reusable ambIT Pump) including all disposable system components, reusable non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the CAA, 2023)
Game Ready System	C9817	Electronic cryo-pneumatic compression, pain management system (e.g. Game Ready® GRPro 2.1 System), including control unit, anatomically correct wrap(s), and other system component(s), non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the CAA, 2023)

*Previously described by HCPCS code C9290.

**HCPCS Code C9088 was replaced by HCPCS code J0668 (Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg) effective October 1, 2025.

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F. 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 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 CY OPPS/ASC 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 to establish a new NTIOL class as published 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 2027

We did not receive any requests for review to establish a new NTIOL class for CY 2027 by March 1, 2026, the due date published in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53909).

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 2027.

We received public comments on our existing policy. The following is a summary of the comments we received and our response.

Comment: Several commenters supported increasing the New Technology Intraocular Lens additional payment from $50 to $100 per lens for CY 2027. The commenters stated that the payment has remained unchanged since the NTIOL policy was established in 1999 and no longer reflects inflation, research and development costs, or advances in lens technology. The commenters stated that a higher payment would encourage innovation and improve beneficiary access to lenses addressing unmet needs following cataract surgery. Some commenters also requested annual updates to the NTIOL payment and annual publication of active NTIOL classes to provide greater transparency, permit submission of new applications, and encourage renewed participation in the program.

Response: We responded to this comment in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81955 through 81956). We refer readers to that final rule with comment period for our response on an increase to the NTIOL $50 per lens payment adjustment. All historical NTIOL classes are publicly available in the NTIOL Application Determination Reference Document on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/new-technology-intraocular-lenses-ntiols.* There are currently no active NTIOL classes.

4. Announcement of CY 2028 Deadline for Submitting Requests for CMS Review of Applications for a New Class of NTIOLs

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 2027.

In accordance with § 416.185(a) of our regulations, CMS announces that to be considered for payment effective beginning in CY 2027, request for review of applications for a new class of new technology IOLs must be received by 5 p.m. Eastern Standard Time, on March 1, 2027. Send requests via email to *outpatientpps@cms.hhs.gov* or by mail to ASC/NTIOL, Division of Outpatient Care, Mailstop C4–05–07, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850. To be considered, requests for NTIOL reviews must include information requested on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/newtechnology-intraocular-lenses-ntiols*.

G. 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)).

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 PFS 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 result 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 provided the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the U.S. 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*.) As discussed in the FY 2025 IPPS/LTCH PPS final rule with comment period (89 FR 69253 through 69266), we finalized our proposal to use the new CBSAs delineations issued by OMB in OMB Bulletin No. 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, in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94362 through 94363) we finalized our proposal to include 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 addition to adopting the revised delineations based on OMB Bulletin No. 23–01, we also finalized our proposal to limit year-to-year ASC wage index value changes to no more than a 5-percent decrease, similar to the policy of other Medicare payment systems under Parts A and B. This 5-percent cap, implemented in a budget neutral manner through the wage index scalar, 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 in Medicare payments.

The proposed CY 2027 ASC wage indexes reflect the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed previously, as set forth in OMB Bulletin No. 23–01). We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. When all of the areas contiguous to the 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). For CY 2026, we applied this methodology to ASCs located in CBSA 35 (Rural North Dakota) (90 FR 53911). For CY 2027, we proposed to continue to apply a proxy wage index based on this methodology to ASCs located in CBSA 35 (Rural North Dakota). 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 CY 2027, we proposed that we continue to apply a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville, GA). Further, the proposed CY 2027 ASC wage index includes our policy finalized in the CY 2025 OPPS/ASC final rule with comment period that limits wage index changes to decrease by no more than 5 percent from the final CY 2026 ASC wage index value. As we discussed in the April 2025 Update to the Ambulatory Surgical Center Payment System (Change Request 14017), to limit wage index changes by no more than 5 percent from the final CY 2026 ASC wage index, some counties may require a transition CBSA before being fully reflected in the OMB labor market delineations as set forth in OMB Bulletin No. 23–01.

We received one public comment on our proposal. The following is a summary of the comment we received and our response.

Comment: A commenter supported policies to mitigate the effects of inadequate wage indices on rural ASCs and requested greater alignment between the ASC and OPPS wage-index methodologies. The commenter stated that, unlike hospitals, ASCs cannot obtain geographic reclassification to another labor market area and do not receive the frontier-state wage-index floor of 1.0. As an example, the commenter noted that the projected CY 2027 rural wage index applicable to ASCs in South Dakota is 0.7979, while hospitals in the State receive a wage index of at least 1.0 under the frontier-state floor. The commenter requested that CMS extend hospital geographic-reclassification and frontier-state wage-index-floor policies to ASCs.

Response: We appreciate the concerns the commenter has raised. The reclassification provision in section 1883(d)(10) of the Act is specific to acute care hospitals. The reclassification provision does not apply to an area but reflects the circumstances of the reclassified hospital and its own reported wages. Therefore, complete alignment between ASC and OPPS wage index methodologies is not currently possible. While 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 will continue to monitor wage index differences between the OPPS and ASC payment systems and may take the commenter's recommendation into consideration in future rulemaking.

After consideration of public comments we received, we are finalizing our proposal to use the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share to create the final CY 2027 ASC wage indexes and to limit wage index decreases by no more than 5 percent from the final CY 2026 ASC wage index for a particular CBSA. The final CY 2027 ASC wage indexes reflect the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed previously, as set forth in OMB Bulletin No. 23–01) unless the county is otherwise in a transition CBSA. Additionally, based on the absence of IPPS hospitals, we are also finalizing our proposal to apply a proxy wage index based 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 2027 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.

As discussed in section II.A.1.a. of this final rule with comment period, we are using the CY 2025 claims data to be consistent with the OPPS claims data for this final rule with comment period. Consistent with our established policy, we proposed to scale the CY 2027 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 2025, we proposed to compare the estimated total payment using the CY 2026 ASC relative payment weights with the estimated total payment using the CY 2027 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2026 and CY 2027.

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 included estimated total spending and estimated utilization for these codes in our budget neutrality calculation for CYs 2023 and 2024. For this final rule with comment period, our proposed ASC complexity adjustment codes for CY 2027 did not impact the ASC weight scalar.

Additionally, as discussed in section XIII.E. of the CY 2025 OPPS/ASC final rule with comment period (89 FR 94342 through 94361), 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 separate payments for non-opioid treatments for pain relief. As discussed in further detail in section XIII.E. of the CY 2025 OPPS/ASC final rule with comment period, for qualifying non-opioid products, we finalized applying an 18 percent payment limitation on the volume-weighted payment average of the top 5 services associated with the use of the qualifying non-opioid product. In CY 2024, four of these qualifying nonopioid products were separately payable without the 18 percent payment limitation—HCPCS Codes C9089 (Bupivacaine implant, 1 mg), J0666 (Inj, bupivacaine liposome), J1096 (Dexametha opth insert 0.1 mg), and J1097 (Phenylep ketorolac opth soln). Therefore, to maintain budget neutrality, we estimated the total anticipated reduction in ASC spending for these qualifying non-opioid products for CY 2025 as a result of the 18 percent payment limitation required by section 4135 of the CAA, 2023. Based on the updated 18 percent payment limitations and CY 2025 utilization, we estimate that the proposed CY 2027 payment limitations will not impact the ASC weight scalar.

We proposed to use the ratio of estimated CY 2026 to estimated CY 2027 total payments (the weight scalar) to scale the proposed ASC relative payment weights for CY 2027. The proposed CY 2027 ASC weight scalar was 0.809. Consistent with historical practice, we proposed to scale, using this method (with an ASC weight scalar rounded to the nearest thousandth), the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

We proposed that we would not scale ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount, would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services or the portion of those services. The ASC payment weights for those services without predetermined national payment amounts would be scaled to eliminate any difference in the total payment between the current year and the update year.

Historically, the device portions of device-intensive procedures were not scaled so that payment for device portions would remain constant between the OPPS and ASC payment systems. However, due to increased utilization of orthopedic procedures in the ASC setting, ASC expenditures on device portions of device-intensive procedures represent a substantially larger share of total ASC expenditures than in prior years. We estimate that spending attributable to device portions increased from approximately 5.4 percent of total ASC expenditures in CY 2016 to roughly 32.4 percent of total ASC expenditures in 2026. As device expenditures account for an increasingly significant share of total ASC spending, large year-to-year increases in the estimated device portions of surgical procedures require correspondingly larger reductions to the non-device portions of surgical procedures and certain ancillary services to maintain budget neutrality.

The change in the proposed ASC weight scalar for CY 2027 illustrates this effect. Specifically, the ASC weight scalar would decrease from 0.872 in CY 2026 to a proposed 0.809 in CY 2027. This reduction is largely attributable to the substantial increase in expenditures for device portions of device-intensive procedures under the ASC payment system. In turn, this increase in device portions results from the proposed budget-neutral increase in OPPS payment rates for surgical procedures that would offset the drug payment reductions associated with our proposed payment policy for 340B acquired drugs as a result of the OPPS Drug Acquisition Cost Survey.

As the ASC payment system uses the OPPS conversion factor to determine payment for the device portions of device-intensive procedures, this alters the payment relativity between services under the OPPS because the entire portion of ASC payment rates for non-device-intensive procedures is based on the lower ASC conversion factor. Because of the proposed large increase in the device portions for device-intensive procedures in CY 2027 as a result of the proposed 340B drug payment policy, we solicited comment on whether the device portions of device-intensive procedures calculated using the OPPS conversion factor should continue to be excluded from the ASC weight scaler, or alternatively, whether these device portions should be subject to scaling through the ASC weight scaler. We estimated that treating device expenditures for device-intensive procedures as scalable prospective expenditures would increase the proposed ASC weight scaler from 0.809 to 0.865 in CY 2027 and would reduce the device portions of device intensive procedures by approximately 14 percent.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. We proposed to use the CY 2025 claims data to model our budget neutrality adjustment for CY 2027.

We received public comments on our proposal. The following is a summary of

the comments we received and our responses.

Comment: Commenters opposed the proposed CY 2027 ASC weight scalar of 0.809, stating that the secondary scaling adjustment unnecessarily reduces ASC payments, widens the disparity with HOPD payments, and discourages migration to lower-cost ASCs. Many commenters urged CMS to eliminate the ASC weight scalar because continued annual application is not statutorily required, or alternatively to establish a single budget-neutrality calculation using combined OPPS and ASC utilization and service mix. Some commenters supported CMS's alternative of including device portions of device-intensive procedures in scalable expenditures, which would increase the scalar to approximately 0.865 and mitigate reductions for non-device-intensive services, although some recommended phasing in or partially applying this approach. Other commenters opposed scaling device portions because device acquisition costs are fixed and warned that the resulting approximately 14-percent reduction could impair access to device-intensive procedures. These commenters recommended maintaining the device-payment exclusion and instead removing the 340B-related OPPS conversion-factor increase from the ASC ratesetting and scalar calculations so that a hospital drug-payment policy does not distort ASC payment rates.

Response: We appreciate the public comments we received on our proposed ASC weight scalar for CY 2027 and our comment solicitation on whether the device portions of device-intensive procedures calculated using the OPPS conversion factor should continue to be excluded from the ASC weight scalar, or alternatively, whether these device portions should be included in the expenditures subject to scaling through the ASC weight scalar. We agree with commenters that our budget neutrality adjustment places the budget neutrality burden on non-device portions of surgical procedures subject to the ASC weight scalar; however, we remain concerned with both the potential payment reduction and payment asymmetry between the OPPS and ASC payment systems from applying the ASC weight scalar to the device portions of device-intensive procedures. We believe that applying the ASC weight scalar to device portions of device-intensive procedures would significantly reduce the ASC payment rate for such procedures and could potentially reduce future access to device-intensive procedures in the ASC setting which are predominantly performed in the hospital outpatient setting. For these reasons, we are not revising our methodology to include device portions as subject to scaling through the ASC weight scalar. We also considered the commenters' recommendation to use an OPPS conversion factor that excludes the 340B-related OPPS budget neutrality adjustment. Unfortunately, this approach would introduce the same payment asymmetry between the OPPS and ASC payment systems for device portions of device-intensive procedures as applying the ASC weight scalar to device portions as well as continuing the budget neutrality burden placed on non-device portions. For these reasons, we did not believe adopting an alternative OPPS conversion factor was appropriate. Therefore, for CY 2027, we are finalizing our proposal to continue our longstanding policy of using the ratio of total payments based on the CY 2026 relative payment weights to total payments based on the CY 2027 relative payment weights to scale the ASC relative payment weights, while continuing to exclude the device portions of device-intensive procedures from expenditures subject to scaling. We will continue to explore alternative methodologies that maintain budget neutrality under the ASC payment system—which preserves the Part B trust fund and reduces beneficiary cost-sharing—while advancing payment policies that expand access to site-neutral options for beneficiaries.

Comment: Commenters opposed proposed CY 2027 ASC payment reductions for ophthalmic, interventional pain, and dialysis vascular-access procedures. Commenters stated that the reductions would occur despite the overall ASC payment update and, in some cases, while corresponding HOPD payments would increase. They stated that the reduced payments do not adequately reflect the costs of the staff, supplies, devices, imaging, equipment, and other resources required to furnish these services, particularly in independent and rural ASCs. Commenters expressed concern that continued reductions could limit access, encourage consolidation, delay time-sensitive care, or shift services to more costly HOPDs or other less desirable treatment alternatives.

With respect to ophthalmic services, commenters opposed reductions for cataract, glaucoma, retinal, and other procedures, including vitreoretinal procedures described by CPT codes 67036, 67041 through 67043, 67108, 67110, 67113, 67210, 67227, and 67228. Commenters requested that CMS verify that the claims data capture all associated device, supply, and equipment costs; consider HOP Panel review and site-of-service substitution; publish relevant claims-volume and trimming information; and provide procedure-specific explanations for any reductions that are finalized. Commenters also requested that CMS reverse or reassess reductions for interventional pain procedures described by CPT codes 62321, 62323, 64479, 64483, 64490, 64493, 64633, and 64635 and evaluate the cumulative effects of successive payment reductions on beneficiary access. Finally, commenters opposed the effect of the reduced ASC weight scalar on dialysis vascular-access services, particularly non-device-intensive procedures such as CPT code 36902 and supported including device expenditures in the weight-scalar calculation. Commenters generally requested that CMS adopt payment methodologies that more accurately recognize ASC resource costs, stabilize or increase payment for these services, and preserve access to care in lower-cost non-hospital settings.

Response: We appreciate the comments regarding our proposed CY 2027 ASC payment rates for the procedures identified by the commenters and understand the concerns raised regarding the potential effects of payment reductions on beneficiary access. ASCs currently do not submit cost reports, so the absence of these data limits our ability to independently assess whether our proposed rates adequately reflect the costs of the staff, supplies, devices, imaging, equipment, and other resources. Additionally, the HOP Panel advises on OPPS matters and the ASC budget neutrality calculation is outside the scope of its charter. We did not revise claims trimming or the underlying ratesetting methodology involved—the payment rate reductions for these procedures are driven by the ASC budget neutrality adjustment providing a corresponding decrease in total nondevice portion expenditures in response to the increase in OPPS device portion expenditures adopted under the ASC payment system.

For the reasons previously described with respect to our budget neutrality methodology, we are finalizing our longstanding budget neutrality calculation because of concerns about underpayment of the significant device costs associated with device-intensive procedures and the importance of preserving beneficiary access to device-intensive procedures in the ASC setting. We intend to continue monitoring beneficiary access to non-device-

intensive procedures in the ASC setting and may consider future payment policies to address this issue.

After consideration of the public comments we received, we are finalizing our proposal to use scaled OPPS relative weights to establish ASC relative payment weights and to use the ratio of CY 2026 to CY 2027 total payments (the weight scalar) to ASC relative payment weights for CY 2027. We are also finalizing our proposal to continue using the OPPS conversion factor, which we are finalizing as $99.970 for CY 2027 in this final rule with comment period, to continue maintaining device portions between the OPPS and ASC payment systems for device-intensive surgical procedures. While we understand the concerns raised by interested parties regarding the payment reductions for non device-intensive procedures for CY 2027, we currently are not adopting an alternative methodology and are maintaining our longstanding calculation of budget neutrality under the ASC payment system and holding device portions constant between the OPPS and ASC payment systems for device-intensive procedures. We will continue to explore alternative methodologies to address concerns with the payment rates for non-device intensive procedures under the ASC payment system while providing budget neutrality under the ASC payment system for future rulemaking. The final CY 2027 ASC weight scalar is 0.814. Consistent with historical practice, we are finalizing our proposal to scale the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider-level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2017 ASC payment system and subsequent years, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79751 through 79753), we finalized our policy to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier-level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor.

For CY 2027, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2025 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2027 ASC wage indexes. Specifically, holding CY 2025 ASC utilization, service-mix, and the proposed CY 2027 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2026 ASC wage indexes and the total adjusted payment using the proposed CY 2027 ASC wage indexes which included the 5-percent cap on wage index decreases for an ASC. 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 2026 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2027 ASC wage indexes and applied the resulting ratio of 1.0016 (the proposed CY 2027 ASC wage index budget neutrality adjustment) to the CY 2026 ASC conversion factor to calculate the proposed CY 2027 ASC conversion factor.

Section 1833(i)(2)(D)(v) of the Act requires that the ASC conversion factor be reduced by a productivity adjustment in each calendar year. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP). We finalized the methodology for calculating the productivity adjustment in the CY 2011 PFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 PFS final rule with comment period (76 FR 73300 through 73301) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501). The proposed productivity adjustment for CY 2027 was projected to be 0.8 percentage point, as published in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19496) based on IGI's 2025 fourth quarter forecast.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (CPI–U), U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at § 416.171(a)(2)(ii)), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized a policy to apply the hospital market basket update (which is the inpatient hospital market basket percentage increase reduced by the productivity adjustment) to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we would assess whether there was a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a hospital market basket update, as well as whether there were any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. At that time, the most recently available full year of claims data to assess the expected migration applying the productivity-adjusted hospital market basket update during the interim period was within the period from CY 2019 through CY 2022. However, the impact of the COVID–19 PHE on health care utilization, CY 2020 in particular, 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 was 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 needed 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 through CY 2024 and CY 2025 which we subsequently extended through CY 2026 in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53914 through 53915). We believed hospital outpatient and ASC utilization data from CYs 2023 through 2025 would enable us to more accurately analyze whether the application of the 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 § 416.171(a)(2)(iii), (iv), (vi), (vii), and (viii) which establish the annual update to the ASC conversion factor, to reflect these extensions.

For the CY 2027 OPPS/ASC proposed rule, we proposed to extend our utilization of the hospital market basket update factor in the ASC payment system for one additional year, through CY 2027, as we continue to review and evaluate hospital outpatient and ASC utilization data, as well as the migration of surgical procedures between settings. In conjunction with our proposal, we proposed revising our regulations at § 416.171(a)(2)(iii), (iv), (vi), (vii), and (viii), which establish the annual update to the ASC conversion factor, the 2.0 percentage point reduction for ASCs that fail to meet the standards for reporting ASC quality measures, and the productivity adjustment, to reflect this one-year extension.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported CMS's proposal to extend use of the productivity-adjusted hospital market basket, rather than the CPI–U, as the ASC payment update factor through CY 2027. Commenters stated that the hospital market basket better reflects ASC cost growth because ASCs purchase similar supplies, equipment, devices, and implants as HOPDs and compete for the same clinical workforce. They also stated that aligning the ASC and OPPS update factors supports migration to lower-cost ASCs, reduces payment disparities, and generates Medicare and beneficiary savings, and many commenters urged CMS to make the hospital market basket update policy permanent rather than extending it for one year. Other commenters opposed the extension, stating that hospitals and ASCs have different cost structures and patient populations and that the hospital market basket does not accurately measure ASC input costs. These commenters recommended that CMS collect minimally burdensome ASC cost data and develop an ASC-specific market basket, while some supporters stated that any new index should apply consistently to both ASCs and HOPDs to preserve alignment between the payment systems.

Response: We appreciate the feedback from commenters. We did not propose to collect ASC-specific cost data in our CY 2027 OPPS/ASC proposed rule. ASCs currently do not submit cost reports, so we are unable to discern if there is a meaningful difference in the cost structures between the hospital and ASC setting and if such differences would necessitate a different update factor. We agree with commenters that providing the same annual update mechanism under the OPPS and ASC payment systems can support the migration of services to the lower-cost ASC setting. We are finalizing our proposal to apply the productivity-adjusted hospital market basket update to the ASC payment system for CY 2027.

2. CY 2027 Final ASC Conversion Factor

For CY 2027, we finalized our proposal to utilize the final inpatient hospital market basket percentage increase of 3.2 percent reduced by the productivity adjustment of 0.9 percentage point, resulting in a final hospital market basket update of 2.3 percent for ASCs meeting the quality reporting requirements. Therefore, we are finalizing our proposal to apply a 2.3 percent hospital market basket update factor to the CY 2026 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2027 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 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 final rule with comment period for a detailed discussion of our policies regarding payment reduction for ASCs that fail to meet ASCQR Program requirements.

For CY 2027, we are adjusting the CY 2026 ASC conversion factor ($56.322) by a wage index budget neutrality factor of 1.0018 in addition to the productivity-adjusted hospital market basket update of 2.3 percent, discussed previously, which results in a final CY 2027 ASC conversion factor of $57.721 for ASCs meeting quality reporting requirements. For ASCs not meeting quality reporting requirements, we are adjusting the CY 2026 ASC conversion factor ($56.322) by the wage index budget neutrality factor of 1.0018 in addition to the reduced productivity-adjusted hospital market basket update of 0.3 percent, discussed previously, which results in a final CY 2027 ASC conversion factor of $56.592 for ASCs not meeting the quality reporting requirements.

3. Display of the Final CY 2027 ASC Payment Rates

Addenda AA and BB to this final rule with comment period (which are available on the CMS website) display the final ASC payment rates for CY 2027 for covered surgical procedures and covered ancillary services, respectively. The final payment rates included in Addenda AA and BB to this final rule with comment period reflect the full ASC payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program.

These Addenda contain several types of information related to the final CY 2027 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.

Comment: Numerous commenters opposed CMS' proposed change from ''No'' to ''Yes'' for multiple-procedure discounting of device-intensive procedures, including CPT codes 54401, 54405, 54410, 54416, 63650, 63655, 63663, 63664, 63685, 64553, 64555, 64561, 64575, and 64590, and requested continuation of the current exemption.

Response: The change to these procedures' multiple procedure discount status in the proposed rule Addendum AA was inadvertent and not an intentional proposed policy change. Therefore, for CY 2027, we are not finalizing the proposed change in the multiple-procedure discounting designation for CPT codes 54401, 54405, 54410, 54416, 63650, 63655, 63663, 63664, 63685, 64553, 64555, 64561, 64575, and 64590. These procedures will continue to be identified with an ''N'' in the ''Subject to Multiple Procedure Discounting'' column of ASC Addendum AA. The values displayed in the column titled ''Final CY 2027 Payment Weight'' are the final relative payment weights for each of the listed services for CY 2027. The final 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 PFS nonfacility PE RVU-based amount; separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS; or services that are contractor-priced or paid at reasonable cost in ASCs. This includes separate payment for non-opioid pain management drugs.

To derive the final CY 2027 payment rate displayed in the ''Final CY 2027 Payment Rate'' column, each ASC payment weight in the ''Final CY 2027 Payment Weight'' column was multiplied by the final CY 2027 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 final CY 2027 ASC conversion factor uses the final CY 2027 productivity adjusted hospital market basket update factor of 2.3 percent (which is equal to the inpatient hospital market basket percentage increase of 3.2 percent reduced by the productivity adjustment of 0.9 percentage point).

In Addendum BB, there are no relative payment weights displayed in the ''Final CY 2027 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Proposed CY 2027 Payment'' column displays the final CY 2027 national unadjusted ASC payment rates for all items and services.

The final CY 2027 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are generally based on the most recently available data used for payment in physicians' offices. 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).

Addendum EE to this final rule with comment period provides the HCPCS codes and short descriptors for surgical procedures that are to be excluded from payment in ASCs for CY 2027 as they are designated as unsafe surgical procedures, unlisted surgical procedures, or on the inpatient-only list.

Addendum FF to this final rule with comment period 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 2027 for covered surgical procedures.

XIV. Measure Removal for the Hospital Outpatient Quality Reporting and Ambulatory Surgical Center Quality Reporting Programs

A. Background

We refer readers to sections XV. and XVII. of this final rule with comment period for program-specific background information, including statutory authority and program measure sets, regarding the Hospital Outpatient Quality Reporting and Ambulatory Surgical Center (ASC) Quality Reporting Programs, respectively.

B. Removal of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure in the Hospital Outpatient Quality Reporting and the ASC Quality Reporting Programs

We refer readers to the CY 2014 OPPS/ASC final rule with comment period where we adopted the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (the Colonoscopy Follow-Up Interval) measure into the Hospital Outpatient Quality Reporting and the ASC Quality Reporting Programs (78 FR 75101 through 75102 and 78 FR 75127 through 75128), and the CY 2024 OPPS/ASC final rule with comment period where we modified the measure to align with updated clinical guidelines (88 FR 81972 through 81973 and 88 FR 82020 through 82021). The Colonoscopy Follow-Up Interval measure assesses the percentage of patients aged 45 to 75 years receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in the colonoscopy report.[179]

When we adopted the Colonoscopy Follow-up Interval measure, we sought to address what was, at the time, the critical issue of colonoscopies potentially performed too frequently and potentially increasing patients' exposure to procedural harm.[180] [181] The measure was designed to promote adherence to recommended screening intervals through documentation of follow-up recommendations in the colonoscopy report, thereby increasing provider and patient awareness of appropriate screening intervals. Importantly, this measure assesses whether the recommended 10-year interval for a follow-up colonoscopy is documented in the colonoscopy report, rather than whether appropriate clinical care is delivered. In other words, the measure does not assess whether the follow-up colonoscopy was performed according to this recommended interval.

We continue to believe that it is important to encourage high-quality colonoscopy care in hospital outpatient departments and ASCs. We note that the Hospital Outpatient Quality Reporting Program and ASC Quality Reporting Program measure sets both currently include another measure that is tied more closely to outcomes of continued interest and importance—the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure (79 FR 66948 through 66955 and 79 FR 66970 through 66979, respectively), which assesses the incidence of hospital returns within 7 days of a colonoscopy, including emergency department visits, observation stays, and unplanned readmissions. The Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure is therefore a more patient-outcome focused measure of procedure-related adverse events across both programs in contrast to the Colonoscopy Follow-Up Interval measure, which assesses documentation of recommended follow-up intervals rather than patient outcomes.[182] For these reasons, in the CY 2027 OPPS/ASC proposed rule (91 FR 41957), we proposed to remove the Colonoscopy Follow-Up Interval measure from the Hospital Outpatient Quality Reporting and the ASC Quality Reporting Programs, beginning with the CY 2027 reporting period/CY 2029 payment determination. For both programs, removal is appropriate under removal factor 6 (42 CFR 419.46(i)(3)(i)(F) and 416.320(c)(2)(vi)), the availability of a measure that is more strongly associated with a desired

[179] Partnership for Quality Measurement. Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients. Available at *https://p4qm.org/measures/0658*.

[180] Lieberman, D. A., Faigel, D. O., Logan, J. R., Mattek, N., Holub, J., Eisen, G., Morris, C., Smith, R., & Nadel, M. (2009). Assessment of the quality of colonoscopy reports: results from a multicenter consortium. *Gastrointestinal endoscopy, 69*(3 Pt 2), 645–653. *https://doi.org/10.1016/j.gie.2008.08.034*.

[181] Goodwin, J. S., Singh, A., Reddy, N., Riall, T. S., & Kuo, Y. F. (2011). Overuse of screening colonoscopy in the Medicare population. *Archives of internal medicine, 171*(15), 1335–1343. *https://doi.org/10.1001/archinternmed.2011.212*.

[182] Partnership for Quality Measurement. Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. Available at *https://p4qm.org/measures/2539*.

patient outcome for the particular topic. The Hospital Outpatient Quality Reporting Program and ASC Quality Reporting Program measure sets would continue to retain the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure.

Additionally, we continue to prioritize appropriate colonoscopy care in our other quality reporting or value-based programs. For example, we have a Colorectal Cancer Screening measure within the gastroenterology Merit-based Incentive Payment System (MIPS) Value Pathway [183] and the Medicare Shared Savings Program,[184] which assesses the percentage of adults 45 to 75 years of age who had appropriate screening for colorectal cancer.

We invited and received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported removing the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure stating that this measure primarily assesses whether a recommended follow-up interval was documented rather than whether appropriate clinical care occurred or meaningful patient outcomes were achieved. Many commenters supported streamlining quality reporting by removing measures and reporting requirements that are duplicative, redundant, or no longer needed and focusing on more clinically meaningful, patient-centered measures that better reflect care quality, patient safety, and outcomes.

Many commenters supported removing the measure stating that chart abstraction, data collection, and reporting requirements create administrative burden, and that removal would allow facilities to focus on higher-priority quality improvement activities that more directly benefit patients. A few commenters supported removing the measure due to consistently high performance with limited meaningful differentiation thereby reducing its value as a quality measure. A few commenters noted that the measure may be topped out and supported focusing resources on measures with greater potential to drive meaningful improvements in patient outcomes and care quality.

Response: We thank commenters for their support. We agree that removing the Colonoscopy Follow-Up Interval measure will reduce reporting burden and allow hospitals and ASCs to focus resources on measurable clinical outcomes and direct patient care. We agree with commenters that the measure has consistently high performance in the Hospital Outpatient Quality Reporting and ASC Quality Reporting Programs.

Comment: A few commenters supported removing the measure from facility-based programs, stating that it was developed to assess clinician performance and is not appropriate for evaluating hospital or ASC performance.

Response: We appreciate commenters' support; however, we disagree that the measure is not appropriate for evaluating hospital outpatient department or ASC performance. As we stated when we adopted the Colonoscopy Follow-Up Interval Measure into the Hospital Outpatient Quality Reporting and ASC Quality Reporting Programs, while this measure was originally developed at the clinician-level, the measure steward later respecified the measure at the facility level and performed field testing for this measure in the Hospital Outpatient Department and ASC settings and CMS determined, based on that testing, that the measure was appropriate and feasible for those settings (78 FR 75099 through 75100 and 78 FR 75125).

We are removing the measure now because another measure is available that more directly assesses procedure-related adverse events, not because we believe this measure is not appropriate for the hospital outpatient department and ASC settings. The retained measure, Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, assesses hospital returns within 7 days of a colonoscopy, including emergency department visits, observation stays, and unplanned readmissions.

Comment: A few commenters expressed concern that removing the Colonoscopy Follow-Up Interval measure could weaken efforts to prevent unnecessary or low-value colonoscopies which could increase procedural risks.

Response: We appreciate commenters' concerns regarding unnecessary or low-value colonoscopies, health care costs, patient safety, continuity of care, and colorectal cancer prevention and follow-up. When we adopted the Colonoscopy Follow-Up Interval measure, we sought to address issues related to colonoscopies potentially being performed too frequently which would increase patients' exposure to procedural harm.[185] [186] The measure was designed to promote adherence to recommended screening intervals through documentation of follow-up recommendations. However, the measure assesses whether the recommended 10-year follow-up interval is documented in the colonoscopy report, rather than whether appropriate clinical care is delivered or whether the follow-up colonoscopy is performed according to the recommended interval. The Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure allows us to better assess procedure-related adverse events than the Colonoscopy Follow-Up Interval measure.

Comment: A few commenters expressed concern that removing this measure could undermine efforts to reduce health care costs.

Response: We appreciate commenters' concerns regarding health care costs. We agree that avoiding unnecessary colonoscopies can reduce health care costs. As we previously stated, however, the Colonoscopy Follow-Up Interval measure does not assess whether a follow-up colonoscopy is performed according to the recommended 10-year follow-up interval. Retaining the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure prioritizes a measure more strongly associated with a desired patient outcome and assesses procedure-related adverse events, including hospital returns within 7 days of a colonoscopy,[187] that can increase health care costs.

Comment: A few commenters stated that this measure supports colorectal cancer prevention. A few commenters expressed concern about removing a measure that aligns with United States Preventive Services Task Force's recommendations and is included in the Core Quality Measures Collaborative (CQMC) Gastroenterology core measure set.

Response: The CQMC's Gastroenterology core measure set is

[183] CMS MIPS Gastroenterology Care Value Pathway. Available at *https://qpp.cms.gov/reporting-requirements/measures-activities/explore-mvps/2026/M1422*.

[184] CMS Measures Inventory Tool. Colorectal Cancer Screening, Medicare Shared Savings Program. Available at *https://cmit.cms.gov/cmit/#/MeasureView?variantId=11552&sectionNumber=1*.

[185] Lieberman, D. A., Faigel, D. O., Logan, J. R., Mattek, N., Holub, J., Eisen, G., Morris, C., Smith, R., & Nadel, M. (2009). Assessment of the quality of colonoscopy reports: results from a multicenter consortium. *Gastrointestinal endoscopy, 69*(3 Pt 2), 645–653. *https://doi.org/10.1016/j.gie.2008.08.034*.

[186] Goodwin, J. S., Singh, A., Reddy, N., Riall, T. S., & Kuo, Y. F. (2011). Overuse of screening colonoscopy in the Medicare population. *Archives of internal medicine, 171*(15), 1335–1343. *https://doi.org/10.1001/archinternmed.2011.212*.

[187] Partnership for Quality Measurement. Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. Available at *https://p4qm.org/measures/2539*.

focused on ambulatory care measures at the clinician reporting level. We agree that the measure's inclusion in this measure set indicates that it has clinical value but note that the Hospital Outpatient Quality Reporting and ASC Quality Reporting Programs assess facility-level performance. In the CY 2027 Physician Fee Schedule proposed rule, the Colonoscopy Follow-up Interval measure was proposed for removal from MIPS because it is topped-out, meaning the median performance rate is 95 percent or higher (91 FR 44160 through 44162 and 91 FR 44416). We appreciate commenters' concerns regarding alignment with United States Preventive Services Task Force recommendations, which recommends screening for colorectal cancer in adults aged 45 to 75 years.[188] We continue to prioritize appropriate colorectal cancer screening in other quality reporting or value-based programs, such as the Colorectal Cancer Screening measure in the gastroenterology MIPS Value Pathway [189] and the Medicare Shared Savings Program.[190]

Comment: A few commenters stated that removing the measure would eliminate a distinct and complementary aspect of quality measurement. These commenters stated that the Colonoscopy Follow-Up Interval and the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure assess different aspects of care, so maintaining both provides a more comprehensive assessment of quality.

Response: We understand commenters' concerns that the Colonoscopy Follow-Up Interval measure and the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measures do not assess the same clinical areas. The Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure provides an outcome-focused assessment of procedure-related adverse events, including hospital returns within 7 days of a colonoscopy.[191] We seek to implement measures that are focused on patient outcomes to evaluate the results of clinical care. The Colorectal Cancer Screening measure, which assesses the percentage of adults 45 to 75 years of age who had appropriate screening for colorectal cancer,[192] is more complementary to the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure than the Colonoscopy Follow-Up Interval measure, which assesses documentation of a recommended follow-up interval.[11]

As discussed above, the Colonoscopy Follow-Up Interval measure sought to address patients' exposure to procedural harm from unnecessarily frequent colonoscopies, while the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure assesses procedure-related adverse events. Moreover, the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure is more strongly associated with patient outcomes than the Colonoscopy Follow-Up Interval measure. Thus, removal of the Colonoscopy Follow-Up Interval measure is appropriate under removal factor 6 (42 CFR 419.46(i)(3)(i)(F) and 416.320(c)(2)(vi)), the availability of a measure that is more strongly associated with a patient outcome for the particular topic.

Comment: A few commenters recommended evaluating or monitoring whether removal of the measure results in unintended effects on clinical practice or adherence to screening recommendations. A commenter recommended improving the reliability of the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure to ensure it provides useful information to facilities. A commenter recommended considering less burdensome approaches, including provider education, clinical decision support tools, or broader quality improvement initiatives, to support guideline-concordant screening practices without maintaining a standalone reporting measure.

Response: We thank commenters for their recommendations and will consider them as we evaluate the effects of removing the Colonoscopy Follow-Up Interval measure. As part of our measure maintenance process, we will conduct ongoing monitoring and evaluation analyses to evaluate measure performance of the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure, and to identify any potential unintended consequences. Regarding burden, the Facility 7-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy measure is calculated from Medicare claims and administrative data making associated burden related to data collection minimal for hospitals and ASCs in contrast to the Colonoscopy Follow-up Interval measure which requires chart-abstraction. Regarding reliability of the measure, sufficient case numbers for reliability purposes were assessed during the measure development process and would be reassessed through the measure maintenance review process.

After consideration of the public comments we received, we are finalizing the removal of the Colonoscopy Follow-Up Interval measure from the Hospital Outpatient Quality Reporting and the ASC Quality Reporting Programs as proposed beginning with the CY 2027 reporting period/CY 2029 payment determination.

XV. Hospital Outpatient Quality Reporting Program

A. Background

The Hospital Outpatient Quality Reporting Program promotes transparency and quality of care furnished at hospital outpatient departments (HOPDs). Section 1833(t)(17)(A) of the Act sets forth 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 fee schedule increase factor. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital Outpatient Quality Reporting Program. We have codified certain program requirements at 42 CFR 419.46. We also refer readers to the CMS website at *https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/hospital-outpatient-quality-reporting-program* for general background on the Hospital Outpatient Quality Reporting Program, as well as the CMS QualityNet website at *https://qualitynet.cms.gov/outpatient* for current program requirements and measure specifications.

[188] United States Preventive Services Task Force. A & B Recommendations. Available at *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations.*

[189] CMS MIPS Gastroenterology Care Value Pathway. Available at *https://qpp.cms.gov/reporting-requirements/measures-activities/explore-mvps/2026/M1422.*

[190] CMS Measures Inventory Tool. Colorectal Cancer Screening, Medicare Shared Savings Program. Available at *https://cmit.cms.gov/cmit/#/MeasureView?variantId=11552&sectionNumber=1.*

[191] Partnership for Quality Measurement. Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. Available at *https://p4qm.org/measures/2539.*

[192] CMS Measures Inventory Tool. Colorectal Cancer Screening, Medicare Shared Savings Program. Available at *https://cmit.cms.gov/cmit/#/MeasureView?variantId=11552&sectionNumber=1.*

B. Hospital Outpatient Quality Reporting Program Measure Set

We refer readers to section XIV. of this final rule with comment period where we discuss the removal of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure from the Hospital Outpatient Quality Reporting and Ambulatory Surgical Center Quality Reporting Programs beginning with the CY 2027 reporting period/CY 2029 payment determination. We did not finalize any other changes to the Hospital Outpatient Quality Reporting Program measure set. Table 97 summarizes the previously finalized and newly finalized Hospital Outpatient Quality Reporting Program measure set for the CY 2028 to CY 2032 payment determinations, which removes the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure.

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TABLE 97: HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM MEASURE SET BY DATA COLLECTION METHOD AND PAYMENT DETERMINATION (PD)

Consensus -Based Entity #	Measure Name	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD	CY 2032 PD
Chart-Abstracted Measures						
0658	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients*	✓	Removed			
0661	Head Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival	✓	✓	✓	✓	✓
None	Left Without Being Seen	✓	✓			
None	Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients	✓	✓			
Claims-Based Measures						
None	Abdomen CT - Use of Contrast Material	✓	✓	✓	✓	✓
3490	Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	✓	✓	✓	✓	✓
None	Breast Cancer Screening Recall Rates	✓	✓	✓	✓	✓
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	✓	✓	✓	✓	✓
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery	✓	✓	✓	✓	✓
Patient-Reported Outcomes-Based Performance Measures (PRO-PMs)						
4210	Patient Understanding of Key Information Related to Recovery After a Hospital-Based Outpatient Procedure or Surgery PRO-PM (Information Transfer PRO-PM)	Voluntary	✓	✓	✓	✓
None	Risk-Standardized PRO–PM Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO-	Voluntary	Voluntary	Voluntary	✓	✓

Consensus-Based Entity #	Measure Name	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD	CY 2032 PD
	PM)					
None	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary
Survey-Based Measures						
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)	✓	✓	✓	✓	✓
Electronic Clinical Quality Measures (eCQMs)						
4625e	Emergency Care Access and Timeliness (ECAT)		Voluntary	✓	✓	✓
3663e	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Hospital Level—Outpatient)	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary
None	ST-Segment Elevation Myocardial Infarction (STEMI)	✓	✓	✓	✓	✓

✓Measure is mandatory for the specified payment determination year.

Voluntary: Submission of this measure is optional, and HOPDs that do not report the measure are not subject to a payment reduction.

*Removed in this final rule with comment period beginning with the CY 2029 payment determination.

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C. Request for Information on the Advance Care Planning Electronic Clinical Quality Measure

1. Background

In this request for information, we sought feedback on potential inclusion of an Advance Care Planning electronic clinical quality measure (eCQM) and other quality measure concepts related to advance care planning for the Hospital Outpatient Quality Reporting Program. Advance care planning is a continuous process that supports patients in understanding and communicating their goals, values, and preferences regarding future medical care and decision-making. The 1990 Patient Self-Determination Act supports advance care planning by requiring health care facilities to inform patients of their rights regarding medical decision-making and to document in the medical record whether the patient has executed an advance directive; however, it does not require that a copy of the directive itself must always be placed in the medical record.[193]

HOPDs provide care for adults with serious and complex conditions, including those receiving cancer treatment, visiting the emergency department (ED), or undergoing surgical procedures. In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53780 through 53786), we finalized the phase-out of the Inpatient-Only (IPO) list over a 3-year period, beginning January 1, 2026, and ending January 1, 2029. As part of the first step of the IPO phase-out, for 2026, we removed 285 HCPCS codes (mostly for musculoskeletal procedures) from the IPO list. As more procedures shift from the inpatient to the outpatient setting, complex procedures may increasingly be furnished in HOPDs. Outpatient encounters can provide repeated opportunities for clinicians to build relationships with patients over time, which may support the initiation or updating of advance care planning documentation, including when patients are relatively stable or before their illness progresses.[194] Many patients assume that their caregivers know their preferences regarding their care; however, research indicates that caregivers incorrectly predict patients' preferences approximately one-third of the time.[195] Additionally, care preferences may change over time,[196] particularly in response to changes in an individual's health status or personal circumstances.[197] [198] Regular

[193] Patient Self Determination Act of 1990. 42 U.S.C. 1395cc(f) and 1396a(w).

[194] Marshall, K. H., Riddiford-Harland, D. L., Meller, A. E., Caplan, G. A., Naganathan, V., Cullen, J., Gonski, P., Zwar, N. A., O'Keeffe, J. A., Krysinska, K., & Rhee, J. J. (2024). Feasibility and Acceptability of Facilitated Advance Care Planning in Outpatient Clinics: A Qualitative Study of Patient and Caregivers Experiences. *Journal of applied gerontology: the official journal of the Southern Gerontological Society, 43*(4), 339–348. Available at *https://doi.org/10.1177/07334648231206742*.

[195] National Institute on Aging. (2022). Advance Care Planning: Advance Directives for Health Care. Available at *https://www.nia.nih.gov/health/advance-care-planning/advance-care-planning-advance-directives-health-care.*

[196] Mastropolo, R., Cernik, C., Uno, H., Fisher, L., Xu, L., Laurent, C. A., Cannizzaro, N., Munneke, J., Cooper, R. M., Lakin, J. R., Schwartz, C. M., Casperson, M., Altschuler, A., Kushi, L., Chao, C. R., Wiener, L., & Mack, J. W. (2024). Evolution in Documented Goals of Care at End of Life for Adolescents and Younger Adults With Cancer. *JAMA network open, 7*(12), e2450489. Available at *https://doi.org/10.1001/jamanetworkopen.2024.50489.*

[197] Shah, M. P., Wenger, N. S., Glaspy, J., Hays, R. D., Sudore, R. L., Rahimi, M., Gibbs, L., Anand, S., Tseng, C. H., & Walling, A. M. (2025). Patient-reported discordance between care goals and

Continued

reassessment and transparent communication are essential to maintaining person-centered care. Advance care planning facilitates shared decision-making by documenting patient preferences and ensuring that care remains aligned with patients' goals across care settings and transitions.[199]

We sought feedback on whether the Advance Care Planning eCQM is appropriate for use in the hospital outpatient setting, with or without modifications. We requested input on this and on other potential quality measures related to this topic that may be appropriate for the hospital outpatient setting.

2. Advance Care Planning Electronic Clinical Quality Measure Overview

The Advance Care Planning eCQM was finalized for adoption for the Hospital Inpatient Quality Reporting, PPS-Exempt Cancer Hospital Quality Reporting, and Medicare Promoting Interoperability Programs in the FY 2027 IPPS/LTCH PPS final rule (91 FR 49932 through 49942). Potentially adopting the eCQM across our quality reporting programs promotes the use of standardized advance care planning documentation in the electronic health record (EHR). Such documentation helps ensure that care remains aligned with patients' stated preferences, leverages EHRs to facilitate health information exchange, and supports the advancement of person-centered care across the care continuum.

We refer readers to the FY 2027 IPPS/LTCH PPS final rule (91 FR 49932 through 49942) for a complete discussion of adoption of the Advance Care Planning eCQM in certain inpatient quality reporting programs. The eCQM currently calculates the proportion of adult patients with one or more hospitalizations during the measurement period who, by the time of discharge for at least one encounter, have either an advance care planning document in the EHR or documentation of an advance care planning discussion that results in a documented decision in the patient's EHR. The numerator comprises any one of the following: (1) an advance care planning document as evidenced by the following types of documents: designated health care agent (health care proxy or medical power of attorney for health care), advance directive (or living will), or a portable medical order (medical order for life-sustaining treatment [MOLST], physician order for life-sustaining treatment [POLST], or do not resuscitate [DNR] orders); [200] or (2) documentation that an advance care planning discussion resulting in a documented decision occurred during the measurement period.[201] [202]

To be counted in the numerator, the advance care planning document must be available in the patient's EHR during any hospitalization in the measurement period. The measure does not require documentation of the date the advance care planning document was originally created or last updated. However, we encourage clinicians to discuss with the patient or their surrogate whether the document accurately reflects the patient's current preferences. To be considered an advance care planning discussion leading to a decision, the documentation of the discussion with a decision must have a date in the EHR that occurs during a hospital encounter in the measurement period. If a patient has multiple encounters during the measurement period, an advance care planning discussion with a decision occurring in any one of the hospital encounters during the measurement period is counted toward the numerator. The denominator includes all patients aged 18 years and older at the start of the measurement period who are discharged from a hospitalization during the 12-month measurement period. The Advance Care Planning eCQM is calculated as a proportion by dividing the number of patients who meet the numerator criterion by the total number of eligible patients who meet the denominator criterion.[203]

There are no exclusions for the Advance Care Planning eCQM as the measure is intended to encourage advance care planning among all adult patients, recognizing that serious illness or injury can occur at any time, regardless of age or baseline health. The measure is designed to account for situations where a patient does not have capacity to engage in, declines, or defers advance care planning by recognizing existing advance care planning decisions documented in the EHR, including qualifying advance care planning documents recorded prior to the measurement period, EHR data elements documenting advance care planning discussions with a decision during a hospital encounter (including those conducted with a surrogate when the patient does not have capacity), and documentation that a patient declined or deferred advance care planning.

For additional information on the Advance Care Planning eCQM, including the measure rationale and numerator criteria, refer to *https://www.p4qm.org/prmr-measures/muc2025-020.* We refer readers to the Electronic Clinical Quality Improvement (eCQI) Resource Center for the detailed measure specifications and guidance at *https://ecqi.healthit.gov/ecqm/hosp-inpt/2028/cms1317v1.*

3. Solicitation for Public Comment

We sought input on the importance, relevance, appropriateness, and applicability of including the Advance Care Planning eCQM in the Hospital Outpatient Quality Reporting Program, as well as on other measure concepts related to advance care planning for the hospital outpatient setting. We invited public comment on the following considerations:

- Tools and measures that capture advance care planning processes and outcomes in hospital outpatient settings, including the potential future use of and modifications to the Advance Care Planning eCQM to better tailor it for the Hospital Outpatient Quality Reporting Program.
- Other approaches or measure concepts that may more effectively capture advance care planning activities in the HOPD setting.
- Relevant aspects of advance care planning for the HOPD setting, such as whether an advance care planning measure should focus on specific patient populations, higher-acuity procedures, or select departments (such

treatment intent in advanced cancer. *Cancer, 131*(17), e35976. Available at *https://doi.org/10.1002/cncr.35976.*

[198] Young Y, Stone A, Perre T. (2022). Are Young Adults Ready to Complete Advance Directives? *American Journal of Hospice & Palliative Medicine, 39*(10), 1188–1193. Available at *https://doi.org/10.1177/10499091211066494.*

[199] McMahan, R. D., Tellez, I., Sudore, R. L. (2021). Deconstructing the Complexities of Advance Care Planning Outcomes: What Do We Know and Where Do We Go? A Scoping Review. *Journal of the American Geriatrics Society, 69*(1), 234–244. Available at *https://doi.org/10.1111/jgs.16801.*

[200] Some state organizations may refer to a MOLST or POLST form by other terms such as medical orders for scope of treatment (MOST), physician orders for scope of treatment (POST), clinical orders for life-sustaining treatment (COLST), or a transportable physician orders for patient preferences (TPOPP).

[201] Documentation that an advance care planning discussion resulting in a documented decision occurred during the measurement period includes a discussion with the patient or the surrogate. This allows discussion with a surrogate in instances where a patient is unable to participate (*e.g.,* incapacitated) without requiring prior discussion with the patient.

[202] Partnership for Quality Measurement. Advance Care Planning. Available at *https://www.p4qm.org/prmr-measures/muc2025-020.*

[203] Centers for Medicare & Medicaid Services. Electronic Clinical Quality Improvement Resource Center. Advance Care Planning. Measure Guidance. Available at *https://ecqi.healthit.gov/ecqm/hosp-inpt/2028/cms1317v1.*

as oncology, emergency department, and surgical areas).

- Timing and frequency of advance care planning, such as when and how often it should occur in the HOPD setting.
- Other measure development/re-specification ideas or opportunities for addressing advance care planning in the HOPD setting, including but not limited to changes to the current Advance Care Planning eCQM.

We received public comments on these topics, summarized below.

Comment: Many commenters expressed support for advance care planning as a quality measurement concept, describing advance care planning as an important component of patient-centered care and a means of aligning care with patients' values, goals, and preferences. Among these commenters, many supported adopting the Advance Care Planning eCQM specifically in the Hospital Outpatient Quality Reporting Program, while a few commenters supported adoption conditionally based on modifications, additional measure testing, or other considerations.

Many commenters opposed adoption or recommended deferral, citing concerns that the measure may not adequately reflect meaningful advance care planning, may not be appropriate across the broad range of hospital outpatient encounters, and may create administrative, reporting, workflow, or EHR burdens. Many commenters submitted different recommendations on whether the eCQM should be applied broadly across HOPDs, which populations and encounters should be measured, and what changes would be needed before adoption.

Many commenters recommended limiting an outpatient advance care planning measure to patients, procedures, departments, or encounters where advance care planning is clinically relevant and there is sufficient opportunity for meaningful discussion. Their recommendations included focusing on patients with serious illness, oncology patients, and patients undergoing higher-acuity procedures. Commenters identified imaging, laboratory services, emergency care, routine procedures, and other episodic encounters as settings that may warrant exclusion or a different approach.

Several commenters also recommended specific denominator or exclusion criteria to operationalize a more targeted measure. A commenter recommended exclusions when an advance care plan was recently completed, was being managed by another clinician or care setting, or was not clinically appropriate for the encounter. Another commenter recommended excluding patients who decline advance care planning discussions or documentation from performance calculations, and a commenter recommended considering exclusion of patients who lack capacity and do not have an appropriate health care agent or surrogate decision-maker. A commenter proposed more detailed eligibility rules, including limiting the measure to specified outpatient services; excluding emergency department patients, medical observation patients, and certain patients recently hospitalized; requiring at least two visits before applying the measure to some recurring services; and applying episode-level measurement to certain surgical observation and outpatient-in-bed services. In contrast, another commenter supported applying the measure broadly to all adults aged 18 and older rather than limiting it to specific patient populations, higher-acuity procedures, or select departments.

Many commenters emphasized that advance care planning measurement should reflect meaningful, voluntary, patient-centered planning rather than documentation alone. Commenters cautioned against measure specifications or incentives that could result in inappropriate or pressured advance care planning discussions or decisions. Commenters recommended that a measure recognize initiation, review, and updates to advance care planning information; respect a patient's decision to defer or decline; and address patient readiness, communication and language needs, disability-related communication support, caregiver or surrogate participation, cultural or religious considerations, and health literacy. Many commenters also described advance care planning as a longitudinal process and recommended that timing and frequency reflect diagnosis, prognosis, changes in health status or treatment, and patient preferences rather than require a comprehensive discussion during every outpatient encounter.

Many commenters raised questions about attribution and provider roles, noting that advance care planning is often initiated or maintained by clinicians with longitudinal responsibility for a patient, while some HOPD clinicians have episodic or procedure-focused encounters. Commenters recommended changes to measure specifications, including numerator and denominator definitions, qualifying advance care planning activities, unit of measurement, exclusions or exceptions, eligible clinicians, recognition of existing advance care planning information or discussions, and other technical rules. Several commenters also recommended clarifying facility and clinician accountability and tailoring responsibility to providers who can influence the relevant advance care planning processes.

Many commenters emphasized the need for advance care planning information to be available across inpatient, outpatient, physician, post-acute, hospice, and other care settings and cautioned against repeated questioning, duplicate or conflicting documentation, and redundant reporting. Many commenters also raised feasibility and implementation concerns involving EHR capabilities, structured and machine-readable data, data extraction, vendor development, workflow changes, staff training, testing, implementation time, and reporting burden. Recommendations included broader testing across vendors and outpatient settings, adequate lead time, phased or voluntary implementation in some circumstances, technical or implementation assistance, and recognition of existing information so that advance care planning information can be retrieved and used across settings.

Many commenters proposed alternative or complementary approaches to assess advance care planning beyond the presence of documentation, including patient-reported experience, shared decision-making, goal concordance, communication quality, and whether advance care planning information is current, accessible, actionable, understood by clinicians, and reflected in care and outcomes. A few commenters recommended that CMS examine whether measure performance differs across populations or providers facing barriers to advance care planning engagement, including populations experiencing financial or social risk, individuals with limited English proficiency, underserved communities, dual-eligible beneficiaries, rural providers, and safety-net hospitals. A commenter specifically recommended stratified analysis to identify whether patients with lower incomes or greater social risk receive comparable quality of care planning and caregiver engagement, while another recommended considering demographic data to identify disparities. Commenters who opposed adoption or recommended deferral cited concerns about the breadth of HOPD applicability, feasibility, burden, duplication, testing,

and whether documentation-based measurement would meaningfully assess advance care planning quality.

Response: We appreciate all the comments and interest in this topic. While we are not responding to specific comments in response to the RFI in this final rule, we believe that this input is valuable and will continue to take all concerns, comments, and suggestions into account for future development of measures related to advance care planning.

D. Updates to the Validation of Hospital Outpatient Quality Reporting Program Data

We refer readers to previous OPPS/ASC rulemaking [204] and 42 CFR 419.46(f) for our existing policies regarding data validation in the Hospital Outpatient Quality Reporting Program. We also refer readers to our outpatient data validation resources at *https://qualitynet.cms.gov/outpatient/data-management/data-validation/resources.*

In the CY 2027 OPPS/ASC proposed rule (91 FR 41962 through 41966), we proposed to include the validation of eCQM data in the Hospital Outpatient Quality Reporting Program's existing validation process as well as to streamline certain validation processes. In addition, we proposed to: (1) change the validation selection pool from 500 to up to 400 hospitals; (2) clarify application of the targeting criteria to eCQMs; (3) update the number of cases for chart-abstracted and eCQM validation; (4) include eCQM validation in the timing and submission of medical record requests; (5) align the submission quarters for chart-abstracted and eCQM validation; (6) establish an eCQM validation scoring method based on data accuracy; and (7) update the educational review process for validation results. We anticipated the cumulative impact of these proposals would reduce burden for hospitals while increasing the accuracy of data reported under the program to better facilitate beneficiary decision-making and hospital quality improvement efforts.

1. Electronic Clinical Quality Measure Data Validation

To include validation of eCQMs in the existing Hospital Outpatient Quality Reporting Program data validation process, we proposed that validation begin with each eCQM when there is a full year of data available (91 FR 41962). For example, hospitals are required to submit all four quarters of data for the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM beginning with data from the CY 2027 reporting period (86 FR 63837 through 63840); therefore, we proposed that validation for the STEMI eCQM would begin with data from the CY 2027 reporting period. Likewise, we proposed that validation for the Emergency Care Access and Timeliness (ECAT) eCQM would begin with data from the CY 2028 reporting period, which is the first year that submitting four quarters of data for this measure is mandatory (90 FR 53925 through 53934). We proposed that any future eCQMs adopted into the measure set would become eligible for validation after mandatory reporting of a full year of data is in effect, and information regarding the measures to be validated would be obtained from the CMS QualityNet website (or other CMS-designated website).

2. Changes to Selection Process for Hospital Outpatient Quality Reporting Program Validation

a. Validation Selection Pool

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74484 through 74485), we finalized an annual process for the Hospital Outpatient Quality Reporting Program of selecting a random sample of 450 hospitals for validation purposes and an additional 50 hospitals based on specific targeting criteria. Since this process was finalized, we have found that hospitals randomly selected for validation generally have high accuracy rates for chart-abstracted measures and believe the number of hospitals randomly selected for validation could be reduced without impacting our ability to assess the accuracy of hospital data. At the same time, we believe that increasing the number of hospitals selected for validation based on specific targeting criteria will help to ensure data accuracy by allowing a greater number of hospitals meeting specific targeting criteria to have their data submissions reviewed for accuracy.

Therefore, in the CY 2027 OPPS/ASC proposed rule (91 FR 41962), we proposed that, beginning with hospital selections for validation affecting the CY 2030 payment determination, up to 200 hospitals would be selected at random and up to 200 hospitals would be selected using targeting criteria, for a total of up to 400 hospitals selected for validation. As we have found consistently high agreement rates and relatively low variation among randomly selected hospitals, this change would reduce the total number of hospitals selected for validation each year from 500 to up to 400 hospitals, while maintaining a sufficiently reliable sample size. Since the total number of hospitals required to participate in validation each year would be fewer, this proposed change would also reduce overall burden for hospitals. Re-balancing the number of randomly selected hospitals compared to the number of hospitals selected by targeting criteria would also more effectively and efficiently direct validation program resources to ensure data accuracy. Beginning with validation affecting the CY 2030 payment determination, we would require any hospital selected for validation, either randomly or after meeting targeting criteria, to submit both chart-abstracted measure and eCQM data for validation. Under the current policy, hospitals selected for validation affecting the CY 2029 payment determination would continue to participate only in chart-abstracted measure validation as no eCQMs would yet be eligible for validation. Hospital selections for validation affecting the CY 2029 payment determination would continue under the existing policy. Additionally, hospitals selected for validation affecting the CY 2030 payment determination would only be required to submit eCQM data for validation when the relevant eCQM is required and eligible for validation for the applicable reporting period. This aligns with the validation process finalized for the Hospital Inpatient Quality Reporting Program, with which hospitals are familiar (85 FR 58946 through 58949). We proposed to update the codified policy at § 419.46(f)(3) to reflect this proposed change (91 FR 41962).

b. Targeting Criteria for Validation Selection Pool

We have previously established several targeting criteria set forth at § 419.46(f)(3)(i) through (v):

- The hospital fails the validation requirement that applies to the previous year's payment determination; or
- The hospital has an outlier value for a measure based on the data it submits.

[204] Existing validation policies were adopted for the Hospital Outpatient Quality Reporting Program in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72103 through 72106), CY 2012 OPPS/ASC final rule with comment period (76 FR 74484 through 74487), CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487), CY 2014 OPPS/ASC final rule with comment period (78 FR 75117), CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66966), CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443), CY 2021 OPPS/ASC final rule with comment period (85 FR 86185), CY 2022 OPPS/ASC final rule with comment period (86 FR 63870 through 63873), and CY 2023 OPPS/ASC final rule with comment period (87 FR 72115 through 72116).

An ''outlier value'' is a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals, and indicates a poor score; or

- Any hospital that has not been randomly selected for validation in any of the previous 3 years; or
- Any hospital that passed validation in the previous year but had a two-tailed confidence interval that included 75 percent; or
- Any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an extraordinary circumstance exception (ECE) for one or more quarters.

In the CY 2027 OPPS/ASC proposed rule (91 FR 41963), we proposed to apply the targeting criteria at § 419.46(f)(3)(i) through (v) to all measures eligible for validation in the Hospital Outpatient Quality Reporting Program, including but not limited to chart-abstracted measures and eCQMs.

3. Case Selection for Validation

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485 through 74486) and CY 2013 OPPS/ASC final rule with comment period (77 FR 68486), where we finalized that for each hospital selected through either random sampling or targeting criteria, we will validate up to 48 randomly selected patient cases (12 cases per quarter) from the total number of cases that the hospital successfully submitted to the CMS Clinical Data Warehouse via the Hospital Quality Reporting (HQR) system.

In the CY 2027 OPPS/ASC proposed rule (91 FR 41963 through 41964), we proposed to revise the number and distribution of cases selected for validation under the Hospital Outpatient Quality Reporting Program to ensure a balanced assessment across measure types. Specifically, we proposed to validate up to 32 randomly selected patient cases for each measure, starting with validation of CY 2027 data affecting the CY 2030 payment determination. For each chart-abstracted measure, cases would be submitted quarterly, with up to 8 cases validated per quarter. For each eCQM, up to 32 cases would be submitted annually, allowing validation of up to 8 cases from each quarter. Table 98 illustrates these proposed changes.

TABLE 98: PROPOSED CASE SELECTION FOR VALIDATION IMPACTING CY 2029 TO CY 2031 PAYMENT DETERMINATIONS

Payment Determination Year	Reporting Period Data	Measures Included in Validation	Number of Measures Validated	Number of Cases Validated
CY 2029	CY 2027	• Median Time from ED Arrival to ED Departure for Discharged ED Patients • Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival	2	48 cases under the current policy
CY 2030	CY 2027	• Median Time from ED Arrival to ED Departure for Discharged ED Patients • Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients Who Received Head CT or MRI Scan Interpretation Within 45 Minutes of Arrival • STEMI eCQM	3	Up to 96 cases under this proposal
CY 2031 (and subsequent years)	CY 2028 (and subsequent years)	• Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients Who Received Head CT or MRI Scan Interpretation Within 45 Minutes of Arrival • STEMI eCQM • ECAT eCQM	3	Up to 96 cases under this proposal

We discussed in the proposed rule that this approach could support a more balanced and representative assessment of data accuracy across both chart-abstracted measures and eCQMs, and that broadening the selection of cases would improve our ability to detect potential data inaccuracies and systemic reporting issues.

In the CY 2027 OPPS/ASC proposed rule (91 FR 41963 through 41964), we noted that all hospitals selected for validation purposes would receive a total of five medical record requests for complete supporting medical record documentation from CMS or its designated contractor: four quarterly requests containing randomly selected chart-abstracted cases and one annual request containing randomly selected eCQM cases. We refer readers to § 482.24(c) for a definition of what is expected in a medical record submitted for validation.

4. Timing and Electronic File Submission for Medical Records Requests

a. Chart-Abstracted Measures

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870 through 63871) and § 419.46(f)(1) for additional information on the use of electronic file submissions for chart-abstracted measure medical records requests and the time period for data validation, including the deadlines for submitting medical records to CMS. In the CY 2027 OPPS/ASC proposed rule (91 FR 41964), we did not propose any changes affecting the time period or deadlines for electronic file submission for chart-abstracted measures under our validation policy.

b. Electronic Clinical Quality Measures

In the CY 2027 OPPS/ASC proposed rule (91 FR 41964), we proposed to apply the same electronic file submissions policy to eCQM medical records requests in alignment with the chart-abstracted measures that hospitals are already familiar with. Upon written request by CMS or its contractor, a hospital would be required to submit portable document format (PDF) copies of medical records using direct electronic file submission via a CMS-approved secure file transmission process (currently, Unified File Management [UFM]/Managed File Transfer [MFT]). A hospital must submit the supporting medical record documentation to CMS or its contractor within 30 days of the date on the written request. We would continue to reimburse hospitals at $3.00 per chart, consistent with current reimbursement for electronic submissions of charts.

5. Submission Quarters

a. Background

Currently, hospitals selected for chart-abstracted validation are required to submit data from 2 years prior to the applicable CY payment determination year, consisting of validation quarter 1 (January 1 through March 31), validation quarter 2 (April 1 through June 30), validation quarter 3 (July 1 through September 30), and validation quarter 4 (October 1 through December 31) (80 FR 70524).

In the CY 2027 OPPS/ASC proposed rule (91 FR 41964 through 41965), we proposed that hospitals selected for eCQM validation for a given payment determination year would be required to submit data from the calendar year that is 3 years prior to the applicable payment determination year because eCQM data are reported annually rather than quarterly. A 3-year cycle allows sufficient time to complete sampling, medical record abstraction, confidence interval calculation, educational reviews, and quality assurance prior to payment determination.

To support the transition to a combined validation process for both chart-abstracted measures and eCQMs, we would shift the payment impact of validation from 2 years after the reporting period to 3 years after the reporting period. During this transition, the validation results for CY 2027 chart-abstracted data would affect both the CY 2029 and the CY 2030 payment determination, as detailed below.

b. Validation Affecting the CY 2029 Payment Determination

To maintain the continuity of annual validation activities while we shift to a 3-year cycle, CY 2027 chart-abstracted data would continue to be used for the CY 2029 payment determination under the existing 2-year cycle in accordance with existing policy for chart-abstracted measure validation. In other words, there will be no change from our current policy for the CY 2029 payment determination.

c. Validation Affecting the CY 2030 Payment Determination

For the CY 2030 payment determination, CY 2027 chart-abstracted data would be used again in combination with CY 2027 eCQM data for validation. That is, validation results for CY 2027 chart-abstracted data would impact both the CY 2029 and CY 2030 payment determinations. Table 99 illustrates our proposed changes, including a transition year, to align the validation for chart-abstracted and eCQM data.

TABLE 99: PROPOSED VALIDATION PROCESS FOR CY 2029 TO CY 2031 PAYMENT DETERMINATIONS

Payment Determination Year	Reporting Period Data	Data Type	Validation Cycle	Notes
CY 2029	CY 2027	Chart-abstracted	Current: 2-years between reporting period and payment determination	Continues current policy to maintain annual validation continuity.
CY 2030	CY 2027	Chart-abstracted and eCQM	Proposed: 3-years between reporting period and payment determination	Supports transition to combined validation process. CY 2027 chart-abstracted data are used again for CY 2030 payment. This overlap ensures no gap in annual validation activities during the transition.
CY 2031 (and subsequent years)	CY 2028 (and subsequent years)	Chart-abstracted and eCQM	Proposed: 3-years between reporting period and payment determination	Steady state begins after transition year.

For the transition year affecting the CY 2030 payment determination, we proposed a one-time modification of the hospital selection and targeting methodology such that hospitals selected for validation based on CY

2027 data, affecting the CY 2029 payment determination, would not be selected again, either randomly or through targeted selection, for validation of the same data affecting the CY 2030 payment determination (91 FR 41964 through 41965). For example, we would not automatically reselect a hospital that failed to meet the validation requirements for the CY 2029 payment determination under the targeting criterion at § 419.46(f)(3)(i) for validation affecting the CY 2030 payment determination. This approach is intended to eliminate the potential burden to hospitals that would have gone through the validation process for the CY 2029 payment determination while allowing validation activities to continue during the transition year.

d. Validation Affecting the CY 2031 Payment Determination and for Subsequent Years

As seen in Table 99, following the transition period, we would adopt a 3-year validation cycle, under which validation results for an annual reporting period would be applied to the applicable payment determination 3 years later. That is, beginning with CY 2028 chart-abstracted and eCQM data, validation results would impact the payment determination 3 years following the reporting period, which for CY 2028 reporting period data is the CY 2031 payment determination. Following the transition year, we would proceed with validation policies under the 3-year validation cycle, including the use of aligned data submission periods and the application of established hospital selection and targeting methodologies. We believe aligning the quarters of submission data used for both chart-abstracted measures and eCQM validation would allow hospitals selected for validation to more easily track and meet validation requirements.

6. Scoring Method

a. Chart-Abstracted Measures

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72103 through 72106), we finalized the calculation of validation scores under the Hospital Outpatient Quality Reporting Program using the upper bound of a 90 percent two-sided confidence interval with a 75 percent lower bound threshold level. In the CY 2027 OPPS/ASC proposed rule (91 FR 41965), we did not propose any changes to this threshold.

b. Electronic Clinical Quality Measures

In the CY 2027 OPPS/ASC proposed rule (91 FR 41965 through 41966), we proposed that eCQM validation scores would be determined using the same methodology currently used to score chart-abstracted measure validation, such that eCQM validation scoring would be based on the accuracy of eCQM data (the extent to which data abstracted for validation match the data submitted to CMS), beginning with CY 2027 eCQM data affecting the CY 2030 payment determination. Consistent with the data validation scoring threshold currently applied to chart-abstracted measures and codified at § 419.46(f)(2), a minimum score of 75 percent accuracy would be required for the hospital to pass the eCQM validation requirement. Applying an upper bound of a 90 percent two-sided confidence interval with a 75 percent lower bound threshold level is appropriate because it accounts for sampling variability, reflects a reasonable standard of data accuracy, and aligns with existing validation thresholds for chart-abstracted measures while allowing for legitimate differences in hospital data implementation.

To incentivize the timely and complete submission of requested medical records, we proposed that any missing medical records would be treated as mismatches, beginning with the validation of the CY 2027 eCQM data affecting the CY 2030 payment determination and for subsequent years. Because mismatches would count against the agreement rate, treating any missing medical records as mismatches would encourage submission of complete medical records and disincentivize selective medical record submissions. We note that this approach is consistent with our existing policy for chart-abstracted measure validation, under which missing records are treated as mismatches.

Using this approach, at the end of each calendar year, we would compute an eCQM confidence interval using the results of all four quarters to determine the final eCQM validation score. Hospital-submitted eCQM data and the submitted medical records would be used to compute an agreement rate and the associated confidence interval around the score. The upper bound of the 90 percent two-sided confidence interval would be used as the final eCQM validation score for the selected hospital. We would then compare this final validation score to the 75 percent accuracy threshold to determine whether the hospital meets the eCQM validation requirement. Data validation scoring is at the measure level, not the individual data element level. If CMS or its contractor does not reach the same outcome as the hospital's original submission, then the case may be considered a mismatch. We selected 75 percent as the threshold for the validation score because we believe this level is reasonable to reflect accurate performance, but still realistic for hospitals to achieve. It also allows for legitimate differences in how hospitals implement measures and map their data. We note that we adopted the same eCQM scoring method for the Hospital Inpatient Quality Reporting Program (89 FR 69574 through 69577).

c. Annual Payment Update

Beginning with the validation of CY 2027 data affecting the CY 2030 payment determination, hospitals would receive two validation scores: one for chart-abstracted measure data and one for eCQM data. As we finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66873 through 66874), a hospital that does not meet validation requirements will not receive the full annual payment update under the OPPS. Therefore, if a hospital does not meet either chart-abstracted validation requirements or eCQM validation requirements, we proposed the hospital would not receive the full OPPS annual payment update. In other words, to be eligible for a full annual payment update, provided all other Hospital Outpatient Quality Reporting Program requirements are met, a hospital selected for validation would need to attain at least a 75 percent validation score for chart-abstracted measure validation and at least a 75 percent validation score for eCQM data validation. In the CY 2027 OPPS/ASC proposed rule (91 FR 41965 through 41966), we also proposed to codify this policy by updating the regulatory text at § 419.46(f)(2).

7. Educational Review Process

a. Chart-Abstracted Measures

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443) and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86185) where we finalized and codified a policy to formalize the Educational Review Process for Chart-Abstracted Measures, including Validation Score Review and Correction. We also refer readers to § 419.46(f)(4) for our policies regarding the educational review process, including validation score review and correction, for chart-abstracted measures. As described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443), for CY 2020 and subsequent years, if a hospital requests an educational review

for any of the first three quarters of validation and this review yields incorrect CMS validation results for chart-abstracted measures, the corrected quarterly score will be used to compute the final confidence interval.

In the CY 2027 OPPS/ASC proposed rule (91 FR 41966), we proposed to revise our policy to allow the results of educational reviews for all four quarters of chart-abstracted measure validation to be reflected in the final validation score prior to the calculation of the confidence interval, beginning with the CY 2030 payment determination. Under our current policy, due to time constraints, educational reviews for the final quarter of data are not completed in time to affect validation results, and hospitals must use the reconsideration process. Under the proposal to extend the validation timeline from a 2-year cycle to a 3-year cycle, sufficient time would become available to complete educational reviews for all four quarters. As a result, any corrected scores from educational reviews across all quarters would be used in calculating the final confidence interval.

b. Electronic Clinical Quality Measures

In the CY 2027 OPPS/ASC proposed rule (91 FR 41966), we proposed extending the educational review process established for chart-abstracted measure validation to eCQM validation beginning with validation affecting the CY 2030 payment determination (that is, starting with validated data from CY 2027). We believe that expanding the educational review process to include eCQMs would allow hospitals to better understand the processes and data for eCQM validation.

Hospitals may request an educational review if they believe they have been scored incorrectly or if they have questions about their validation of eCQMs. A hospital would have 30 calendar days from the date the validation results are made available to contact CMS' Validation Support Contractor requesting a written explanation of its performance. Because hospitals receive eCQM validation results on an annual basis, they would have the opportunity to request an educational review once annually. Upon receipt of an educational review request, we would review the requested data elements and written justifications provided by the hospital. We would also provide the results of the eCQM validation educational review to the requesting hospital, including our findings of whether the scores were correct or incorrect, through a CMS-approved secure file transmission process (currently, UFM/MFT). If the results of a validation educational review determine that the original validation score was incorrect, the corrected score would be used to compute the final validation score and confidence interval at the end of each calendar year.

In the CY 2027 OPPS/ASC proposed rule (91 FR 41966), we proposed to codify this policy by revising § 419.46(f)(4) to include eCQMs. As proposed, § 419.46(f)(4) would indicate that hospitals selected for validation may request an educational review within 30 calendar days from the date validation results are made available. Under the proposed revisions to § 419.46(f)(4), if the results of an educational review indicate one or more measures were incorrectly scored, the corrected validation score would be used to compute the final validation score used for payment determination. We refer readers to section XXIV.A. of this final rule with comment period for more information on the burden estimates associated with these proposals.

We invited public comment on these validation of Hospital Outpatient Quality Reporting Program data proposals, including eCQM validation into the existing validation processes for chart-abstracted measures, reducing the validation selection pool from 500 to up to 400 hospitals, applying targeting criteria to eCQMs, updating the number of cases for chart-abstracted and eCQM validation, transitioning from a 2-year to a 3-year cycle between the reporting period and the payment determination year to align submission quarters, extending the electronic file submissions policy to eCQM medical records requests, establishing the eCQM validation scoring method, and expanding the educational review process.

Comments Regarding Electronic Clinical Quality Measure Data Validation

Comment: Many commenters supported efforts to reduce reporting burden and streamline Hospital Outpatient Quality Reporting Program requirements to improve facility accountability and the reliability of submitted data, especially as CMS continues to expand the use of electronic measures. Some commenters appreciated CMS' efforts to use consistent definitions, confidence intervals, sampling methodologies, and reconsideration procedures across inpatient and outpatient programs to reduce administrative complexity, promote greater consistency in program oversight, and allow hospitals to focus resources on improving data quality and patient care rather than navigating varying validation requirements.

Response: We thank commenters for their support and agree that streamlining our requirements and aligning them across programs reduces burden while promoting data accuracy and reliability across measure types.

Comment: A commenter stated that the administrative workload associated with eCQM reporting and validation can be substantial, particularly for small and rural facilities with limited staff to support internal compliance, information technology, data analytics, or quality reporting, and recommended that CMS should provide special support for these facilities.

Response: We understand concerns regarding the impact on hospitals with limited health IT resources available. We acknowledge that introducing eCQM validation affects burden; however, we believe the benefits of ensuring that hospitals report accurate data outweigh the increase in burden as these data are made publicly available for consumer use. We refer readers to section XXIV.A. of this final rule with comment period for more information on the burden estimates associated with our validation policies. We have sought to reduce overall burden by reducing the total number of hospitals selected and focusing on a more targeted selection of hospitals via our targeting criteria.

Comment: A commenter suggested expanding the scope of data validation to include claims-based measures as the commenter stated CMS' existing audit processes are focused on improper payment identification rather than measure validity.

Response: We appreciate the commenter's recommendation. Our validation processes relate to assessing the accuracy of quality data that hospitals themselves abstract, calculate, or submit to CMS based on agreement rate. For claims-based measures, we can retrieve necessary information to calculate the quality measures from our own claims databases. Medicare claims are subject to audit for improper payment, system edits, and other program integrity activities to help ensure claims data are supported, compliant, and suitable for payment and secondary uses including quality measure calculations. Additionally, all our measures, including claims-based measures, undergo the rigorous measure development lifecycle outlined at the CMS Measures Management System website,[205] which includes measure

[205] Centers for Medicare & Medicaid Services. Blueprint Measure Lifecycle. Measures Management System. Available at *https://*

testing and reliability analysis which evaluates whether a measure is repeatable and stable.

We are finalizing the proposal to begin validating each eCQM in the Hospital Outpatient Quality Reporting Program when there is a full year of data available for that measure.

Comments Regarding Changes to Selection Process for Hospital Outpatient Quality Reporting Program Validation

Comment: Many commenters supported reducing the hospital selection pool from 500 to up to 400 hospitals, of which up to 200 hospitals are randomly selected and up to 200 hospitals are selected based on targeting criteria. Several commenters stated that the change to more targeted selection would help lower-performing hospitals improve based on targeted interventions, while allowing already higher-performing hospitals to continue performing well without additional burden.

Response: We thank commenters for their support and agree that rebalancing the number of hospitals selected by targeting criteria would more effectively and efficiently direct validation program resources to assessing agreement rates for hospitals that evidence data accuracy concerns.

Comment: A commenter expressed concern that a smaller overall validation sample would not provide the same level of confidence in program-wide data quality and recommended that CMS ensure that there are no unintended consequences.

Response: We recognize that sampling a smaller number of hospitals increases the estimate of variability for the overall data. Since the overall performance on chart-abstracted measures is consistently high across hospitals, there is little true variation to detect for those measures, and confidence remains high regarding overall data quality for chart-abstracted reporting. As eCQMs are newer to the validation process, we have less historical experience to draw upon; this is one of the reasons we believe it is important to begin validating eCQM data now, so that we can build a similar evidentiary basis over time. In determining the number of hospitals eligible for selection for validation, we seek to balance burden with a validation approach that assesses data quality across both measure types. Our many years of experience validating hospital measure data in the Hospital Outpatient Quality Reporting Program, Hospital Inpatient Quality Reporting Program, and Hospital-Acquired Condition Reduction Program, including observed validation results and failure rates based on agreement rates, demonstrates that a larger selection pool is not necessary. Additionally, retaining the selection pool at its current size of up to 500 hospitals would yield only a marginal improvement in the precision of our population-level confidence estimate, while placing additional administrative burden on approximately 100 more hospitals each year. Consistent with the statistical principle underlying our approach to Hospital Inpatient Quality Reporting Program sample sizing, the precision gained from increasing a sample size beyond a certain point diminishes relative to the administrative burden of doing so. We believe the pool of up to 400 hospitals appropriately balances maintaining robust program-wide confidence with minimizing unnecessary burden on additional hospitals.

We will continue to monitor the number of hospitals passing validation and if the pass rate falls to a level where we can no longer be confident in the agreement rates of hospitals participating in the Hospital Outpatient Quality Reporting Program, we will address this issue in future rulemaking.

Comment: A few commenters did not support the requirement that any hospital selected for validation must submit both chart-abstracted and eCQM data as this could increase administrative burden on health systems. Instead, a commenter recommended limiting the audit of hospitals selected under targeted criteria to the specific data modality that triggered the selection.

Response: We interpret these comments to mean that commenters are concerned about the burden of submitting data required to validate both eCQMs and chart-abstracted measures. While there may be some instances of increased burden for specific hospitals, we disagree with the commenters that this approach is more burdensome for the majority of hospitals. Requiring selected hospitals to submit documentation for both measure types allows us to maintain oversight of data quality across the full range of measures subject to validation and helps ensure that the continued expansion of eCQMs in the measure set of the Hospital Outpatient Quality Reporting Program does not result in reduced attention to the accuracy and reliability of chart-abstracted data. While our proposed policy would add the requirement for selected hospitals to submit eCQMs in addition to chart-abstracted measures, the total number of validated measures remains low as chart-abstracted measures have been phased out and eCQMs are phased in. We note in section XIV. of this final rule with comment period, we are removing the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure which, while not validated, will reduce hospital burden. After this removal, there will be one remaining chart-abstracted measure in the Hospital Outpatient Quality Reporting Program, the Head Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival measure.

We are finalizing the proposal to update the validation selection pool and application of existing targeting criteria to eCQMs.

Comments Regarding Case Selection for Validation

Comment: A few commenters supported reducing the quarterly validation requirements for chart-abstracted measures from 12 cases and validating up to 8 cases per measure to accommodate validation of both chart-abstracted measures and eCQMs.

Response: We thank commenters for their support and agree that the change promotes data accuracy while balancing burden. As discussed further in our response to comments below, based on the results of a power analysis, we are finalizing an even greater reduction—up to 7 cases per quarter (28 cases annually) per applicable measure, rather than the up to 8 cases per quarter (32 cases annually) that was proposed.

Comment: A commenter opposed establishing a validation sample size of up to 32 cases per measure annually due to the commenter's concern regarding the increase in burden as new measures are added to the program. Instead, the commenter advised implementing a fixed, aggregate hospital-level cap across all measures combined to maintain rigorous, statistically sound audit oversight without placing increasing strain on health care operations.

Response: We appreciate the commenter's concern regarding the cumulative burden associated with validating an increasing number of measures over time. We note that one of the goals of the Hospital Outpatient Quality Reporting Program is to move forward in the least burdensome manner possible, while maintaining a parsimonious set of the most

mmshub.cms.gov/blueprint-measure-lifecycle-overview.

meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. We carefully evaluate each measure proposed for adoption to ensure that its benefits outweigh the cumulative burden of requirements across the program, including data validation policies.

In light of this comment, and consistent with a power analysis conducted to evaluate whether the proposed sample size could be reduced without compromising validation accuracy, we are finalizing a sample size of up to 28 cases annually per applicable measure (up to 7 cases per quarter), rather than the up to 32 cases per measure (up to 8 cases per quarter) that was proposed. This represents a 12.5 percent reduction in the annual case burden relative to our proposal. Our analysis found that a sample size of 28 cases produced agreement with historical hospital classifications of 98.4 percent, with a false-pass rate of 0.1 percent and a false-fail rate of 1.6 percent, indicating that this reduced sample size continues to provide a reliable and statistically sound basis for validation while reducing burden on hospitals. We also note that our analysis found that approximately 89.9 percent of requested cases were available for sampling in the modeled scenario; we will continue to monitor case availability as we implement this change and will address any issues in future rulemaking if warranted.

We decline to adopt the commenter's alternative recommendation of a fixed, aggregate hospital-level cap across all measures combined. While our validation scoring methodology computes a confidence interval using the results from a hospital's applicable measures combined at the hospital level, we continue to believe that establishing a minimum number of cases per measure, rather than a single aggregate cap, better ensures that each individual measure is adequately represented within that combined sample, particularly as additional eCQMs become eligible for validation over time. A fixed aggregate cap could result in a disproportionately small number of cases being drawn from any individual measure, which would reduce our ability to detect measure-specific reporting or specification issues even though the overall hospital-level score remains statistically sound. We will continue to monitor the cumulative impact of this policy as new measures are added to the program and will consider further refinements in future rulemaking as appropriate.

Comments Regarding the Timing and Electronic File Submission for Medical Records Requests

Comment: A few commenters supported applying the same file submission process to eCQMs as chart-abstracted measures as it facilitates administrative simplicity.

Response: We thank commenters for their support and agree that this alignment creates simplicity.

Comment: A commenter stated that reimbursement of $3.00 per chart does not approximate the cost of retrieving, reviewing, redacting, and transmitting a complete record.

Response: We understand the commenter's concern that $3.00 per chart may not cover the full time and materials associated with record submission. We note that this reimbursement is consistent with the existing reimbursement rates for submitting charts for validation in the Hospital Outpatient Quality Reporting Program (86 FR 63871) as well as the reimbursement rate across other quality reporting programs, such as the Hospital Inpatient Quality Reporting Program (78 FR 50956) and Inpatient Psychiatric Facilities Quality Reporting Program (88 FR 51143). We will continue to consider the burden associated with medical record submission as we evaluate and refine our validation policies.

We are finalizing the same file submission process for eCQMs as chart-abstracted measures.

Comments Regarding Submission Quarters

Comment: A few commenters supported aligning submission quarters across both measure types by moving to a 3-year cycle as this alignment should make it easier for hospitals to track their validation activities and allow CMS sufficient time to complete the validation and review process.

Response: We thank commenters for their support and agree that this alignment adds simplicity while allowing sufficient time to complete validation activities.

Comment: A commenter stated that moving from a 2-year to a 3-year cycle between the reporting period and payment determination appears unnecessary, particularly as CMS continues to transition toward more eCQMs.

Response: The shift to a 3-year cycle between the reporting period and payment determination is operationally necessary as we adopt eCQMs. Since eCQMs are reported on an annual basis, a 3-year cycle allows sufficient time to complete sampling, medical record abstraction, confidence interval calculation, and educational reviews following the data reporting deadline. As the annual eCQM submission deadline for the Hospital Outpatient Quality Reporting Program is May 15, there is not enough time to request and receive records from selected hospitals, validate an entire year's worth of eCQM data, and calculate the confidence interval by August when we select hospitals for the next payment determination's validation cycle. By shifting to a 3-year cycle, we can effectively include eCQMs and provide an educational review opportunity for eCQMs and the last quarter of chart-abstracted measures. Currently, if a hospital's Q4 educational review determines that a record was incorrectly scored, there is not sufficient time to include that corrected score into the end-of-year confidence interval calculation before the calculation must be finalized for payment determination. As we further leverage Fast Healthcare Interoperability Resources® (FHIR®) [206] for eCQMs, we will consider opportunities to expedite the data validation cycle in the future.

Comment: A commenter supported CMS' effort to reduce administrative burden by exempting hospitals for validation from being reselected within the subsequent year but believed many hospitals would prefer the possibility of consecutive year selection rather than having a single set of validation results place their annual payment update at risk across multiple payment determinations. Another commenter stated that applying CY 2029 validation findings for chart-abstracted measures to CY 2030 validation findings creates a double jeopardy concern for a single year's validation results.

Response: We interpret these comments to mean the commenters are concerned about CY 2027 chart-abstracted data validation impacting their annual payment update for CY 2029 and CY 2030. We wish to clarify that a hospital would not be validated again for the CY 2030 payment determination if they were already selected for CY 2029 payment determination data validation so that validation findings of CY 2027 chart-abstracted data would not affect more than one year's payment determination.

Comment: A commenter asked CMS to provide a clear explanation of how hospitals selected during the transition year will be treated. Another commenter asked CMS to ensure that the criteria

[206] FHIR® is the registered trademark of Health Level Seven International (HL7), and its use does not constitute endorsement by HL7.

used to select hospitals for eCQM validation are transparent, consistently applied, and clearly communicated in advance.

Response: For the transition year (that is, validation of CY 2027 data for the CY 2030 payment determination), up to 200 hospitals would be randomly selected and up to 200 hospitals would be selected using the targeting criteria at § 419.46(f)(3)(i) through (v), but only if the hospital did not participate in validation affecting the CY 2029 payment determination. In other words, all hospitals selected for validation affecting the CY 2029 payment determination would be excluded from reselection for validation affecting the CY 2030 payment determination to avoid validating the same CY 2027 chart-abstracted data over again. After the transition year affecting the CY 2030 payment determination, up to 200 hospitals would be randomly selected and up to 200 hospitals would be selected using the targeting criteria at § 419.46(f)(3)(i) through (v).

We are finalizing the transition from validation results affecting payment 2 years after the reporting period to 3 years after the reporting period beginning with the CY 2030 payment determination.

Comments Regarding the Scoring Method

Comment: A few commenters supported applying the same scoring methodology process to eCQMs as chart-abstracted measures as it balances administrative simplicity while acknowledging that eCQMs and the data that inform them are different in nature from chart-abstracted measures.

Response: We thank commenters for their support and agree that this alignment creates simplicity.

Comment: A commenter suggested shifting the focus of assessing the validity of the data elements to evaluating whether the level of data accuracy is sufficient for a measure to produce valid results. They stated that a minimum threshold at a 75 percent level of data accuracy may not result in a measure with either reasonable validity or reliability, and the public and the provider community need a higher level of assurance that the measure results reflect the quality of care of a facility as opposed to the accuracy of a number of data elements. A commenter asked for clarity on which record elements CMS will use to adjudicate a match.

Response: We confirm that data validation scoring is at the measure level as the commenter recommends, not the individual data element level. While individual data elements are assessed during the data validation process to confirm that a clinical event actually occurred, was documented appropriately in the source records, was interpreted correctly, and was mapped correctly into reporting fields, the validation score for the measure reflects whether the CMS validation process obtained the same measure outcome as the hospital's original submission. If the CMS validation process does not obtain the same measure outcome, then the case may be considered a mismatch. Applying an upper bound of a 90 percent two-sided confidence interval with a 75 percent lower bound threshold level accounts for sampling variability, reflects a reasonable standard of data accuracy, and aligns with existing validation thresholds for chart-abstracted measures while allowing for legitimate differences in hospital data implementation. However, we will consider increasing the threshold in future rulemaking as hospitals gain further experience with eCQM reporting over time.

Comment: Many commenters supported validation overall but recommended modifications to the validation processes to include eCQMs. Several commenters recommended validating eCQMs after one or two full years of mandatory reporting of data or providing an initial reporting-only year as a phased implementation to provide health systems with the necessary operational runway to establish, test, and stabilize electronic data extraction workflows before being subjected to formal audits and financial penalties. If CMS did a reporting-only year as recommended, commenters also suggested that CMS conduct targeted validation activities. These commenters indicated that results from an initial reporting-only year could provide hospitals with educational feedback regarding identified issues to allow hospitals to identify documentation deficiencies, data abstraction concerns, measure logic inconsistencies, and submission errors and better ensure that validation results accurately reflect performance rather than implementation challenges. A commenter emphasized that clear communication regarding expectations, common validation errors, and areas requiring corrective action will improve reporting accuracy and help ensure validation activities function as a quality improvement tool rather than solely a compliance exercise.

Many commenters expressed concern with beginning validation with CY 2027 reporting period data for the STEMI eCQM due to issues in accurately identifying patients in the numerator and denominator and concerns that the current measure logic is not designed well for electronic data capture. Several commenters stated that the two denominator exceptions for the CY 2026 reporting period are helpful, but challenging to implement, which further complicates efforts to improve accuracy of STEMI data capture. A few commenters asked CMS to ensure that validation methodologies adequately account for the complexity of emergency cardiovascular care workflows, including data originating from emergency medical service systems, transferring facilities, emergency departments, and cardiac catheterization laboratories.

Several commenters who were concerned about beginning validation of the STEMI eCQM with CY 2027 reporting period data also supported a reporting-only period or delaying scoring until electronic capture of STEMI is mature. Another commenter recommended delaying validation activities until hospitals have completed at least one full reporting cycle using the revised STEMI eCQM specifications.

Response: We appreciate commenters raising these concerns and sharing their recommendations. We agree with commenters that delaying the timeline for eCQM validation and providing an opportunity for educational review would allow hospitals to gain experience with measure requirements and identify deficiencies before validation scores affect payment. We also recognize that STEMI care, by its nature, is fast-moving and frequently spans multiple clinicians and care settings, including the emergency department, the cardiac catheterization laboratory, and interpreting cardiology services, which can present documentation and systems integration challenges. We believe the measure is appropriately designed for electronic capture as the eCQM is endorsed by the consensus-based entity [207] and underwent the rigorous measure development lifecycle outlined at the CMS Measures Management System website,[208] to ensure the measure is precisely specified, feasible, valid, and reliable. However, we acknowledge that the STEMI eCQM specifications were

[207] Partnership for Quality Measurement. Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED). Available at *https://p4qm.org/measures/3613e.*

[208] Centers for Medicare & Medicaid Services. Blueprint Measure Lifecycle. Measures Management System. Available at *https://mmshub.cms.gov/blueprint-measure-lifecycle-overview.*

recently revised, and we agree with commenters that payment penalties associated with validation scores should be delayed for the STEMI eCQM as initial scores may reflect challenges with implementing recent measure updates rather than the true accuracy of hospital STEMI eCQM submissions.

Based on commenter concerns about the STEMI eCQM and data issues during the first year of mandatory implementation of any eCQM, we are finalizing the data validation policy with a modification to delay payment penalties associated with validation scores until an eCQM has been mandatory in the program for one year of reporting. During the first full year of mandatory reporting, validation scores will only be used to provide selected hospitals with an opportunity for educational review, and payment penalties will only be assessed if a hospital does not submit requested records. If a hospital does not submit at least 75 percent of the requested records for the applicable eCQM under validation, the hospital will fail validation even during this unscored period. This modification allows at least one full reporting cycle using the revised STEMI eCQM specifications before a payment impact and provides an opportunity for educational feedback to identify and resolve errors before validation score results may affect payment.

As an example of how the finalized policy will be applied, the STEMI eCQM validation for the CY 2027 reporting period impacting the CY 2030 payment determination will serve as an educational review opportunity, with a payment penalty only for failure to submit at least 75 percent of the requested records. For the CY 2028 reporting period impacting the CY 2031 payment determination, payment penalties for the STEMI eCQM validation will be based on attaining at least a 75 percent validation score for eCQM data validation.

Comment: Several commenters expressed that eCQM performance and reporting are heavily dependent upon EHR configuration, vendor programming, data mapping, and interoperability among health information systems. These commenters stated that this means CMS should ensure that validation findings appropriately distinguish hospital reporting issues from technology-related discrepancies that may be outside a hospital's direct control, particularly as CMS moves towards automated and FHIR®-based measurement.

Specifically, a few commenters did not support treating missing or flawed medical records as mismatches, stating that eCQM discrepancies often stem from vendor specification updates, structured data mapping, or electronic file transmission protocols, which would unfairly penalize facilities for circumstances unrelated to actual measure accuracy. A commenter recommended that CMS instead establish an eCQM-specific validation scoring framework that accommodates electronic data architecture nuances and provide a technical remediation window prior to impacting annual payment determinations. Another commenter encouraged CMS to consider alternative approaches, including a grace period, an exception process for circumstances outside a hospital's control, or, in the case of unavailable records, a separate classification that does not automatically equate unavailable records with measure inaccuracy.

Response: We understand that hospitals rely on measure developers and EHR vendors for eCQM reporting. However, we do not agree that records unavailable for validation should be excluded from the calculation of the validation score. The purpose of validation is to assess whether the CMS validation process obtains the same measure outcomes as the hospital's original submission. If a record is not received or does not contain the necessary information, then we cannot determine that the reported result agrees with the medical records, so it causes a mismatch. Yet, we recognize that data mapping and data quality issues may arise with eCQM implementation. The 75 percent scoring threshold is intended to account for sampling variability and reasonable differences in hospital data implementation while maintaining a reasonable standard for data accuracy. Our modification to delay any payment penalties associated with validation scores until an eCQM has been mandatory in the program for one year of reporting also allows additional time for hospitals and their vendors to resolve data reporting issues.

After consideration of the public comments we received, we are finalizing our proposal that a minimum score of 75 percent accuracy will be required for the hospital to pass the eCQM validation requirement with a modification to delay the payment penalties associated with the eCQM validation score until the second full year an eCQM has been mandatory in the program. During the first full year of mandatory reporting, validation scores will only be used to provide selected hospitals with an opportunity for educational review, and payment penalties will only be assessed if a hospital does not submit requested records. If a hospital does not submit at least 75 percent of the requested records for the applicable eCQM under validation, the hospital will fail validation even during this unscored period.

Comments Regarding the Educational Review Process

Comment: A few commenters supported expanding the educational review process to eCQMs and allowing educational results from all four quarters of chart-abstracted measure validation to be included in the final validation scores. These commenters stated that hospitals should have a meaningful opportunity to identify and resolve questions or errors in their validation results before those results affect payment.

Response: We thank commenters for their support and agree that educational reviews are a meaningful opportunity to address questions and errors in validation results.

We are finalizing the educational review process to include the last quarter of chart-abstracted measures and to integrate eCQMs into the final validation scores.

Table 100 summarizes our finalized validation process for CY 2029 to CY 2032 payment determinations, which includes a modification to validate up to 28 cases annually per measure (up to 7 cases per quarter) and a modification to begin scoring eCQM validation based on data accuracy after one full year of mandatory reporting in the Hospital Outpatient Quality Reporting Program.

TABLE 100: FINALIZED VALIDATION PROCESS FOR CY 2029 TO CY 2032 PAYMENT DETERMINATIONS

Payment Determination	Reporting Period Data	Measure Type	Validation Cycle	Annual Number of Cases Validated	Notes
CY 2029	CY 2027	Chart-Abstracted	Current 2-year cycle	48 cases under current policy	Continues current policy - no change from existing validation process
CY 2030	CY 2027	Chart-Abstracted and eCQM (STEMI)	Finalized 3-year cycle	Up to 84 cases (28 cases per measure × 3 measures)	Hospitals selected for validation affecting the CY 2029 payment determination are excluded from reselection for validation affecting the CY 2030 payment determination, to avoid validating the same CY 2027 data twice. STEMI eCQM validation results serve as an educational review opportunity only during this transition year (validation score will not result in a payment penalty).**
CY 2031	CY 2028	Chart-Abstracted and eCQM (STEMI, ECAT)	Finalized 3-year cycle	Up to 84* cases (28 cases per measure × 3* measures)	Transition to 3-year cycle complete; STEMI eCQM validation scoring based on data accuracy and potential impacts to payment begins; ECAT eCQM validation serves as an educational review opportunity only (validation score will not result in a payment penalty).**
CY 2032 (and subsequent years)	CY 2029 (and subsequent years)	Chart-Abstracted and eCQM (STEMI, ECAT)	Finalized 3-year cycle	Up to 84* cases (28 cases per measure × 3* measures)	ECAT eCQM validation scoring based on data accuracy and potential impacts to payment begins.**

*Number of cases and measures for subsequent years will correspond to the sum of the number of chart-abstracted and eCQM measures subject to the validation process for the applicable reporting and payment periods, with a total of up to 28 cases per measure.

**As new eCQMs are added to the program, validation results will serve as an educational review opportunity only for the first mandatory reporting period, and scoring based on data accuracy will begin with the eCQM's second mandatory reporting period. Submission of at least 75 percent of requested medical records is required for the educational review opportunity in addition to when validation with scoring based on data accuracy begins.

E. Updates to the Hospital Outpatient Quality Reporting Program Validation Reconsiderations and Appeals Procedures

1. Reconsiderations and Appeals

We refer readers to § 419.46(g) for our reconsideration and appeals procedures. Under our existing requirements at § 419.46(g)(2)(vii), hospitals submitting reconsideration requests are required to submit a copy of all materials that the hospital submitted to comply with the requirements of the affected payment determination year. In the CY 2022 OPPS/ASC final rule with comment period, we finalized a requirement for hospitals to submit only electronic files rather than paper copies of medical records for validation of chart-abstracted measures, beginning with validation affecting the CY 2024 payment determination and for subsequent years (86 FR 63871).

2. Removal of the Re-Submission of Supporting Medical Documentation for Validation Reconsideration Requests

With the transition to all electronic submission of copies of medical records for Hospital Outpatient Quality Reporting Program data validation, the current reconsideration requirement to resubmit records used for validation results in a validation-related reconsideration request is no longer necessary and creates duplicative files

and administrative burden. We note that the Hospital Inpatient Quality Reporting Program finalized a policy in the FY 2025 IPPS/LTCH PPS final rule with comment period to remove the requirement to resubmit medical records as part of their request for reconsideration of a validation determination beginning with CY 2023 discharges affecting the FY 2026 payment determination (89 FR 69577).

In the CY 2027 OPPS/ASC proposed rule (91 FR 41966 through 41967), we proposed to revise existing § 419.46(g)(2)(vii) and (viii) of our regulations to no longer require hospitals to resubmit materials previously submitted to CMS for validation reconsideration requests, unless specifically requested by CMS, and to require only that the hospital provide any evidence supporting its validation reconsideration request. Under this proposal, hospitals that need to submit a revised medical record may still do so, but those hospitals that would otherwise be submitting copies of previously submitted records would no longer be required to submit them. Removing resubmission of medical documentation as a requirement for validation reconsideration would reduce administrative burden for most hospitals that do not have revised records to submit, as well as for CMS to collect and track medical records that are already available. Please refer to section XXIV.A.5. of this final rule with comment period for more information on the burden estimates associated with this proposed removal.

We invited public comment on this proposal to remove the requirement for hospitals to resubmit medical documentation as part of their request for reconsideration of validation, beginning with data from the CY 2026 reporting period affecting the CY 2028 payment determination. We also proposed to codify this policy by updating the regulatory text at § 419.46(g).

Comment: Many commenters supported the removal of the requirement for hospitals to resubmit medical documentation as part of their request for reconsideration of validation as part of CMS' efforts to streamline and modernize requirements. Several commenters stated that with the transition to electronic medical record submission and CMS' existing access to these records, the resubmission requirement imposes unnecessary administrative burden without providing meaningful programmatic value. A few commenters remarked that the proposal preserves hospitals' ability to submit additional information relevant to a reconsideration request when necessary. A commenter supported aligning the Hospital Outpatient Quality Reporting Program's policies with established Hospital Inpatient Quality Reporting Program procedures.

Response: We thank commenters for their support and agree that resubmission is no longer necessary and creates duplicative files and work. Removing this requirement would align with the Hospital Inpatient Quality Reporting Program reconsideration processes.

After consideration of the public comments we received, we are finalizing the removal of the reconsideration requirement to resubmit records used for validation results in a validation-related reconsideration request as proposed.

F. Payment Reduction for Hospitals That Fail To Meet the Hospital Outpatient Quality Reporting (OQR) Program Requirements for the CY 2027 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 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 this final rule with comment period, 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 OPPS/ASC final rule with comment period, we multiplied the final full national unadjusted payment

rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final rule with comment period reporting ratio of 0.980 (74 FR 60642).

We note that the only difference in the calculation for the full conversion factor and the calculation for the reduced conversion factor is that the full conversion factor uses the full OPD update, and the reduced conversion factor uses the reduced OPD update. The baseline OPPS conversion factor calculation is the same since all other adjustments would be applied to both conversion factor calculations. Therefore, our standard approach of calculating the reporting ratio as described earlier in this section is equivalent to dividing the reduced OPD update factor by that of the full OPD update factor. In other words:

Full Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor)

Reduced Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor − 0.02)

Reporting Ratio = Reduced Conversion Factor/Full Conversion Factor

Which is equivalent to:

Reporting Ratio = (1 + OPD Update factor − 0.02)/(1 + OPD update factor)

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment, the multiple procedure adjustment, the interrupted procedure adjustment, the rural sole community hospital adjustment, and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of the CY 2023 OPPS/ASC proposed rule (87 FR 44533 through 44534).

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2027

We proposed to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2027 annual payment update factor. For the CY 2027 OPPS/ASC proposed rule, the proposed reporting ratio was 0.9805, which, when multiplied by the proposed full conversion factor of $102.004, 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 $100.015. We proposed to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. We proposed to continue to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of ''J1,'' ''J2,'' ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' and ''U'' (other than New Technology APCs to which we have proposed status indicator assignments of ''S'' and ''T''). We proposed to continue to exclude services paid under New Technology APCs. We proposed to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also proposed to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we proposed to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. In addition to our proposal to implement the policy through the use of a reporting ratio, we proposed to continue to calculate the reporting ratio to four decimals.

We did not receive public comments on this provision and are finalizing as proposed. For this final rule with comment period, the final reporting ratio is 0.9804, which, when multiplied by the final full conversion factor of $ 99.970, equals a final conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $98.011. We are finalizing our proposal to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. We are also finalizing our proposals to implement the policy through the use of a reporting ratio, and to calculate the reporting ratio to four decimals (rather than the previously used three decimals) to more precisely calculate the reduced adjusted payment and copayment rates for hospitals that fail to meet the Hospital OQR Program requirements for CY 2027 payment.

XVI. Rural Emergency Hospital (REH) Quality Reporting Program

The Rural Emergency Hospital (REH) Quality Reporting Program, implemented under section 1861(kkk)(7) of the Act, ensures transparency and quality for rural emergency hospitals (REHs), defined at section 1861(kkk)(2) of the Act. We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 82046 through 82047) for a detailed discussion of the history of the REH Quality Reporting Program. The REH Quality Reporting Program requirements are codified at 42 CFR 419.95. We also refer readers to the CMS QualityNet REH Quality Reporting Program website at *https://qualitynet.cms.gov/reh/rehqr* for current program requirements and measure specifications. We did not propose any changes to the REH Quality

Reporting Program in the CY 2027 OPPS/ASC proposed rule (91 FR 41968).

XVII. Ambulatory Surgical Center Quality Reporting Program

A. Background

The Ambulatory Surgical Center (ASC) Quality Reporting Program promotes transparency regarding the quality of care provided at ASCs. Section 1833(i)(7)(A) of the Act authorizes the Secretary to reduce any annual increase under the revised ASC payment system by 2.0 percentage points for such year that an ASC fails to submit required data on quality measures specified by the Secretary in accordance with section 1833(i)(7)(B) of the Act. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74494) for a detailed discussion of the statutory authority of the ASC Quality Reporting Program. We have codified certain ASC Quality Reporting Program requirements at 42 CFR part 416, subpart H (§§ 416.300 through 416.330). We also refer readers to the CMS website at *https://www.cms.gov/medicare/quality/initiatives/asc-quality-reporting* for general background on the ASC Quality Reporting Program and to the CMS QualityNet ASC Quality Reporting Program website at *https://qualitynet.cms.gov/asc* for current program requirements and measure specifications.

B. ASC Quality Reporting Program Measure Set

We refer readers to section XIV. of this final rule with comment period where we discuss the removal of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure from the ASC Quality Reporting and Hospital Outpatient Quality Reporting Programs beginning with the CY 2027 reporting period/CY 2029 payment determination. We are not finalizing any other changes to the ASC Quality Reporting Program measure set.

Table 101 summarizes the previously finalized and newly finalized ASC Quality Reporting Program measure set for the CY 2028 to CY 2032 payment determinations, which removes the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure.

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TABLE 101: ASC QUALITY REPORTING PROGRAM MEASURE SET BY DATA COLLECTION METHOD AND PAYMENT DETERMINATION (PD)

Consensus-Based Entity #	Measure Name	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD	CY 2032 PD
	Chart-Abstracted Measures					
None	All-Cause Hospital Transfer/Admission	✓	✓	✓	✓	✓
0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients*	✓	Removed			
None	Normothermia Outcome	✓	✓	✓	✓	✓
None	Patient Burn	✓	✓	✓	✓	✓
None	Patient Fall	✓	✓	✓	✓	✓
None	Unplanned Anterior Vitrectomy	✓	✓	✓	✓	✓
None	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	✓	✓	✓	✓	✓
	Claims-Based Measures					
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	✓	✓	✓	✓	✓
3357	Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at ASCs	✓	✓	✓	✓	✓
3366	Hospital Visits After Urology ASC Procedures	✓	✓	✓	✓	✓
3470	Hospital Visits After Orthopedic ASC Procedures	✓	✓	✓	✓	✓
	Patient-Reported Outcomes-Based Performance Measures					
None	Risk-Standardized PRO-PM Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO-PM)	Voluntary	Voluntary	Voluntary	✓	✓
None	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary
	Survey-Based Measures					
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare	✓	✓	✓	✓	✓

Consensus-Based Entity #	Measure Name	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD	CY 2032 PD
	Providers and Systems (OAS CAHPS)					

✓Measure is mandatory for the specified payment determination year.
Voluntary: Submission of this measure is optional, and ASCs that do not report on the measure are not subject to a payment reduction.
* Removed in this final rule with comment period beginning with the CY 2029 payment determination.

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C. Request for Information on Stratification of the All-Cause Hospital Transfer/Admission Measure

We previously adopted the All-Cause Hospital Transfer/Admission measure in the ASC Quality Reporting Program in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74499). The All-Cause Hospital Transfer/Admission measure is an outcome measure that assesses the rate of patients receiving care in an ASC who require transfer to a hospital or admission to a hospital upon discharge from the ASC. Currently, the measure does not distinguish the phase of care in which a transfer occurs (pre-procedure, intra-procedure, or post-procedure).[209]

As reported in MedPAC's 2025 Report to Congress, extracapsular cataract removal with intraocular lens insertion was the most common Medicare Fee-for-Service procedure performed by ASCs in 2023, accounting for 19 percent of all ASC Fee-for-Service volume. In addition, a substantial number of ASCs that bill Medicare specialize in a single clinical area, with gastroenterology and ophthalmology among the most common specialties providing services to Medicare beneficiaries.[210] A recent retrospective study which examined the causes and timing of direct hospital transfers from an ophthalmology-specific surgery center over a 2-year period reported that about 77 percent of hospital transfers were associated with concerns identified prior to the induction of anesthesia, including transfers identified in the preoperative area or upon connection to monitoring equipment in the operating room.[211] Nearly 23 percent of these transfers were directly related to anesthesia or the surgical procedure, including events occurring during induction or intraoperatively. These findings suggest that the majority of hospital transfers from ophthalmology-specific ASCs could be occurring preoperatively rather than procedural complications. While many of these events occur prior to anesthesia induction, they are often identified during anesthesia-led pre-procedure evaluation, reflecting important safety checks in patient assessment.[212]

Based on these findings and discussions with interested parties, we considered whether adding a phase-of-care stratification relative to the surgical encounter (for example, pre-procedure, intra-procedure, and post-procedure) could improve the interpretability and usefulness of the All-Cause Hospital Transfer/Admission measure in the ASC Quality Reporting Program. The current measure reports an overall rate of transfers/admissions and does not specify when during the ASC encounter the need for transfer/admission is identified. Stratification by phase of care would improve attribution and interpretability across the diverse range of ASC services, including nonoperative procedures such as those associated with pain management, for hospital transfers/admissions associated with ASC care.

It is important to measure and monitor transfers/admissions that occur pre-procedure, intra-procedure, and post-procedure, as each stratum could provide insight into care processes between facilities. Pre-procedure events may reflect the effectiveness of pre-procedure evaluation, patient selection, and escalation or transfer processes, while intra-procedure and post-procedure events may be more closely associated with anesthesia administration, the procedure itself, and immediate recovery, including complications that arise during or after the ASC encounter. A phase-of-care stratification may also provide more comprehensive information to support beneficiary decision-making and patient safety monitoring.

We sought public comment on clinically meaningful and operationally feasible approaches for including a phase-of-care stratification for the All-Cause Hospital Transfer/Admission measure. Specifically, we requested input on potential stratification frameworks, including appropriate time anchors, their operational definitions, and the corresponding time windows that could be used to define each stratification category.

We received public comments on these topics. The following is a summary of the comments we received:

Comment: Many commenters supported stratifying the All-Cause Hospital Transfer/Admission measure by phase of care, stating that the current measure combines events occurring under different clinical circumstances and therefore provides limited information about when or why a transfer or admission occurred. Many commenters stated that phase-of-care stratification could improve the measure's usefulness and ease of interpretation, support attribution and quality improvement, and provide more meaningful information about patient safety and the circumstances surrounding transfers. Several commenters specifically noted that preoperative transfers may reflect the identification of previously unrecognized clinical conditions, appropriate patient selection, or other safety-related clinical decisions rather than complications associated with the procedure.

Many commenters recommended distinguishing transfers occurring during the pre-procedure, intra-procedure, and post-procedure phases, although commenters differed regarding the precise definitions and boundaries.

[209] Partnership for Quality Measurement. All-Cause Hospital Transfer/Admission. Available at *https://p4qm.org/measures/0265*.

[210] MedPAC. (2025). Report to the Congress: Medicare Payment Policy-Ambulatory Surgical Center Services: Status Report. Available at *https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch10_MedPAC_Report_To_Congress_SEC.pdf*.

[211] Stange, N. R., & Rauen, M. P. (2025). Evaluating ASC–4 transfer rates in cataract surgery: insights into timing and causes of hospital transfers. *Journal of cataract and refractive surgery, 51*(5), 376–381. *https://doi.org/10.1097/j.jcrs.0000000000001613*.

[212] Stange, N. R., & Rauen, M. P. (2025). Evaluating ASC–4 transfer rates in cataract surgery: insights into timing and causes of hospital transfers. *Journal of cataract and refractive surgery, 51*(5), 376–381. *https://doi.org/10.1097/j.jcrs.0000000000001613*.

Several commenters recommended using specific clinical or workflow events, including anesthesia or procedure start, procedure completion, entry into or exit from the operating or procedural setting, arrival in recovery, and discharge, as phase boundaries. A commenter specifically recommended using procedure start and stop times rather than anesthesia start and stop times because not all procedures involve anesthesia and an anesthesia-based anchor could limit completeness and comparability. A few commenters recommended determining the phase based on when the condition or need for transfer is first identified rather than when the patient physically leaves the ASC, while a few commenters proposed broader groupings, including combining intra- and post-procedure events. A commenter also recommended that CMS partner with measure developers and other interested parties to design and test methods for stratification.

Many commenters supported stratification while emphasizing that CMS should address potential unintended consequences in developing and using the measure. Several commenters recommended accounting for patient complexity, case mix, procedural risk, clinical context, or differences among patients, procedures, and facilities to avoid misleading comparisons or inappropriate attribution. Several commenters also emphasized that the measure should not create incentives to avoid, delay, or otherwise discourage medically appropriate transfers or treatment of patients with greater clinical complexity. A commenter further cautioned against attributing events to ASCs when they are not reasonably within the facility's control, noting that pre-procedure transfers may result from incomplete clearance, changes in patient condition, or appropriate referral decisions, while post-discharge hospital encounters may reflect unrelated acute illness, patient non-adherence, chronic conditions, or other events not reasonably predictable or preventable by the ASC. Several commenters raised concerns about validity, reliability, attribution, statistical stability, or the need for testing before phase-specific results are used for comparison, payment, public reporting, or other consequential purposes; a few commenters specifically raised concerns about small numbers or statistically unstable phase-specific rates.

Several commenters recommended considering information beyond phase of care to provide additional context for interpreting transfers and admissions. A few commenters recommended including information about the reason for or appropriateness of a transfer, including distinctions between potentially preventable events and medically appropriate escalation of care. A few commenters recommended consideration of downstream outcomes or information available from other care settings, while a few commenters recommended including additional patient, procedure, facility, or other characteristics because phase of care alone may not fully explain differences in transfer or admission rates. Several commenters also addressed implementation and data requirements. A few commenters recommended using information already available in clinical documentation, claims, or other existing data infrastructure where possible to limit additional reporting requirements. A few commenters recommended clear definitions, guidance, or examples to support consistent implementation, and a few commenters emphasized the need for consistently recorded or structured data to support reliable phase classification.

Several commenters raised concerns about how phase-specific results would be reported and used. A few commenters recommended limiting public reporting, comparison, payment, or other consequential uses until the methodology is established or the results are sufficiently reliable, while a few commenters expressed concern that patients or other users could misunderstand phase-specific results and recommended clear explanations to support appropriate interpretation. A few commenters recommended retaining the overall All-Cause Hospital Transfer/Admission measure while adding phase-of-care stratified results. A commenter stated that retaining the overall measure would preserve information for public reporting and consumer decision-making, while another commenter stated that it would preserve a broad patient-safety signal while providing additional context about the circumstances contributing to that signal.

A few commenters did not support phase-of-care stratification at this time or questioned whether stratification by phase of care alone would provide sufficiently meaningful or actionable information. A few commenters cited differences in phase-specific transfer rates across datasets. Specifically, a commenter cited their own internal data aggregated across more than a thousand ASCs where most transfers occurred postoperatively, which contrasted from the study from a single-specialty ophthalmology ASC in which the majority occurred preoperatively.[213] The commenter stated that these differences raised questions about whether phase-only stratification alone would be meaningful, and suggested further stratification by single-specialty or multi-specialty status, case type, and characteristics of the patient population may be needed to produce actionable information. One of these commenters supplied the example of a single facility with a high pre-surgery transfer rate to support this view. The same commenter also questioned whether the additional burden of phase-of-care stratification would provide information sufficiently useful and valuable to warrant the effort. A commenter recommended that CMS remove the All-Cause Hospital Transfer/Admission measure altogether to reduce administrative burden and streamline reporting requirements.

Response: We appreciate all the comments on this topic. While we are not responding to specific comments in response to the RFI in this final rule, we believe that this input is very valuable and will continue to take such comments into account for a potential future stratification of the All-Cause Hospital Transfer/Admission measure that may be proposed in future rulemaking.

D. Form, Manner, and Timing of Data Submission

We refer readers to prior OPPS/ASC final rules with comment period identified in footnotes below and § 416.310 for information regarding the data submission and reporting requirements for claims-based,[214] survey-based,[215] web-based [216] (that is, data submitted via a CMS-designated information system), and patient-reported outcome-based performance measures [217] in the ASC Quality

[213] Stange, N. R., & Rauen, M. P. (2025). Evaluating ASC–4 transfer rates in cataract surgery: insights into timing and causes of hospital transfers. *Journal of cataract and refractive surgery, 51*(5), 376–381. *https://doi.org/10.1097/j.jcrs.0000000000001613.*

[214] We refer readers to §§ 416.310(a) and (b) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70534 through 70536) for information regarding the claims-based measure data submission and reporting requirements.

[215] We refer readers to § 416.310(e) and the CY 2022 OPPS/ASC final rule with comment period (86 FR 63905 through 63909) for information regarding the survey-based data submission and reporting requirements.

[216] We refer readers to § 416.310(c)(1) and the CY 2025 OPPS/ASC final rule with comment period (89 FR 94435 and 94436) for details regarding submission of web-based data via a CMS-designated information system (currently the Hospital Quality Reporting (HQR) system).

[217] We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 82041

Continued

Reporting Program. We maintain measure technical specification manuals (referred to as Specifications Manuals) that can be found on the CMS website at *https://qualitynet.cms.gov/asc/specifications-manuals*.

In the CY 2027 OPPS/ASC proposed rule (91 FR 41972), we did not propose any changes to these policies.

E. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 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 2027, 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 was the annual update for the ASC payment system for a 5-year period (CY 2019 through CY 2023), which was extended an additional 2 years (through CY 2025) in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81960). In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53915), we extended the interim period an additional year (through the end of CY 2026). As discussed in section XIII. of this final rule with comment period, we proposed to continue using the productivity-adjusted hospital market basket update as the update factor for the ASC payment system for CY 2027. Under the ASCQR Program, in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499), any annual increase in certain payment rates under the ASC payment system shall be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates (77 FR 68500). For a complete discussion of the calculation of the ASC conversion factor and our finalized proposal to update the ASC payment rates using the inpatient hospital market basket update for CYs 2019 through 2023, we refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59073 through 59080).

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 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 this proposed rule, which are available via the internet on the CMS website): ''A2'', ''D2'', ''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, biologicals, and radiopharmaceuticals, skin substitute supplies, 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

through 82045) for information regarding the patient-reported outcome-based performance measure data submission and reporting requirements.

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 2026 OPPS/ASC final rules with comment period, we did not make any other changes to these policies. We proposed to continue applying these policies for the CY 2027 reporting period/CY 2029 payment determination and for subsequent years.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed the continuation of these policies for the CY 2027 reporting period/CY 2029 payment determination and for subsequent years.

XVIII. Accrediting Organization (AO) Deeming Authority for the Emergency Medical Treatment and Labor Act (EMTALA)

A. Background

The Emergency Medical Treatment and Labor Act (EMTALA) was enacted in 1986 and codified at section 1867 of the Act (42 U.S.C. 1395dd) to address concerns regarding the inappropriate transfer of, or refusal to treat individuals with emergency medical conditions who are seeking emergency department care, commonly referred to as ''patient dumping.'' EMTALA applies to hospitals that participate in Medicare and operate emergency departments, including critical access hospitals (CAHs) and rural emergency hospitals (REHs). For purposes of this discussion, the term ''hospitals'' includes CAHs and REHs. To enroll and be qualified to participate in Medicare under section 1866(a)(1)(I) of the Act (42 U.S.C. 1395cc(a)(1)(I)), all such hospitals must agree to comply with EMTALA's statutory and regulatory requirements, among other applicable requirements.

Section 1867 of the Act establishes the three core obligations of EMTALA.

- First, when an individual comes to a hospital's emergency department and requests examination or treatment, the hospital must provide an appropriate medical screening examination to determine whether an emergency medical condition exists.
- Second, if the hospital determines that the individual has an emergency medical condition, the hospital must provide either necessary stabilizing treatment within its capability or arrange for an appropriate transfer to another medical facility. Note, when assessing whether there is an emergency medical condition with respect to a pregnant woman, consideration has to be given to whether the condition places the health of the woman or the unborn child in serious jeopardy, and with respect to a pregnant woman having contractions, it requires consideration of whether a transfer would pose a threat to the health or safety of the woman or the unborn child.
- Third, hospitals with specialized capabilities or facilities shall not refuse to accept appropriate transfers of individuals requiring such capabilities or facilities if the receiving hospital has the capacity to treat the individual. The statute also authorizes the imposition by the Office of Inspector General (OIG) of civil monetary penalties against hospitals and physicians and, for physicians, exclusion from participation in Federal health care programs for violations, and permits the Centers for Medicare & Medicaid Services (CMS) to impose involuntary termination of a hospital's Medicare provider agreement for non-compliance in accordance with 42 CFR 489.53.

CMS has implemented EMTALA through regulations at 42 CFR 489.20 and 489.24, which address two distinct categories of obligations. Section 489.20(l), (m), (q) and (r) sets forth administrative requirements, including to post EMTALA signage, maintain a central log of individuals who present to the emergency department, retain transfer records for 5 years, and maintain an on-call physician list. These administrative obligations support transparency, documentation, and accountability in emergency care operations. These requirements are provider agreement commitments and obligations hospitals accept as a condition of Medicare participation under section 1866(a)(1)(I) of the Act. They are distinct from the substantive individual care protections at § 489.24.

Section 489.24 implements the statute's substantive protection requirements for individuals who present to the emergency department and request examination or treatment, including detailed provisions governing the provision of appropriate medical screening examinations, stabilizing treatment, appropriate transfers, and receiving hospital responsibilities. These requirements reflect the core protections established by section 1867 of the Act and are directly enforceable by CMS and/or the OIG.

Enforcement of EMTALA has historically occurred through complaint investigations conducted by State Survey Agencies (SAs) under CMS direction. Pursuant to § 488.6, CMS ''deems'' a hospital to meet Medicare requirements if it is accredited by an AO with a hospital accreditation program approved by CMS. CMS will approve such organizations if it finds that its standards and survey processes provide reasonable assurance that accredited entities meet or exceed applicable Medicare requirements. Hospitals accredited by such AOs are deemed to meet the Medicare Conditions of Participation (CoPs) but are subject to CMS validation surveys and complaint investigations in accordance with existing CMS policies and procedures. More than 90 percent of Medicare-participating hospitals (excluding CAHs and REHs) and more than 40 percent of CAHs, independent of hospitals, are accredited by AOs with CMS-approved accreditation programs. At this time, no REHs are deemed to meet requirements through a CMS-approved accreditation program.

We proposed that if an AO identifies EMTALA deficiencies at § 489.24 during an accreditation or reaccreditation survey, the matter must be referred to the CMS location for further review and possible SA investigation. If an AO identifies EMTALA deficiencies at § 489.20(l), (m), (q) and (r), they would require the hospital or CAH to submit an acceptable Plan of Correction (PoC) addressing how it would come into compliance with the cited EMTALA requirements. If the PoC is accepted and the hospital has returned to compliance, then no further enforcement action would be taken. If the PoC is rejected, the AO would be required to contact the CMS location for further review. Under § 488.5(a)(4)(ix), AOs are already required to notify CMS timely if an AO survey identifies an ''immediate jeopardy.'' The proposed EMTALA requirement would augment the already-existing reporting requirement. If a complaint alleging an EMTALA violation is received by CMS (or the SA acting under an agreement pursuant to section 1864 of the Act), it would be triaged to determine its investigation

priority level. The SA or CMS conducts an onsite investigation, and if a violation is identified, a deficiency is cited and the survey findings are documented. Currently the CMS location refers § 489.24 violations to the OIG, which has independent statutory authority to impose civil money penalties against hospitals and physicians, and potential exclusion of physicians from Federal health care programs. CMS retains the authority to terminate a hospital's Medicare provider agreement for EMTALA noncompliance at § 489.53.

In CY 2025, we issued 1,071 EMTALA citations for violations of the two applicable regulations, underscoring the need for Medicare-participating hospitals to comply with emergency care obligations. Of these, 521 citations were issued under § 489.20 requirements, 530 citations were issued under § 489.24, and 20 citations were issued under both §§ 489.20 and 489.24. Section 489.24 is the more expansive regulation governing the specific medical screening, stabilization, and transfer requirements hospitals must fulfill when an individual requests emergency care. Administrative compliance under § 489.20 appears to be a leading indicator of overall EMTALA program integrity. A hospital that cannot maintain accurate on-call logs, post required notices, or retain transfer documentation is a hospital whose broader EMTALA compliance posture warrants closer scrutiny. Including a structured, thorough review of § 489.20 requirements into every hospital survey is essential to fulfilling the protective intent of EMTALA. The inclusion of the requirements at § 489.20(l), (m), (q) and (r) into the accreditation and reaccreditation survey process mean that AOs would assess whether hospitals are maintaining the documentation, recordkeeping, and operational safeguards that support transparency and accountability in emergency care. Because these obligations are record-based and procedural, we proposed to review AO survey processes as part of our hospital accreditation program approval to check that EMTALA requirements are included within the existing accreditation framework.

It should be noted that findings related to potential § 489.24 violations must be referred to CMS for SA investigation and those findings would continue to follow existing public disclosure procedures applicable to complaint-based SA investigations, which are separate from AO accreditation survey reports. Section 1865(b) of the Act explicitly permits the Secretary to publicly disclose AO surveys and information related to them to the extent that such surveys and information relate to an enforcement action taken by the Secretary.

Our regulations at 42 CFR part 488 govern AO approval and oversight. The proposal we are finalizing in this rule will operate within section 1865 of the Act and part 488 statutory and regulatory structures by integrating review of EMTALA's administrative requirements into existing accreditation organization processes for accrediting and re-accrediting hospitals, while preserving CMS and OIG enforcement authority over EMTALA's core statutory protections under section 1867 of the Act. We anticipate several benefits associated with this change. First, integrating EMTALA administrative review into accreditation and CMS or state survey agency certification surveys would minimize operational disruption for hospitals. Rather than undergoing separate review processes triggered by administrative deficiencies, hospitals will be able to address these requirements within the structured accreditation or state survey framework.

Second, this policy may improve compliance consistent with the documentation and operational safeguards at § 489.20(l), (m), (q) and (r). Because these requirements are record-based and procedural in nature, they are well-suited to routine survey evaluation. Regular review during accreditation and recertification surveys may enhance sustained compliance.

Third, this final rule with comment period will allow SAs to concentrate more resources on complaint-based investigations involving potential violations of § 489.24, including issues related to appropriate medical screening examinations, stabilizing treatment, and appropriate transfers. These investigations often require case-specific fact-finding and clinical review, and preserving SA capacity for these activities supports effective enforcement of EMTALA's core protections.

Nothing in this final rule with comment period alters a hospital's obligations under Federal civil rights conscience (protections) laws, or the authority of the HHS Office for Civil Rights to enforce those laws.

B. CMS Approval of Accreditation Organizations

We proposed to clarify at § 488.5(a) that an AO with a CMS-approved accrediting program for hospitals under section 1865 of the Act may assess compliance with the EMTALA-related administrative requirements set forth at § 489.20(l), (m), (q) and (r) as part of their hospital initial accreditation and reaccreditation surveys, which must be completed no later than 36 months after the prior accreditation effective date consistent with § 488.5(a)(4), for those provider types. This proposal was limited to AOs conducting initial accreditation or reaccreditation surveys within the scope of their existing CMS-approved accrediting programs. This amendment would formally require CMS-approved AOs to include review of these specified EMTALA obligations into the existing accreditation framework, while preserving CMS' direct enforcement authority over EMTALA's core statutory protections.

As proposed, AOs would evaluate hospital compliance with the administrative commitments codified at § 489.20(l), (m), (q) and (r), including requirements to post appropriate EMTALA signage; maintain a central log of individuals who present to the emergency department; retain transfer records for a period of 5 years; and maintain an on-call physician list to ensure availability of specialty services. These obligations are documentary and administrative in nature, are well-established in regulation, and are conducive to structured review within the context of accreditation and reaccreditation surveys.

If an AO identified noncompliance with any of the EMTALA administrative requirements at § 489.20(l), (m), (q) and (r), the AO would cite the deficiency and address it through its established procedures, consistent with the procedures it used to address other Medicare deficiencies identified during accreditation and reaccreditation surveys. This would include requiring corrective action plans, monitoring compliance, and reporting findings to CMS in accordance with existing oversight and validation protocols. CMS would retain ultimate oversight responsibility and could take additional action as appropriate under its survey and enforcement authorities.

We believe that the administrative requirements at § 489.20(l), (m), (q) and (r) are appropriate for evaluation during initial accreditation and reaccreditation surveys. Integrating review of these provisions into the AO survey process would promote more consistent monitoring of established documentation and recordkeeping obligations, reduce duplicative investigations triggered solely by administrative concerns, and minimize disruption to hospital operations. At the same time, this approach would allow SAs to concentrate their resources on complaint-based investigations

involving potential violations of § 489.24.

To implement this proposal, we proposed to revise § 488.5 by adding a new paragraph (a)(23), laying out the AO's responsibility to include the EMTALA administrative requirements into its accreditation standards and survey processes and to identify and address noncompliance with those provisions within the deeming framework.

C. Evaluation of Accreditation Authority Request

AOs would have to document the procedures used to assess compliance with these requirements and would be required to cite and address any identified deficiencies through their established accreditation procedures, consistent with the procedures used to address Medicare deficiencies identified during accreditation and reaccreditation surveys.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported CMS's proposal to have AOs review administrative EMTALA requirements (signage, logs, transfer records, and on-call lists) during accreditation surveys, provided CMS retains ultimate enforcement authority over substantive EMTALA protections.

Response: We appreciate the broad support for this proposal and confirm that this rule does not delegate authority over substantive EMTALA determinations, including allegations involving inadequate screening, failure to stabilize, or improper transfer to AOs. CMS and SAs will continue to investigate and adjudicate all substantive EMTALA complaints and immediate jeopardy findings as well as review and investigate AO referrals regarding the administrative EMTALA requirements. The scope of AO review under this rule is limited to the administrative elements specified in the proposed rule. We are finalizing as proposed, with the clarifications discussed below.

Comment: Two commenters recommended a transition period, suggesting through at least CY2028 before full implementation, to allow AOs, SAs, and hospitals time to align processes.

Response: The AOs with hospital deeming programs will need to first submit applications to update their accreditation programs to include review of the EMTALA administrative requirements and submit them to CMS for approval before an AO can start surveying for the EMTALA administrative requirements. Accordingly, we do not believe a transition period is needed.

Comment: Two commenters raised concerns that expanded AO survey responsibilities could result in duplicative or conflicting requirements if not applied consistently across AOs and SAs.

Response: We intend to issue standardized interpretive guidance and survey protocols specific to the administrative EMTALA elements, which all approved AO accreditation programs should include in their own standards. This guidance will clearly delineate the respective roles of AOs, SAs, and hospitals: AOs with hospital deeming programs will assess the specified administrative documentation and postings during regular accreditation and reaccreditation surveys, while SAs will retain jurisdiction over complaint-driven and substantive EMTALA investigations.

In addition, our guidance will affirm that compliance with the administrative requirements at § 489.20(l), (m), (q), and (r) is distinct from, and does not establish compliance with, Federal civil rights conscience (protections) laws; and that individuals retain the right to file a complaint with the HHS Office for Civil Rights. OCR staff are available to review the civil rights content of that material at CMS's request.

Comment: One commenter requested rigorous reviewer qualifications and EMTALA-specific training for AO surveyors and cautioned against shifting hospital-level administrative compliance burden onto individual physicians.

Response: We agree that surveyor competency is essential to consistent application of these requirements. We will require AOs to demonstrate that surveyors assigned to EMTALA administrative reviews have completed CMS-approved EMTALA training prior to conducting these assessments, as a condition of AO approval. We also clarify that the administrative requirements addressed by this rule are hospital-level requirements. Nothing in this rule shifts EMTALA compliance responsibility from the hospital to individual physicians, and we do not intend for AO findings related to these administrative requirements to be used as a basis for adverse action against individual practitioners.

Comment: Several commenters cautioned against ''scope creep,'' urging that AO reviews remain confined to administrative requirements and not expand into substantive EMTALA screening or stabilization determinations, and called for a single, nationally standardized enforcement framework.

Response: We confirm that the scope of AO survey activity under this rule is limited to the administrative requirements and does not extend to clinical screening, stabilization, or transfer-decision review requirements at § 489.24, which remain within CMS and SA exclusive investigation authority.

Comment: One commenter recommended that CMS apply lessons learned from AOs' prior experience with EMTALA-adjacent survey activity.

Response: We will draw on existing AO deeming experience, including prior CMS validation surveys and complaint outcome data, to inform the interpretive guidance and training requirements discussed previously, and will continue to use our validation survey process to monitor AO performance on these administrative EMTALA elements after implementation.

After consideration of public comments, we are finalizing these provisions as proposed.

XIX. Expansion of Botulinum Toxin Injection Codes for Hospital Outpatient Department (OPD) Prior Authorization Process

A. Background

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services (84 FR 61142, 61446 through 61456) using our authority under section 1833(t)(2)(F) of the Act, which requires the Secretary to develop ''a method for controlling unnecessary increases in the volume of covered OPD services''.[218] As part of the CY 2021 OPPS/ASC final rule with comment period, we added two additional service categories to the prior authorization process for certain hospital OPD services (85 FR 85866, 86236 through 86248). Through the CY 2023 OPPS/ASC final rule with comment period, we added one more 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 for certain hospital OPD services are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89, with the specific service categories listed in § 419.83.

Section 419.83(a)(1) lists the specific service categories for which prior authorization must be obtained for service dates on or after July 1, 2020:

[218] See also correction notice issued January 3, 2020 (85 FR 224).

blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation. Section 419.83(a)(2) lists two additional service categories for which prior authorization must be obtained for service dates on or after July 1, 2021: cervical fusion with disc removal and implanted spinal neurostimulators. Section 419.83(a)(3) lists Facet Joint Interventions as an additional service category for which prior authorization must be obtained for service dates on or after July 1, 2023. Section 419.83(b) states that CMS will adopt the list of hospital outpatient department service categories requiring prior authorization, and any updates or geographic restrictions, through formal notice-and-comment rulemaking. Section 419.83(c) describes the circumstances under which CMS may elect to exempt a provider from the prior authorization process, and § 419.83(d) states that CMS may suspend the prior authorization process requirements generally or for a particular service at any time by issuing a notification on the CMS website.

B. Controlling Unnecessary Increases in the Volume of Covered OPD Services

In accordance with § 419.83(b), we proposed to expand prior authorization requirements to include additional Botulinum Toxin Injection services. The eight additional Botulinum Toxin Injection codes would be included in the existing list at proposed revised § 419.83(a)(2) and would require prior authorization for services provided on or after July 1, 2027. Additionally, to improve readability and brevity, we proposed to remove effective date language from the regulatory text and revise the section numbering. The former paragraphs (a)(1)(i) through (v), (a)(2)(i) and (ii), and (a)(3) would be redesignated as paragraphs (a)(1) through (8).

1. Expansion of Service Category

The additional Botulinum Toxin Injection codes that would require prior authorization beginning on July 1, 2027, are those identified by the HCPCS codes in Table 102. For ease of reference, in Table 102 we have included the 2020, 2021, and 2023 Final Lists of Outpatient Services that Require Prior Authorization, covering the five initial service categories, two additional service categories, and one more service category, respectively. As we mentioned previously, we proposed to include additional codes in the existing Botulinum Toxin Injections service category that was established through the CY 2020 OPPS/ASC final rule with comment period.

2. Basis for Expanding Service Category

As part of our responsibility to protect the Medicare Trust Funds, we routinely analyze data associated with all aspects of the Medicare program. This responsibility includes monitoring the total amount or types of claims submitted by providers; analyzing the claims data to assess the growth in the number of claims submitted over time (for example, monthly and annually, among other intervals); and conducting comparisons of the data with other relevant data, such as the total number of Medicare beneficiaries served by providers, to help ensure the continued appropriateness of payment for services furnished in the hospital OPD setting.

In proposing the addition of these new services, we reviewed over 100 million OPD claims from 2017 through 2024. We determined that, on average, the number of OPD claims submitted for payment to the Medicare program decreased yearly by 1.1 percent. This reflects a decrease from approximately 114 million OPD claims submitted for payment in 2017 to approximately 104 million claims submitted for payment in 2024, with claim counts rounded for reporting purposes. The 1.1 percent decrease in overall OPD claims annually represents a decrease compared to the 0.6 percent increase identified in the CY 2023 OPPS/ASC proposed rule when we looked at the period from 2012 through 2021. Our analysis also showed that the Medicare allowed amount (the amount Medicare would pay for services regardless of external variables, such as beneficiary plan differences, deductibles, and appeals) for overall OPD claims increased from approximately $53.1 billion in 2017 to approximately $69.8 billion in 2024, representing an average annualized growth rate of 3.5 percent. Again, this is a decrease when compared to the 4.2 percent rate of growth identified in the CY 2023 OPPS/ASC proposed rule from 2012 through 2021. This analysis provides a benchmark regarding overall Medicare spending trends for OPD services during the same period.

In contrast to overall OPD utilization trends, utilization of all Botulinum Toxin Injection codes listed in Table 102 (2027 List of Additional Outpatient Department Services That Require Prior Authorization) has grown at a notably higher rate. This difference suggests that these services are increasing faster than overall OPD utilization, which warrants further review to ensure appropriate utilization. Our analysis of Integrated Data Repository (IDR) [219] data showed that claim volume for Botulinum Toxin Injection codes listed in Table 102 increased by 42.8 percent overall between 2017 and 2024 [220], based on a direct comparison of claims volume in 2017 and 2024, and there was a 4.6 percent average annualized growth rate increase during the same time period. Specifically, claims volume for the additional Botulinum Toxin Injection codes increased from approximately 43,500 claims submitted for payment in 2017 to approximately 62,103 claims submitted for payment in 2024. By comparison, the overall OPD claims volume decreased by 8.3 percent between 2017 and 2024 [221], based on a direct comparison of total OPD claims in 2017 and 2024, and by the 1.1 percent average annualized rate decrease in OPD claims submitted for payment during the same time period. We also examined claims for each of the seven injection procedure codes proposed for addition to the prior authorization list. Between 2017 and 2024, claims containing HCPCS CPT 64611 increased from 2,788 to 5,124, or 83.8 percent. Claims containing CPT 64616 increased from 15,502 to 22,934 (47.9 percent); CPT 64617 from 3,573 to 3,951 (10.6 percent); CPT 64642 from 12,469 to 17,914 (43.7 percent); CPT 64644 from 9,913 to 14,303 (44.3 percent); CPT 64646 from 1,970 to 2,914 (47.9 percent); and CPT 64647 from 322 to 355 (10.2 percent). CPT codes 64616, 64642, and 64644 had the largest increases in the number of claims.

We also recognize that additional FDA-approved indications for botulinum toxin products during this period may have contributed to some increase in utilization. We reviewed new FDA-approved indications from 2017 through 2024 and principal diagnoses on botulinum toxin injection claims. Claims potentially related to expanded indications increased from 1,731 in 2017 to 3,354 in 2024 but remained a small share of the claims analyzed. However, the newly approved

[219] The IDR is a high-volume data warehouse integrating Medicare Parts A, B, C, and D, and durable medical equipment claims, beneficiary and provider data sources, along with ancillary data such as contract information and risk scores. Additional information is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR/index.html.*

[220] Using the formula (2024 claims − 2017 claims) ÷ 2017 claims, this results in a 42.8 percent increase. This calculation is separate from the 4.6 percent compound annual growth rate, which reflects the annualized rate of growth during the same period.

[221] Using the formula (2024 claims − 2017 claims) ÷ 2017 claims, this results in an 8.3 percent decrease. This calculation is separate from the 1.1 percent average annualized decrease, which reflects the average year-over-year change during the same period.

indications represent a limited number of additional clinical uses and are not expected to account for the full magnitude of the observed increase in utilization, suggesting that other factors may also be contributing. Accordingly, we do not believe that expanded indications alone fully explain the magnitude of the observed growth, which suggests that other factors may also be contributing to increased utilization. Specifically, overall OPD claims decreased from approximately 114 million unique claims in 2017 to approximately 104 million unique claims in 2024. The codes included in our proposal represent approximately $102 million in annual Medicare payments and constitute a subset of overall botulinum toxin utilization selected based on observed utilization volume, growth trends, and program integrity considerations.

When analyzing the data, we took the COVID–19 Public Health Emergency (PHE) into consideration. As a result of the PHE, health care use and spending dropped sharply due to cancellations of elective and non-emergency care to increase hospital capacity and social distancing measures to reduce the community spread of the coronavirus. Consequently, the claims data for CY 2020 showed a notable decrease in volume of services compared to the previous year. This decline in CY 2020 due to the PHE is reflected in the overall trend for the 2017 through 2024 period, including calculations of the 1.1 percent average annualized decrease in OPD claims submitted for payment over the 2017 through 2024 period discussed previously, which is based on year-over-year changes across all years in the period, including CY 2020. Although a decline in utilization was observed in CY 2020, claims volume for these services increased significantly in subsequent years and exceeded levels that would have been reasonably expected based on overall OPD utilization trends. Accordingly, we do not believe any claim decreases resulting from the PHE affect our conclusion that there were ''unnecessary increases in the volume of covered'' claims for these services. This determination is based on several considerations, including utilization growth for Botulinum Toxin Injection services substantially exceeding overall OPD utilization trends during the same period, despite overall OPD claims volume declining. In addition, the increased utilization persisted over multiple years rather than reflecting a temporary fluctuation. CMS also reviewed potential explanations for the increase in utilization, including changes in clinical need, coding changes, and other factors that could reasonably explain sustained growth in service volume, but did not identify sufficient evidence to account for the magnitude of the increase observed. CMS further considered broader program integrity concerns, including billing patterns and utilization trends that may indicate a risk of unnecessary utilization.

Our conclusion that increases in volume for Botulinum Toxin Injections are unnecessary is based not only on data specific to these services but also on a comparison of the rate of increase for these procedures to the overall trends for all OPD services. We believe that comparing the utilization rate for specific services to the overall Medicare OPD utilization trends is generally an appropriate method for identifying unnecessary increases in volume, particularly when there are no legitimate clinical or coding reasons for the changes. The Medicare allowed amount analysis discussed above provides additional information regarding broader Medicare spending trends during the same period. As we have stated in the previous OPPS/ASC final rules with comment period, we believe that prior authorization is an effective mechanism to ensure Medicare beneficiaries receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in the volume of covered OPD Services without adding onerous new documentation requirements. Therefore, we believe prior authorization for these additional codes will be an effective method for controlling unnecessary increases in the volume of these services and expect that it will reduce the instances in which Medicare pays for services that are determined not to be medically necessary. This will also serve as a tool within CMS' broad program integrity strategy to address potential fraud, waste, and abuse. We requested comments on the addition of these new services, specifically on the potential for unintended clinical consequences that may result from this addition.

We received 122 public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for CMS's efforts to improve interoperability, streamline prior authorization, and reduce administrative burden.

Response: We thank the commenters for their support of CMS's efforts to improve interoperability, streamline prior authorization processes, promote appropriate utilization of Medicare resources, and reduce administrative burden. We remain committed to improving the efficiency of prior authorization processes while supporting appropriate access to care.

Comment: A couple of commenters noted that consumers may be unable to determine whether a service requires prior authorization.

Response: We appreciate the commenters' concern regarding access to information about prior authorization requirements. Regarding Medicare Fee-for-Service, prior authorization requirements apply only to certain items and services. CMS and the Medicare Administrative Contractors (MACs) make information regarding applicable prior authorization requirements publicly available. In addition, MAC websites generally provide tools or searchable resources that allow providers to determine whether a particular service or procedure is subject to prior authorization requirements. Accordingly, providers can consult the applicable MAC's resources to identify whether prior authorization is required for a service before it is furnished.

Comment: A commenter recommended that CMS require or encourage the use of structured, auditable, clinician-owned clinical logic frameworks for prior authorization while preserving licensed clinician oversight of final determinations. The commenter also recommended clinician-owned, auditable governance for SI-assisted prior authorization decisions and cited recent developments involving the WISeR Model as an example of the importance of transparency and clinical accountability in SI-enabled utilization management. The commenter urged CMS to consider these principles as it implements the hospital OPD program.

Response: We appreciate the commenter's recommendations regarding the use of structured, auditable clinical logic frameworks in prior authorization processes while maintaining licensed clinician authority over final determinations. The hospital OPD prior authorization program has been operational since 2020. We will consider the comments regarding transparency, auditability, interoperability, and clinician oversight as we evaluate policies for the hospital OPD program and future rulemaking. To the extent the comment references the WISeR Model, that model is a separate CMS Innovation Center (CMMI) model and is outside the scope of this rulemaking. Comments specific to the

WISeR Model should be directed to *WISeR@cms.hhs.gov*.

Comment: A commenter recommended that CMS include standards-based, FHIR/mCODE-enabled prior authorization using validated software as a medical service (SaMS) and pilot a structured submission pathway with automated approvals and gold-carding for qualifying providers.

Response: We appreciate the commenter's recommendations regarding the use of standards-based, interoperable technologies and automated processes to streamline prior authorization and reduce provider burden. We also appreciate the commenter's suggestions regarding structured submission pathways and exemptions, sometimes called ''gold carding,'' for qualifying providers. Although it is beyond the scope of our proposal, we note that the hospital OPD prior authorization process currently includes an exemption from prior authorization requirements for qualifying providers that demonstrate a high level of compliance with Medicare requirements. Under 42 CFR 419.83(c), CMS may exempt a provider that demonstrates compliance with Medicare coverage, coding, and payment rules. Under the current annual assessment process, a provider that submits at least 10 prior authorization requests and receives provisional affirmations for at least 90 percent of its initial requests may qualify for an exemption from submitting further requests while the exemption is in effect. CMS continues to assess exempt providers' compliance and may withdraw an exemption.

The commenter's recommendations regarding FHIR/mCODE-enabled prior authorization, validated software as a medical service (SaMS), structured submission pathways, and automated approvals are also beyond the scope of the proposed expansion of the hospital OPD prior authorization process. We note, however, that MACs may accept prior authorization requests submitted using FHIR-based approaches, as applicable. We will consider these comments as we continue to evaluate opportunities to improve and streamline prior authorization processes.

Comment: Several commenters raised concerns regarding prior authorization for services outside the scope of the proposed expansion. One commenter expressed concerns regarding prior authorization for botulinum toxin injections used to treat certain urologic conditions. Other commenters opposed existing prior authorization requirements for cervical fusion with disc removal, facet joint interventions, and implanted spinal neurostimulator services. Another commenter urged CMS to exercise caution in any future expansion of prior authorization to metabolic and bariatric surgery services, citing potential treatment delays, patient harm, and administrative burden.

Response: We appreciate the commenters' concerns. The proposal addressed in this rule is limited to the eight additional Botulinum Toxin Injection codes identified in the proposed rule. The procedure used for botulinum toxin injection into the bladder is not among the eight additional codes proposed for inclusion in the hospital OPD prior authorization process. In addition, we did not propose changes to the existing prior authorization requirements for cervical fusion with disc removal, facet joint interventions, or implanted spinal neurostimulator services, nor did we propose to expand prior authorization to additional metabolic and bariatric surgery services. Therefore, comments and recommendations concerning prior authorization for these services are outside the scope of this rulemaking.

Comment: A commenter requested that CMS issue implementation guidance sufficiently in advance of July 1, 2027, effective date for the additional botulinum toxin injection codes to allow hospitals adequate time to update prior authorization workflows and avoid disruptions to patient care.

Response: We appreciate the commenter's request. We intend to provide education and implementation guidance well in advance of the July 1, 2027, effective date to support provider preparation and facilitate implementation of the expanded prior authorization requirements. CMS currently provides guidance, educational resources, and program updates for the hospital OPD prior authorization program on the program's website, including the Operational Guide, Frequently Asked Questions, applicable HCPCS lists, and information regarding changes to program requirements and implementation timelines [222]. We intend to update these resources, as appropriate, and provide additional information through established CMS and MAC communication channels.

Comment: Several commenters expressed concern that expanding prior authorization to additional botulinum toxin injection services could delay medically necessary treatment and adversely affect beneficiary access and outcomes. Commenters emphasized that these services are used to treat chronic neurologic and other disabling conditions and stated that treatment delays could result in worsening symptoms, pain, functional decline, or other complications. Some commenters noted particular concerns for beneficiaries with significant disabilities and those in rural or underserved areas.

Response: We appreciate the commenters' concerns regarding potential delays in access to medically necessary botulinum toxin injection services and the resulting impact on beneficiaries. We recognize the importance of timely treatment, particularly for beneficiaries with significant functional impairments. The Medicare prior authorization process includes established review timeframes designed to support timely access to medically necessary services. Prior authorization requests are generally reviewed within 7 calendar days for standard requests, though the average review time over the past year was 3.6 days, and expedited review within 2 business days is available when a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function. In addition, as noted in response to the previous comment, providers who demonstrated compliance with Medicare coverage requirements through their prior authorization affirmation rate may qualify for an exemption from prior authorization. We believe these safeguards help address concerns regarding timely beneficiary access while supporting appropriate Medicare program oversight.

Comment: Several commenters stated that botulinum toxin injections are recurring, individualized treatments and expressed concern that requiring prior authorization for each treatment cycle could disrupt established treatment plans. Commenters also noted that a beneficiary's clinical condition and treatment needs may change between authorization and the date of service, requiring practitioners to modify the muscles treated or applicable procedure code. Commenters recommended streamlined renewals, longer authorization periods or multi-cycle authorizations for established patients, and flexibility to accommodate clinically necessary changes in treatment.

Response: We appreciate the commenters' concerns regarding the recurring and individualized nature of botulinum toxin treatment, continuity of care, and the need for clinical flexibility. Prior authorization is intended to ensure that Medicare

[222] *https://www.cms.gov/data-research/monitoring-programs/medicare-fee-service-compliance-programs/prior-authorization-pre-claim-review-initiatives/prior-authorization-certain-hospital-outpatient-department-opd-services.*

coverage, coding, and payment requirements are met before services are furnished and is not intended to interfere with the treating practitioner's clinical judgment or delay medically necessary care. We recognize that a beneficiary's clinical condition and treatment needs may change between submission of a prior authorization request and the date of service. We considered commenters' recommendations regarding flexibility for clinically necessary changes, streamlined authorization for established patients, and consideration of ongoing treatment in determining whether and how to finalize the proposal. We will continue to evaluate implementation of the prior authorization requirements and consider appropriate operational flexibilities and safeguards to support timely access to medically necessary services while protecting the Medicare Trust Funds.

Comment: Several commenters expressed concern that expanding prior authorization would increase administrative burden on hospitals, physicians, and clinical staff, diverting resources from patient care. Commenters stated that the burden may include preparing and tracking requests, submitting additional documentation, responding to non-affirmations, resubmitting requests, and pursuing further review. Some commenters questioned whether CMS's burden estimates fully account for the clinical and administrative staff time associated with these activities.

Response: We appreciate the commenters' concerns regarding the administrative burden associated with prior authorization. We recognize the importance of minimizing unnecessary burden on providers and beneficiaries while supporting appropriate utilization of Medicare services. Prior authorization does not establish new Medicare coverage or documentation requirements; rather, it requires documentation supporting applicable Medicare coverage, coding, and payment requirements to be submitted before the service is furnished.

As discussed in the Collection of Information Requirements section of this final rule, we estimate that the average time for office clerical activities associated with preparing and submitting a prior authorization request is 30 minutes, which is equivalent to the time estimated for prepayment or postpayment medical review. We continue to believe that 30 minutes represents a reasonable average estimate of the time needed to prepare and submit a prior authorization request. We acknowledge that the actual time associated with an individual request may vary depending on the circumstances, including whether additional documentation or resubmission is necessary.

We will continue to monitor the program, including its impact on providers and beneficiaries.

Comment: Several commenters questioned whether increased utilization of botulinum toxin injection services demonstrates unnecessary or inappropriate utilization. Commenters stated that utilization growth may reflect factors such as expanded indications, evolving clinical practice, improved access, changes in the Medicare population, or shifts in site of service. Commenters recommended that CMS conduct additional analysis and use more targeted program integrity approaches, such as focused medical review, provider education, Targeted Probe and Educate, post-payment review, or data-driven review of providers or utilization patterns presenting greater program integrity risk, rather than broadly expanding prior authorization.

Response: We appreciate the commenters' concerns regarding the basis for the proposed expansion. We agree that increased utilization, standing alone, does not establish that services are medically unnecessary or improperly billed. We recognize that utilization trends may be influenced by a variety of factors, including changes in approved indications, clinical practice, beneficiary access, the Medicare population, and site of service. As discussed in the proposed rule, we identified a significant increase in utilization of these services relative to overall hospital OPD utilization during the same period and acknowledged that expanded FDA-approved indications may have contributed to some of this growth. While increased utilization does not, by itself, demonstrate that services are medically unnecessary or improperly billed, the magnitude of the utilization increase supports additional oversight to ensure that applicable Medicare coverage, coding, and payment requirements are met.

We also appreciate the recommendations to use more targeted program integrity approaches. CMS uses a variety of program integrity tools based on the circumstances. Prior authorization allows CMS to review documentation before the service is furnished and the claim is submitted for payment to determine whether applicable Medicare requirements are met. It does not establish new coverage requirements or change existing Medicare coverage criteria. We believe prior authorization is an appropriate program integrity tool in these circumstances.

Comment: Several commenters recommended that, if CMS finalizes the proposed expansion, it adopts safeguards to minimize administrative burden and disruptions in care. Recommendations included expedited review, clear and consistent criteria, streamlined processes for established patients, reduced or standardized documentation, provider exemptions for demonstrated compliance, electronic prior authorization workflows, timely appeals, and monitoring and public reporting of denials, processing times, treatment delays, beneficiary access, and other program outcomes.

Response: We appreciate the commenters' recommendations regarding safeguards to minimize administrative burden and disruptions in care. We recognize the importance of minimizing unnecessary administrative burden and avoiding disruptions in medically necessary care while ensuring that Medicare coverage, coding, and payment requirements are met.

The hospital OPD prior authorization process includes safeguards intended to reduce burden and protect beneficiary access to care. For example, the process provides for expedited review when a delay could seriously jeopardize a beneficiary's life, health, or ability to regain maximum function. This standard is not limited to the situations in which the beneficiary is recovering from an acute event. The process also includes an exemption from prior authorization requirements for qualifying providers that demonstrate a high level of compliance with Medicare requirements.

We will continue to monitor the hospital OPD prior authorization process and consider opportunities to improve transparency, automation, and standardized electronic workflows while maintaining appropriate program integrity safeguards.

Comment: Several commenters asserted that CMS lacks statutory authority to expand prior authorization to the additional hospital OPD botulinum toxin injection services. The commenters argued that section 1833(t)(2)(F) of the Act does not authorize CMS to impose prior authorization requirements for hospital outpatient services.

Response: We appreciate the commenters' concerns. We disagree that we lack authority to establish prior authorization requirements for these hospital OPD services. Section 1833(t)(2)(F) of the Act requires the

Secretary to develop a method for controlling unnecessary increases in the volume of covered OPD services. Thus, where, as here, we have determined that there have been unnecessary increases in the volume of covered OPD services, section 1833(t)(2)(F) of the Act gives us authority to utilize prior authorization as a method to control those unnecessary increases. The hospital OPD prior authorization process is an appropriate exercise of this authority because it provides a mechanism to ensure that Medicare payment requirements are met before services are furnished and claims are submitted. Prior authorization does not prohibit or limit coverage of medically necessary botulinum toxin injection services that meet applicable Medicare coverage, coding, and payment requirements.

After consideration of public comments, we are finalizing our proposal to add eight Botulinum Toxin Injection codes to the hospital OPD prior authorization process.

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TABLE 102: 2027 LIST OF ADDITIONAL OUTPATIENT DEPARTMENT SERVICES THAT REQUIRE PRIOR AUTHORIZATION

Beginning for service dates on or after July 1, 2027	
Code	(2) Botulinum Toxin Injections
64611	Chemodenervation of parotid and submandibular salivary glands, bilateral
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed.
64642	Chemodenervation of one extremity; 1-4 muscle(s)
64644	Chemodenervation of one extremity; 5 or more muscles
64646	Chemodenervation of trunk muscle(s); 1-5 muscle(s)
64647	Chemodenervation of trunk muscle(s); 6 or more muscles
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit

TABLE 103: FINAL LIST OF OUTPATIENT DEPARTMENT SERVICES THAT REQUIRE PRIOR AUTHORIZATION

Beginning for service dates on or after July 1, 2020	
Code	(1) Blepharoplasty, Blepharoptosis Repair, and Brow Ptosis Repair[223]
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
67901	Repair of blepharoptosis; frontalis muscle technique with suture or other material (eg, banked fascia)
67902	Repair of blepharoptosis; frontalis muscle technique with autologous fascial sling (includes obtaining fascia)
67903	Repair of blepharoptosis; (tarso) levator resection or advancement, internal approach
67904	Repair of blepharoptosis; (tarso) levator resection or advancement, external approach
67906	Repair of blepharoptosis; superior rectus technique with fascial sling (includes obtaining fascia)
67908	Repair of blepharoptosis; conjunctivo-tarso-Muller's muscle-levator resection (eg, Fasanella-Servat type)
Code	(2) Botulinum Toxin Injection
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)
J0585	Injection, onabotulinumtoxina, 1 unit
J0586	Injection, abobotulinumtoxina, 5 units
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxin a, 1 unit
Code	(3) Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and related services
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication)
15877	Suction assisted lipectomy; trunk
Code	(4) Rhinoplasty, and related services[224]
20912	Cartilage graft; nasal septum

21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
30460	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip only
30462	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip, septum, osteotomies
30465	Repair of nasal vestibular stenosis (eg, spreader grafting, lateral nasal wall reconstruction)
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
Code	(5) Vein Ablation, and related services
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated
36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated
36483	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites
Beginning for service dates on or after July 1, 2021	
Code	(6) Cervical Fusion with Disc Removal
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace

Code	(7) Implanted Spinal Neurostimulators [225]
63650	Percutaneous implantation of neurostimulator electrode array, epidural
Beginning for service dates on or after July 1, 2023	
Code	(8) Facet Joint Interventions[226]
64490	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
64491	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level
64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level
64494	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint

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XX. Codification of Section 6225 of the Consolidated Appropriations Act, 2026 for the Requirements for Provider-Based Status (§§ 413.65 and 419.23)

A. Background

Section 1861(u) of the Act lists the types of facilities that are regarded as providers of services but does not use or define the term ''provider-based''. Since the beginning of the Medicare program, however, some providers, referred to as *main providers,* have functioned as a single entity while owning and operating multiple subordinate facilities that were treated as part of the main provider for Medicare purposes (as related to, for instance, payment; certification; coverage; and/or billing). With this treatment, compared to being treated as a freestanding facility, provider-based facilities might experience a number of advantages, including most notably, increased payments from Medicare. Therefore, we have maintained that having clear criteria for treating a facility as provider-based, as opposed to operating as a freestanding facility, is important because failure to properly distinguish between the two risks inaccurate program payments, which can result in provider overpayments and increased beneficiary coinsurance liability, with no commensurate benefit to the Medicare program or its beneficiaries. Section 413.65 specifies the criteria for treating a facility as provider-based and the requirements for a CMS determination of provider-based status, including an attestation by the provider that the facility meets the provider-based criteria. Provider compliance with provider-based rules is mandatory, but since the passage of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000 (Pub. L. 106–554, App'x F), a provider has needed to submit an attestation only if it wishes to obtain a CMS determination of provider-based status.

B. Requirements at Section 6225 of the Consolidated Appropriations Act, 2026

Section 6225 of the Consolidated Appropriations Act, 2026 (CAA, 2026), Public Law 119–75, enacted on February 3, 2026, amends section 1833(t) of the Act by adding new paragraph (23). In brief, section 6225 of the CAA, 2026 will prohibit Medicare payments under the OPPS beginning January 1, 2028, unless off-campus outpatient departments of a provider bill using a separate National Provider Identifier (NPI) and the main provider has submitted an attestation that the departments meet the provisions at § 413.65. As noted previously, although provider compliance with provider-based rules is mandatory, payment had not been conditioned on verification of such compliance.

Section 1833(t)(23)(A) of the Act, as added by section 6225 of the CAA, 2026, specifies that no payment may be made under that subsection (or under an applicable payment system pursuant to

[223] CPT 67911 (Correction of lid retraction) was removed on January 7, 2022.

[224] CPT 21235 (Obtaining ear cartilage for grafting) was removed on June 10, 2020.

[225] CPT codes 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver) and 63688 (Revision or removal of implanted spinal neurostimulator pulse generator or receiver) were temporarily removed from the list of OPD services that require prior authorization, as finalized in the CY 2021 OPPS/ASC final rule with comment period.

[226] CPT codes 64492 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s)) and 64495 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s)) will be removed on August 16, 2024.

paragraph (21) of section 1833(t) of the Act) for items and services furnished on or after January 1, 2028, by an off-campus outpatient department of a provider unless that department has obtained, and the items and services are billed under, an NPI that is separate from the NPI of the main provider; the main provider has submitted to the Secretary, during the 2-year period ending on the date such items and services are furnished, an initial provider-based status attestation that the off-campus outpatient department is compliant with the requirements described in section § 413.65 (or a successor regulation); and the main provider has submitted a subsequent attestation within the timeframe specified by the Secretary. The initial attestation may include an attestation submitted in accordance with existing § 413.65(b)(3) until the Secretary establishes the new attestation submission process, which is discussed further below.

New section 1833(t)(23)(B)(i) of the Act requires the Secretary, through notice and comment rulemaking, to establish a process for each provider with an off-campus outpatient department to submit an initial and subsequent attestation, for the review of each such attestation and for the determination, through site visits, remote audits, or other means (as determined appropriate by the Secretary), whether each off-campus outpatient department is compliant with the requirements described in subparagraph (A). In addition, new section 1833(t)(23)(C) of the Act defines an ''off-campus outpatient department of a provider'' for purposes of paragraph (23) as a department of a provider (as defined in § 413.65) that is not located on the campus (also defined in § 413.65) of the main provider or is not within the distance described in such definition of campus from a remote location of a hospital (also defined in § 413.65).

C. Modifications To Implement the Provisions of Section 6225 of the CAA, 2026

1. Modification to the Hospital OPPS Regulations

As discussed previously, section 1833(t)(23)(A) of the Act, as added by section 6225 of the CAA, 2026, specifies that no payment may be made under the OPPS for items and services furnished on or after January 1, 2028, by an off-campus outpatient department of a provider unless that department has obtained, and the items and services are billed under, an NPI that is separate from the NPI of the main provider; the main provider has submitted to the Secretary, during the 2-year period ending on the date such items and services are furnished, an initial provider-based status attestation that the off-campus outpatient department is compliant with the requirements described in section § 413.65; and the main provider has submitted a subsequent attestation within the timeframe specified by the Secretary. In the CY 2027 OPPS/ASC proposed rule (91 FR 41981), we proposed to add new section § 419.23 to codify this requirement. (We note the proposed changes to the provider-based regulations at § 413.65 to implement the attestation requirements are discussed in the next section. We also note, as discussed in greater detail in the next section, we proposed that prior to submitting an attestation, providers must obtain an NPI for each provider-based department.) Public comments on our proposals and our responses are discussed in the subsequent sections.

2. Modifications to the Provider-Based Regulations at § 413.65

In the proposed rule (91 FR 41980 through 41984), we proposed changes to the provider-based regulations at § 413.65 to implement the new requirements in section 6225 of the CAA, 2026. First, we proposed the addition of a new entry in the list of definitions in § 413.65(a)(2) for an ''Off-campus outpatient department of a provider''. We currently define a ''department of a provider'' as a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider. The definition of a department of a provider does not include rural health clinics (RHCs) or, except as specified in § 413.65(n), Federally Qualified Health Centers (FQHCs). In accordance with the statutory definition provided in section 1833(t)(23)(C) of the Act, we proposed to add a new definition to paragraph (a)(2) describing an off-campus outpatient department of a provider as a department of a provider that is not located on the campus of the main provider or within 250 yards of a remote location of a hospital. Under this proposed definition, facilities or organizations that are not located on the campus of the main provider would be considered off-campus for provider-based purposes. This would include remote locations of a hospital, which are defined in § 413.65 as facilities that provide inpatient services in a location off the campus of a main provider. Remote locations are often referred to as secondary or subordinate ''multi-campus'' locations of a hospital, and in most cases operate in a substantially similar manner as the main provider. Section 6225 of the CAA, 2026, adding section 1833(t)(23)(C) to the Act, defines an ''off-campus outpatient department of a provider'' as neither being on the campus of the main provider, nor within the distance specified in the definition of campus of a remote location of a hospital.

Comment: A commenter requested CMS clarify whether the relevant remote location encompasses the broader area surrounding the inpatient facility or is limited to the specific building or buildings providing inpatient services.

Response: As discussed previously, the term ''remote location of a hospital'' is defined by regulation and it means, in part, a facility that provides inpatient hospital services under the name, ownership, and financial and administrative control of the main provider (see § 413.65(a)(2)). Remote locations are subject to the additional provider-based status requirements applicable to ''off-campus'' facilities at § 413.65(e). The ''campus'' definition at § 413.65(a)(2) applies to the physical area encompassing the main buildings of the main provider. We believe the inclusion of the 250-yard limit in section 1833(t)(23)(C) of the Act is intended as an alternative for an on-campus designation for purposes of section 6225 of the CAA, 2026. For this reason, we proposed to amend the regulations to clarify that any outpatient department that is located within 250 yards of a remote location facility would not be included in the definition of an ''off-campus outpatient department of a provider'' (and therefore would not be subject to the attestation or separate NPI requirements).

Comment: We received a few comments requesting CMS provide additional clarification on how the measurement from a remote location would be implemented. Specifically, a commenter inquired from what point of the remote location facility would the measurement be taken, and whether certain structures, like awning, walkways, etc., would be acceptable starting points for measurement.

Response: We understand the commenters' interest in this issue. Section 1833(t)(23)(C) of the Act, as added by 6225 of the CAA, 2026, refers to the distance specified in the definition of campus, which is codified at § 413.65(a)(2). In the campus definition, any area or structure within 250 yards of a main building of the

hospital is considered on-campus for purposes of applying the provider-based regulations. We proposed that, for purposes of implementing section 6225 of the CAA, 2026, we would add a new definition to paragraph (a)(2) describing which facilities or organizations would be considered off-campus outpatient departments of a provider (91 FR 41981). Under the proposal, any facility on the campus of the main provider or within 250 yards of a remote location of a hospital would *not* meet the regulatory definition of an ''off-campus outpatient department of a provider'', and would therefore not be subject to the attestation or separate NPI requirements. We did not propose any modification to the definition of a campus in the proposed rule. Based on current practices, the 250-yard measurement could begin at any point of the remote location facility that provides patient care. Typically, when making provider-based on-campus determinations, we have reviewed publicly available satellite mapping software to make these determinations, using straight-line measurements from the main building to the nearest point of the potential provider-based department. In some cases, applicants may supply additional survey material to assist in this measurement process using a submission process designed by CMS. We would expect to follow the same practice in deciding whether a facility meets the requirements of section 6225 of the CAA, 2026. Regarding the inclusion of certain features, like awnings or walkway overhangs, we believe that non-structural components are not consistent with the definition of a remote location of a hospital and would not be an appropriate measuring point.

After consideration of public comments, we are finalizing the definition of ''off-campus outpatient department of a provider'' as proposed, without modification.

Section 413.65(e) includes additional requirements applicable to off-campus facilities or organizations. These requirements apply to all off-campus outpatient facilities, including those that are in close proximity to (and often within the same building as) inpatient remote locations. The implementation of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74) in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and interim final rule with comment period (81 FR 79720 through 79729), however, excepted outpatient departments located within 250 yards of a remote location from payment policy implications for off-campus departments. Given the definition of an ''off-campus outpatient department of a provider'' in section 603 of the Bipartisan Budget Act of 2015 and section 6225 of the CAA, 2026 separates outpatient departments located outside the regulatorily-specified distance of a remote location of a hospital and provider off-campus outpatient departments, we stated in the proposed rule that we believe that it would be appropriate to distinguish off-campus requirements from those for hospital outpatient departments that are within 250 yards of a remote location of the main provider (91 FR 41981). Therefore, we proposed to revise § 413.65(e) to specifically exclude outpatient departments located within 250 yards of a remote location of a hospital, and to revise § 413.65(b)(3)(ii), (g)(1)(i), and (h) to append ''or within 250 yards of a remote location of a hospital'' to the references of being on the campus of the main provider. We stated we believe these proposed conforming changes would better clarify which facilities are affected by the new legislation and would better align the current provider-based rules with statutory provisions regarding the distinction between on- and off-campus locations and services. In addition, we proposed to make a technical change to § 413.65(g)(1)(i) and (ii) to revise ''treated by Medicare'' to ''treated by CMS'' consistent with the other proposals discussed in this section.

Comment: A commenter urged CMS not to finalize the proposed revisions to § 413.65(e) that would treat outpatient departments located within 250 yards of a hospital's remote location as located on the main provider's campus. The commenter requested that CMS preserve the existing standard to provide stability and avoid imposing any unnecessary burden beyond those required by statute.

Response: We believe the commenter misunderstood the effect of the proposal to revise § 413.65(e) to exclude outpatient departments located within 250 yards of a remote location of a hospital (91 FR 41981). Currently, remote locations of a hospital are considered to be ''off-campus'', along with any outpatient departments located in close proximity to the inpatient facility that is the remote location of the hospital. Any off-campus facilities are currently subject to the additional applicable off-campus requirements of § 413.65(e), because they are not considered to be located on the main provider's campus. As stated previously, we believe these proposed conforming changes would better align the current provider-based rules with statutory provisions regarding the distinction between on- and off-campus locations and services. Our proposal to revise § 413.65(e) would exclude outpatient departments located within 250 yards of a remote location of a hospital from the additional provider-based status requirements applicable to off-campus facilities, so our proposal would reduce regulatory burden on outpatient departments that are within 250 yards of a remote location of a hospital.

After consideration of public comments, we are finalizing these revisions as proposed.

In the proposed rule (91 FR 41981), we proposed to add new section § 419.23 to codify the separate NPI and attestation requirements for payment under the OPPS for items and services furnished on or after January 1, 2028. In addition, we proposed to add a reference in § 413.65 to the new mandatory attestation requirements required by section 6225 of the CAA, 2026 and proposed a maximum 5-year timeframe for any subsequent attestation(s) (91 FR 41981). Specifically, we proposed to add § 413.65(b)(6) to state that, as of January 1, 2028, a main provider must submit an initial attestation of provider-based status for each of its off-campus outpatient departments within the 2-year period prior to furnishing services, and subsequent attestation(s) within a period not to exceed 5 years thereafter (91 FR 41981). We stated that we anticipate addressing the subsequent attestation requirement in the 2028 rulemaking cycle; nonetheless, we welcomed comments on the subsequent attestation (91 FR 41982). For all off-campus outpatient departments providing services on or before January 1, 2028, we proposed initial attestations must be submitted between January 1, 2026 and December 31, 2027, and off-campus outpatient departments that begin providing services after January 1, 2028 must submit an attestation within the 2 years prior to when the billed services are delivered. Subsequent attestation(s) would be submitted at an interval to be specified by CMS and not to exceed 5 years thereafter. In addition, we proposed providers that submit initial attestations within the 2-year period prior to January 1, 2028, would meet the attestation requirements of section 6225 of the CAA, 2026, even if they have not received a provider-based status determination from CMS by January 1, 2028. We also sought comments on an initial mandatory attestation for provider departments that received a determination of provider-based status prior to January 1, 2026,

and remain in compliance with all applicable provisions of § 413.65. For these departments, we stated that we were considering having the authorized official attest with a letter to CMS with evidence of CMS determination attached affirming its continued compliance with § 413.65.

Comment: Numerous commenters strongly opposed the mandatory NPI and attestation requirements, citing administrative burden and payment disruption concerns and requested CMS consider a longer implementation timeline than what is currently required by law. They additionally recommended establishing a ''good-faith'' correction period or exercising enforcement discretion due to downstream operational impacts on hospital billing, NPI assignments, and system testing and updates. A commenter stated that the separate NPI required for an off-campus outpatient department of a provider under the provisions of section 6225 of the CAA, 2026 be consistently reflected on both the hospital's facility claim (paid under the OPPS or applicable payment system under 1833(t)(21)) and the associated physician's professional claim (paid under the Medicare Physician Fee Schedule (PFS)) to allow for a ''cross-claim linkage''.

Response: We acknowledge the commenters' opposition to the mandated separate NPI and attestation requirements, particularly as related to anticipated administrative burden and payment disruption concerns. The statute establishes January 1, 2028, as the date on which CMS must stop making payments for items and services furnished at an off-campus outpatient department of a provider unless the NPI and attestation requirements are met. Specifically, section 1833(t)(23)(A) of the Act sets forth the requirements for payment for items and services ''furnished on or after January 1, 2028, by an off-campus outpatient department of a provider.'' Failure to meet the separate NPI or attestation requirements would affect payments for the items and services furnished by a specific off-campus outpatient department of a provider, not all OPPS payments to the main provider. As discussed throughout this section, we have sought to minimize the burden on providers in complying with the requirements of section 6225 of the CAA, 2026 while also maintaining appropriate oversight, and will continue to make every effort in doing so. As we implement these provisions, such efforts will include the development of billing, enrollment, and other subregulatory guidance. However, we will monitor implementation progress and may consider these suggestions for future rulemaking. We may consider the commenter's feedback regarding the cross-claim linkage on related professional claims in the development of future billing or other subregulatory guidance.

Comment: Commenters questioned whether multiple hospital services operating at the same physical address require separate NPIs or may be covered by a single NPI, and whether an off-campus location providing multiple hospital services (such as providing both laboratory and radiology services) would need separate NPIs for each service line. Another commenter requested CMS provide clarity on how the location designation in the Provider Enrollment, Chain, and Ownership System (PECOS) would impact the NPI assignment. For example, whether multiple off-campus provider-based departments located at the same address but with separate identifiers (*e.g.* room numbers or suite numbers) assigned in PECOS would require a separate NPI for each off-campus provider-based department. Some comments requested clarity on whether hospitals should obtain NPIs by the physical address level, based on how the location is designated in PECOS, or by each individual department.

Response: For purposes of the requirements of section 6225 of the CAA, 2026, and consistent with § 413.65(a)(2), ''department of a provider'' is identified by the hospital's submission of its physical facility location in the enrollment system—its street address, including suite or floor number, where applicable. A single off-campus location operating at one address is one ''department of a provider'' and, therefore, needs only one NPI even if multiple types of services are being provided there. For example, a hospital with an off-campus location providing both laboratory and radiology services would obtain one NPI for that location, not separate NPIs per service line.

Comment: Other comments related to the separate NPI requirement included concerns that separate NPIs for off-campus provider-based departments could conflict with CMS requirements to combine same-day outpatient services on a single claim because the Health Insurance Portability and Accountability Act (HIPAA) standard claim format permits only one billing NPI. Some commenters also expressed concern about potential Medicare Advantage (MA) implications of new department-specific NPIs. Commenters stated that new NPIs could trigger new prior authorization requirements for MA patients, disrupt coordination of benefits, and cause supplemental insurance claim denials due to NPI mismatches. Commenters further argued that requiring separate NPIs undermines HIPAA's goal of a single provider identifier and urged CMS to clarify that department-specific NPIs are administrative requirements only and do not indicate new independent provider entities.

Response: The establishment or use of an NPI to satisfy the requirements of section 6225 of the CAA, 2026 does not, by itself, change the nature of the department, which remains a provider-based department of the hospital. To address certain issues mentioned in the comments, we are taking measures to allow the entry of multiple NPIs within a claim—the claim level NPI of the hospital plus the service line NPIs for the various services provided during a given day.

We will continue to consider commenters' feedback—including concerns about burden and operational challenges—as the agency develops policies and subregulatory guidance for implementing the NPI requirement.

Comment: Commenters generally supported our proposals related to timing of the initial attestation, including the proposal to submit initial attestations in the 2-year period prior to January 1, 2028, and the proposal that initial attestations submitted by January 1, 2028 will meet the requirement even if CMS has not issued a provider-based determination by that date. Some commenters recommended that attestation approvals granted prior to January 1, 2026, be ''grandfathered'' as having met the initial attestation requirement. Other commenters requested that the initial attestation requirement be limited to new off-campus outpatient departments of a provider. Another commenter urged CMS to tie the initial attestation deadline to the existing Form CMS–855A enrollment activation date, such as 60 days following that enrollment activation date. The commenter stated that it is ''administratively irrational'' to require a provider-based attestation prior to this enrollment activation since the facility does not yet legally exist within the Medicare system. A commenter requested that CMS clarify in the regulation text at § 419.23 that claims for services provided at a department with a complete, timely attestation under review will continue to be paid without interruption.

Response: We appreciate commenters' feedback on our proposals related to the timing of the initial attestation, and are finalizing them, with one modification discussed below. Specifically, we are

finalizing our proposal that for departments providing services on or before January 1, 2028, initial attestations must be submitted between January 1, 2026 and December 31, 2027; for departments beginning services after January 1, 2028, initial attestations must be submitted within the 2 years prior to delivering billed services; and providers submitting initial attestations within the required 2-year period will meet the initial attestation requirement, even if a provider-based status determination has not been received by that date. Based on feedback from commenters, we are adding paragraph (c) to § 419.23 to clarify that a provider satisfies the submission requirement at paragraph (a)(2) of this section even if CMS has not made a determination of provider-based status before the first day on which the outpatient department renders services.

Regarding attestation approvals granted prior to January 1, 2026, section 6225 of the CAA, 2026 specifies the timing for the initial attestation by requiring that payment cannot be made for items or services furnished on or after January 1, 2028 by an off-campus outpatient department of a provider unless such provider has submitted an initial provider-based attestation ''during the 2 year period ending on the date such items or services are so furnished.'' Although attestations submitted before the statutory ''2 year period'' deadline do not meet the initial attestation requirement, our streamlined attestation process aims to reduce provider burden.

Regarding the request to use the Form CMS–855A enrollment activation date as the deadline for the initial attestation, under current procedures a Form CMS–855A must be submitted, reviewed by the MAC, and assigned an effective date of enrollment activation before an off-campus outpatient department of a provider can be added to a provider's enrollment record. However, as previously discussed, the provisions of section 6225 of the CAA, 2026 specify the timing for the initial attestation, tying it to the date the items or services for which payment is being sought are furnished. We appreciate the commenter's concern and encourage providers to take into account the time needed to add a potential provider-based off-campus outpatient department to their enrollment record when considering when to submit an initial attestation within the statutory 2-year period.

Comment: Several commenters requested CMS modify the proposed maximum 5-year timeframe for the required subsequent attestation to reduce the overall burden on hospitals. Some suggested a timeframe of seven to ten years, and some requested a timeframe of no less than 10 years. Another commenter expressed the importance of maintaining provider-based compliance for equitable payment policy, and suggested CMS implement a shorter timeframe, such as 3 years or upon a change in ownership, for the subsequent attestation. Many commenters recommended requiring only one subsequent attestation after the initial attestation, or only requiring periodic re-attestations in specified circumstances, such as when there is a material change in the relationship between the hospital and its off-campus provider-based department, a change in ownership, or a management contract change. A commenter also requested CMS clarify when the proposed 5-year ''countdown'' for the subsequent attestation would begin, such as when the initial attestation is submitted or when CMS issues the provider-based status determination.

A commenter stated that CMS should establish the subsequent (post-CY 2028) attestation cadence in the final rule, rather than deferring it to future rulemaking or guidance, to provide adequate lead time for compliance planning.

Response: We appreciate the commenters' feedback. In response to the comment regarding the start of the subsequent attestation timeline, we are clarifying that the time-period for the subsequent attestation would begin on the date the attestation is submitted as we believe this is the most consistent with the statute.

At this time, we continue to believe that a maximum 5-year subsequent attestation period is an appropriate timeframe to balance provider burden while ensuring continued provider-based compliance. As we gain experience with these new requirements, we may revisit this policy, including commenters' suggestions regarding the timing, frequency and/or circumstances of a subsequent attestation.

We appreciate the commenter's request to address the subsequent attestation process in this final rule with comment period. We believe addressing the subsequent attestation requirement, including its timing, frequency, and applicable circumstances, in the 2028 rulemaking cycle will allow CMS to gain experience implementing the initial attestation requirement and to consider additional operational information before establishing the subsequent attestation process.

In response to our request, we also received comments on the subsequent attestation requirement process. We appreciate those suggestions and feedback and will take them into consideration for future rulemaking. As stated in the proposed rule (91 FR 41982), we anticipate addressing the subsequent attestation requirement in the 2028 rulemaking cycle.

In summary, after consideration of public comments, we are finalizing our proposal to codify, at § 419.23, the separate NPI and attestation requirements for payment under the OPPS for items and services furnished on or after January 1, 2028, with one technical edit in paragraph (a)(3) and the modification to address situations where CMS has not issued a provider-based status determination before the first date services are furnished. We are also finalizing our proposal to add § 413.65(b)(6), including a reference to the separate NPI and attestation requirements, with a modification, as discussed below. Specifically, § 413.65(b)(6) provides that, as of January 1, 2028, a main provider must submit an initial attestation of provider-based status for each of its off-campus outpatient departments within the 2-year period prior to furnishing services, and subsequent attestation(s) within a period not to exceed 5 years thereafter. For all off-campus outpatient departments providing services on or before January 1, 2028, initial attestations must be submitted between January 1, 2026 and December 31, 2027, and for off-campus outpatient departments that begin providing services after January 1, 2028, initial attestations must be submitted within the 2 years prior to delivering billed services. For purposes of § 413.65(b)(6), an off-campus outpatient ''department'' comprises all hospital operations at one physical address as listed in PECOS.

In the proposed rule (91 FR 41982), we discussed that Indian Health Service and Tribal facilities described in § 413.65(m) and certain FQHCs and ''look alikes'' described in § 413.65(n) are considered to be in compliance with provider-based requirements, and would not be subject to review of provider-based status. We, therefore, proposed to exclude these facilities from the proposed attestation requirements. We stated that other parts of § 413.65 not specifically addressed are outside the scope of this rulemaking.

Comment: We received several comments requesting clarification as to whether certain off-campus facilities for which CMS currently does not make a provider-based determination, such as those listed in § 413.65(a)(1)(ii), would be subject to the requirements of section 6225 of the CAA, 2026. Commenters

also inquired whether facilities not paid under the OPPS, such as Critical Access Hospitals (CAHs), Rural Health Clinics (RHCs), and hospitals participating in the Achieving Healthcare Efficiency through Accountable Design (AHEAD) payment model, such as those located in Maryland, would be subject to the requirements of section 6225 of the CAA, 2026.

Response: Section 6225 of the CAA, 2026 specifies that no payment may be made under the OPPS (or under an applicable payment system pursuant to § 1833(t)(21)) of the Act for items and services furnished by an off-campus outpatient department of a provider unless the separate NPI and attestation requirements are met. CAHs are excluded from the OPPS at § 419.20(b)(2), and payment for outpatient CAH services is governed by § 1834(g) of the Act. Therefore, we do not believe that section 6225 of the CAA, 2026 applies to CAHs.

Regarding RHCs, we note that because provider-based RHCs furnish health care services of a *different* type from those of the main provider, an RHC would meet the § 413.65(a)(2) definition of a ''provider-based entity'', not a ''department of a provider''. Because § 1833(t)(23)(C), added by Section 6225 of the CAA, 2026, includes the regulatory term ''department of a provider'' only, ''provider-based entities'' such as RHCs would not fall within the scope of section 6225 of the CAA, 2026 applicable to off-campus outpatient departments of a provider.

We also believe that the requirements of section 6225 of the CAA, 2026 do not apply to hospitals, such as those located in Maryland, that are participating in the AHEAD Model since they are not paid under section 1833(t) of the Act. The AHEAD Model is a voluntary state total cost of care model with hospital global budgets that was created under section 1115A of the Social Security Act by CMS's Center for Medicare and Medicaid Innovation (CMS Innovation Center) that specifies participating hospitals payments; participating hospitals are not paid under the OPPS.

Initially, we determined we would not make a provider-based determination for facilities listed at § 413.65(a)(1)(ii) because we believe obtaining provider-based status typically would have no direct payment impact. Facility types mentioned in § 413.65(a)(1)(ii) may be paid under a separate payment system from OPPS. In the case of therapy services described in § 413.65(a)(1)(ii)(H), we make no provider-based status determination when there is no annual financial cap amount on payments for provider-based and freestanding facilities.[227] Section 6225 requirements apply to any facility that meets the definition of an ''off-campus outpatient department of a provider'' and section 6225 does not distinguish between facilities that receive different payments. However, we will take into consideration the concerns expressed regarding those facilities for which we historically have not made provider-based status determinations and may consider appropriate ways to minimize burden as we develop subregulatory guidance implementing the requirements of section 6225 of the CAA, 2026.

Comment: A commenter requested clarification as to whether a remote location of a hospital must obtain and maintain its own organizational (Type 2) NPI.

Response: As discussed previously, a ''remote location of a hospital'' refers only to a facility that furnishes inpatient services, and is not, itself, an ''off-campus outpatient department of a provider'' and therefore is not subject to the provisions of Section 6225 of the CAA, 2026.

Comment: A commenter requested CMS to confirm that an off-campus outpatient department of a provider that does not submit Medicare claims for OPPS payments is not required to obtain a separate NPI or submit an attestation unless and until it intends to bill Medicare. Other commenters specifically asked about outpatient departments of Children's Hospitals, requesting an exclusion for facilities with a de minimis number of Medicare claims.

Response: As stated previously, section 6225 of the CAA specifies that no payment may be made under the OPPS (or under an applicable payment system pursuant to section 1833(t)(21)) for items and services furnished by an off-campus outpatient department of a provider unless the separate NPI and attestation requirements are met. It contains no de minimis exception. However, a facility that is not seeking payment under the referenced payment systems would not be compelled to comply with the requirements of section 6225 of the CAA, 2026.

After consideration of public comments, we are finalizing our proposal to exclude Indian Health Service and Tribal facilities described in § 413.65(m) and certain FQHCs and ''look alikes'' described in § 413.65(n) from the attestation requirements. In addition, we are adding language to § 413.65(b)(6) to specify that an off-campus department operating as part of CAH is excluded from the attestation requirements.

In the proposed rule (91 FR 41982), to implement section 6225 of the CAA, 2026, we proposed to establish a standardized attestation form for provider-based determinations, which would replace the current Medicare Administrative Contractor (MAC)-specific templates and ensure consistency across MACs. Through this standardization, CMS proposed that main providers would submit the attestation through a centralized electronic system, which we stated we believed would result in a reduction in administrative burden for providers and a more efficient review process for MACs and CMS. Further, we stated that we anticipated that standardization and centralized submission processes may reduce unnecessary duplicative documentation burden while continuing to support appropriate compliance review and program integrity oversight. Until the standardized form and centralized electronic system are finalized, we stated that providers may continue to submit attestations in accordance with existing § 413.65(b)(3)(ii) in satisfaction of section 6225 of the CAA, 2026 to their servicing MAC. (91 FR 41982)

Comment: Commenters generally supported CMS's proposal to establish a centralized electronic system for submitting provider-based attestations, noting that such a system could promote greater consistency and efficiency. Commenters requested that the system support streamlined or bulk submissions for providers with multiple off-campus departments.

Response: We thank commenters for their support of a centralized electronic submission system. We intend for the centralized system to provide a standardized mechanism for submitting and maintaining provider-based attestations and to eliminate variations with the existing MAC processes. We also intend for the system to eliminate duplication in documentation submission for multiple attestations, where practicable. We will ensure that the system provides the necessary information for providers to attest to the provider-based requirements and will provide additional operational instructions regarding use of the system through subregulatory guidance.

After consideration of public comments, we are finalizing our proposal to adopt the centralized electronic system for attestations as proposed.

[227] Currently, the financial cap is applicable to both freestanding and provider-based facilities described in § 413.65(a)(1)(ii)(H).

To ensure providers have clarity on how to satisfy the mandatory attestation requirement under section 6225 of the CAA, 2026, we proposed to require that providers submit attestations using the referenced CMS-standardized attestation form. The attestation would be a list of identifying information of the main provider and provider-based department such as name, address, and NPI that includes a list of the requirements at § 413.65(d)(e), (g), and (h) with a certifying statement affirming compliance to be signed by an authorized official of the main provider. A draft was made available at the following link for comment: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1850-p.* Under the current attestation process, providers submit their attestations and supporting documentation to their MAC, which performs a preliminary review and forwards its recommendation to CMS for the initial determination. We proposed to modify this process so that CMS' contractors, including MACs, conduct standardized review and validation activities in support of initial determination regarding compliance with § 413.65, rather than requiring separate CMS review of each attestation recommendation. To reflect this proposal, we proposed to revise § 413.65(b)(3)(iii) to specify that CMS ''or its agents'' will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness and consistency with information in the possession of CMS ''or its agents'' at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based (91 FR 41982). We also proposed that the determinations issued through this process would constitute CMS initial determinations for purposes of § 498.3(b)(2). In conducting review and validation activities, we proposed that CMS and its contractors, including MACs, would employ standardized review, validation, and risk-based screening processes to assess attestations for completeness, consistency with the provider's enrollment records, and compliance with the applicable requirements of § 413.65. We stated these processes may include automated validation activities, data analysis, targeted documentation review, and contractor review procedures designed to support consistent national implementation and program integrity oversight. We proposed to establish, through operational guidance, specific review criteria, validation protocols, and documentation standards that CMS and its contractors, including MACs, must apply in conducting review and validation activities and supporting initial determinations, in order to promote consistent assessment of provider-based requirements across all CMS contactors including MAC jurisdictions. We stated that CMS would conduct ongoing quality review and oversight of attestation determinations and related review activities (91 FR 41982). (For additional discussion of our proposed documentation requirements for provider-based attestations and proposed verification and oversight activities, refer to sections XX.D, and XX.E, respectively, of this preamble.)

Comment: We received a number of comments on the attestation process, including the initial attestation pathway and form design. Commenters generally supported a streamlined attestation process and form but requested clarification or modification of several data elements. For example, commenters noted that the proposed form does not provide a means to identify a designated contact acting on behalf of the provider. Several commenters also recommended that CMS allow delegated submission authority so that an authorized submitter can complete and submit attestations and supporting documents on behalf of the organization without requiring the direct involvement of the authorized official. A commenter requested CMS avoid open-ended review timelines and establish a specific review and determination timeframe, such as 60 or 90 days.

Response: We thank commenters for their recommendations and will make every effort to include appropriate changes to the attestation process and form, including the ability to designate a provider contact and delegation authority. We note that section 6225 of the CAA, 2026 does not establish a deadline by which CMS must complete the review of attestations or make provider-based determinations. We understand the commenter's concern regarding extended review periods and, as we gain experience with the implementation of the mandatory attestation, review and determination requirements, we will continue to refine or revise our policies and procedures to minimize unnecessary delays.

In the proposed rule (91 FR 41982), we proposed an additional modification to § 413.65(b)(3)(ii) to revise the timing and modernize submission of supporting documentation for off-campus provider-based facilities and organizations. We proposed CMS and its contractors, including MACs, employ standardized review and validation processes, including automated validation activities, data analysis, risk-based screening methodologies, targeted documented review, and other program integrity activities, to evaluate attestations and identify submissions requiring additional review of compliance verification. Providers would continue to be required to maintain documentation demonstrating compliance with applicable provider-based requirements and to furnish such information to CMS or its contractors, including MACs, upon request as part of review, validation, audit, or oversight activities. We stated that we believe these proposals would afford providers greater flexibility in meeting the statutory deadlines imposed by section 6225 of the CAA, 2026, while continuing to allow CMS oversight and access to information necessary to evaluate compliance and make a determination. We also proposed a modification to § 413.65(k) to remove references to what constitutes a ''complete'' attestation, with supporting documentation and additional information to be requested from the provider, as necessary, after the standardized attestation form has been submitted (91 FR 41982).

Comment: Commenters generally supported our proposed centralized electronic system and streamlined attestation process and offered recommendations to reduce administrative burden, particularly for health systems with multiple off-campus departments. These commenters urged CMS to minimize duplicative documentation for departments that already received an affirmative provider-based determination from CMS. Commenters also asked us to clarify whether providers must submit supporting documentation along with their attestation.

Response: We thank commenters for their support of a streamlined attestation process and for their detailed operational recommendations. We clarify at the outset that an attestation serves as a provider's certification of compliance with the applicable provider-based requirements at § 413.65. We do not intend to require the submission of documentation supporting the basis for the claims made in the attestation at the time the attestation is submitted. Providers will be expected, however, to furnish documentation demonstrating compliance with the provider-based requirements upon our request.

Departments that received an affirmative provider-based determination before January 1, 2026, are required to submit a new attestation under the streamlined process described. The streamlined process is intended to reduce burden for all attestations, including for departments that previously received an affirmative provider-based determination. We expect to address this process further in future rulemaking or subregulatory guidance.

We received general support from commenters regarding the proposals to streamline and reduce the administrative burden of the provider-based attestation process. After consideration of public comments, we are finalizing as proposed our proposal to revise the timing and modernize the manner in which supporting documentation is submitted for off-campus provider-based facilities and organizations at § 413.65(b)(3)(ii). We are also finalizing our proposal to modify § 413.65(k) to remove references to what constitutes a 'complete' attestation as proposed.

We proposed that main providers, prior to submitting an attestation, must obtain an NPI for each provider-based department and update PECOS. As discussed previously, to implement section 6225 of the CAA, 2026, we proposed to establish a standardized attestation form for provider-based determinations that would replace the current MAC-specific templates; the attestation would then be submitted through a centralized electronic system. We stated we believe this standardized approach would ensure consistency across MACs and would result in a reduction in administrative burden for providers and a more efficient review process for MACs and CMS. For providers that submit attestations for more than one off-campus outpatient department, we stated that we were considering streamlined supporting documentation requirements and sought input on how best to minimize burden while ensuring robust oversight. Further, we stated we anticipated a reduction in the documentation supporting the attestation. For instance, we anticipated leveraging system capabilities to reduce duplicative documentation submissions by allowing supporting documentation applicable to multiple locations to be submitted a single time, where appropriate (91 FR 41983).

Comment: Commenters expressed concern about the administrative burden associated with repeatedly submitting the same information and supporting documentation for multiple off-campus departments within the same hospital or health system. Commenters recommended that CMS allow information and documentation applicable to multiple departments to be submitted once and applied across the relevant departments, rather than requiring duplicative submissions.

Response: We thank commenters for these recommendations. As discussed, providers will not be required to submit supporting documentation with the initial attestation. When we request supporting documentation, we intend to use the centralized electronic system to minimize duplicative submissions, including by allowing providers to submit documentation once when the same information applies to multiple off-campus departments or demonstrates compliance with multiple provider-based requirements.

After consideration of public comments, we are finalizing these provisions concerning the use of a centralized electronic system, standardized attestation, and supporting documentation as proposed. We are also finalizing that, prior to submitting an attestation, main providers must obtain an NPI for each provider-based department and update their enrollment record in CMS's system of record—currently PECOS—or any successor system accordingly.

In the proposed rule (91 FR 41983), we stated that the future standard attestation format would request identifying information for both the main provider and the provider-based entity, including applicable NPIs. We stated that once all attestations are submitted, providers would indicate their submission is complete. We stated CMS and its contractors, including MACs, may employ automated validation, screening, targeted review and risk-based methodologies to identify attestations requiring additional review, supporting documentation, or follow-up activities. We stated that we anticipate giving providers a reasonable period, generally not to exceed 60 days, to furnish requested supporting documentation.

If CMS or its contractors, including MACs, determine that an attestation demonstrates compliance with the provider-based requirements at § 413.65, we proposed that an approval notice would be issued. We proposed CMS and its contractor, including MACs, would request supporting documentation at any stage of the review, validation, audit or oversight process to evaluate compliance with applicable provider-based requirements. If CMS or its contractor determines that an attestation fails to demonstrate compliance with the provider-based requirements, or if the provider fails to furnish all requested information or attest to all applicable requirements, we proposed that a denial would be issued, including applicable appeal rights. Until the standardized form and centralized electronic system are finalized, we proposed providers may continue to submit attestations in accordance with § 413.65(b)(3), in satisfaction of section 6225 of the CAA, 2026 (91 FR 41983). As noted previously, an off-campus outpatient department of a provider will also need to obtain an NPI by January 1, 2028 to be paid under the OPPS (or under an applicable payment system in accordance with section 1833(t)(21)) of the Act, consistent with section 1833(t)(23)(A)(i) of the Act as added by section 6225 of the CAA, 2026.

In addition in the proposed rule (91 FR 41983), we proposed to use program integrity mechanisms currently available to CMS, or that may become available in the future, whether through improved technology, contracting, data analysis or other means, to evaluate compliance with provider-based requirements and identify attestations requiring additional review or oversight activities. In § 413.65(k), we proposed to specify that these activities may include site visits, remote audits, investigations, or require submission of additional documentation as may be necessary to make a determination of compliance with the provider-based requirement, and the use of current or future Medicare program integrity contractors. We stated that we believe this proposal would continue to address CMS' longstanding concerns, regarding potential increased costs to the Medicare program and its beneficiaries by ensuring compliance with provider-based regulations. (For additional discussion of our proposed documentation requirements for provider-based attestations, refer to section XX.D of this preamble. For additional discussion of the proposed CMS verification and oversight activities, refer to section XX.E of this preamble.)

Comment: Commenters requested that CMS establish clear procedures for communicating the outcome of provider-based attestation reviews, including written notice of findings, opportunities to correct deficiencies before a denial, and information regarding applicable appeal rights.

Response: We thank commenters for these recommendations. We will provide written notification of the outcome of an attestation review, including a determination as to whether the department satisfies the applicable

provider-based requirements. If we determine that a department does not satisfy the requirements, the notification will identify the basis for the adverse determination and provide information with applicable appeal rights. As appropriate, providers that CMS determines would otherwise satisfy the provider-based requirements, but have minor attestation-based deficiencies may also be afforded an informal opportunity to correct those deficiencies before we issue a determination.

After consideration of public comments, we intend to provide written notice of the review outcome with applicable appeal rights. We are also finalizing without modification the proposed changes to § 413.65(k) regarding program integrity mechanisms for compliance with the provider-based requirements.

D. Documentation Requirements for Provider-Based Attestations

To support meaningful CMS oversight of provider compliance with the provider-based requirements of § 413.65, and consistent with the mandatory attestation requirement established by section 6225 of the CAA, 2026, in the proposed rule (91 FR 41983), we proposed that attestations submitted through the proposed standardized attestation process would include, or be supported by, documentation sufficient to demonstrate compliance with the applicable provisions of § 413.65(d), (e), (g), and (h). We described, as discussed later in this section, the categories of documentation that providers may be required to submit or retain in connection with their attestations. As discussed further, we stated that CMS anticipated that not all documentation described herein would be required at the time of initial attestation submission; rather, CMS and its contractors, including MACs, will employ risk-based screening and targeted documentation review processes to identify those attestations for which additional documentation is warranted. We stated the rationale behind using targeted documentation review is that any main provider typically manages its departments in a consistent manner. By drawing a sample from each main provider's universe of provider-based departments, we would be able to gain a reliable understanding of their universe. This approach would not only ensure adequate representation across all providers, regardless of their volume—it would also provide meaningful insight into whether compliance standards are being upheld across all departments. We invited public comment on the appropriate scope of documentation requirements, including whether any of the categories described should be modified, consolidated, or eliminated in order to reduce provider burden while preserving CMS' ability to evaluate compliance and protect the Medicare program. Specifically, in the proposed rule (91 FR 41983 through 41984) we proposed the following documentation framework:

- *Attestation Form Completeness and Authorization:*

++ We proposed that providers must submit a completed attestation using the CMS-standardized attestation form, signed and dated by an authorized official of the main provider as identified in PECOS. The attestation would be required to identify both the main provider and each off-campus outpatient department of the provider for which provider-based status is sought, including the applicable NPIs, provider numbers, addresses, and the date on which provider-based conditions were met or the date the department was acquired, as applicable. Where a provider designates a consultant or outside representative as the primary contact for the attestation, we proposed the provider must authorize the representative in writing.

- *Location:*

++ We stated we anticipate the attestation system would have the ability to measure the distance requirement. However, if the distance is not systematically verified or exceeds 35-miles, we proposed providers would be required to submit supporting documentation in support of § 413.65(e)(3).

- *Licensure:*

++ We proposed providers must be prepared to demonstrate that the off-campus outpatient department is operated under the same licensure as the main provider, consistent with § 413.65(d)(1), or to provide documentation that the applicable State does not require a separate license for the department.

- *Clinical Services Integration:*

++ We proposed providers must be prepared to demonstrate that the off-campus outpatient department meets the clinical integration requirements of § 413.65(d)(2), including that professional staff at the department hold privileges at the main provider; that appropriate monitoring and oversight of the department by the main provider is in place; that inpatient and outpatient services of the department and the main provider are integrated; and that patients treated at the department who require further care have full access to all services of the main provider.

- *Financial Integration:*

++ We proposed providers must be prepared to demonstrate that the revenues and expenses of the off-campus outpatient department are integrated with those of the main provider, consistent with § 413.65(d)(3), such that the department does not maintain a separate general ledger or trial balance independent of the main provider.

- *Public Awareness:*

++ We proposed that providers must be prepared to demonstrate that the off-campus outpatient department is clearly identified to the public as part of the main provider, consistent with § 413.65(d)(4), and that patients entering the department are aware they are receiving services from the main provider.

- *Obligations of Hospital Outpatient Departments:*

++ For off-campus outpatient departments that are departments of hospitals, we proposed that providers must be prepared to demonstrate compliance with the applicable obligations of hospital outpatient departments under § 413.65(g), including compliance with Emergency Medical Treatment and Labor Act (EMTALA) requirements, antidumping rules, site-of-service billing requirements, and the requirement to provide written notice to Medicare beneficiaries of their potential financial liability prior to the delivery of services at an off-campus location.

- *Ownership, Control, Administration, and Supervision (Off-Campus Departments):*

++ We proposed providers must be prepared to demonstrate that the department operates under the ownership and control of the main provider consistent with § 413.65(e)(1), including that the department is 100 percent owned by the main provider and that the main provider retains final approval over administrative decisions, personnel policies, and medical staff appointments. We also proposed providers must also be prepared to demonstrate that the administrative functions of the department are integrated with those of the main provider consistent with § 413.65(e)(2), including through submission of an organizational chart reflecting the reporting relationship between the department and the main provider.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters requested greater clarity and consistency regarding the documentation CMS may require demonstrating compliance with the provider-based requirements. A commenter recommended a uniform national documentation checklist identifying the evidence necessary to demonstrate compliance with § 413.65.

Response: We thank commenters for their recommendations on the documentation requirements for the provider-based requirements. We plan to provide specific guidance on the required documentation for each provider-based requirement in future rulemaking or subregulatory guidance.

E. CMS Verification and Oversight Activities

Section 1833(t)(23)(B)(i) of the Act directs the Secretary to establish a process for determining, through site visits, remote audits, or other means as determined appropriate by the Secretary, whether each off-campus outpatient department of a provider is compliant with the applicable requirements. Consistent with this statutory direction, in the proposed rule (91 FR 41984), we proposed that CMS and its contractors, including MACs, employ a layered, risk-based approach to verification and oversight that would be designed to promote efficient processing of the significantly increased volume of attestations expected under the mandatory attestation requirement while preserving meaningful CMS oversight of provider compliance with § 413.65.

We proposed that, at the initial review stage, CMS and its contractors, including MACs, would conduct automated validation and screening of all submitted attestations to verify completeness, consistency with PECOS enrollment records, and the presence of required attestation elements. Attestations that pass automated validation would be processed for initial determination. Attestations that present indicators of incompleteness, inconsistency, or elevated compliance risk would be flagged for targeted documentation review, during which CMS or its contractors may request that the provider furnish supporting documentation from any or all of the categories described.

At the extended review stage, we proposed that CMS and its contractors, including MACs, would employ risk-based methodologies to select a subset of attestations for more extensive compliance review. Such methodologies may include remote audits of provider records and documentation, site visits conducted by CMS or its contractors to verify that the attested department meets the physical, financial, clinical, and administrative integration requirements of § 413.65, or investigations of potential non-compliance identified through data analysis, referral, or other sources. We stated the criteria and methodologies CMS would use to select attestations for extended review would be established through operational guidance and would be designed to focus oversight resources on providers and departments that present the highest risk of non-compliance with the provider-based requirements. We proposed that failure to submit requested documentation within the timeframe specified by CMS may result in a determination of non-compliance and recovery of payments as described in § 413.65(k).

We invited public comment on the appropriate scope and sequencing of documentation requirements, including whether the categories described should be further prioritized, consolidated, or phased in over time to facilitate provider compliance with the January 1, 2028 statutory deadline.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported CMS's use of risk-based verification and oversight but requested greater clarity regarding the criteria and procedures for targeted reviews, documentation requests, remote audits, and site visits.

Response: We thank commenters for their support regarding our proposed verification and oversight activities. Following our reviews of submitted attestations, we anticipate we will prioritize resources to perform extended reviews for hospitals with only a single off-campus outpatient department and targeted extended reviews for hospitals with multiple off-campus departments by selecting a random sample of submissions. Providers will be asked to submit specific documentation to demonstrate compliance with each provider-based requirement at § 413.65. If a provider is found to be out of compliance for a specific requirement, we may extend the review of that requirement to departments not included in the sample. We will continue to develop policies and procedures, such as remote audits, data analysis, alternative data sourcing approaches and site visits, as we gain experience with the oversight of these off-campus provider-based requirements.

After consideration of public comments, we are finalizing these provisions as proposed.

XXI. Payment for Direct and Indirect Graduate Medical Education (GME) Costs—Notice of Closure of Teaching Hospitals and Opportunity To Apply for Available Slots

a. Background

Section 5506 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, ''Affordable Care Act''), authorizes the Secretary to redistribute residency slots after a hospital that trained residents in an approved medical residency program closes. Section 5506 of the Affordable Care Act instructs the Secretary to establish a process by regulation that redistributes slots from teaching hospitals that close to hospitals that meet certain criteria, with priority given to certain hospitals including those located in the same Core Based Statistical Area (CBSA), in a contiguous CBSA or in the same state as the closed hospital.

Specifically, section 5506 of the Affordable Care Act amended the Act by adding subsection (vi) to section 1886(h)(4)(H) of the Act and modifying language at section 1886(d)(5)(B)(v) of the Act. These changes instruct the Secretary to establish a process to increase the FTE resident caps at other hospitals based upon the FTE resident caps at teaching hospitals that closed on or after March 23, 2008. In the CY 2011 Outpatient Prospective Payment System (OPPS) final rule with comment period (75 FR 72264), we established regulations at 42 CFR 413.79(o) and an application process for qualifying hospitals to apply to CMS to receive direct GME and IME FTE resident cap slots from the hospital that closed. We made certain additional modifications to § 413.79 in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434), and we made changes to the section 5506 application process in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50122–50134). The procedures we established apply to teaching hospitals that closed between March 23, 2008, and August 3, 2010, and to teaching hospitals that close after August 3, 2010 (75 FR 72215).

b. Notice of Closure of St. Luke's Des Peres Hospital Located in Des Peres, MO, and the Application Process—Round 32

CMS learned of the closure of St. Luke's Des Peres Hospital, located in

Des Peres, MO (CCN 260176). Accordingly, we are providing notice of the closure of this teaching hospital and initiating another round of the application and selection process to redistribute the closed hospital's FTE resident caps. This round will be the 32nd round (''Round 32'') of the application and selection process. Table 104 contains the identifying information for the closed teaching hospital and its IME and direct GME FTE resident caps, which are part of the Round 32 application process under section 5506 of the Affordable Care Act.

TABLE 104: ST. LUKE'S DES PERES HOSPITAL FTE RESIDENT CAPS

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME FTE Resident Cap	Direct GME FTE Resident Cap
260176	St. Luke's Des Peres Hospital	Des Peres, MO	41180	July 31, 2025	25.16[1]	26.06[2]

1 St. Luke Des Peres Hospital's 1996 IME FTE resident cap is 25.16.
2 St. Luke Des Peres Hospital's 1996 Direct GME FTE resident cap is 26.06.

c. Notice of Closure of Franciscan Health Hammond Located in Hammond, IN, and the Application Process—Round 33

CMS learned of the closure of Franciscan Health Hammond, located in Hammond, IN (CCN 150004). Accordingly, we are providing notice of the closure of this teaching hospital and initiating another round of the application and selection process to redistribute the closed hospital's FTE resident slots. This round will be the 33rd round (''Round 33'') of the application and selection process. Table 105 contains the identifying information for the closed teaching hospital and its IME and direct GME FTE resident caps, which are part of the Round 33 application process under section 5506 of the Affordable Care Act.

TABLE 105: FRANCISCAN HEALTH HAMMOND FTE RESIDENT CAPS

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME FTE Resident Cap (including +/- MMA Sec. 422[1] adjustments)	Direct GME FTE Resident Cap (including +/- MMA Sec. 422 adjustments)
150004	Franciscan Health Hammond	Hammond, IN	29414	December 31, 2022	6.11 – 1.72 sec. 422 reduction = 4.39[2]	6.11 – 1.75 sec. 422 reduction = 4.36[3]

1 Section 422 of the MMA, Public Law 108–173, redistributed unused IME and direct GME residency slots effective July 1, 2005.
2 Franciscan Health Hammond's 1996 IME FTE resident cap is 6.11. Under section 422 of the MMA, the hospital received a reduction of 1.72 to its IME FTE cap = 6.11 – 1.72 = 4.39.
3 Franciscan Health Hammond's 1996 Direct GME FTE resident cap is 6.11. Under section 422 of the MMA, the hospital received a reduction of 1.75 to its Direct GME FTE cap = 6.11 – 1.75 = 4.36.

d. Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 of the Affordable Care Act is 90 days following notice to the public of a hospital closure (77 FR 53436). Therefore, hospitals that wish to apply for and receive slots from the previously noted hospitals' FTE resident caps must submit Round 32 and 33 applications using the electronic application intake system, Medicare Electronic Application Request Information System™ (MEARIS™) no later than February 2, 2027. The Section 5506 application can be accessed at *https://mearis.cms.gov/public/home.*

CMS will only accept Round 32 and 33 applications submitted via MEARIS™. Applications submitted through any other method will not be considered. Within MEARIS™, we have built in several resources to support applicants:

- Please refer to the ''Resources'' section for guidance regarding the application submission process at *https://mearis.cms.gov/public/resources.*
- Technical support is available under ''Useful Links'' at the bottom of the MEARIS™ web page.
- Application related questions can be submitted to CMS using the form available under ''Contact'' at *https://mearis.cms.gov/public/resources.*

Application submission through MEARIS™ will not only help CMS track applications and streamline the review process, but it will also create efficiencies for applicants when compared to a paper submission process.

We have not established a deadline for when CMS will issue the final determinations to hospitals that receive slots under section 5506 of the Affordable Care Act. However, we review all applications received through MEARIS™ by the application deadline and notify applicants of our determinations as soon as possible.

We refer readers to the CMS Direct Graduate Medical Education (DGME) website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/direct-graduate-medical-education-dgme.* Hospitals should access this website for a list of additional section 5506 guidelines for applying for slots, and the redistribution of the slots under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Act.

XXII. Consideration of Potential Approaches for Separate IPPS Payment for Domestic Procurement of Personal Protective Equipment and Essential Medicines

In the CY 2027 OPPS/ASC proposed rule (91 FR 41985 through 41996), we sought public comment on potential options we could consider for Medicare participating hospitals to help foster a more resilient supply chain for American-made PPE and essential medicines to secure our nation's health and safety, and to reflect the additional resource costs incurred when procuring these domestically manufactured items. Specifically, we solicited public comment on potentially eligible PPE and essential medicines, the applicable definitions of ''domestic'' for PPE and essential medicines, respectively, the use of standardized cost differentials for eligible domestic PPE and essential medicines, a potential manufacturer attestation of domestic origin, potential approaches under the IPPS to separately pay for the additional resource costs that hospitals face when purchasing eligible domestic PPE and essential medicines, and an appropriate maximum annual amount of aggregate separate payment under this potential policy. We also solicited general input on additional options from the public.

We thank commenters for the many thoughtful comments we received on this topic and will consider them for future rulemaking as appropriate.

XXIII. Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency Data

In the CY 2027 OPPS/ASC proposed rule (91 FR 41996 through 41999), we included a RFI on strengthening the standardization and comparability of the hospital price transparency data. Specifically, we asked questions on how to strengthen the transparency and utility of the machine-readable files and on how to enhance the comparability of the consumer-friendly display. We received 185 timely pieces of correspondence that were submitted in response to the hospital price transparency RFI questions. The public comments received reflected input from a diverse range of interested parties, including academic researchers, consumers and consumer advocacy organizations, employer organizations, hospitals and hospital associations, health technology organizations, and users of the hospital price transparency machine-readable files. We thank all interested parties for their comments and will take them into consideration for future rulemaking.

XXIV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, we are required to provide 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. To fairly evaluate whether an information collection should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs for the Hospital Outpatient Quality Reporting (OQR) Program

1. Background

In sections XIV. and XV. of this final rule with comment period, we discuss the finalized requirements for the Hospital Outpatient Quality Reporting Program. The Hospital Outpatient Quality Reporting Program is generally aligned with the CMS quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting Program. We refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 54029 through 54037) for detailed discussions of the previously finalized Hospital Outpatient Quality Reporting Program ICRs which are currently approved under OMB control number 0938–1109 (expiration date July 31, 2029).

In this final rule with comment period, we are: (1) removing the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2027 reporting period/CY 2029 payment determination; (2) including electronic clinical quality measures (eCQMs) into the existing validation process for chart-abstracted measures beginning with eCQM data from the CY 2027 reporting period affecting the CY 2030 payment determination; (3) reducing the validation selection pool from 500 to up to 400 HOPDs beginning with validation affecting the CY 2030 payment determination; and (4) removing the requirement for hospitals to resubmit medical documentation as part of their request for reconsideration of validation noncompliance, beginning with data from the CY 2026 reporting period affecting the CY 2028 payment determination.

As part of including eCQMs into the existing validation process for chart-abstracted measures beginning with CY 2027 eCQM data affecting the CY 2030 payment determination, we are: (1) modifying the number of chart-abstracted cases required for validation from 12 per quarter to a maximum of 7 per quarter per measure beginning with validation affecting the CY 2030 payment determination; (2) replacing the previously finalized 2-year validation cycle with a 3-year validation cycle, where hospitals selected for validation based on CY 2027 data affecting the CY 2029 payment determination will not be selected again for validation of the same data affecting the CY 2030 payment determination; (3) determining eCQM validation scores using the same methodology currently used to score chart-abstracted measure validation; (4) revising the policy to allow the results of educational reviews for all four quarters of chart-abstracted measure validation to be reflected in the final validation score prior to the calculation of the confidence interval; and (5) extending the educational review process established for chart-abstracted measure validation to eCQM validation.

In the CY 2026 OPPS/ASC final rule with comment period, we calculated reporting burden estimates for the Hospital Outpatient Quality Reporting Program by utilizing the Bureau of Labor Statistics (BLS) median hourly wage rate for Medical Records Specialists (90 FR 54029). Specifically, we used the industry-specific wage for Medical Records Specialists working in ''general medical and surgical hospitals'', as this categorization aligns the closest with the Hospital Outpatient Quality Reporting Program care setting. The most recent data from BLS' May 2025 National Occupational Employment and Wage Estimates reflects a median hourly wage of $28.59 per hour for Medical Records Specialists working in ''general medical and surgical hospitals'' (SOC 29–2072).[228]

[228] U.S. Bureau of Labor Statistics. (2026). Occupational Outlook Handbook, Medical Records Specialists. Available at *https://data.bls.gov/oes/#/industry/622100/2025*. Accessed May 18, 2026.

We calculated the cost of overhead, including fringe benefits, at 100 percent of the median 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 ($28.59 × 2 = $57.18) to estimate total cost burden is reasonably accurate. Accordingly, unless otherwise specified, we calculate cost burden to hospitals using a wage plus benefits estimate of $57.18 per hour throughout the discussion in this section of this final rule with comment period for the Hospital Outpatient Quality Reporting Program.

In the CY 2026 OPPS/ASC final rule with comment period, our burden estimates assumed that approximately 3,200 hospital outpatient departments (HOPDs) will report data to the Hospital Outpatient Quality Reporting Program (90 FR 54029). For this final rule with comment period, based on the most recent available data from the CY 2026 Hospital Outpatient Quality Reporting Program payment determination, we estimate that 3,000 HOPDs will report data to the Hospital Outpatient Quality Reporting Program for the CY 2027 reporting period/CY 2029 payment determination and future years.

2. Information Collection Burden Estimate for the Removal of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Beginning With the CY 2027 Reporting Period/CY 2029 Payment Determination

As discussed in section XIV.B. of this final rule with comment period, we are removing the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2027 reporting period/CY 2029 payment determination. For this measure, HOPDs are required to abstract data from patient charts as well as report the measure electronically via CMS' Hospital Quality Reporting (HQR) system. According to the current Hospital Outpatient Quality Reporting Program Specifications Manual, the sample size requirement for HOPDs with populations of 900 patients or less is 63 cases annually, and the requirement for HOPDs with populations of greater than 900 patients is 96 cases annually.[229] To be conservative, we base our burden estimates on an estimate of 96 cases per HOPD annually. Under OMB control number 0938–1109, the currently approved burden is 2.92 minutes (0.049 hours) per case for chart-abstraction and 10 minutes (0.167 hours) per HOPD to report the measure via the HQR. Therefore, we estimate that this measure removal will result in a decrease in burden for all 3,000 HOPDs of 14,612 hours [(0.049 hours × 96 cases × 3,000 HOPDs) + (0.167 hours × 3,000 HOPDs)] at a savings of $835,514 (14,612 hours × $57.18) beginning with the CY 2027 reporting period.

We did not receive public comments on this information collection burden estimate.

3. Information Collection Burden Estimate for the Validation of eCQMs Beginning With Validation of CY 2027 Data Affecting the CY 2030 Payment Determination

As discussed in section XV.D. of this final rule with comment period, we are including eCQMs in the Hospital Outpatient Quality Reporting Program's existing validation process for chart-abstracted measures. We assume HOPDs will upload only one PDF file per case to CMS' HQR system with an estimated burden of 1 minute (0.0167 hours) per case per HOPD. In the CY 2027 OPPS/ASC proposed rule, we proposed to validate up to 32 eCQM cases annually from four calendar quarters of eCQM data (91 FR 41963). In this final rule with comment period, we are finalizing to validate up to 28 eCQM cases annually from four calendar quarters of eCQM data (up to 7 cases × 4 quarters) for each eCQM with mandatory reporting, starting with validation of CY 2027 eCQM data affecting the CY 2030 payment determination. As discussed in section XXIV.A.4. of this final rule with comment period, we are finalizing a reduction of the validation selection pool from 500 to up to 400 HOPDs; therefore validation burden is estimated for up to 400 HOPDs. We note submission of medical documentation will occur in the CY immediately following the CY of the data being submitted (for example, CY 2027 data will be submitted in CY 2028 affecting the CY 2030 payment determination, and CY 2028 data will be submitted in CY 2029 affecting the CY 2031 payment determination). For the CY 2030 payment determination, in which HOPDs will be selected for validation of the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM, we estimate an increase in burden of 187 hours across the 400 HOPDs selected for eCQM validation (0.0167 hours × 4 quarters × 7 cases × 400 HOPDs) at a cost of $10,674 (187 hours × $57.18). For the CY 2031 payment determination and subsequent years, HOPDs will be selected for validation of both the STEMI and Emergency Care Access & Timeliness eCQMs; thus, we estimated an increase in burden of 373 hours across the 400 HOPDs selected for eCQM validation (0.0167 hours × 4 quarters × 14 cases × 400 HOPDs) at a cost of $21,347 (373 hours × $57.18).

As discussed in section XV.D. of this final rule with comment period, we are finalizing policies which will align the inclusion of eCQMs into the existing validation process for chart-abstracted measures beginning with CY 2027 eCQM data. However, we are finalizing that impacts to payment for validation of eCQM data will not begin until the CY 2030 payment determination, which will be based off CY 2028 eCQM data. In the CY 2027 OPPS/ASC proposed rule, we proposed to validate up to 32 randomly selected patient cases annually for each chart-abstracted measure (91 FR 41963). In this final rule with comment period, we are finalizing a change to the number of cases selected for chart-abstracted measure validation under the Hospital Outpatient Quality Reporting Program to align with the number of cases selected for eCQM validation. Specifically, we will validate up to 28 randomly selected patient cases annually for each chart-abstracted measure. Under these policies, we will validate up to 28 randomly selected patient cases for chart-abstracted clinical process of care measures (up to 7 cases per quarter), starting with validation of CY 2027 data affecting the CY 2030 payment determination. Submission of medical documentation will occur in the CY immediately following the CY of the data being submitted (for example, CY 2027 data will be submitted in CY 2028 affecting the CY 2030 payment determination). As currently approved under OMB control number 0938–1109, selected HOPDs are required to submit medical documentation for validation for 48 cases (12 cases per quarter), for which we estimate an information collection burden of 15 minutes (0.25 hours) per case, or 12 hours per HOPD (0.25 hours/case × 48 cases). For the CY 2030 payment determination, in which HOPDs will be selected for validation of both the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients and the Head Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients Who Received Head CT or MRI Scan

[229] CMS. (2025). Hospital OQR Program Specifications Manual Release Notes version 19.0. Available at *https://qualitynet.cms.gov/files/69274c02ec892eacec2209b5?filename=OQR_SpecManual_v19.0a.pdf.*

Interpretation Within 45 Minutes of Arrival measures, we estimate the burden associated with these policies for the 400 HOPDs selected for validation to be 5,600 hours (0.25 hours × 56 cases × 400 HOPDs) at a cost of $320,208 (5,600 hours × $57.18). For the CY 2031 payment determination and subsequent years, in which HOPDs will be selected for validation of only the Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients Who Received Head CT or MRI Scan Interpretation Within 45 Minutes of Arrival measures, we estimate the burden associated with these policies for the 400 HOPDs selected for validation to be 2,800 hours (0.25 hours × 28 cases × 400 HOPDs) at a cost of $160,104 (2,800 hours × $57.18). We discuss the revised information collection burden for all HOPDs selected for chart-abstracted measure validation in section XXIV.A.4. of this final rule with comment period where we discuss modifying the validation selection pool from 500 HOPDs to 400 HOPDs.

Additionally, we are replacing the previously finalized 2-year validation cycle with a 3-year validation cycle beginning with CY 2027 data affecting the CY 2030 payment determination, under which validation results for a single year of data will be applied to the applicable payment determination 3 years later. Under this policy, HOPDs selected for chart-abstracted measure validation based on CY 2027 data, affecting the CY 2029 payment determination, will not be selected again for validation of the same data affecting the CY 2030 payment determination. We will also determine eCQM validation scores using the methodology currently used to score chart-abstracted measure validation; revise our policy to allow the results of educational reviews for all four quarters of chart-abstracted measure validation to be reflected in the final validation score prior to the calculation of the confidence interval; and extend the educational review process established for chart-abstracted measure validation to eCQM validation. These changes to the HOPD validation cycles, scoring methodology, validation scoring, and the educational review process do not affect information collection burden as neither the amount of data nor frequency of data submission is impacted.

We did not receive public comments on this information collection burden estimate.

4. Information Collection Burden Estimate for the Modification of the Validation Selection Pool From 500 to up to 400 HOPDs Beginning With Validation of CY 2027 Data Affecting the CY 2030 Payment Determination

As discussed in section XV.D.2.a. of this final rule with comment period, we are reducing the number of hospitals selected at random for validation from 450 HOPDs to up to 200 HOPDs and increasing the number of hospitals selected by targeting criteria from 50 HOPDs to up to 200 HOPDs, for a total of up to 400 HOPDs selected each year beginning with validation of CY 2027 data affecting the CY 2030 payment determination. As discussed in section XXIV.A.3. of this final rule with comment period, HOPDs will be required to submit medical record documentation for 28 cases. As discussed in section XXIV.A.3. of this final rule with comment period, for the CY 2030 payment determination, we estimate these two policies will result in a revised total burden of 5,600 hours (0.25 hours × 4 quarters × 14 cases × 400 HOPDs) at a cost of $320,208 (5,600 hours × $57.18); a decrease of − 400 hours and $22,872 from our currently approved burden of 6,000 hours and $343,080. For the CY 2031 payment determination and subsequent years, we estimate these two policies will result in a revised total burden of 2,800 hours (0.25 hours × 4 quarters × 7 cases × 400 HOPDs) at a cost of $160,104 (2,800 hours × $57.18); a decrease of − 3,200 hours and $182,976 from our currently approved burden estimate.

We did not receive public comments on this information collection burden estimate.

5. Information Collection Burden Estimate for the Removal of the Requirement for Hospitals To Resubmit Medical Documentation as Part of a Validation Reconsideration Request, Beginning With Data From the CY 2026 Reporting Period Affecting the CY 2028 Payment Determination

As discussed in section XV.E. of this final rule with comment period, we are removing the requirement for HOPDs to resubmit medical documentation as part of their request for reconsideration of validation noncompliance, beginning with data from the CY 2026 reporting period affecting the CY 2028 payment determination. Instead, we will re-use the medical documentation previously submitted by the HOPD during the validation process. The removal of this requirement will not affect burden related to validation requirements, as reconsideration is an optional administrative activity, and HOPDs will still be required to submit the same number of requested medical records to validate the accuracy of eCQM data (the extent to which data abstracted from the submitted medical record matches the data submitted in the QRDA I file). Additionally, as currently approved under OMB control number 0938–1109, consistent with regulations under the Paperwork Reduction Act of 1995, 5 CFR 1320.4, the burden associated with filing a Reconsideration Request is excluded from our calculation of information collection burden because this collection occurs during the conduct of an administrative action.

We did not receive public comments on this information collection burden estimate.

6. Summary of Information Collection Burden Estimates for the Hospital OQR Program

Tables 106 through 108 summarize the information collection burden changes under OMB control number 0938–1109. We estimate that the finalized measure removal and modifications to the validation process in this final rule with comment period will result in a net decrease in information collection burden of 17,439 hours at a savings of $997,143 annually for all 3,000 program-eligible HOPDs beginning with the CY 2029 reporting period/CY 2031 payment determination. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1109. With respect to any costs/burdens unrelated to data submission, we refer readers to the regulatory impact analysis in section XXVII. of this final rule with comment period.

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TABLE 106: SUMMARY OF FINALIZED HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2027 REPORTING PERIOD/CY 2029 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2027 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of HOPDs reporting**	**Average number records per HOPDs per quarter**	**Annual burden (hours) per HOPD**	**Finalized annual burden (hours) across HOPDs**	**Previously finalized annual burden (hours) across HOPDs**	**Net difference in annual burden hours**
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Chart Abstraction)	2.92	1	3,000	96	4.7	0	14,112	-14,112
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Measure Reporting)	10	1	3,000	1	0.167	0	500	-500
	Total Change in Information Collection Burden Hours: -14,612							
	Total Cost Estimate: Updated Hourly Wage ($57.18) x Change in Burden Hours (-14,612) = **-$835,514**							

TABLE 107: SUMMARY OF FINALIZED HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2028 REPORTING PERIOD/CY 2030 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2028 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of HOPDs reporting**	**Average number records per HOPDs per quarter**	**Annual burden (hours) per HOPD**	**Finalized annual burden (hours) across HOPDs**	**Previously finalized annual burden (hours) across HOPDs**	**Net difference in annual burden hours**
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Chart Abstraction)	2.92	1	3,000	96	4.7	0	14,112	-14,112
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Measure Reporting)	10	1	3,000	1	0.167	0	500	-500
Implement Updates to Chart-Abstracted Measure Validation	15	4	400	14	14	5,600	6,000	-400
Implement eCQM Validation	1	4	400	7	0.467	187	0	187
	Total Change in Information Collection Burden Hours: -14,825							
	Total Cost Estimate: Updated Hourly Wage ($57.18) x Change in Burden Hours (-14,825) = **-$847,712**							

TABLE 108: SUMMARY OF FINALIZED HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2029 REPORTING PERIOD/CY 2031 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2029 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of HOPDs reporting**	**Average number records per HOPDs per quarter**	**Annual burden (hours) per HOPD**	**Finalized annual burden (hours) across HOPDs**	**Previously finalized annual burden (hours) across HOPDs**	**Net difference in annual burden hours**
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Chart Abstraction)	2.92	1	3,000	96	4.7	0	14,112	-14,112
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Measure Reporting)	10	1	3,000	1	0.167	0	500	-500
Implement Updates to Chart-Abstracted Measure Validation	15	4	400	7	7	2,800	6,000	-3,200
Implement eCQM Validation	1	4	400	14	0.933	373	0	373
	Total Change in Information Collection Burden Hours: -17,439							
	Total Cost Estimate: Updated Hourly Wage ($57.18) x Change in Burden Hours (-17,439) = **-$997,143**							

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B. ICRs for the Rural Emergency Hospital (REH) Quality Reporting Program

1. Background

In section XVI. of this final rule with comment period, we summarize the previously approved requirements for the REH Quality Reporting Program. We are not finalizing any changes to the previously finalized REH Quality Reporting Program policies in this final rule with comment period. The REH Quality Reporting Program is generally aligned with the CMS quality reporting program for HOPDs, known as the Hospital Outpatient Quality Reporting Program. We refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 54037 through 54041) for detailed discussions of the previously finalized REH Quality Reporting Program ICRs, which have been approved under OMB control number 0938–1454 (expiration date July 31, 2029).

In the CY 2026 OPPS/ASC final rule with comment period, we calculated reporting burden estimates for the REH Quality Reporting Program by utilizing the BLS median hourly wage rate for Medical Records Specialists (90 FR 54037). Specifically, we used the industry-specific wage for Medical Records Specialists working in the ''general medical and surgical hospitals'' industry, as this categorization aligns the closest with the REH Quality Reporting Program care setting. The most recent data from BLS'

May 2025 National Occupational Employment and Wage Estimates reflects a median hourly wage of $28.59 per hour for Medical Records Specialists working in ''general medical and surgical hospitals'' (SOC 29–2072).[230] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median 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, doubling the hourly wage rate ($28.59 × 2 = $57.18) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to REHs using a wage plus benefits estimate of $57.18 per hour throughout the discussion in this section of this rule for the REH Quality Reporting Program.

In the CY 2026 OPPS/ASC final rule with comment period, our burden estimates were based on the 38 acute care and critical access hospital conversions to REH status as of April 11, 2025 (90 FR 54037). For this final rule with comment period, based on the actual number of acute care and critical access hospital conversions to REH status as of April 6, 2026, we estimate that 48 REHs will report data to the REH Quality Reporting Program during the CY 2027 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. of this final rule with comment period, REHs are required by statute to submit quality data. Therefore, we assume that all 48 REHs will submit data under the REH Quality Reporting Program for the CY 2027 reporting period and subsequent years. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1454.

2. Revised Information Collection Burden Estimates for Currently Approved Measures

Our currently approved information collection burden estimates of 464 hours at a cost of $26,532 (using revised wage rates) are based on an estimate of 38 REHs reporting data for the REH Quality Reporting Program. This burden is entirely associated with the reporting of chart-abstracted measures as REHs have the option to report either the Median Time for Discharged Emergency Department (ED) Patients measure or the Emergency Care Access & Timeliness eCQM to meet program requirements, and the estimated burden for the Median Time for Discharged ED Patients is greater than the estimated burden for the Emergency Care Access & Timeliness eCQM. As discussed in section XXIV.B.1. of this final rule with comment period, we are updating our assumption of the number of REHs that will submit data under the REH Quality Reporting Program from 38 REHs to 48 REHs, an increase of 10 REHs. Our currently approved burden estimates assume that for chart-abstracted measures where patient-level data are submitted directly to CMS, REHs require 2.9 minutes, or 0.049 hours per case per measure to collect and submit the data for each submitted case. We further assume that each REH will abstract and submit data from 63 cases per quarter, for a total of 252 cases per year. Therefore, we estimate each REH requires 12.2 hours (0.049 hours × 252 cases) at a cost of approximately $698 (12.2 hours × $57.18) to collect and report data for the Median Time for Discharged ED Patients measure. For the increase of 10 REHs, we estimate an increase in annual chart-abstraction burden of 122 hours (12.2 hours × 10 REHs) at a cost of $6,976 (122 hours × $57.18).

C. ICRs for the Ambulatory Surgical Center (ASC) Quality Reporting Program

1. Background

In sections XIV. and XVII. of this final rule with comment period, we discussed the finalized requirements for the ASC Quality Reporting Program. We refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 54041 through 54045) for detail regarding the previously finalized ASC Quality Reporting Program ICRs which are currently approved under OMB control number 0938–1270 (expiration date July 31, 2029). We are removing the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2027 reporting period/CY 2029 payment determination.

In the CY 2026 OPPS/ASC final rule with comment period, we calculated reporting burden estimates for the ASC Quality Reporting Program by utilizing the BLS median hourly wage rate for Medical Records Specialists (90 FR 54042). Specifically, we used the industry-specific wage for Medical Records Specialists working in the ''general medical and surgical hospitals'' industry, as this categorization aligns the closest with the ASC Quality Reporting Program care setting. The most recent data from BLS' May 2025 National Occupational Employment and Wage Estimates reflects a median hourly wage of $28.59 per hour for Medical Records Specialists working in ''general medical and surgical hospitals'' (SOC 29–2072).[231] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median 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, doubling the hourly wage rate ($28.59 × 2 = $57.18) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to ASCs using a wage plus benefits estimate of $57.18 per hour throughout the discussion in this section of this rule for the ASC Quality Reporting Program.

Based on the most recent analysis of the CY 2026 payment determination data, we found that of the 6,930 ASCs that were actively billing Medicare, 4,399 were required to participate in the ASC Quality Reporting Program. Of the 2,531 ASCs not required to participate in the program, 650 ASCs did so and met full requirements. On this basis, we estimate that 5,149 ASCs (4,399 + 650) will submit data for the ASC Quality Reporting Program for the CY 2027 reporting period/CY 2029 payment determination and future years.

2. Information Collection Burden Estimate for the Removal of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Beginning With the CY 2027 Reporting Period/CY 2029 Payment Determination

As discussed in section XIV.B. of this final rule with comment period, we are removing the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2027 reporting period/CY 2029 payment determination. For this measure, ASCs are required to both abstract data from patient charts as well as report the measure electronically via the HQR system. Regarding the number of cases required for chart-abstraction, based on the current ASC Quality Reporting Program

[230] U.S. Bureau of Labor Statistics. (2026). Occupational Outlook Handbook, Medical Records Specialists. Available at *https://data.bls.gov/oes/#/industry/622100/2025.* Accessed May 18, 2026.

[231] U.S. Bureau of Labor Statistics. (2026). Occupational Outlook Handbook, Medical Records Specialists. Available at *https://data.bls.gov/oes/#/industry/622100/2025.* Accessed May 18, 2026.

Specifications Manual, we estimate that each participating ASC will abstract and submit data for the minimum yearly sample size of 63 annually.[232] Under OMB control number 0938–1270, the currently approved burden is 2.92 minutes (0.049 hours) per case for chart-abstraction and 10 minutes (0.167 hours) per ASC to report the measure via the HQR. Therefore, we estimate that this measure removal will result in a decrease in burden for all 5,149 ASCs of 16,753 hours [(0.049 hours × 63 cases × 5,149 ASCs) + (0.167 hours × 5,149 ASCs)] at a savings of $957,937 (16,753 hours × $57.18).

We did not receive public comments on this information collection burden estimate.

3. Summary of Information Collection Burden Estimates for the ASC Quality Reporting Program

Table 109 summarizes the information collection burden changes for OMB control number 0938–1270. We estimated the finalized measure removal in this final rule with comment period will result in a decrease in information collection burden of 16,753 hours at a savings of $957,937 annually for all 5,149 program-eligible ASCs beginning with 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 0938–1270. With respect to any costs/burdens unrelated to data submission, we refer readers to the regulatory impact analysis in section XXVII. of this final rule with comment period.

We received a public comment on the information collection burden for the ASC Quality Reporting Program. The following is a summary of the comment we received and our response.

Comment: A commenter expressed support for the continued use of the ASC Quality Reporting Program as an important mechanism for quality improvement due to its belief that quality reporting promotes accountability, supports performance measurement, and encourages facilities to continually evaluate patient outcomes and care processes. However, the commenter stated that participation in these programs requires significant administrative resources for data collection, reporting, compliance monitoring, staff education, and performance improvement activities, all while maintaining daily patient care and surgical operations. The commenter therefore encouraged CMS to continue supporting meaningful quality reporting while ensuring that reporting requirements remain practical and achievable for ASCs of varying sizes and resources; provide timely performance feedback; and provide reasonable opportunities to correct reporting deficiencies before payment penalties are imposed to strengthen compliance efforts and continued beneficiary access to high-quality outpatient care.

Response: We thank the commenter for their support and acknowledge challenges related to the varied size and resource availability across ASCs. We seek to support ASCs in meeting program requirements and will consider their concerns and recommendations in future rulemaking.

[232] *https://qualitynet.cms.gov/files/692dbe71ec892eacec22890b?filename=ASC_v15.0a_FullSpecMan.pdf.*

TABLE 109: SUMMARY OF ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2027 REPORTING PERIOD/CY 2029 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2027 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Finalized annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Chart Abstraction)	2.92	1	5,149	63	3.1	0	15,895	-15,895
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Reporting)	10	1	5,149	1	0.167	0	858	-858
	Total Change in Information Collection Burden Hours: -16,753							
	Total Cost Estimate: Updated Hourly Wage ($57.18) x Change in Burden Hours (-16,753) = **-$957,937**							

D. ICRs for the Implementation of Section 6225 of the Consolidated Appropriations Act, 2026 for the Requirements for Provider-Based Status (§ 413.65)

The requirements for a determination that a facility or an organization has provider-based status are in the regulations at § 413.65. Section 6225 of the CAA, 2026 added paragraph (23) to section 1833(t) of the Act, and prohibits Medicare payments for items and services furnished on or after January 1, 2028, unless off-campus outpatient departments of a provider meet certain conditions. New section 1833(t)(23)(A) of the Act requires, as a condition of receiving payment, that off-campus outpatient departments of a provider obtain and bill under separate NPIs and that main providers submit provider-based attestations in accordance with provisions at § 413.65. New section 1833(t)(23)(B)(i) of the Act requires the Secretary, through notice and comment rulemaking, to establish a process for each provider with an off-campus outpatient department to submit an initial and subsequent attestation, for the review of each such attestation and for the determination, through site visits, remote audits, or other means (as determined appropriate by the Secretary), whether each off-campus outpatient department is compliant with the requirements described in subparagraph (A). In addition, new section 1833(t)(23)(C) of the Act defines an ''off-campus outpatient department of a provider'' for purposes of paragraph (23) as a department of a provider (as defined in § 413.65) that is not located on the campus (also defined in § 413.65) of the main provider or is not within the distance described in such definition of campus from a remote location of a hospital (also defined in § 413.65).

As discussed in greater detail section XX. of this final rule with comment period, we finalized with certain modifications proposed changes to the provider-based regulations at § 413.65 to implement the new requirements of section 6225 of the CAA, 2026. Among those changes, we are revising § 413.65(b) to add a reference to the new mandatory attestation requirement for an off-campus outpatient department of a provider required by section 6225 of the CAA, 2026 and a maximum 5-year timeframe for any subsequent attestation(s), as proposed. In addition, as we proposed, we are establishing a standardized attestation form for provider-based determinations, in connection with the provisions of section 6225 of the CAA, 2026, that providers will submit through a centralized electronic system. The standardized form will replace the current MAC-specific templates. We are also finalizing our proposal to eliminate the mandatory requirement for off-campus provider-based facilities or organizations to supply supporting documentation at the time of attestation. Under our final policy, until the

standardized form and centralized electronic system are finalized, providers may continue to submit attestations using the current process in satisfaction of section 6225 of the CAA, 2026.

The collection of information requirements for the existing regulations at § 413.65 that govern the requirements for a determination that a facility or an organization has provider-based status is associated with OMB control number 0938–0798 (expiration date December 31, 2027). For the existing attestation requirement in § 413.65(b)(3), OMB has currently approved 2,500 hours of burden at a cost of approximately $327,150 based on accounting for information collection burden experienced by approximately 250 main providers. This estimated burden is based on the expectation that it would take a main provider 10 hours per attestation and each main provider would submit 1 attestation. Later in this section, we describe the burden changes regarding collection of information, under OMB control number 0938–0798.

The burden associated with this new attestation requirement continues to be the time for the main provider to report the facility's status to CMS and furnish the necessary documentation to support a provider-based determination. We believe this is reasonable as the information submitted by the provider is typically information that the provider already has regarding their business. However, as discussed in greater detail in section XX.3. of this final rule with comment period, under the finalized policy to establish a standardized attestation form for provider-based determinations that providers will submit through a centralized electronic system, we expect there will be a reduction in administrative burden for providers, and a more efficient review process for MACs and CMS. We anticipate that this reduction in administrative burden for providers will decrease the time required to submit each attestation by 25 to 75 percent.

As discussed in section XX.C. of this final rule with comment period, under existing regulations the attestation process was required only if the main provider sought a CMS determination of provider-based status. However, under the provisions of section 6225 of the CAA, 2026, Medicare payments will be prohibited unless off-campus outpatient departments of a provider meet certain conditions, including that the main provider has submitted an initial provider-based status attestation that the off-campus outpatient department is compliant with the requirements described in section § 413.65 (or a successor regulation); and the main provider has submitted a subsequent attestation within the timeframe specified by the Secretary. As a result of this new mandatory attestation requirement, as discussed in the proposed rule, we expect there to be an increase in both the number of main providers submitting attestations and the number of attestations submitted by each main provider. In the proposed rule (91 FR 42007), we stated that under these new provider-based status attestation requirements, it is estimated that 1,832 main providers would take 5 hours per attestation, and, on average, each main provider would submit 9 attestations for provider-based departments. Therefore, we calculated the burden as follows: 16,488 responses times 5 hours per response = 82,440 burden hours. We stated that we believe that an executive officer will be making the attestation because an executive officer is in the best position to have access to the business information required to make the attestation. Based on the most recent Bureau of Labor and Statistics Occupational and Employment Data (May 2024) at *http://www.bls.gov/oes/current/oes_nat.htm#* for Category 11–0000 for the position of Top Executives, the mean hourly wage for a top executive is $67.24. We added 100 percent for fringe and overhead benefits, which calculates to $134.48 per hour. We estimated the total cost is $11,086,531 (82,440 hours × $134.48 per hour). The estimated number of attestations increased due to section 6225 of the CAA, 2026 requiring providers submit attestations for all off-campus provider-based departments. As such, the estimated number of attestations increased from 250 to 16,488 and the estimated total cost increased from $327,150 to $11,086,531. (See 91 FR 42007.)

We received public comments on these estimates included in the proposed rule. The following is a summary of the comments we received and our responses.

Comment: Some commenters stated that CMS' estimate understates the actual burden and fails to account for certain costs associated with the new requirements. Some commenters indicated that attestation process costs include coordinating and maintaining documentation for distance and location, clinical and financial integration, ownership and control, and public awareness, which would require substantial staff time across multiple organizational components. Commenters requested that CMS revise its estimate to include administrative, operational, and systems costs as well as the costs of obtaining separate NPIs. These commenters stated that the documentation required for attestations may be spread out across multiple organizational components. Some commenters suggested that the size or location of the main provider may affect the number of hours required for each attestation. Some commenters provided alternate estimates for the number of hours required for the attestation process, some of which separated the burden associated with submitting the initial attestation (which some estimated to be shorter than CMS' estimate) and gathering and submitting additional information that may be requested after the initial submission (which some estimated to be longer than CMS' estimate). A commenter stated that while CMS' estimate is based on an attestation completed by a top executive, in practice an executive signs a package that takes a team more than five hours to prepare.

Response: We appreciate the additional information provided by commenters related to the time and costs associated with the attestation requirement. We believe that the best way to calculate the burden is to use an estimate of the number of hours associated with a typical provider's typical attestation. Although we recognize that the time taken to complete individual attestations may be shorter or longer than our estimate, and unique circumstances may contribute to this variation, it would not be feasible to include every possible situation into our estimate.

However, in response to the commenters' feedback that the burden estimate should account for additional factors and costs, including the need for multiple departments to be involved in the attestation process, and that the estimated time per attestation is not adequate, we are revising our estimate of the burden in this final rule with comment period. Specifically, we are revising the estimate of the total amount of time for submitting an attestation from 5 hours to 8 hours (representing a 25 percent reduction of the currently-approved estimate of 10 hours to account for the streamlined process). Therefore, under this revised estimate, we calculated the burden as follows: 16,488 responses times 8 hours per response = 131,904 burden hours. Rather than estimating that the 8 hours will be done solely by a chief executive, we are estimating the following staffing mix for each attestation: Compliance Officers account for 3.5 hours, Lawyers for 1 hour, Medical and Health Service Managers for 2 hours, Secretaries and

Administrative Assistants for 1 hour, and Top Executives for 0.5 hours. Based on the most recent Bureau of Labor and Statistics Occupational and Employment Data (May 2025) at *http://www.bls.gov/oes/current/oes_nat.htm#* (although the proposed rule used the May 2024 data, we are using the most recent data available for this final rule) we estimate the cost as follows:

For Category 13–1041 for the position of Compliance Officers, we estimate that each attestation would require 3.5 hours. Therefore, the total hour burden for Compliance Officers is 57,708 (16,488 responses × 3.5 hours per response). The mean hourly wage for a compliance officer is $42.50. We add 100 percent for fringe and overhead benefits, which calculates to $85.00 per hour. We estimate the total cost is $4,905,180.00 (57,708 hours × $85.00 per hour).

For Category 23–1101 for the position of Lawyers, we estimate that each attestation would require 1 hour. Therefore, the total hour burden for Lawyers is 16,488 (16,488 responses × 1 hour per response). The mean hourly wage for a lawyer is $89.35. We add 100 percent for fringe and overhead benefits, which calculates to $179.70 per hour. We estimate the total cost is $2,946,405.60 (16,488 hours × $179.70 per hour).

For Category 11–9111 for the position of Medical and Health Service Managers, we estimate that each attestation would require 2 hours. Therefore, the total hour burden for Medical and Health Service Managers is 32,976 (16,488 responses × 2 hours per response). The mean hourly wage for a medical and health service manager is $67.77. We add 100 percent for fringe and overhead benefits, which calculates to $135.54 per hour. We estimate the total cost is $4,469,567.04 (32,976 hours × $135.54 per hour).

For the Category 43–6010 for the position of Secretaries and Administrative Assistants, we estimate that each attestation would require 1 hour. Therefore, the total hour burden for Secretaries and Administrative Assistants is 16,488 (16,488 responses × 1 hour per response). The mean hourly wage for secretaries and administrative assistants is $25.63. We add 100 percent for fringe and overhead benefits, which calculates to $51.26 per hour. We estimate the total cost is $845,174.88 (16,488 hours × $51.26 per hour).

For Category 11–0000 for the position of Top Executives, we estimate that each attestation would require 0.5 hours. Therefore, the total hour burden for Top Executives is 8,224 (16,488 responses × 0.5 hours per response). The mean hourly wage for a top executive is $68.33. We add 100 percent for fringe and overhead benefits, which calculates to $136.66 per hour. We estimate the total cost is $1,126,625.04 (8,224 hours × $136.66 per hour).

Therefore, under our revised estimate, the total cost of the burden is $14,292,952.56 ($4,905,180 for Compliance Officers + $2,946,405.60 for Lawyers + $4,469,567.04 for Medical and Health Service Managers + $845,174.88 for Secretaries and Administrative Assistants + $1,126,625.04 for Top Executives).

We plan to submit an update to the currently approved PRA package (OMB number 0938–0798) for the attestation requirements once the revised estimates have been finalized.

With respect to the comments about the burden associated with the separate NPI requirement, we note that the PRA package for NPIs is currently approved under OMB control number 0938–0931.

E. ICRs for Expansion of Botulinum Toxin Injection Codes for Hospital Outpatient Department (OPD) Prior Authorization Process

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which requires the Secretary to develop a method for controlling unnecessary increases in the volume of covered OPD services (84 FR 61142, 61446 through 61456).[233] As part of the CY 2021 OPPS/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 2023 OPPS/ASC final rule with comment period, we added an eighth service category to the list of OPD services requiring prior authorization (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 accordance with § 419.83(b), we proposed to expand the Botulinum Toxin Injection service category to include additional codes requiring prior authorization. To improve readability and brevity, as we indicated earlier in the preamble, effective dates were removed and the section numbering in the regulatory text was updated. The former paragraphs (a)(1)(i) through (v), (a)(2)(i) and (ii), and (a)(3) have been renumbered as (a)(1) through (8). The additional Botulinum Toxin Injection codes would be added to existing codes located at proposed revised § 419.83 (a)(2) and would require prior authorization beginning for service dates on or after July 1, 2027.

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. The request must be submitted before the service is provided to the beneficiary and before the claim is submitted for processing.

The burden associated with the prior authorization process for the additional Botulinum Toxin Injection codes 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, and to forward the information to CMS or its contractor (Medicare Administrative Contractor) 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 would be 30 minutes, which is equivalent to that for normal prepayment or postpayment medical review. We anticipate that most prior authorization requests will be sent by means other than mail. However, we estimate a cost of $5 per request for mailing medical records. Based on CY 2024 data for the new services, we estimate that annually, there would be 17,699 initial requests mailed during a year. In addition, we estimate there would be 5,808 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total annual mailing cost is estimated at $117,537 (23,507 mailed requests × $5). We also estimate that an additional 3 hours per provider would be required to attend educational meetings, train staff on what services require prior authorization, and review training documents.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data available from the Bureau of Labor Statistics (BLS). Based on the BLS 2024 rate for Healthcare Support Workers, All

[233] See also Correction Notice issued January 3, 2020 (85 FR 224).

Other,[234] we estimate an average median clerical hourly rate of $22.14 with a loaded rate of $44.28. The prior authorization program for the new services will not create any new documentation requirements. Instead, it will only require the same documents needed to support claim payments to be submitted earlier in the claim process. The estimate uses the clerical rate since we do not believe that clinical staff will need to spend more time completing the documentation that will be needed in the absence of the prior authorization policy. The hourly rate reflects the time required for the additional clerical work of submitting the prior authorization request. We believe providers will need to educate their staff on what services are included in the prior authorization process. Following this education, the staff will know which services need prior authorization and will not need additional time or resources to determine whether a service requires prior authorization. We estimate that the total annual number of submissions would be 78,358 (54,851 submissions via fax or electronic means + 23,507 mailed submissions). The annual burden hours for the new services, allotted across all providers, would be 41,555 hours (0.5 hours × 78,358 submissions plus 3 hours × 792 providers for education). The annual burden cost would be $1,957,592 (41,555 hours × $44.28 plus $117,537 for mailing costs). The ICR approved under OMB control number 0938–1368 will be revised and submitted to OMB for approval.

Table 110 is a chart reflecting the total burden and associated costs for the provisions included in this final rule with comment period.

TABLE 110: TOTAL BURDEN FOR NEW SERVICES

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Addition of Additional Services for Hospital OPD Prior Authorization Process	+41,555	+$1.96 M

* Numbers rounded.

XXV. Files Available to the Public Via the Internet

The Addenda to the OPPS/ASC proposed rules and final rules with comment period are published and available via the internet on the CMS website. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59154), for CY 2019, we changed the format of the OPPS Addenda A, B, and C by adding a column titled ''Copayment Capped at the Inpatient Deductible of $1,364.00'' where we flag, through use of an asterisk, those items and services with a copayment that is equal to or greater than the inpatient hospital deductible amount for any given year (the copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year). In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86266), we updated the format of the OPPS Addenda A, B, and C by adding a column titled ''Drug Pass-Through Expiration during Calendar Year'' where we flag, through the use of an asterisk, each drug for which pass-through payment is expiring during the calendar year on a date other than December 31. In the CY 2026 final rule with comment period (90 FR 54058), we retained these columns that are updated to reflect the drug codes for which pass-through payment is expiring in the applicable year.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72250) for CY 2023, we changed the format of the OPPS Addenda A, B, and C by adding a column titled ''Drug Pass-Through Expiration during Calendar Year'' to include devices, so that the column reads: ''Drug and Device Pass-Through Expiration during Calendar Year'' where we flagged, through the use of an asterisk, each drug and device for which pass-through payment was expiring during the calendar year on a date other than December 31.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 82131), 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 sections 1833(t)(8)(F) and 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 OPPS Addenda A, B, and C by adding another column for ''IRA Coinsurance Percentage'' to identify the percentage for the inflation-adjusted copayment of a Part B rebatable drug per sections 1833(t)(8)(F) and 1833(i)(9) of the Act, as added by section 11101 of the IRA.

In the CY 2026 OPPS/ASC proposed rule, we proposed that for CY 2026 and subsequent years to keep the same format for the addenda A, B, and C, and we did not propose any additional changes for CY 2026 (90 FR 33837). In the CY 2026 OPPS/ASC final rule with comment period, we finalized our policy as proposed (90 FR 54058).

For CY 2027, we did not propose any changes relating to the format for the addenda A, B, and C and therefore, we are finalizing the addenda, A, B, and C format as proposed.

To view the Addenda to this final rule with comment period pertaining to CY 2027 payment rates under the OPPS, we refer readers to the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices* select ''CMS–1850–FC'' from the list of regulations. All OPPS Addenda to this final rule with comment period are contained in the zipped folder titled ''2027 NFRM OPPS Addenda'' in the related links section at the bottom of the page. To view the Addenda to this final rule with comment period pertaining to CY 2027 payment rates under the ASC payment system, we refer readers to the

[234] *https://www.bls.gov/oes/current/oes_nat.htm.*

CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices;* select ''CMS–1850–FC'' from the list of regulations. The ASC Addenda to this final rule with comment period are contained in a zipped folder titled ''2027 NFRM Addendum AA, BB, DD1, DD2, EE, and FF'' in the related links section at the bottom of the page.

XXVI. 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.

XXVII. Economic Analyses

A. Statement of Need

This final rule with comment period is necessary to make updates to the Medicare hospital OPPS rates. It is also necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2027. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We are revising the APC relative payment weights using claims data for services furnished on and after January 1, 2025 through and including December 31, 2025, and processed through June 30, 2026, and updated HCRIS cost report information.

This final rule with comment period is also necessary to make updates to the ASC payment rates for CY 2027, 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 2027. 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 with comment period, 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). In the CY 2026 OPPS/ASC final rule with comment period, we finalized a policy to extend our utilization of the hospital market basket update as the update factor for the ASC payment system for one additional year, through CY 2026 (90 FR 54058). As discussed in section XIII. of this final rule with comment period, we are finalizing our proposal to extend our utilization of the hospital market basket update as the update factor for the ASC payment system for one additional year (through CY 2027). The ASC impacts discussed below reflect our application of the hospital market basket update for CY 2027.

In addition, this final rule with comment period is necessary to make policy changes for facilities reporting data under the Hospital Outpatient Quality Reporting and ASC Quality Reporting Programs. The primary objective of these quality reporting programs is to promote higher quality, more efficient health care for Medicare beneficiaries by collecting and reporting on quality-of-care metrics. This information is made available to consumers, both to empower Medicare beneficiaries and inform decision making, as well as to incentivize healthcare facilities to make continued improvements.

B. Overall Impact of Provisions of this Final Rule With Comment Period

We have examined the impacts of this rule as required by Executive Order 12866, ''Regulatory Planning and Review''; Executive Order 13132, ''Federalism''; Executive Order 13563, ''Improving Regulation and Regulatory Review''; Executive Order 14192, ''Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Social Security Act; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4); and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more 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, 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 impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant per section 3(f)(1). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

We estimate that the total increase in Federal Government expenditures under the OPPS for CY 2027, compared to CY 2026, due to the changes to the OPPS in this final rule with comment period, will be approximately $1.78 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2027, we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2027 will be approximately $114.4 billion, which is approximately $10.7 billion higher than estimated OPPS expenditures in CY 2026. We also estimate that the final 2.0 percentage point adjustment for the 340B Remedy Offset is expected to reduce overall OPPS payments by $1.6 billion in CY 2027. Table 112 of this final rule with comment period displays the distributional impact of the CY 2027

changes in OPPS payment to various groups of hospitals and for CMHCs.

We note that under our final CY 2027 policy, drugs and biologicals are generally paid at ASP plus 6 percent, WAC plus 6 percent, or 95 percent of AWP, as applicable. However, under the final 340B drug payment policy for CY 2027, we would pay for drugs acquired through the 340B Drug program at ASP minus 28.0 percent.

We estimate that the final update to the conversion factor will increase total OPPS payments by 2.3 percent in CY 2027. The final changes to the APC relative payment weights, the final changes to the wage indexes, the continuation of a payment adjustment for rural SCHs, including EACHs, the final cost-of-living adjustment for hospitals in Alaska and Hawaii, the final 340B-Drug payment adjustment, and the final payment adjustment for cancer hospitals would not increase total OPPS payments because these changes to the OPPS are budget neutral. However, these updates would change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2026 and CY 2027, considering all budget-neutral payment adjustments, final changes in estimated total outlier payments, the application of the frontier State wage adjustment, the final payment adjustment for imaging without contrast services furnished at excepted off campus PBDs, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act will increase total estimated OPPS payments by 1.7 percent. We note that, as previously discussed in section V.B.7 of this final rule with comment period, we finalized to reduce payments for non-drug items and services for hospitals for whom the annual reduction to payment amounts under § 419.32(b)(1)(iv)(B)(12) applies by 2.0 percentage points in CY 2027. We estimate that this reduction would reduce OPPS spending by approximately $1.6 billion in CY 2027.

We estimate the total increase (from changes to the ASC provisions in this final rule with comment period, as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures (not including beneficiary cost-sharing) under the ASC payment system for CY 2027 compared to CY 2026, to be approximately $560 million. Tables 112 and 113 of this final rule with comment period display the redistributive impact of the CY 2027 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

C. Detailed Economic Analyses

1. Estimated Effects of OPPS Changes in This Final Rule With Comment Period

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the final CY 2027 policy changes on various hospital groups. We post our hospital-specific estimated payments for CY 2027 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–1850–FC'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this final rule with comment period. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 112 of this final rule with comment period. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this final rule with comment period for a discussion of the hospitals whose claims we do not use for ratesetting or impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available but do not attempt to predict behavioral responses to our policy changes in order to isolate the effects associated with specific policies or updates, but any policy that changes payment could have a behavioral response. In addition, we have not made any adjustments for future changes in variables, such as service volume, service-mix, or number of encounters.

b. Estimated Effects of the Proposal To Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider Based Departments (PBDs)

In section X.A. of this final rule with comment period, we discuss our CY 2027 policy to control for unnecessary increases in the volume of outpatient services by paying for imaging without contrast services furnished at an off-campus PBD at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate). Specifically, we will pay for HCPCS codes billed with modifier ''PO'' and assigned to and paid through imaging without contrast APCs 5521 through 5524 and composite imaging without contrast APCs 8004, 8005, and 8007 at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate).

To develop an estimated impact of this policy, we began with CY 2025 outpatient claims data used, for claim lines with HCPCS codes assigned for payment through imaging without contrast APCs 5521 through 5524 and composite imaging without contrast APCs 8004, 8005, and 8007 that contained modifier ''PO'' because the presence of this modifier indicates that such claims were billed for services furnished by an off-campus department of a hospital paid under the OPPS. We then simulated payment for the remaining claim lines as if they were paid at the PFS-equivalent rate, removing a portion of the payment associated with rural sole community hospitals based on our finalized exception for those hospitals. An estimate of the final policy that includes the effects of estimated changes in enrollment, utilization, and case-mix based on the FY 2027 Mid-Session review budget approximates the estimated decrease in total payments at $260 million, with Medicare OPPS payments decreasing by $190 million and beneficiary copayments decreasing by $70 million in CY 2027.

This estimate is utilized for the accounting statement displayed in Table 111 of this final rule with comment period because the impact of this final CY 2027 policy, which is not budget neutral, is combined with the impact of the OPD update, which is also not budget neutral, to estimate changes in Medicare spending under the OPPS as a result of the changes in this final rule with comment period.

We note our estimates may differ from the actual effect of the final policy due to offsetting factors, such as changes in provider behavior. We note that by removing this payment differential that may influence site-of-service decision-making, we anticipate an associated decrease in the volume of imaging without contrast services provided in the excepted off-campus PBD setting.

TABLE 111: ESTIMATED EFFECT OF CHANGES TO IMAGING WITHOUT CONTRAST SERVICES WHEN FURNISHED AT EXCEPTED OFF-CAMPUS PROVIDERS (IN $ MILLIONS)

CY	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2027 – 2036
Part B Trust Fund benefits	(260)	(680)	(750)	(820)	(900)	(980)	(1,070)	(1,180)	(1,290)	(1,400)	(9,330)
Premium offset	70	170	190	210	230	250	260	290	320	350	2,340
Net Part B Trust Fund impact	(190)	(510)	(560)	(610)	(670)	(730)	(810)	(890)	(970)	(1,050)	(6,990)
Beneficiary cost-sharing	(70)	(170)	(190)	(210)	(230)	(250)	(270)	(300)	(330)	(360)	(2,380)

c. Estimated Effects of OPPS Changes to Part B Drug Payment on 340B Eligible Hospitals Paid Under the OPPS

In section V.B.7. of this final rule with comment period, we discuss our finalized policies to reduce the payment for nonpass-through, separately payable drugs purchased by certain 340B-participating hospitals through the 340B Program. Rural SCHs, children's hospitals, and PPS-exempt cancer hospitals are excepted from this payment policy in CY 2027. Specifically, in this final rule with comment period, for CY 2027, for hospitals paid under the OPPS (other than those that are excepted for CY 2027), we are paying for separately payable drugs and biologicals that are obtained with a 340B discount, excluding those on pass-through payment status and vaccines, at ASP minus 28 percent instead of ASP+6 percent. For context, based on CY 2025 claims data, the total OPPS Part B drug payment is approximately $27.7 billion.

We note that in the CY 2025 claims available for OPPS ratesetting purposes that the modifier ''TB'' continued to be active, and identifies drugs and biologicals acquired through the 340B Drug Pricing program. Therefore, we used separately payable drug lines with prospective status indicator ''K,'' which would be subject to the 340B Payment policy, that also were billed with status indicator ''TB'' to identify lines that would be included for purposes of determining the budget neutrality adjustment. Under our final CY 2027 policy, rural SCHs, children's hospitals, and PPS-exempt cancer hospitals would be excepted from this payment policy and so they were similarly excepted from these calculations for budget neutrality and impact analysis purposes.

Using that claims data, we estimate that OPPS payments for separately payable drugs, including beneficiary copayments, will decrease by approximately $4.65 billion under this finalized policy, which reflects a $200 million decrease in the estimated reduction relative to the proposed rule estimate of $4.85 billion. This change is largely attributable to the changes made in the final CY 2027 340B Payment Policy and additional claims data available in the final rule. Because we are implementing this payment reduction in a budget neutral manner within the OPPS, the reduced payments for separately payable drugs purchased through the 340B Program will increase payment rates for other non-drug items and services paid under the OPPS by an offsetting aggregate amount.

In this final rule, we project that reducing payment for 340B drugs to ASP minus 28.0 percent will increase OPPS payment rates for non-drug items and services by approximately 7.5 percent in CY 2027. The estimated impacts of this policy are displayed in Table 112. We note that the payment rates included in Addendum A and Addendum B of this final rule with comment period do not reflect the reduced payments for drugs purchased under the 340B Program; however, they do include the increase to payments rates for non-drug items and services due to the corresponding increase in the conversion factor.

In summary, to maintain budget neutrality within the OPPS, the estimated $4.65 billion in reduced drug payments from adoption of this final 340B payment methodology will be redistributed in an equal offsetting amount to all hospitals paid under the OPPS through increasing the payment rates by 7.5 percent for nondrug items and services furnished by all hospitals paid under the OPPS for CY 2027.

d. Estimated Effects of OPPS Changes on Hospitals

Table 112 shows the estimated impact of the final rule on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-Balanced Budget Act (BBA) amount. We also include CMHCs in the first line that includes all providers. We include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 112, and we discuss them separately below, because CMHCs are paid only for partial hospitalization and intensive outpatient program services under the OPPS and are a different provider type from hospitals. In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94269 through 94270), we finalized paying CMHCs for partial hospitalization services and intensive outpatient services under APCs 5851 through 5854. For CY 2027, we are maintaining the same APC structure and are continuing our CY 2026 methodology for calculating rates by applying the 40 percent Medicare Physician Fee Schedule (MPFS) Relativity Adjuster to calculate PHP and IOP payment rates for CMHCs.

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor, as discussed in detail in section II.B. of this final rule with comment period.

Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The final IPPS market basket percentage increase applicable to the OPD fee schedule for CY 2027 is 3.2 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 3.2 percent by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is a final 0.9 percentage point for CY 2027 (which is also the productivity adjustment for FY 2027 in the FY 2027 IPPS/LTCH PPS final rule (91 FR 50459) resulting in the final CY 2027 OPD fee schedule increase factor of 2.3 percent. We are using the OPD fee schedule increase factor of 2.3 percent in the calculation of the final CY 2027 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the estimates in Table 112 of this final rule with comment period.

To illustrate the impact of the CY 2027 changes, our analysis begins with a baseline simulation model that uses the CY 2026 relative payment weights, the CY 2026 final OPPS wage indexes that include reclassifications, and the final CY 2026 conversion factor. Table 112 shows the estimated redistribution of the increase or decrease in payments for CY 2027 over CY 2026 payments to hospitals and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2026 and CY 2027 (Column 2); the wage indexes and the provider adjustments (Column 3); the effect of the final payment adjustment for drugs acquired through the 340B Program (Column 4); the combined impact of all of the changes described in the preceding columns plus the 2.3 percent OPD fee schedule increase factor update to the conversion factor (Column 5); the additional estimated impact for the final payment adjustment for imaging without contrast services furnished at excepted off campus PBDs (Column 6); the estimated impact taking into account all payments for CY 2027 relative to all payments for CY 2026, including the impact of changes in estimated outlier payments and changes to the pass-through payment estimate (Column 7).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are maintaining the current adjustment percentage for CY 2027. Because the final updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2027 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, or what proportion of OPPS payments to the hospital are for services compared to drugs), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this final rule with comment period redistribute money during implementation will also depend on changes in volume, practice patterns, and the mix of services billed between CY 2026 and CY 2027 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed rates for CY 2027 would increase Medicare OPPS payments by an estimated 1.7 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 1.7 percent increase in Medicare payments to all other hospitals. These estimated payments would not significantly impact other providers. We note that providers not considered ''new providers'' for purposes of the 340B remedy offset would receive an adjustment to their OPPS payment rates of minus 2.0 percent, which we estimate reduces overall provider payment by 2.0 percent.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 112 shows the total number of facilities (3,620), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2025 hospital outpatient and CMHC claims data to model CY 2026 and CY 2027 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 2026 or CY 2027 payment and entities that are not paid under the OPPS. 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 final rule with comment period. At this time, we are unable to calculate a DSH variable for hospitals that are not also paid under the IPPS because DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,502), 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 42 CMHCs at the bottom of the impact table (Table 112) 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 an increase of 0.1, with the impact ranging from a decrease of 0.3 to an increase of 0.7, depending on the number of beds. Rural hospitals would experience a decrease of 0.3 percent overall. Major teaching hospitals would experience a decrease of 0.3 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 2027 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 2026 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

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 2027 scaled weights and a CY 2026 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2026 and CY 2027.

Column 3 reflects the independent effects of the updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the final CY 2027 changes in wage index policy, discussed in section II.C. of this final rule with comment period. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are continuing the rural payment adjustment of 7.1 percent to rural SCHs for CY 2027, as described in section II.E. of this final rule with comment period. We modeled a budget neutrality adjustment for the final cancer hospital payment adjustment because the final payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2027 is 0.88, which is higher than the PCR target adopted in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53501). We note that, in accordance with section 16002 of the 21st Century Cures Act, we apply a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.89, not the 0.88 target payment-to-cost ratio we discuss in section II.F. of this final rule with comment period.

Column 3 also includes the effects of the final COLA factors for hospitals located in Hawaii and Alaska, which would apply to the non-labor portion of OPPS payments. This policy is discussed in detail in section X.C of this final rule with comment period.

Column 4: Effect of the Final Payment Adjustment for 340B Drugs

Column 4 demonstrates the total payment effect of the final payment adjustment for drugs acquired under the 340B Program from ASP plus 6 percent to ASP minus 28.0 percent. This column includes both the reduced payment for 340B acquired drugs and the increase to the conversion factor for budget neutrality purposes, which increases payment for all non-drug OPPS services. For rural sole community hospitals, this column shows a 5.3 percent increase, reflecting no payment adjustment for drugs (because these providers are exempt from these reductions) and a 7.5 percent increase for non-drug services.

We also note that the proposed 340B drug payment policy described in this column can significantly affect an OPPS provider's estimated CY 2027 payment depending on the proportion of a provider's payment represented by drugs purchased through the 340B Drug Program. For providers that are excepted from the 340B drug payment proposal and for non-340B hospitals, we would generally expect an increase in these providers' estimated 2027 OPPS payments under this column, as they would receive an increase to their non-drug service payments through the budget neutral adjustment to the OPPS conversion factor due to this policy but no change to their drug payments. However, for 340B hospitals, estimated payment changes due to this policy would depend on the volume of 340B drugs the provider furnishes and how that compares to the volume of non-drug services provided by the provider. For most 340B providers, the decreased 340B drug payments will outweigh the increased payments for non-drug services.

Column 5: All Budget Neutrality Changes Combined With the Market Basket Update

Column 5 demonstrates the combined impact of all the final changes previously described and the final update to the conversion factor of 2.3 percent. Overall, these changes would increase payments to urban hospitals by 2.0 percent and to rural hospitals by 5.6 percent. Rural sole community hospitals would receive an estimated increase of 7.9 percent while other rural hospitals would receive an estimated increase of 1.9 percent.

Column 6: Final Off-Campus PBD Imaging Without Contrast Payment Policy

Column 6 displays the estimated effect of our final CY 2027 policy to pay for imaging without contrast services assigned to APCs 5521 through 5524 and composite imaging without contrast APCs 8004, 8005, and 8007 when billed with modifier ''PO'' at a PFS-equivalent rate. We note that the numbers provided in this column isolate the estimated effect of this final policy adjustment relative to the numerator of Column 5. Therefore, the numbers reported in Column 6 show how much of the difference between the estimates in Column 5 and the estimates in Column 7 are a result of the off-campus PBD imaging without contrast policy.

Column 7: All Changes With Outlier—Final CY 2027 Update

Column 7 depicts the full impact of the final CY 2027 policies on each hospital group by including the effect of all changes for CY 2027 and comparing them to all estimated payments in CY 2026. Column 7 shows the combined budget neutral effects of Columns 2 and 3 and 4; the effect of the off-campus provider-based department drug administration policy; the OPD fee schedule increase; the impact of estimated OPPS outlier payments, as discussed in section II.G. of this final rule with comment period; 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 XV. of this final rule with comment period); and other rule adjustments to the CY 2027 OPPS payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2026 update (and assumed, for modeling purposes, to be the same number for CY 2027), we included 66 hospitals in our model because they had both CY 2025 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2027 would increase payments to all facilities by 1.7 percent for CY 2027. We modeled the independent effect of all changes in Column 7 using the final relative payment weights for CY 2026 and the final relative payment weights for CY 2027. We used the final conversion factor for CY 2026 of $91.415 and a CY 2027 conversion factor of $99.970 discussed in section II.B. of this final rule with comment period.

Column 7 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the FY 2027 IPPS/LTCH PPS final rule (91 FR 50383) of 7.3 percent (1.07268) to increase charges on the CY 2025 claims, and we used the overall CCR in the July 2026 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2026. Using the CY 2025 claims and a 7.3 percent charge inflation factor, we currently estimate that outlier payments for CY 2026, using a multiple threshold of 1.75 and a fixed-dollar threshold of $6,225, would be approximately 1.21 percent of total payments. The estimated current outlier payments of 1.21 percent are incorporated in the comparison in Column 7. We used the same set of claims and a charge inflation factor of 15.1 percent (1.15064) and the CCRs in the July 2026 OPSF, with an adjustment of 0.971037 (91 FR 50383), to reflect relative changes in cost and charge inflation between CY 2026 and CY 2027, to model the proposed CY 2027 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed dollar threshold of $7,150. The charge

inflation and CCR inflation factors are discussed in detail in the FY 2027 IPPS/LTCH PPS final rule with comment period (91 FR 50380 through 50385).

Overall, we estimate that facilities would experience an increase of 1.7 percent under this final rule with comment period in CY 2027 relative to total spending in CY 2026. This projected increase (shown in Column 7) of Table 112 of this final rule with comment period reflects the final 2.3 percent OPD fee schedule increase factor, removing the 0.21 difference in estimated outlier payments between CY 2026 (1.21 percent) and CY 2027 (1.0 percent), including the 0.4 percent decrease due to the payment adjusted for imaging without contrast services at off campus PBDs, plus 0.07 percent for the change in the pass-through payment estimate between CY 2026 and CY 2027. We estimate that the combined effect of all changes for CY 2027 would increase payments to urban hospitals by 1.3 percent. Overall, we estimate that rural hospitals would experience a 5.3 percent increase as a result of the combined effects of all the changes for CY 2027. Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes include a decrease of 2.7 percent for major teaching hospitals and an increase of 6.0 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated increase of 2.8 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience an increase of 1.4 percent, proprietary hospitals would experience an increase of 10.1 percent, and governmental hospitals would experience a decrease of 1.7 percent.

Reduction for Providers Subject to the 340B Remedy Offset

In column 8 we have included additional information to account for estimated payment changes in the CY 2027 OPPS for providers subject to the 340B Remedy Offset which will be a 2.0 percentage point decrease in CY 2027.

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TABLE 112: ESTIMATED IMPACT OF FINAL CY 2027 CHANGES FOR SERVICES PROVIDED IN THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**340B Adjustment**	**All Budget Neutral Changes (combined cols 2-4) with Market Basket Update**	**Payment Adjustment for Imaging w/o Contrast at Off Campus Providers**	**All CY 2027 Changes**	*Impact of Adjustment only for Providers Subject to 340B Remedy Offset*
ALL PROVIDERS *		3,620	0.0	0.1	0.0	2.4	-0.4	**1.7**	-2.0
ALL HOSPITALS		3,502	0.1	0.1	-0.1	2.3	-0.4	**1.7**	-2.0
	(excludes hospitals held harmless and CMHCs)								
URBAN HOSPITALS		2,837	0.1	0.0	-0.5	2.0	-0.4	**1.3**	-2.0
	LARGE URBAN (>1 M)	1,342	0.2	-0.2	-0.8	1.4	-0.4	**0.8**	-2.0
	OTHER URBAN (<=1 M)	1,495	0.1	0.3	-0.2	2.4	-0.4	**1.7**	-2.0
RURAL HOSPITALS		665	-0.3	0.3	3.3	5.6	-0.1	**5.3**	-2.0
	SOLE COMMUNITY	324	-0.3	0.6	5.3	7.9	0.0	**7.7**	-2.0
	OTHER RURAL	341	-0.3	-0.1	0.0	1.9	-0.3	**1.4**	-2.0
BEDS (URBAN)									
	0 - 99 BEDS	1004	0.7	-0.1	4.5	7.6	-0.2	**7.1**	-1.8
	100-199 BEDS	787	0.3	0.4	2.7	5.8	-0.3	**5.2**	-2.0
	200-299 BEDS	425	0.4	0.0	1.8	4.5	-0.5	**3.9**	-2.0
	300-499 BEDS	387	0.3	-0.1	0.5	3.0	-0.4	**2.3**	-2.0
	500 + BEDS	234	-0.3	0.0	-4.8	-2.9	-0.5	**-3.7**	-2.0
BEDS (RURAL)									

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**340B Adjustment**	**All Budget Neutral Changes (combined cols 2-4) with Market Basket Update**	**Payment Adjustment for Imaging w/o Contrast at Off Campus Providers**	**All CY 2027 Changes**	*Impact of Adjustment only for Providers Subject to 340B Remedy Offset*
	0 - 49 BEDS	309	-0.1	0.7	4.3	7.3	0.0	**6.9**	-2.0
	50- 100 BEDS	203	-0.2	0.3	3.8	6.3	0.0	**6.0**	-2.0
	101- 149 BEDS	87	-0.4	-0.3	1.6	3.2	-0.2	**3.0**	-2.0
	150- 199 BEDS	36	-0.4	0.6	3.5	6.2	-0.2	**5.3**	-2.0
	200 + BEDS	30	-0.5	0.1	2.6	4.6	-0.2	**4.4**	-2.0
REGION (URBAN)									
	NEW ENGLAND	122	-0.1	0.1	-0.8	1.5	-0.6	**0.7**	-2.0
	MIDDLE ATLANTIC	300	0.0	0.4	-1.1	1.6	-0.8	**0.7**	-2.0
	SOUTH ATLANTIC	474	0.2	0.4	-0.1	2.8	-0.4	**2.3**	-1.9
	EAST NORTH CENTRAL	426	0.0	0.3	-0.7	1.9	-0.6	**1.2**	-2.0
	EAST SOUTH CENTRAL	177	0.0	-1.0	-2.6	-1.4	-0.4	**-1.8**	-2.0
	WEST NORTH CENTRAL	182	0.0	0.0	-1.6	0.7	-0.2	**-0.6**	-2.0
	WEST SOUTH CENTRAL	478	0.7	-0.5	1.4	4.0	-0.4	**3.6**	-2.0
	MOUNTAIN	239	0.3	-0.1	1.0	3.5	-0.2	**2.6**	-1.9
	PACIFIC	387	0.2	-0.3	-0.6	1.6	-0.3	**1.1**	-2.0
	PUERTO RICO	52	0.9	-2.3	4.5	5.4	0.0	**5.4**	0.0
REGION (RURAL)									
	NEW ENGLAND	20	-0.6	0.8	3.8	6.3	0.0	**6.2**	-2.0
	MIDDLE ATLANTIC	45	-0.4	0.0	1.4	3.3	-0.2	**3.2**	-2.0
	SOUTH ATLANTIC	109	-0.3	0.8	2.8	5.6	-0.4	**5.3**	-2.0
	EAST NORTH CENTRAL	110	-0.2	0.3	3.1	5.6	-0.2	**5.4**	-2.0
	EAST SOUTH CENTRAL	124	-0.2	-1.1	1.0	1.9	-0.1	**2.0**	-2.0
	WEST NORTH CENTRAL	72	-0.4	-0.2	5.1	6.9	0.0	**6.1**	-2.0
	WEST SOUTH CENTRAL	121	0.3	-0.5	4.7	6.9	-0.2	**6.9**	-2.0
	MOUNTAIN	39	-0.4	1.3	5.2	8.5	0.0	**6.7**	-1.9
	PACIFIC	24	-0.6	2.8	2.9	7.6	0.0	**7.6**	-2.0
	PUERTO RICO	1	0.8	3.6	9.3	16.9	0.0	**9.8**	0.0
TEACHING STATUS									
	NON-TEACHING	2,081	0.4	0.2	3.5	6.5	-0.3	**6.0**	-1.9

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**340B Adjustment**	**All Budget Neutral Changes (combined cols 2-4) with Market Basket Update**	**Payment Adjustment for Imaging w/o Contrast at Off Campus Providers**	**All CY 2027 Changes**	*Impact of Adjustment only for Providers Subject to 340B Remedy Offset*
	MINOR	955	0.3	0.1	0.8	3.5	-0.4	**2.8**	-2.0
	MAJOR	466	-0.3	0.0	-3.9	-2.0	-0.5	**-2.7**	-2.0
DSH PATIENT PERCENT									
	0	11	1.4	-0.8	7.4	10.5	0.0	**10.5**	-0.7
	> 0 - 0.10	254	0.8	0.2	6.5	10.1	-0.4	**9.5**	-1.9
	>= 0.10 - 0.16	263	0.6	0.5	6.3	9.9	-0.5	**9.2**	-1.9
	>= 0.16 - 0.23	546	0.6	0.2	5.6	8.9	-0.5	**8.3**	-2.0
	>= 0.23 - 0.35	1,135	-0.1	0.2	-0.8	1.6	-0.4	**0.9**	-2.0
	>= 0.35	743	-0.3	-0.3	-5.2	-3.6	-0.3	**-4.2**	-2.0
	DSH NOT AVAILABLE **	550	4.5	-0.8	6.4	12.9	-0.3	**12.7**	-1.9
URBAN TEACHING/DSH									
	TEACHING & DSH	1,234	0.0	0.0	-1.8	0.5	-0.5	**-0.2**	-2.0
	NO TEACHING/DSH	1,067	0.5	0.1	3.4	6.4	-0.4	**5.8**	-1.9
	NO TEACHING/NO DSH	9	1.6	-0.2	7.3	11.3	0.0	**11.4**	-1.0
	DSH NOT AVAILABLE**	526	4.5	-0.7	6.4	13.0	-0.4	**12.7**	-1.9
TYPE OF OWNERSHIP									
	VOLUNTARY	1,989	0.0	0.1	-0.4	2.1	-0.4	**1.4**	-2.0
	PROPRIETARY	1,106	1.3	-0.2	6.8	10.5	-0.2	**10.1**	-1.9
	GOVERNMENT	407	-0.3	-0.2	-2.9	-1.1	-0.3	**-1.7**	-2.0
CMHCs		42	17.2	-0.4	7.4	28.3	0.0	**29.0**	-0.1
Column (1) shows total hospitals and/or CMHCs.									
Column (2) includes all CY 2027 OPPS policies and compares those to the CY 2026 OPPS.									

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**340B Adjustment**	**All Budget Neutral Changes (combined cols 2-4) with Market Basket Update**	**Payment Adjustment for Imaging w/o Contrast at Off Campus Providers**	**All CY 2027 Changes**	*Impact of Adjustment only for Providers Subject to 340B Remedy Offset*
Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2027 hospital inpatient wage index. The rural SCH adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 0.9996 because the CY 2027 target payment-to-cost ratio is higher than the CY 2026 PCR target.									
Column (4) shows the impact of the final 340B drug payment adjustment and the corresponding increase in non-drug payment.									
Column (5) shows the impact of all budget neutrality adjustments and the addition of the 2.3 percent OPD rate update factor (3.2 percent reduced by 0.9 percentage points for the productivity adjustment).									
Column (6) shows the separate impact of the payment adjustment for imaging without contrast APC services furnished at excepted off campus providers.									
Column (7) shows the combined impact of columns 5 and 6, plus 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 included the frontier adjustment to Column 3 in this table.									
The column for providers subject to the 340B Remedy Offset shows the separate impact of applying the final 2.0 percentage point reduction to the OPPS conversion factor update as part of the 340B Remedy Offset.									
We estimate that 3,322 providers would be subject to the reduction to payments that result from the 340B remedy offset.									
*These 3,620 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.									
** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.									

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d. Estimated Effects of OPPS Changes on CMHCs

The last line of Table 112 demonstrates the isolated impact on CMHCs, which furnished only partial hospitalization and intensive outpatient program services under the OPPS during CY 2025. As discussed in section VIII.C. of this final rule with comment period, we proposed for CY 2027 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 and IOP care as seen in the CY 2025 claims used for ratesetting in this final rule with comment period. We did not exclude days with one or two services from our modeling for CY 2027, because our final policy would pay the per diem rate for APC 5853 for such days in CY 2027. As a result of the final PHP APC changes for CMHCs, we estimate that CMHCs would experience a 17.2 percent increase in CY 2027 payments relative to their CY 2026 payments (shown in Column 2). For a detailed discussion of our final PHP and IOP policies, please see section VIII. of this final rule with comment period.

Column 3 shows the estimated impact of adopting the final FY 2027 wage index values, which result in an estimated decrease of 0.4 percent to CMHCs.

Column 5 shows that combining the OPD fee schedule increase factor, along with the final changes in APC policy for CY 2027 and the final FY 2027 wage index updates, and final 340B payment policy, would result in an estimated increase of 28.3 percent.

f. 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 final rule with comment period. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be approximately 18 percent for all services paid under the OPPS in CY 2027. The estimated aggregate beneficiary coinsurance reflects general system adjustments. We note that the individual payments, and therefore copayments, associated with services may differ based on the setting in which they are furnished.

g. 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 with comment period. Hospitals, CMHCs, and ASCs will be affected by the changes in this final rule with comment period. Additionally, the payment policies we established for IOP services affect RHCs and FQHCs. These providers of IOP are not paid under the OPPS and are not included in the impact analysis shown in Table 112. However, the final payment amount for OPPS APC 5861 will 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.

h. 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 2027. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We estimate that the changes in this final rule would increase these Medicaid beneficiary payments by approximately $40 million in CY 2027. Currently, there are approximately 11.8 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 12 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 $40 million Medicaid increase, approximately $25 million would be from the Federal Government and $15 million would be from State governments.

i. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we finalized and the reasons we finalized the selected policies are discussed throughout this final rule with comment period. We received public comments on our impact analysis. The following is a summary of the comments we received and our responses.

Comment: A commenter requested that we incorporate site-of-service substitution effects into the impact analysis.

Response: As noted earlier in this section, we do not attempt to predict behavioral responses to our policy changes 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.

Comment: A commenter requested that we develop a case-mix like variable for the OPPS impact files, similar to that included in the inpatient PPS impact files, that would help represent year-over-year changes to service weighting.

Response: We appreciate the commenter's recommendation and will take it into consideration in the future.

After consideration of the comments, we are finalizing our impact methodology as proposed.

2. Estimated Effects of CY 2027 ASC Payment System Changes

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII. of this final rule with comment period, we are setting the CY 2027 ASC relative payment weights by scaling the final CY 2027 OPPS relative payment weights by the final CY 2027 ASC scalar of 0.814. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 113 and 114.

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. In the CY 2026 OPPS/ASC final rule with comment period, we extended the interim period an additional year through 2026. As discussed in further detail in section XIII. of this final rule with comment period, we proposed and are finalizing an extension of our utilization of the hospital market basket update as the update factor to the ASC payment system for 1 additional year (through CY 2027). 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 economywide 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 2027 payment determinations would be based on the application of a 2.0 percentage point reduction to the hospital market basket update for CY 2027. We calculated the final CY 2027 ASC conversion factor by adjusting the CY 2026 ASC conversion factor ($56.322) by 1.0018 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2026 and CY 2027, which includes our policy to limit wage index declines of greater than 5 percent, and by applying the CY 2027 hospital market basket update factor of 2.3 percent (which is equal to the final inpatient hospital market basket percentage increase of 3.2 percent reduced by a productivity adjustment of 0.9 percentage point). The final CY 2027 ASC conversion factor is $57.721 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the final changes for CY 2027 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2026 and CY 2027 with precision. We believe the net effect on

Medicare expenditures resulting from the final CY 2027 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. Individual ASCs will experience changes in payment that differ from the aggregated estimated impacts presented below.

b. Estimated Effects of ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform a wide range of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as ophthalmology, digestive system, or orthopedic procedures. The combined effect of the final update to the 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 final CY 2027 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2025 claims data. Table 113 depicts the estimated aggregate percent change in payment by surgical specialty by comparing estimated CY 2026 payments to estimated CY 2027 payments, and Table 114 shows a comparison of estimated CY 2026 payments to estimated CY 2027 payments for items and procedures that we estimate would receive the most Medicare payment in CY 2026.

In Table 113, we have aggregated the surgical HCPCS codes by specialty group and then estimated the effect on aggregated payment for surgical specialty. 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 113.

- Column 1—Surgical Specialty Group indicates the surgical specialty into which ASC procedures are grouped. 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 2026 ASC Payments were calculated using CY 2025 ASC utilization data (the most recent full year of ASC utilization) and CY 2026 ASC payment rates. The surgical specialty groups are displayed in descending order based on estimated CY 2026 ASC payments.
- Column 3—Estimated CY 2027 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty that is attributable to the final update to ASC payment rates for CY 2027 compared to CY 2026.

As shown in Table 113, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the final update to ASC payment rates for CY 2027 would result in a 1 percent decrease in aggregate payment amounts for eye and ocular adnexa procedures, a 6 percent increase in aggregate payment amounts for musculoskeletal system procedures, a 6 percent increase in aggregate payment amounts for nervous system procedures, a 1 percent decrease in aggregate payment amounts for digestive system procedures, a 5 percent increase in aggregate payment amounts for cardiovascular system procedures, and a 1 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. After the payment rate update is accounted for, aggregate payment increases or decreases for a category of services can be higher or lower than the final 2.3 percent increase, depending on if payment weights in the OPPS APCs after application of the ASC weight scaler that correspond to the applicable services increased or decreased, 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 1 percent decrease in eye surgical procedure payments and a 1 percent decrease in gastrointestinal surgical procedure payments. The decrease in expenditures for these surgical specialties is attributable to the 2.3 percent hospital market basket update being offset by the reduction in the ASC weight scaler. The reduction in the ASC weight scaler from 0.872 in CY 2026 to our final 0.814 for CY 2027 is attributable to the increase in device portions under the ASC payment system as a result of the increase in OPPS payment rates for clinical services for CY 2027 and our policy to treat device portions of device-intensive procedures as constant between the OPPS and ASC payment system. The increase in final CY 2027 OPPS payment rates for clinical services is a result of the OPPS budget neutrality adjustment from the final 340B drug payment policy. Therefore, surgical specialties that predominantly consist of procedures designated as device-intensive under the ASC payment system will see an increase in expenditures greater than the 2.3 percent hospital market basket update whereas surgical procedures that are not device-intensive will see a relatively smaller increase or decrease in CY 2027 expenditures. The increases in expenditures for musculoskeletal, nervous system, and cardiovascular surgical specialties groups is a result of the higher share of device-intensive procedures that are assigned to these surgical specialty groups. For estimated changes for selected procedures, we refer readers to Table 113.

TABLE 113: ESTIMATED IMPACT OF THE FINAL CY 2027 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2026 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2026 ASC Payments (in Millions) (2)	Estimated CY 2027 Percent Change (3)
Total	$8,349	2
Eye	$2,120	-1
Musculoskeletal	$2,019	6
Nervous System	$1,580	6
Gastrointestinal	$1,059	-1
Cardiovascular	$635	5
Genitourinary	$365	1

Table 114 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2027. The table displays 30 of the procedures receiving the greatest estimated CY 2026 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2026 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2026 ASC Payments were calculated using CY 2025 ASC utilization (the most recent full year of ASC utilization) and the CY 2026 ASC payment rates. The estimated CY 2026 payments are expressed in millions of dollars.
- Column 4—Estimated CY 2027 Percent Change reflects the percent differences between the estimated ASC payment for CY 2026 and the estimated payment for CY 2027 based on the final update.

TABLE 114: ESTIMATED IMPACT OF THE FINAL CY 2027 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2026 ASC Payment (in millions) (3)	Estimated CY 2027 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	$1,383	-2
27447	Total knee arthroplasty	$529	4
63685	Ins/rplc spi npg/rcvr pocket	$421	13
27130	Total hip arthroplasty	$284	5
45385	Colonoscopy w/lesion removal	$273	-1
45380	Colonoscopy and biopsy	$253	-1
23472	Reconstruct shoulder joint	$215	7
43239	Egd biopsy single/multiple	$174	-1
63650	Implant neuroelectrodes	$161	5
64590	Ins/rpl prph sac/gstr npg/r	$131	8
66991	Xcapsl ctrc rmvl insj 1+	$125	9
64483	Njx aa&/strd tfrm epi l/s 1	$108	-3
66982	Xcapsl ctrc rmvl cplx wo ecp	$103	-2
64635	Destroy lumb/sac facet jnt	$103	-3
29827	Sho arthrs srg rt8tr cuf rpr	$97	35
36902	Intro cath dialysis circuit	$90	0
64628	Trml dstrj ios bvn 1st 2 l/s	$75	6
64493	Inj paravert f jnt l/s 1 lev	$74	-3
0627T	Perq njx algc fluor lmbr 1st	$73	7
66821	After cataract laser surgery	$67	-3
G0105	Colorectal scrn; hi risk ind	$64	-1
65820	Relieve inner eye pressure	$57	-1
64561	Implant neuroelectrodes	$56	7
64555	Implant neuroelectrodes	$54	8
15823	Revision of upper eyelid	$51	-5
G0121	Colon ca scrn not hi rsk ind	$47	-1
62323	Njx interlaminar lmbr/sac	$44	-2
64721	Carpal tunnel surgery	$42	-3
33285	Insj subsq car rhythm mntr	$41	3
27279	Arthrd si jt perq/min nvas	$40	7

c. Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the CY 2027 update to the ASC payment system will be generally positive (that is, result in lower cost-sharing) for beneficiaries with respect to the procedures we are finalizing to add to the ASC CPL for CY 2027. First, other than certain preventive services where coinsurance and the Part B deductible are 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 finalized to designate as office-based in CY 2027, 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/2025/08/CircularA-4.pdf,* we have prepared accounting statements to illustrate the impacts of the OPPS and ASC changes in this final rule with comment period. The first accounting statement, Table 115, illustrates the classification of expenditures for the CY 2027 estimated hospital OPPS incurred benefit impacts associated with the final CY 2027 OPD fee schedule increase and the final policy for imaging without contrast services furnished at excepted off-campus PBDs. The second accounting statement, Table 116, illustrates the classification of expenditures associated with the 2.3 percent CY 2027 update to the ASC payment system, based on the provisions of this final rule with comment period and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers.

TABLE 115: ACCOUNTING STATEMENT: CY 2027 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2026 TO CY 2027 ASSOCIATED WITH THE CY 2027 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$1.78 billion
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS

3. Effects of Changes in Requirements for the Hospital Outpatient Quality Reporting Program

a. Background

We refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 54071 and 54072) for the previously estimated effects of changes to the Hospital Outpatient Quality Reporting Program for the CY 2026 reporting period and subsequent years. Of the 2,984 hospital outpatient departments (HOPDs) that met eligibility requirements for the CY 2026 payment determination for the Hospital Outpatient Quality Reporting Program, we determined that 35 HOPDs did not meet the program requirements to receive the full annual Outpatient Department (OPD) fee schedule increase factor while an additional 47 HOPDs elected not to participate.

b. Impact of CY 2027 OPPS/ASC Final Rule Policies

We finalized to: (1) remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2027 reporting period/CY 2029 payment determination; (2) incorporate electronic clinical quality measures (eCQMs) into the existing validation process for chart-abstracted measures beginning with eCQM data from the CY 2027 reporting period affecting the CY 2030 payment determination; (3) reduce the validation selection pool from 500 to up to 400 HOPDs beginning with validation affecting the CY 2030 payment determination; and (4) remove the requirement for hospitals to resubmit medical documentation as part of their request for reconsideration of validation, beginning with data from the CY 2026 reporting period affecting the CY 2028 payment determination.

As part of the incorporation of eCQMs into the existing validation process for chart-abstracted measures, we will also update our data validation policies for chart-abstracted measures, including modifying the number of chart-abstracted measure cases required for validation from 12 per quarter to up to 7 per quarter per measure beginning with validation affecting the CY 2030 payment determination.

We refer readers to section ''XXIV. Collection of Information'' of this final rule with comment period for a detailed discussion of the calculations estimating the changes to the information collection and reporting burden for data requirements under the Hospital Outpatient Quality Reporting Program for the estimated 3,000 program-eligible HOPDs. As shown in summary Table 108 in section XXIV.A.6. of this final rule with comment period, we estimate a total information collection and reporting burden net decrease of 17,439 hours at a savings of $997,143 annually associated with our policies beginning with the CY 2029 reporting period/CY 2031 payment determination compared to our information collection burden estimates which are currently approved under OMB control number 0938–1109 (expiration date July 31, 2029).

In addition to the reduced information collection burden associated with the policies in this final rule with comment period, we believe there will be administrative cost savings associated with the removal of the requirement for HOPDs to resubmit medical documentation as part of their request for reconsideration of validation noncompliance. Regarding the incorporation of eCQMs into the existing validation process for chart-abstracted measures, with more than 98 percent of HOPDs eligible to participate in the Hospital Outpatient Quality Reporting Program affiliated with hospital systems that are already familiar with the eCQM validation process under the Hospital Inpatient Quality Reporting Program, we anticipate their experience with eCQM validation for the Hospital Inpatient Quality Reporting Program will minimize the additional costs beyond the information collection burden discussed in section XXIV.A. of this final rule with comment period associated with eCQM validation by leveraging existing or similar personnel and processes.

We do not believe the remaining policies will result in any additional economic impact beyond that discussed in section ''XXIV. Collection of Information'' of this final rule with comment period.

We did not receive public comments on the estimated impacts of these policies.

4. Effects of Requirements for the Rural Emergency Hospital (REH) Quality Reporting Program

We refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 54072 and 54073) for the previously discussed effects of changes to the REH Quality Reporting Program

for the CY 2026 reporting period and subsequent years. For the CY 2027 reporting period, we have estimated there will be 48 REHs required to report under the REH Quality Reporting Program based on acute care and critical access hospital conversions to REH status as of April 6, 2026. We note that this estimate is an increase of 10 REHs from our estimate of 38 provided in the CY 2026 OPPS/ASC final rule with comment period, resulting in an increase in total information collection burden for the REH Quality Reporting Program of 122 hours and $6,976 (90 FR 54072). We are not finalizing any changes to our previously finalized REH Quality Reporting Program policies in this final rule with comment period.

5. Effects of Changes in Requirements for the Ambulatory Surgical Center (ASC) Quality Reporting Program

a. Background

We refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 54073) for the previously estimated effects of changes to the ASC Quality Reporting Program for the CY 2026 reporting period and subsequent years. Based on the most recent analysis of the CY 2026 payment determination data, we found that, of the 6,930 ASCs that were actively billing Medicare, 4,399 were required to participate in the ASC Quality Reporting Program. Of the 2,531 ASCs not required to participate in the program, 650 ASCs did so and met full requirements. On this basis, we estimate that 5,149 ASCs (4,399 + 650) will submit data for the ASC Quality Reporting Program for the CY 2027 reporting period and subsequent years unless otherwise noted. We note that this estimate is an increase of 559 ASCs from our estimate of 4,590 provided in the CY 2026 OPPS/ASC final rule with comment period (90 FR 54073) due to more recent data analysis regarding numbers of eligible ASCs.

b. Impact of CY 2027 OPPS/ASC Final Rule Policies

We finalized to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2027 reporting period/CY 2029 payment determination. We refer readers to section ''XXIV. Collection of Information'' of this final rule with comment period for a detailed discussion of the calculations estimating the changes to the information collection and reporting burden for data requirements under the ASC Quality Reporting Program for the estimated 5,149 program-eligible ASCs. As shown in summary Table 109 in section XXIV.C.3. of this final rule with comment period, we estimate a total information collection and reporting burden decrease of 16,753 hours at a savings of $957,937 annually associated with our policy for the CY 2027 reporting period/CY 2029 payment determination and subsequent years compared to our information collection burden estimates which are currently approved under OMB control number 0938–1270 (expiration date July 31, 2029). We do not believe this policy will result in any additional economic impact beyond those discussed in section ''XXIV. Collection of Information'' of this final rule with comment period.

We did not receive public comments on the estimated impacts of these policies.

6. Effects of Addition of New Codes for Hospital Outpatient Department (OPD) Prior Authorization Process

a. Overall Impact

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which requires the Secretary to develop ''a method for controlling unnecessary increases in the volume of covered OPD services'' (84 FR 61142, November 12, 2019).[235] As part of the CY 2021 OPPS/ASC final rule with comment period, we added additional service categories to the prior authorization process (85 FR 85866, December 29, 2020). Through the CY 2023 OPPS/ASC final rule with comment period, we added an eighth service category to the list of OPD services requiring prior authorization (87 FR 71748, 72224 through 72233, November 23, 2022). The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In accordance with § 419.83(b), we proposed to expand the Botulinum Toxin Injection service category to include additional codes requiring prior authorization. To improve readability and brevity, as we indicated earlier in section XVIII. of this final rule with comment period, effective dates were removed and the section numbering in the regulatory text was updated. The former paragraphs (a)(1)(i) through (v), (a)(2)(i) and (ii), and (a)(3) have been renumbered as (a)(1) through (8). The additional Botulinum Toxin Injection codes would be added to the existing codes located at proposed revised § 419.83(a)(2) and would require prior authorization beginning for service dates on or after July 1, 2027.

The addition of these services is consistent with our authority under section 1833(t)(2)(F) of the Act and is based upon our determination that there has been an unnecessary increase in the volume of these services.

The overall economic impact on the healthcare sector to require prior authorization for these additional codes is dependent on the number of claims affected. Table 118, Overall Economic Impact on the Health Sector, lists an estimate of the overall economic impact on the health sector for the new services. The values populating Table 117 were obtained from the cost reflected in Table 118, Annual Private Sector Costs, and Table 119, Estimated Annual Administrative Costs to CMS. Tables 118 and 119 combine to convey the overall economic cost impact to the health sector for the new services, which is illustrated in Table 117.

Based on the estimate, the overall economic cost impact is approximately $9.6 million in the first year for the new services. The 5-year impact is approximately $48 million, and the 10-year impact is approximately $95.9 million. Additional administrative paperwork costs to private sector providers and an increase in Medicare spending to conduct reviews combine to create the financial impact; however, this impact is offset by Medicare savings. Annually, we estimate an overall Medicare savings of $25 million. We believe there are likely to be other benefits that result from the prior authorization requirement for the new services, though many of those benefits are difficult to quantify. For instance, we expect to see savings in the form of reduced unnecessary utilization, fraud, waste, and abuse, including a reduction in improper Medicare fee-for-service payments (we note that not all improper payments are fraudulent). We solicited public comments on the potentially increased costs and benefits associated with this proposed provision for the new services, but we did not receive any comments on this matter.

[235] See also Correction Notice issued January 3, 2020 (85 FR 224).

TABLE 117: OVERALL ECONOMIC COST IMPACT ON THE HEALTH SECTOR

	Year 1	5 Years	10 Years
Private Sector Costs	$1,957,592	$9,787,962	$19,575,924
Medicare Costs	$7,632,439	$38,162,195	$76,324,390
Total Economic Impact to Health Sector	$9,590,031	$47,950,157	$95,900,314

According to the RFA's use of the term, most suppliers and providers are small entities. Likewise, the vast majority of physician and nurse practitioner (NP) practices are considered small businesses according to the SBA's size standards of having total revenues of $10 million or less in any 1 year. While the economic costs and benefits are substantial in the aggregate, the economic impact on individual entities compliant with Medicare program coverage and utilization rules and regulations will be relatively small. We estimate that 90 to 95 percent of providers who provide these services are small entities under the RFA definition. The rationale behind requiring prior authorization is to control unnecessary increases in the volume of covered OPD services. The impact on providers not in compliance with Medicare coverage, coding, and payment rules and regulations could be significant, as the proposed rule may change the billing practices of those providers. The purpose of the statute and this final rule with comment period is to avoid unnecessary increases in utilization of OPD services. Therefore, we do not view decreased revenues from the additional OPD services to be a condition that we must mitigate. We believe that the effect would be minimal on providers who are compliant with Medicare coverage, coding, and payment rules and requirements. Adding the new services would offer additional protection to a provider's cash flow as the provider would know in advance if the Medicare requirements were met.

b. Anticipated Specific Cost Effects

(1) Private Sector Costs

We do not believe that this final rule with comment period would significantly affect the number of legitimate claims submitted for the new services. However, we expect a decrease in the overall amount paid for the services resulting from a reduction in unnecessary utilization of the services requiring prior authorization.

We estimate that the private sector's per-case time burden attributed to submitting documentation and associated clerical activities in support of a prior authorization request for the additional services will be equivalent to that of submitting documentation and clerical activities associated with prepayment review, which is 0.5 hours. We apply this time burden estimate to initial submissions and resubmissions.

TABLE 118: ANNUAL PRIVATE SECTOR COSTS

Activity	Responses Per Year (i.e. number of reviewed claims)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic Submitted Requests- Initial Submissions	41,299	0.5	20,649	$914,351
Fax and Electronic Submitted Requests- Resubmissions	13,552	0.5	6,776	$300,041
Mailed in Requests- Initial Submissions	17,699	0.5	8,850	$391,865
Mailed in Requests- Resubmissions	5,808	0.5	2,904	$128,589
Mailing Costs	23,507	5		$117,537
Provider Demonstration-Education	792	3	2,376	$105,209
Total			41,555	$1,957,592

(2) Administrative Costs to CMS

CMS would incur additional costs associated with processing the prior authorization requests for the new services. We use the range of potentially affected cases (submissions and resubmissions) and multiply it by $95, the estimated cost to review each request. The combined cost also includes other elements such as appeals, education, outreach, and system changes.

TABLE 119: ANNUAL ESTIMATED ADMINISTRATIVE COSTS TO CMS

Additional Services	Estimated Annual Administrative Cost
Botulinum Toxin Injections	$7,632,439

(3) Estimated Beneficiary Costs

We expect a reduction in the utilization of the new Medicare OPD services when such utilization does not comply with one or more of Medicare's coverage, coding, and payment rules. While there may be an associated burden on beneficiaries while they wait for the prior authorization decision, we are unable to quantify that burden. Although this final rule with comment period permits utilization that is medically necessary, OPD services that are not medically necessary may still provide convenience or usefulness for beneficiaries; any rule-induced loss of such convenience or usefulness constitutes a cost of the rule that we lack data to quantify. Additionally, beneficiaries may have out-of-pocket costs for those services that are determined not to comply with Medicare requirements and, thus, are not eligible for Medicare payment. We lack the data to quantify these costs as well.

(4) Estimated Benefits

There will be quantifiable benefits for this final rule with comment period because we expect a reduction in the unnecessary utilization of the new Medicare OPD services subject to prior authorization. It is difficult to project the exact decrease in unnecessary utilization; however, based on a 25 percent savings percentage, we estimate an overall gross savings of $25 million. These savings represent a Medicare benefit from more efficient use of health care resources while still maintaining the same health outcomes for necessary services. We will closely monitor utilization and billing practices. The expected benefits would also include changed billing practices that would also enhance the coordination of care for the beneficiary. For example, requiring prior authorization for the additional OPD services would help ensure that the primary care practitioner recommending the service and the facility collaborate more closely to provide the most appropriate OPD services to meet the needs of the beneficiary. The practitioner recommending the service would evaluate the beneficiary to determine what services are medically necessary based on the beneficiary's condition. This would require the facility to collaborate closely with the practitioner early in the process to ensure the services are truly necessary and meet all requirements and that their supporting documentation is complete and correct. Improper payments made because the practitioner did not evaluate the patient, or the patient does not meet the Medicare requirements, would likely be reduced by requiring a provider to submit clinical documentation as part of its prior authorization request.

We solicited comments on the potential additional burden associated with applying prior authorization requirements to these additional botulinum toxin injection codes, including any impacts on providers and beneficiaries. We received comments regarding the potential additional burden associated with applying prior authorization requirements to these additional Botulinum Toxin Injection services, including impacts on providers and beneficiaries. We summarized and responded to these comments in the section XIX. of this final rule with comment period.

D. Regulatory Review Cost Estimation

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 final rule with comment period. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we believe that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcomed comments on the approach in estimating the number of entities that would review the proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule with comment period, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $119.10 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it would take approximately 8 hours for the staff to review half of this final rule with comment period. For each entity that reviews the rule, the estimated cost is $952.80 (8 hours × $119.10). Therefore, we estimate that the total cost of reviewing this regulation is $2,898,418 ($952.80 × 3,042).

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, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business (having revenues of less than $9.0 million to $47.0 million in any 1 year). (For

details, see the SBA's website at *http://www.sba.gov/content/small-business-size-standards* (refer to the 620000 series or Sector 62, Health Care and Social Assistance).)

The North American Industry Classification System (NAICS) was adopted in 1997 and is the current standard used by the Federal statistical agencies related to the U.S. business economy. We utilized the NAICS U.S. industry title ''Hospitals'' and corresponding NAICS code 622 in determining impacts for small entities for this rule. The NAICS code 622 has a size standard of $47 million.[236] Table 120 shows the number of firms, revenue, and estimated impact per hospital category.

TABLE 120: NUMBER OF FIRMS, REVENUE, AND AVERAGE REVENUE PER FIRM OF HOSPITALS FOR NAICS CODE 622

NAICS	NAICS Description	Enterprise Size ($1,000)	Number of Firms	Number of Establishments	Receipts ($1,000)	Average Receipts Per Firm ($1,000)
622	Hospitals	<100	68	68	3,235	48
622	Hospitals	00-499	176	176	47,198	268
622	Hospitals	500-999	61	62	43,484	713
622	Hospitals	1,000-2,499	36	36	55,875	1,552
622	Hospitals	2,500-4,999	43	46	160,867	3,741
622	Hospitals	5,000-7,499	45	47	285,858	6,352
622	Hospitals	7,500-9,999	77	80	653,169	8,483
622	Hospitals	10,000-14,999	158	165	1,852,000	11,722
622	Hospitals	15,000-19,999	173	193	2,919,720	16,877
622	Hospitals	20,000-24,999	154	158	3,391,347	22,022
622	Hospitals	25,000-29,999	128	135	3,342,680	26,115
622	Hospitals	30,000-34,999	126	131	3,876,502	30,766
622	Hospitals	35,000-39,999	87	93	3,061,225	35,186
622	Hospitals	40,000-49,999	162	179	6,839,652	42,220
622	Hospitals	50,000-74,999	276	312	15,547,026	56,330
622	Hospitals	75,000-99,999	144	178	11,728,762	81,450
622	Hospitals	100,000+	1,222	5,654	1,300,730,378	1,064,427
622	Hospitals	Total	3,136	7,713	1,354,538,978	431,932

Source: Data obtained from United States Census Bureau table "us_6digitnaics_rcptsize_2022" (SOURCE: 2022 SUSB Annual Data Tables by Establishment Industry) Release Date: 4/10/2025: *https://www2.census.gov/programs-surveys/susb/tables/2022/us_6digitnaics_rcptsize_2022.xlsx.*

Notes: The 'Average Receipts Per Firm' is calculated as the Receipts ($1,000)/Number of Firms. The 'Total' row represents all the hospital firms under NAICS 622. Overall receipts (revenue) for the 3,136 firms (NAICS 622) are approximately $1,355 billion.

[236] *https://www.sba.gov/sites/sbagov/files/2023-03/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023%20%281%29%20%281%29_0.pdf.*

TABLE 121: ESTIMATED IMPACT ON SMALL BUSINESSES*

	Total Facilities	Estimated Small Businesses	Total Impact ($1 million)	Estimated Impact of Payment Update to Small Businesses	Effect of Additional OPPS Policies**	Estimated Average Impact per Small Business
OPPS Hospitals	3,621	1,669	$1,780	$32,040,000	$136,500,000	$100,983
ASCs	6,179	5,560	$170	$59,200,000		$10,647

* Based on the assumptions that small firms represent 46.1 percent of OPPS Hospitals and account for approximately 1.8 percent of total industry revenues, and, small firms represent 90.0 percent of ASCs and account for approximately 34.8 percent of total industry revenues using the SBA size standards.
**Individual impact of each additional OPPS policy is displayed in Table 122.

TABLE 122: ESTIMATED EFFECT OF SPECIFIC OPPS POLICIES ON SMALL BUSINESSES

	ALASKA/ HAWAII COLA	340B Payment Policy	Volume Control Method for Imaging without Contrast Services	340B Remedy Offset	Net Effect of Specified Policies
Impact on Small Businesses	$1,500,000	$214,000,000	-$6,000,000	-$73,000,000	**$136,500,000**

For purposes of the RFA, approximately half of all hospitals are considered to be small entities. As shown in Table 120, hospitals with enterprise size of $49 million or less (1,494) are approximately 48 percent of total firms (3,136). Because roughly half of hospitals qualify as small entities under the RFA, the impacts described in this final rule with comment period generally affect small entities. Individuals and States are not included in the definition of a small entity. MACs are also not considered to be small entities because they do not meet the SBA definition of a small business.

HHS interprets the RFA to consider economic effects of a rule to impact a substantial number of small firms when more than 5 percent of providers incur significant impacts of at least 3 to 5 percent or more of total revenue or total costs. This final rule with comment period includes a number of policy changes that can significantly increase or decrease estimated 2027 payments at an individual level, including changes such as the final exceptions to the 340B drug payment proposal and the payment adjustment for imaging without contrast services furnished at provider-based departments. Based on this impact analysis, we estimate that the policies finalized in this rule would affect more than 5 percent of hospitals with changes in Medicare revenue of at least 3 to 5 percent.

Therefore, CMS expects that this final rule with comment period will have a significant economic impact on a substantial number of small entities.

We estimate that a majority of the 3,621 OPPS providers included in the impact analysis presented in Table 112 would experience average payment increases of approximately 1.7 percent. We attribute those changes primarily to the final OPPS update. Across hospital categories, we estimate that impacts would range from an increase of 7.7 percent for rural sole community hospitals to an estimated decrease of 4.2 percent for hospitals with a DSH patient percentage greater than 35 percent.

As shown in Tables 115 and 116, we estimate that this final rule with comment period would result in aggregate transfers of approximately $1.78 billion to OPPS providers and $170 million to ASCs. In Table 121, we estimate the impact of this rule on small entities by applying the SBA size standards and approximating the share of affected firms and revenues attributable to small entities. Specifically, we assume that small firms represent 46.1 percent of affected entities and account for approximately 1.8 percent of total industry revenues. Using these assumptions, we estimate that of the 3,621 OPPS providers, approximately 1,669 are small entities. Applying the 1.8 percent revenue share, we estimate that approximately $32.0 million of the OPPS rate update impacts would accrue to small entities. In Table 122, we estimate the impact of individual OPPS policies on the estimated 1,6669 small entities in this final rule. That results in an estimated increase in CY 2027 payment of about $136,500,000 as the combined result of the 340B Payment Policy, the COLA for hospitals in Alaska and Hawaii, the volume control method for imaging without contrast services, and the 340B Remedy Offset for CY 2027. The combined effect of the approximately $32 million payment increase as a result of the OPPS update and the $136.5 million as a result of other OPPS payment policies across 1,669 small entities corresponds to an average impact of approximately $100,983 per small OPPS provider.

As discussed earlier in this section, this final rule with comment period

includes a range of provisions. While none of these policies specifically target small businesses, there are a number of significant policy changes that may affect them. These include the final 340B payment policy and its exception for rural sole community hospitals; the volume control method for imaging without contrast services furnished in excepted off-campus provider-based departments and its exception for rural sole community hospitals, the increase in the 340B remedy offset for CY 2027, and the cost-of-living adjustment (COLA) policy for hospitals in Alaska and Hawaii.

As noted earlier in this section, the update to the OPPS conversion factor will be positive for OPPS providers, including small businesses. While there may be differences in the impacts on individual small entities, the 340B Payment Policy will generally be positive for small businesses due to the increase to the OPPS conversion factor associated with the policy having a greater impact on small businesses overall than the reduction to 340B drug payments, as fewer small businesses have significant 340B drug payments compared with larger businesses. Additionally, the exception for rural sole community hospitals means 340B drug payments are not affected for these hospitals, many of which are small businesses. Overall, the small business category is expected to have payments increase by about $214 million in CY 2027 as a result of the 340B Payment Policy, including the associated budget neutral adjustment to the OPPS CF for non-drug services. Similarly, the volume control method for imaging without contrast services will reduce payments to some small businesses. Rural sole community hospitals, including those that qualify as small businesses, are excepted from this policy. As a result of the volume control method for imaging without contrast services and exception for rural sole community hospitals we expect that small businesses will see a payment decrease of about $6 million.

The increase in the 340B remedy offset for CY 2027 will reduce payments to small businesses subject to the offset in CY 2027. However, the larger offset is expected to reduce the need for a remedy offset in future years, thereby increasing revenue for affected small businesses in those years compared with the existing offset schedule. Additionally, hospitals that were not billing Medicare as of January 1, 2018, were excepted from the offset. The vast majority of those excepted hospitals are small businesses, with about 273 small businesses anticipated to be excepted from the remedy offset. Finally, the COLA for hospitals in Alaska and Hawaii will increase payments to hospitals in Alaska and Hawaii that qualify as small businesses. We expect the policy to increase CY 2027 payments by about $1.5 million to 4 hospitals that are likely to be small businesses.

As noted earlier in this section and in section XIII. of this final rule with comment period, we are extending the hospital market basket update as the update factor for the ASC payment system for CY 2027, which will increase overall payment to ASCs, the majority of which qualify as small businesses. The increase in the device portion of device-intensive procedures as a result of the increase in OPPS payment for non-drug services otherwise reduces the payment for non device-intensive procedures and has varying impact on certain surgical specialties as shown in Table 113. Some small business ASCs could be multispecialty facilities that perform a wide range of surgical procedures while others may focus on a single specialty and perform only a limited range of surgical procedures, such as ophthalmology, gastrointestinal, or orthopedic procedures. Therefore, the combined effect of the final ASC payment system policies in this rule on an individual small business ASC would depend on the mix of surgical procedures the ASC will provide in CY 2027.

We describe the applicable statutory provisions, identify the policies, present the rationale for these provisions, and, where appropriate, in the corresponding sections of this final rule with comment period. We note that in many cases the individual effects for a provider will depend on multiple factors.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. This final rule with comment period will affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant. However, as noted in the impact analysis of this final rule with comment period, this rule is expected to generally increase OPPS payments to the approximately 512 small rural hospitals. Therefore, the Secretary has certified that this final rule with comment period will have a significant impact on the operations of a substantial number of small rural hospitals.

The analyses presented in this section and throughout the preamble of this final rule with comment period provides a regulatory flexibility analysis and a regulatory impact analysis.

F. Unfunded Mandates Reform Act (UMRA)

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 2026, that threshold is approximately $193 million.

This final rule with comment period would not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $193 million in any 1 year.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

We have examined the OPPS and ASC provisions included in this final rule with comment period in accordance with Executive Order 13132, Federalism, and have determined that they 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 112 of this final rule with comment period, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would decrease by 1.7 percent under this final rule with comment period. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this final rule with comment period, in conjunction with the remainder of this document, demonstrate that this rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

H. E.O. 14192, ''Unleashing Prosperity Through Deregulation''

Executive Order 14192, entitled ''Unleashing Prosperity Through Deregulation'' was issued on January 31, 2025, and requires that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations''. This rule is expected to be an E.O. 14192 regulatory action. We estimated that this rule will generate $6.23 million in net annualized costs at a 7 percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

XXVIII. Waiver of Delay in Effective Date

The Congressional Review Act (CRA) (Pub. L. 104–121, Title II) requires a 60-day delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines. 5 U.S.C. 801(a)(3) and 808(2).

We believe that further notice and public procedure are unnecessary, and that it would be impracticable and contrary to the public interest to delay the effective date of the OPPS and ASC final rule with comment period for the following reasons.

If the effective date of this final rule with comment period is delayed by 60 days, the finalized OPPS and ASC payment system updated policies (including the Hospital Outpatient Quality Reporting (OQR) Program, the Ambulatory Surgical Center Quality Reporting (ASCQR) Program, prior authorization for additional Botulinum Toxin Injection services, implementation of certain Consolidated Appropriations Act, 2026 provisions for off-campus outpatient departments of a provider, Graduate Medical Education (GME) policies, and hospital accrediting organization policies concerning certain Emergency Medical Treatment and Labor Act (EMTALA) administrative requirements) will not be effective as of the beginning of the payment year, and CMS will be compelled to continue to use obsolete reimbursement rates which will disadvantage health care providers and suppliers.

In accordance with sections 1833(t)(9) and 1833(i)(2)(D) of the Act, the OPPS and the ASC payment systems are calendar year payment systems. We typically issue the OPPS/ASC final rule with comment period by November 1 of each year to both comply with the statutory requirement under section 1833(t)(9)(A) of the Act to annually review and update the OPPS on a calendar year basis and ensure 60 days' notice so that the payment policies for these systems are effective on January 1, the first day of the calendar year to which the policies are intended to apply. The Hospital OQR Program, REHQR Program, and the ASCQR Program are intended to align with the OPPS and the ASC payment systems, respectively.

In this final rule with comment period, we review and revise payment rates for specific services and adopt or revise other policies that relate to the OPPS/ASC payment system for CY 2027. Section 1833(t)(9)(A) of the Act requires that no less often than annually, the Secretary shall review and revise the groups, the relative payment weights, and the wage and other adjustments for outpatient services 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. In addition, section 1833(i)(2)(D) of the Act states that the payment amount made for facility services furnished in connection with a surgical procedure furnished to an individual in an ambulatory surgical center should be reviewed and updated annually to take account of varying conditions in different areas. We find that, in order to comply with the statutory requirements to annually review and update these payment systems, to ensure that the payment policies for these systems are effective on an annual basis, and to promote an orderly transition to a new payment year, it is in the public interest to ensure that the rule is effective no later than 1 full year after the effective date of the previous year's update (that is, January 1 of each year). Moreover, it is in the public interest to waive the 60-day delay of the effective date, so that providers and suppliers are adequately reimbursed starting at the beginning of the calendar year. Therefore, we find good cause exists to waive the 60-day delay in the effective date for this final rule with comment period.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 29, 2026.

List of Subjects

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, 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 427

Administrative practice and procedure, Biologics, Inflation rebates, Medicare, Prescription drugs.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 2. Section 413.65 is amended—

■ a. In paragraph (a)(2) by adding the definition of ''Off-campus outpatient department of a provider'' in alphabetical order;

■ b. By revising paragraphs (b)(3)(ii) and (iii);

■ c. By adding paragraph (b)(6);

■ d. By revising paragraphs (e) introductory text, (g)(1)(i) and (ii), (h) introductory text, and (k).

The additions and revisions read as follows:

§ 413.65 Requirements for a determination that a facility or an organization has provider-based status.

(a) * * *

(2) * * *

* * * * *

Off-campus outpatient department of a provider means a department of a provider that is not located on the campus of the main provider (as defined in this section) or within 250 yards of a remote location of a hospital (as defined in this section).

* * * * *

(b) * * *

(3) * * *

(ii) If the facility is not located on the campus of the potential main provider or within 250 yards of a remote location of a hospital, the attesting provider would be required to submit an attestation stating that the facility meets the criteria in paragraphs (d) and (e) of this section, and if the facility is operated under a management contract, the requirements of paragraph (h) of this section. If the potential main provider is a hospital, the hospital also would be required to attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. The provider would be required to maintain documentation of the basis for its attestations to CMS and to furnish such information upon request.

(iii) Whenever a provider submits an attestation of provider-based status for an on-campus facility or organization, as described in paragraph (b)(3)(i) of this section, CMS or its agents will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness, consistency with the criteria in this section, and consistency with information in the possession of CMS or its agents at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.

* * * * *

(6) As of January 1, 2028, for each off-campus outpatient department of a provider, a provider must submit an initial attestation of provider-based status within the 2-year period prior to furnishing services, and a subsequent attestation within a period not to exceed 5 years thereafter. This does not apply to Critical Access Hospitals and those entities described in paragraphs (m) or (n) of this section.

* * * * *

(e) *Additional requirements applicable to off-campus facilities or organizations.* Except as described in paragraphs (b)(2) and (5) of this section, any facility or organization for which provider-based status is sought that is not located on the campus of a potential main provider or within 250 yards of a remote location of a hospital must meet both the requirements in paragraph (d) of this section and all of the following additional requirements, in order to be determined by CMS to have provider-based status.

* * * * *

(g) * * *

(1) * * *

(i) Any facility or organization that is located on the main hospital campus or within 250 yards of a remote location of a hospital and is treated by CMS under this section as a department of the hospital; and

(ii) Any facility or organization that is located off the main hospital campus that is treated by CMS under this section as a department of the hospital and is a dedicated emergency department, as defined in § 489.24(b) of this chapter.

* * * * *

(h) *Management contracts.* A facility or organization that is not located on the campus of the potential main provider or within 250 yards of a remote location of a hospital and otherwise meets the requirements of paragraphs (d) and (e) of this section, but is operated under management contracts, must also meet all of the following criteria:

* * * * *

(k) *Temporary treatment as provider-based.* If a provider submits an attestation of compliance with the requirements for provider-based status, as described in paragraph (b) of this section, for a facility or organization that has not previously been found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section, the provider may bill and be paid for services of the facility or organization as provider-based from the date it submits an attestation until the date that CMS determines that the facility or organization does not meet the provider-based rules. CMS may, at any time, initiate an extended review to validate the attestation of compliance, including through site visits, remote audits, desk reviews, investigations, or any other means CMS determines appropriate. As part of such a review, the provider must submit supporting documentation sufficient to demonstrate compliance with the provider-based requirements set forth in this section, in the form and manner and within the timeframe specified by CMS. Failure to submit requested documentation within the timeframe specified by CMS may result in a determination of non-compliance and recovery of payments as described in this paragraph (k). If CMS determines that the requirements for provider-based status are not met, CMS will recover the difference between the amount of payments that actually was made since the date the attestation of compliance with provider-based requirements was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 3. The authority citation for part 416 is revised to read as follows:

Authority: 42 U.S.C. 273, 1302, 1320b–8, and 1395hh.

■ 4. Section 416.171 is amended by revising paragraphs (a)(2)(iii) through (viii) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

(a) * * *

(2) * * *

(iii) For CY 2019 through CY 2027, the update is the hospital inpatient market basket percentage increase as defined under section 1886(b)(3)(B)(iii) of the Act.

(iv) For CY 2028 and subsequent years, the update is the Consumer Price Index for All Urban Consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(v) For CY 2014 through CY 2018, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(ii) of this section was reduced by 2.0 percentage points for ASCs that failed to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vi) For CY 2019 through CY 2027, the hospital inpatient market basket percentage increase determined under paragraph (a)(2)(iii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vii) For CY 2028 and subsequent years, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(iv) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(viii)(A) For CY 2011 through CY 2018, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(ii) of this section, after application of any reduction under paragraph (a)(2)(v) of this section, was reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(B) For CY 2019 through CY 2027, the hospital inpatient market basket

percentage increase determined under paragraph (a)(2)(iii) of this section, after application of any reduction under paragraph (a)(2)(vi) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(C) For CY 2028 and subsequent years, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(iv) of this section, after application of any reduction under paragraph (a)(2)(vii) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 5. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 6. Adding § 419.23 to subpart B to read as follows:

§ 419.23 Special rule for off-campus outpatient department of a provider.

(a) No payment may be made under this part for items and services furnished on or after January 1, 2028, by an off-campus outpatient department of a provider (as defined in paragraph (b) of this section) unless—

(1) Such department has obtained, and such items and services are billed under, a National Provider Identifier that is separate from such identifier for such provider;

(2) Such provider has submitted an initial attestation of provider-based status in accordance with § 413.65(b)(6) of this chapter; and

(3) After such provider has submitted an initial attestation under paragraph (a)(2) of this section, such provider has submitted a subsequent attestation within the timeframe specified in § 413.65(b)(6) of this chapter.

(b) For purposes of this section, off-campus outpatient department of a provider is defined at § 413.65(a)(2) of this chapter.

(c) A provider satisfies the submission requirement at paragraph (a)(2) of this section even if CMS has not made a determination of provider-based status before the first day on which the outpatient department renders services.

■ 7. Section 419.32 is amended by—

■ a. Revising paragraph (b)(1)(iv)(B)(*12*); and

■ b. Adding paragraph (b)(1)(iv)(B)(*13*).

The revision and addition read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*12*) For calendar year 2026, a multifactor productivity adjustment (as determined by CMS), and 0.5 percentage point reduction, except that the 0.5 percentage point reduction shall not apply to hospital outpatient items and services, not including separately payable drugs or biologicals, furnished by a hospital with a CMS certification number (CCN) effective date of January 2, 2018, or later.

(*13*) Beginning in calendar year 2027, a multifactor productivity adjustment (as determined by CMS), and 2.0 percentage point reduction, except that the 2.0 percentage point reduction shall not apply to hospital outpatient items and services furnished by a hospital with a CMS certification number (CCN) effective date of January 2, 2018, or later. This reduction and associated exception to the reduction will be in effect until the estimated payment reductions made in accordance with paragraph (b)(1)(iv)(B)(*12*) of this section and this paragraph (b)(1)(iv)(B)(*13*) for all applicable hospital outpatient items and services reaches $7.769 billion, as further described in each calendar year's rule.

* * * * *

■ 8. Section 419.41 is amended by—

■ a. Revising paragraph (d); and

■ b. Adding paragraph (k).

The revision and addition read as follows:

§ 419.41 Calculation of national beneficiary copayment amounts and national Medicare program payment amounts.

* * * * *

(d) Notwithstanding paragraphs (a) through (c) of this section, for a drug or biological for which payment is not packaged into a payment for a covered outpatient department (OPD) service (or group of services) and is not a rebatable drug that meets the conditions described in paragraph (e) of this section, CMS calculates the program payment and copayment amounts as follows:

(1) Determines the payment rate for the drug or biological for the quarter, which is:

(i) The amount determined by the Secretary pursuant to section 1833(t)(14)(A)(iii)(I) of the Act; or

(ii) If no amount is available under paragraph (d)(1)(i) of this section, the amount established under the methodology described by section 1842(o), section 1847A, or section 1847B of the Act, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14) of section 1833(t) of the Act.

(2) Subtracts from the amount determined under paragraph (d)(1) of this section the amount of the applicable Part B deductible provided under § 410.160 of this chapter.

(3) Multiples the amount determined under paragraph (d)(1) of this section (less any applicable deductible under paragraph (d)(2) of this section) by 20 percent. This is the beneficiary's copayment amount for the drug or biological.

(4) Subtracts the amount determined under paragraph (d)(3) of this section from the amount determined under paragraph (d)(1) of this section (less any applicable deductible determined under paragraph (d)(2) of this section). This amount is the preliminary program amount.

(5) Adds to the preliminary program amount determined under paragraph (d)(4) of this section the amount by which the copayment amount would have exceeded the inpatient hospital deductible for that year. This amount is the final Medicare program payment amount.

* * * * *

(k) Notwithstanding paragraphs (f) through (i) of this section, CMS calculates the program payment and copayment amounts as follows:

(1) The amount determined by the Secretary pursuant to section 1833(t)(14)(A)(iii)(I) of the Act; or

(2) If no amount is available under paragraph (k)(1) of this section, the amount determined under paragraphs (f) through (i) of this section, as applicable.

■ 9. Section 419.43 is amended by adding paragraph (l) to read as follows:

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

* * * * *

(l) *Cost-of-living adjustment.* An additional adjustment is made for hospitals located in Alaska and Hawaii to account for the higher cost-of-living in those States.

■ 10. Section 419.46 is amended by revising paragraphs (f)(2), (f)(3) introductory text, (f)(4), and (g)(2)(vii) and (viii) to read as follows:

§ 419.46 Requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(f) * * *

(2) A hospital meets the validation requirements with respect to a calendar year if it achieves:

(i) An overall reliability score of at least 75-percent for chart-abstracted measure validation, as determined by CMS; and

(ii) Beginning with validation affecting the CY 2030 payment determination, an overall reliability score of at least 75-percent for eCQM validation, as determined by CMS. For the first year that an eCQM is eligible for validation, a hospital meets validation requirements for that eCQM for the year if it provides at least 75-percent of requested records.

(3) CMS will select a random sample of up to 200 hospitals, beginning with validation affecting the CY 2030 payment determination, or 450 hospitals, for validation affecting payment determinations prior to CY 2030, for validation purposes, and will select up to an additional 200 hospitals, beginning with validation affecting the CY 2030 payment determination, or 50 hospitals for validation affecting payment determinations prior to CY 2030, for validation purposes based on the following criteria. For validation affecting the CY 2030 payment determination only, CMS will exclude from selection for validation any hospital that was selected for validation affecting the CY 2029 payment determination.

* * * * *

(4) Hospitals that are selected and receive a score for validation may request an educational review in order to better understand the results within 30 calendar days from the date the validation results are made available. If the results of an educational review indicate that a hospital's medical records selected for validation were incorrectly scored, the corrected validation score will be used to compute the hospital's final validation score at the end of the calendar year.

(g) * * *

(2) * * *

(vii) Except as provided in paragraph (g)(2)(viii) of this section, a copy of all materials that the hospital submitted to comply with the requirements of the affected Hospital OQR Program payment determination year; and

(viii) If the hospital is requesting reconsideration on the basis that CMS determined it did not meet the affected payment determination year's validation requirement set forth in paragraph (f)(2) of this section, the hospital must provide:

(A) A written justification of why the hospital believes CMS incorrectly determined that the hospital did not meet the applicable validation requirements, including, as applicable, identification of any data elements the hospital believes were improperly classified during the validation process as a mismatch. Only data elements that affect a hospital's validation score are eligible to be reconsidered; and

(B) Any evidence that supports the hospital's reconsideration request, including, as applicable, copies of patient charts, emails, and other documents. The hospital is not required to resubmit materials previously submitted to CMS unless specifically requested by CMS.

* * * * *

■ 11. Section 419.83 is amended by revising paragraph (a) to read as follows:

§ 419.83 List of hospital outpatient department services requiring prior authorization.

(a) *Service categories for the list of hospital outpatient department services requiring prior authorization.* The following service categories comprise the list of hospital outpatient department services requiring prior authorization:

(1) Blepharoplasty.

(2) Botulinum toxin injections.

(3) Panniculectomy.

(4) Rhinoplasty.

(5) Vein ablation.

(6) Cervical Fusion with Disc Removal.

(7) Implanted Spinal Neurostimulators.

(8) Facet Joint Interventions.

* * * * *

PART 427—MEDICARE PART B DRUG INFLATION REBATE PROGRAM

■ 12. The authority citation for part 427 continues to read as follows:

Authority: 42 U.S.C. 1395w–3a(i), 1302, and 1395hh.

■ 13. Section 427.303 is amended by revising paragraph (b)(1)(iv) to read as follows:

§ 427.303 Determination of total number of billing units.

* * * * *

(b) * * *

(1) * * *

(iv) Separately payable billing units in claim lines billed with the ''TB'' modifier or successor billing modifiers to identify 340B units, for claims with dates of service on or after January 1, 2025.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 14. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 15. Section 488.5 is amended by—

■ a. Reserving paragraphs (a)(21) and (22); and

■ b. Adding paragraph (a)(23),

The addition reads as follows:

§ 488.5 Application and re-application procedures for national accrediting organizations.

(a) * * *

(23) For accrediting organizations seeking or maintaining CMS approval of accrediting programs for hospitals, Critical Access Hospitals, and Rural Emergency Hospitals, the application must include a description of the policies and procedures the organization will use to assess compliance with the EMTALA-administrative requirements set forth at § 489.20(l), (m), (q), and (r) during accreditation and reaccreditation surveys, including—

(i) Procedures for reviewing required EMTALA signage;

(ii) Procedures for verifying that transfer records are maintained and retained for at least 5 years;

(iii) Procedures for verifying the on-call physician lists are maintained as required;

(iv) Procedures for verifying a central log of individuals presenting to the emergency department is maintained as required;

(v) Procedures for reporting identified noncompliance with § 489.20 to CMS in accordance with CMS oversight requirements; and

(vi) Procedures for reporting identified noncompliance with § 489.24 subsequently identified during survey to CMS in accordance with CMS oversight requirements.

* * * * *

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2026–22739 Filed 11–4–26; 5:00 pm]

BILLING CODE 4169–69–P



FEDERAL REGISTER

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Part VI

The President

Proclamation 11078—Anti-Communism Week, 2026
Proclamation 11079—The American Declaration of Freedom in Space

Federal Register
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Presidential Documents

Title 3—

The President

Proclamation 11078 of November 3, 2026

Anti-Communism Week, 2026

By the President of the United States of America

A Proclamation

For more than a century, human freedom has been threatened by communist and socialist ideologies that eliminate individual opportunity, subjugate individuals to the state, and extinguish the God-given rights upon which free nations are built. This Anti-Communism Week, we are reminded of the devastating consequences of state control over human thought, creativity, and political expression, resulting in suffering, poverty, exploitation, violence, and misery for millions, and we renew our commitment to protect the sacred values of life, liberty, and the pursuit of happiness from the chains of tyranny.

Our Republic was founded upon the enduring conviction that our rights are inherent, our liberties are sacred, and our Government derives its just powers from the consent of the governed. These principles have defined our national character for over 250 years and continue to distinguish our way of life from that of all other countries on Earth.

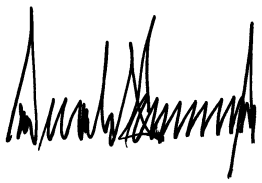
Today, however, our American experiment faces renewed threats as socialist, communist, and radical leftist ideologies find increased expression in our Nation. We must remain vigilant in defending the principles that sustain our Republic and ensure the lessons of history are never forgotten nor repeated. Under my leadership, America will never fall victim to these evil ideologies, and the United States will never become a communist country.

The story of America is, above all, a story of a Nation uniting as one, standing up to tyranny, and charting its own destiny as a free and self-governing Republic. As President, I will always protect the founding principles for which so many fought and died. Together, we will defend our Constitution, which protects our freedoms; uphold the dignity of every individual; strengthen the free market, which has made us the most prosperous country ever to exist; and ensure that the promise of America remains alive and well for generations to come.

This week, we honor the victims of socialism and communism by remembering their lives, defending the freedoms that were denied, renewing our resolve to safeguard the Republic entrusted to us, and reminding ourselves that what we have created as a Nation stands as the greatest testament to human freedom in the history of the world.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim the week of November 1 through November 7 as Anti-Communism Week. I call upon all Americans to stand firm in their defense against any threat to the American way of life and to protect our burning flame of liberty from the darkness of communism.

IN WITNESS WHEREOF, I have hereunto set my hand this third day of November, in the year of our Lord two thousand twenty-six, and of the Independence of the United States of America the two hundred and fifty-first.



[FR Doc. 2026–22787
Filed 11–5–26; 11:15 am]
Billing code 3395–F4–P

Presidential Documents

Proclamation 11079 of November 3, 2026

The American Declaration of Freedom in Space

By the President of the United States of America

A Proclamation

It is America's destiny to explore and expand our frontiers beyond Earth to the farthest depths of space. Today, my Administration reaffirms that our solar system and all of outer space beyond Earth are the province of all humans, and that our Nation will lead the way in the exploration, development, use, and settlement of these new frontiers—forging an interplanetary civilization founded on the enduring and inalienable rights of freedom and individual liberty.

From the intrepid Apollo 11 astronauts who took humanity's first steps on the Moon to the pioneering rovers that explored the surface of Mars, the United States has always blazed a trail into the great unknown, shattering boundaries and pushing mankind to extraordinary new heights. Behind each triumph are generations of astronauts, scientists, engineers, and workers whose tireless dedication and unmatched ingenuity turn impossible dreams into reality.

Under my leadership, the United States is once again writing a bold new chapter in space exploration. This past April, the Artemis II mission successfully carried astronauts around the Moon and farther from Earth than any human had ever traveled before. This historic voyage is only the beginning. Next summer, Artemis III will undertake one of the most complex and consequential test flight campaigns in the history of our Nation's space program.

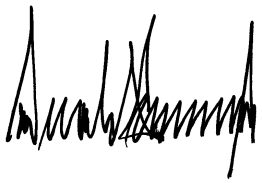
This proud legacy of innovation is our sacred inheritance, and our Nation bears the solemn responsibility to advance it by continuing to open new horizons of exploration and discovery. Through the landmark Executive Orders and directives I have signed, we are reinvigorating human spaceflight, unleashing a competitive and thriving commercial space industry, and ensuring American space superiority for all eternity. We will return to the Moon by 2028, lay the foundation for a permanent American lunar presence, and hasten the day when an American becomes the first human to set foot on the red dunes of Mars. Together, we will build the facilities, develop the resources, and establish a permanent presence in space to extend the reach of American exploration, preserve our frontier spirit, and strengthen our national security for centuries to come. The nation that leads in space will shape the future of humanity—and that nation will be the United States of America.

Today, we renew our solemn and righteous mission to propel humanity toward the farthest reaches of the universe. We reaffirm that the United States will lead the way in this bold endeavor, for the nation with the best scientific understanding of space, the most advanced space economy, and the greatest spacefaring citizens, will be the most prosperous nation for centuries to come. Above all, we pledge to carry our sacred values of faith and freedom wherever we journey, so that freedom may forever ring among the stars and beyond.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim that the solar system

and all of outer space beyond Earth are the province of all humans and are open to exploration, development, use, and the establishment of a permanent presence by American citizens consistent with United States law and the international obligations of the United States.

IN WITNESS WHEREOF, I have hereunto set my hand this third day of November, in the year of our Lord two thousand twenty-six, and of the Independence of the United States of America the two hundred and fifty-first.



[FR Doc. 2026–22789
Filed 11–5–26; 11:15 am]
Billing code 3395–F4–P

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